BRINGING THE CHLOE SED A STEP CLOSER TO KENYAN WOMEN

A strategy for the certification of a medical device for the Kenyan market

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Master thesis report
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PREFACE

This project has been very special to me as it has been a journey that allowed me to meet numerous inspiring people and allowed me to grow in an academic sense.

As a student, I had never before dealt with such a multi-faceted process as this topic. I encountered information on a very detailed level and initially struggled to grasp the bigger picture. It was also the first time I have been confronted with sensitive and conflicting information and I learned to respect and organise this.

Moreover, I knew nothing about the topic before diving into it. I would never have thought beforehand to do a master thesis on the project of certification of medical devices. Both the medical device industry and the topic of certification were a new world for me and its uniqueness sparked great curiosity!

I feel very lucky to have come into contact with this industry and to have seen the context of this project first hand. Travelling to Kenya and experiencing the inner workings of Kenyan hospitals and how they are dealing with the constraints of providing healthcare, made the project very real to me. It has made me understand and appreciate the resourcefulness of healthcare providers and medical device entrepreneurs of the healthcare industry in Kenya

Many thanks to Jan-Carel, Jo, Roos, Karl and all the people who have helped me understand the topic of designing for healthcare in and for the Global South and the certification of medical devices. I feel privileged to have met you and come into contact with the sector and its precious and distinctive mentality to help one another so we can all aim for a more equal and healthier world.

I would also like to thank my mentors, my friends and family who have helped me throughout this project and Liz who has assisted me in making this report a far more enjoyable and readable result!

I hope that you will enjoy this read!

EXECUTIVE SUMMARY

Background

Half of the planet's population have little or no access to essential healthcare services. This is especially the case in low- and middle- income countries (WHO, 2017). Particularly in Sub-Saharan Africa, many medical devices are not accessible to the majority of people in need. New sustainable initiatives have been launched to increase accessibility while reducing environmental impact. One such initiative is the design of the Chloe Syringe Extension Device (SED). The Chloe SED is a reusable, 3D-printable device that extends the locally available 10ml syringes. The device can be used for procedures related to pregnancy issues, such as Manual Vacuum Aspiration (MVA), where uterine contents are removed with the help of a vacuum suction device (Ipas, 2014). The device extends the syringe in such a way that the needle can reach the womens' cervix to inject analgesia before the procedure. Currently, the Chloe SED is an initiative that focuses on the Kenyan market. The embodiment design of Chloe SED is nearly ready. This study is a contribution to the existing Chloe SED project and aims to answer the question: what next steps should the Chloe SED project take regarding legal and non-legal aspects to introduce this medical device to the Kenyan market?

Research Aim and Scope

The aim of this research is to provide recommendations for the Chloe SED project about legal and non-legal aspects that can contribute to the acceptance of the Chloe SED by the Kenyan market. Regarding the legal aspect, this study aims to provide recommendations for the certification of the device. Regarding non-legal aspects, this study aims to identify prerequisites in the reprocessing and the procurement of medical devices that may contribute to the device's acceptance.

The Chloe SED project is executed in the Netherlands at the University of Technology Delft and in Kenya parallel. The project focuses on the Kenyan market. The scope of this study includes the comparison between the EU and Kenyan certification processes. Given the limited time available for this study, other global certifications such as FDA approval (USA) have been excluded from the scope of this study.
This scope also includes the research that has been carried out on the reprocessing and the procurement process of medical devices. The study investigates how Kenyan health care facilities reprocess their MVA kits in practice and investigates how stakeholders, relevant to the Chloe SED project, procure medical devices in Kenya. Once again, time constraints preclude a broader focus. Other non-legal aspects that may contribute to the acceptance of the Chloe SED by the Kenyan market are excluded from the scope of this study.

Research

To investigate what future steps are needed for the Chloe SED project to introduce their medical device to the Kenyan market, exploratory research has been conducted. The research is split into two parts; the first part focuses on the legal aspect of the Chloe SED by looking at next steps in the certification process. The second part of the research investigates prerequisites that are mentioned by relevant stakeholders that can contribute to the Chloe SEDs acceptance by the Kenyan market, where the research will focus on two non-legal aspects; reprocessing and procuring of medical devices. This study aims to answer the following research questions:

1. **What next steps should the Chloe SED project take regarding the certification process to introduce the device to the Kenyan market?**

a. What is medical device certification and why is it there?
b. What certification path do medical equipment manufacturers from the Global North choose and why?
c. What certification path do Kenyan manufacturers that design medical equipment for Kenya choose and why?
d. What are the opportunities and challenges in bringing Chloe SED to Kenya?

2. **What non-legal prerequisites can be derived from relevant stakeholders for the acceptance of the Chloe SED regarding its design and application?**

a. What prerequisites can be derived from relevant stakeholders regarding the procurement process of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?
b. What prerequisites can be derived from relevant stakeholders regarding the reprocessing of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?

Outcome

Certification

This research has shown that obtaining local Kenyan certification for medical devices without prior approval from abroad e.g., the CE-mark is possible, albeit challenging. The PPB and KEBS, two bodies involved in medical device certification in Kenya, are still in a learning environment and the certification process is still in development. Few manufacturers have succeeded to complete this path and its progression may be uncertain, especially for higher class medical devices. The next steps for the Chloe SED project to obtain certification is to continue investing their time and resources into completing the Keyan national certification process to obtain the PPB DPER Registration Certificate. Reasons for this are the Chloe SED can reduce costs and aim for offering their device more affordably and can collect data more efficiently while the device is still under development. There are also more advantages of carrying out the process of product development, certification and manufacturing for Kenya. It is a good lever for the environment, it can boost the innovation capacity of the country, it can encourage other manufacturers to do the same. One key condition, however, is that the Chloe SED project must find a local subcontractor to manufacture the device locally. This manufacturer must hold an SM Permit (Kenyan approved QMS system for their production plant, which includes ISO 13485) to be authorised to produce the device. Generally, the options for finding a contract manufacturer do not seem broad. Manufacturers have indicated that they have difficulty in finding an ISO-certified sub contract manufacturer in the country. Until now, this research has identified that Revital Healthcare may be interesting as a partner.

This research has found that medical device manufacturers from the Global North opt for the CE-mark from the EU because this certification is widely accepted by LMIC. Since, the Chloe SEDs market is not limited to Kenyan women but can be of use to many women on this planet, this research recommends that the Chloe SED project eventually obtains the CE mark. With this certification, the Chloe SED can enter markets in multiple countries and reach as many patients as possible. Therefore, it is recommended that the Chloe SED project obtains EU certification in the future by partnering with an established organisation that is experienced in certifying their medical equipment though the EU process. Suggestions are large global MVA kit suppliers or other large medical companies.

Procurement

Hospitals procure MVA equipment as a kit. In order to reach the Kenyan market, the Chloe SED must become a standard component of an MVA kit.
An interesting stakeholder, IPAS, is a large MVA kit supplier both in Kenya and globally. IPAS has partnered with DKT to increase their reach. Another interesting stakeholder for the Chloe SED project is Marie Stopes, an international NGO located in Kenya that provides MVA procedures in their own clinics. They have their own brand of MVA kits. Both IPAS and Marie Stopes have CE certified and ISO 13485 compliant MVA kits. A stakeholder that is interested in the Chloe SED with only a Kenyan certificate is an interesting lead after the Chloe SED project has found a manufacturer. Marie Stopes or local NGOs that provide MVA could be interested in procuring the kits locally, but this requires further research.
This research has also found that there are two large distributors in Kenya, KEMSA and MEDS, which cater to the public, private and faith-based sector. Crown Healthcare is also mentioned as a large distributor of medical equipment. These can be interesting leads for the Chloe SED project to find out which brands of MVA kits they sell.
It is also interesting to consider if the Chloe SED is an added value to the Loop Electrosurgical Procedure. This requires further research to determine the market potential of the Chloe SED to this medical procedure.

Reprocessing

This research has investigated how Kenyan healthcare facilities reprocess their medical equipment. Research found that their methods deviate from what is recommended by WHO protocols. They lack the resources to follow WHO practices and reprocess based on available materials.
Therefore, this research recommends testing the device with the reprocessing method used in Kenya to ensure device safety, with a special attention to adding the decontamination step and incorporating longer soaking times. This may lead to modifications. It is also recommended to test the device on longer soaking times and if applicable, adjust the life cycles and incorporate this information into the instructions.

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1

INTRODUCTION TO THE PROJECT

This thesis is a contribution to an existing project about a medical device, the Chloe Syringe Extension Device (SED). Information in this chapter has been taken from the Chloe SED project and two previous research reports on the project carried out by students from the University of Technology Delft. The Chloe SED is a reusable medical device that is designed to improve the Manual Vacuum Aspiration (MVA) procedure. This chapter will introduce you to the people involved in the Chloe SED project and provides more detail about the Chloe SED and the MVA procedure. Additionally, this chapter provides more information on the focus and aim of the thesis, the related research questions and research method. The aim of this study is to answer the following questions: What are the next steps for the Chloe SED to obtain certification in order to be used in Kenya? What non-legal prerequisites can be derived from relevant stakeholders for the acceptance of the Chloe SED regarding its design and application?

1 CHAPTER

Who is involved in the Chloe SED project?

This project is initiated by the Global Health Initiative Lab and the Inclusive Global Healthcare lab, both from the University of Technology, Delft. See figure 1, for a visual overview of the stakeholders involved in the Chloe SED project. The section bellow provides additional information:

The Global Health Initiative Lab is a collaboration of scientists that use expertise to boost Global development, improving the lives of people living in poverty.

The Inclusive Global Healthcare Lab consists of scientists who use expertise to increase access to healthcare for the Global South.

Karl Samenjo, design engineer and researcher at Global Healthcare Initiative Lab. He is the co-inventor of the tChloe SED, together with Dr Aparna Ramanathan (a gynaecologist from the US) and Dr Stephen Gwer (a gynaecologist from Kenya). Karl is my client in the project.

Jan-Carel Diehl, director of The Inclusive Global Health Lab and associate professor at TU Delft, has been my chair during the master thesis.

Jo van Engelen, member of The Inclusive Global Health Lab and professor at TU Delft, has been my coach during the master thesis.

Roos M. Oosting, postdoc and team member of the Healthcare Lab at TU Delft has been my second coach.

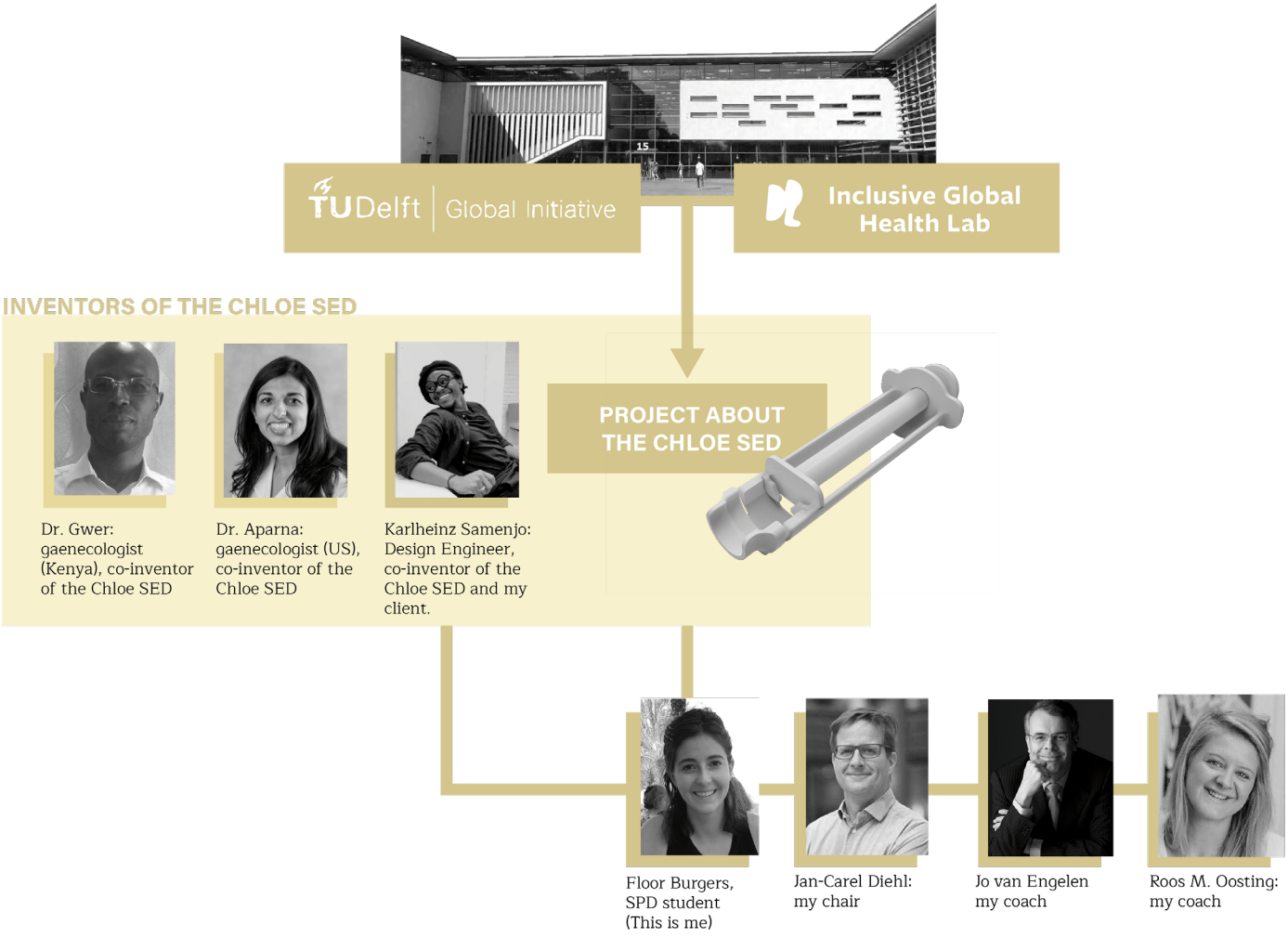
Users of the Chloe SED are nurses, doctors and healthcare workers in public, private and faith-based hospitals in Kenya. These people are not always trained at the same level.

Patients are women who are undergoing an MVA procedure due to e.g. a miscarriage. They can have complications due to an abortion or a miscarriage.

The Kenyan government is in charge of the policies related to reproductive health. Currently, abortion is only legal if the life of the mother is at stake.

NGOs are sometimes involved with supplying medical devices and carrying out procedures related to pregnancy issues.

(Me) Graduate student looking into the Chloe SED project, exploring the certification processes and giving recommendations based on this process and other aspects.



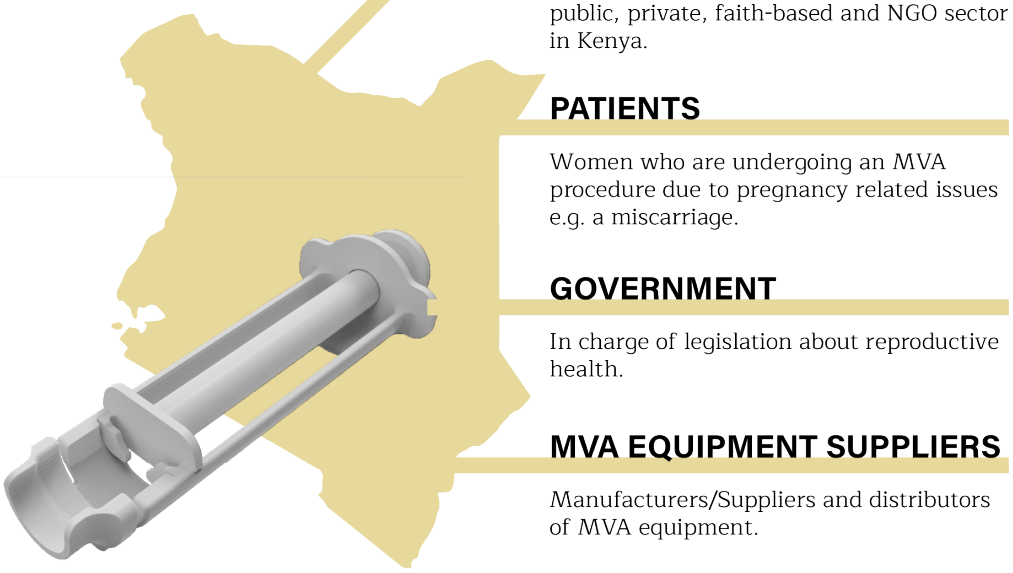


Figure 1: An overview of the stakeholders in the Chloe SED project

1 CHAPTER

The Chloe SED

Worldwide annually, there are 210 million pregnancies of which 21.6 million undergo unsafe abortions. These unsafe abortions cause an estimation of 47000 women to die from infections and bleeding due to complications from unsafe abortion procedures or organ damage. There are 6.2 million unsafe abortions in Africa, of which 89% (5.5 million) occur in Sub-Saharan Africa (SSA). In numbers, this means that 28600 Sub-Saharan women lose their lives. The number of maternal deaths in SSA accounts for 61% of the global maternal deaths. The risk of dying of unsafe abortion is highest in Eastern, Middle and Western Africa, where 500 lives are lost per 100 000 unsafe abortions (WHO, 2011). Figure 2 shows the comparison of the number of unsafe abortions and the resulting maternal deaths worldwide against Africa and SSA. One of the procedures that help recover after an abortion is MVA. It is a safe method of surgical uterine evacuation, a procedure that empties the uterus after incomplete abortions (Tunçalp, 2010). The MVA section in this chapter will provide more information on this procedure. The world takes different standpoints on women's reproductive rights. This makes the introduction of Post Abortion Care (PAC) difficult in some countries. The Center for Reproductive Rights (2022), a global human rights organisation of lawyers and advocates who strive for the protection of reproductive rights in law as fundamental human rights state that in Kenya, abortion is accepted if, in the opinion of a healthcare professional, the pregnant person's life is at stake.

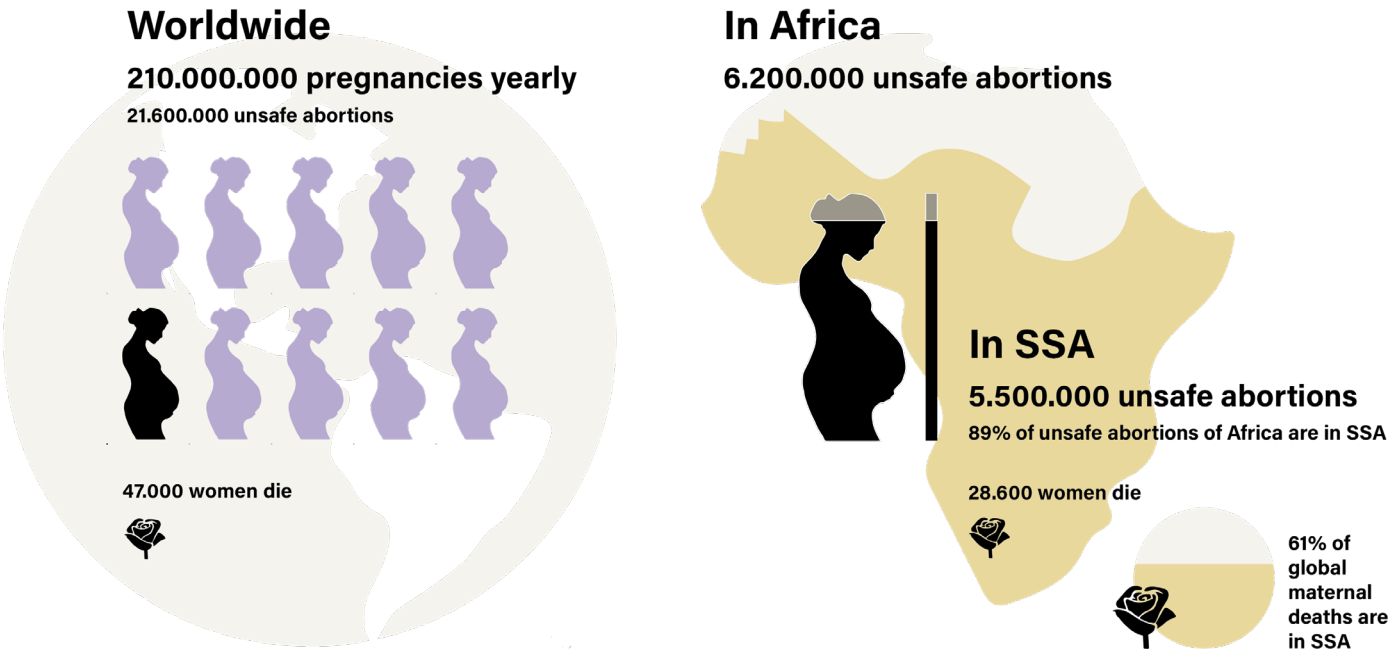


Figure 2: An overview of the worldwide numbers of unsafe abortions and maternal deaths as a result of unsafe abortions compared to the numbers in Africa and SSA. Information for this visual has been taken from a report by the WHO (2011).

The Chloe SEDs Function

The Chloe Syringe Extension Device (SED) is a reusable device designed for the Kenyan market. It extends the length of locally available 10 ml syringes (see figure 3) and enables the injection of analgesia into a woman's cervix (see figure 4) before an MVA procedure. It allows the patients to receive pain-relief medicine before treatment.

The Chloe SED can be disassembled in 3 parts when being prepared for reuse (see figure 3). The device is designed to be reprocessed in autoclaves and chemical baths in Kenyan hospitals. The Chloe SED is 3D printable. It is currently tested with materials PEEK, PP and Aluminium. Depending on the volumes required for the Kenyan market, it could also be injection blow moulded.

The Chloe SEDs reusability is a good lever for the environment and it reduces costs. The Chloe SED project aims at offering the device under $5. This can be a great advantage, especially for low resource settings (LRS). Moreover, according to the Chloe SED project, in Europe, long spinal needles are used to inject analgesia (see figure 5). However, in low- and middle-income countries (LMIC) such as Kenya, these needles are absent because they are considered to be too expensive. Even though MVA is regarded as a safe procedure, without pain-relief medicine, pregnant women may still turn to illegal and unsafe solutions.

The next section takes a closer look at what an MVA procedure entails.

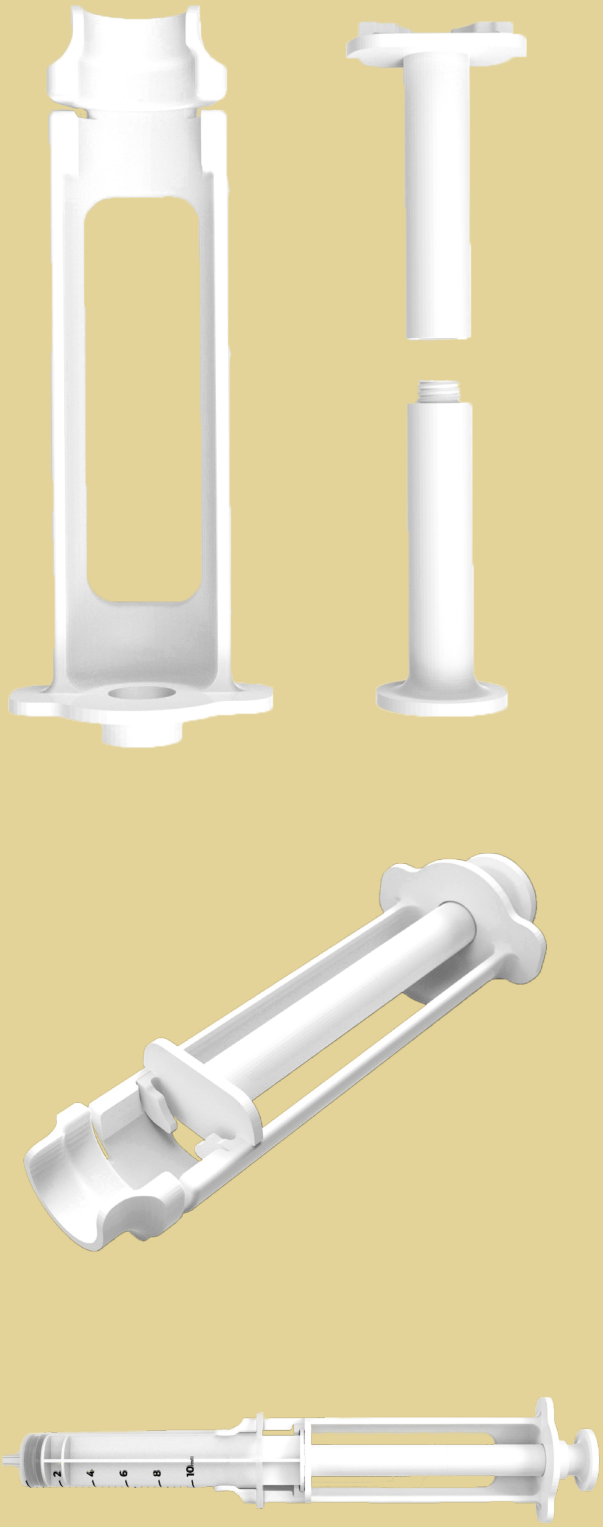


Figure 3: The Chloe SED. The top image shows the three parts of the device. The middle image shows an assembly of the Chloe SED. The bottom image shows how the Chloe SED extends the length of a 10 ml syringe. These images are adapted versions of images provided by the Chloe SED project.

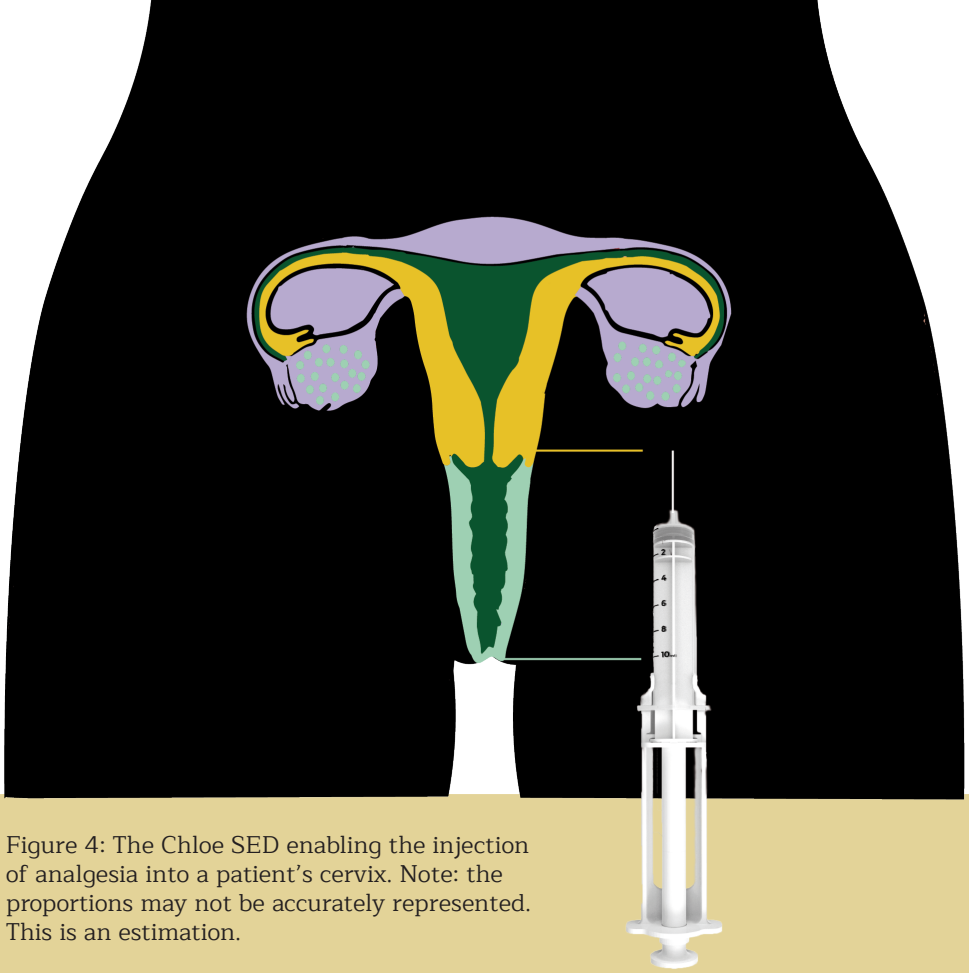


Figure 4: The Chloe SED enabling the injection of analgesia into a patient's cervix. Note: the proportions may not be accurately represented. This is an estimation.

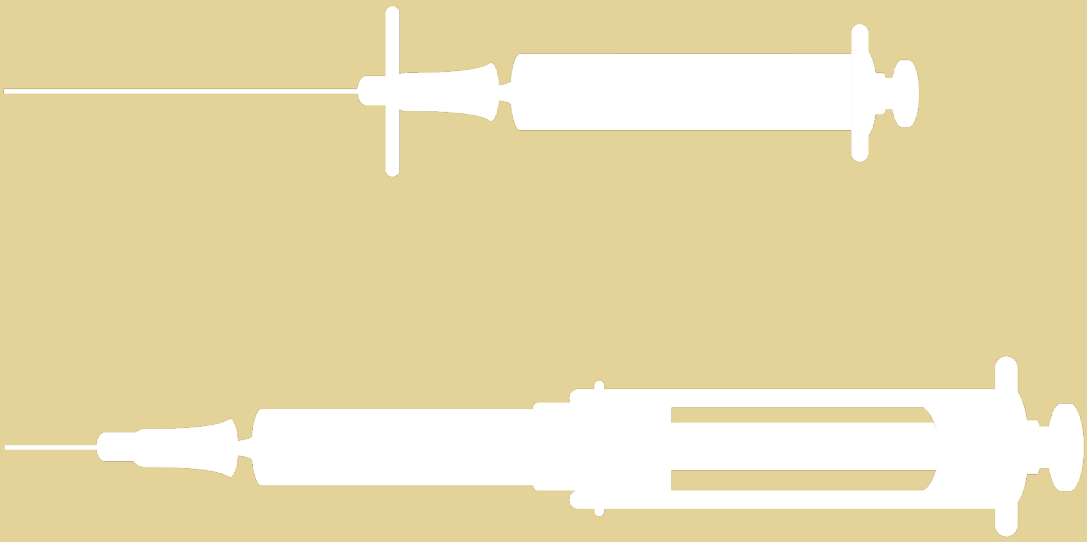


Figure 5: Silhouettes of a 10 ml syringe in the Chloe SED and a 10 ml syringe with a long needle available in the EU. The source for the syringe with a long needle is based on an epidural needle taken from Braun Medical Inc. (2022)

1 CHAPTER

What is MVA?

MVA is a small surgical procedure where a healthcare provider extracts the contents from the uterus using a handheld suction device, namely the aspirator. The procedure can be performed under local analgesia in either a hospital or healthcare centre. It has a short recovery time and patients do not need to be admitted to the hospital. It is a safe and effective method for ending pregnancies up to 12 weeks after the last menstrual period. Vacuum aspiration is recommended by the world's leading gynaecological and obstetric organizations, including FIGO (the International Federation of Gynecology and Obstetrics) and the World Health Organisation, for abortion care and miscarriage management (Womancare. 2022). Appendix A depicts a summarised overview of the steps in an MVA procedure. MVA procedures can be applied for two main proceedings; uterine evacuation and endometrial biopsy. These proceedings can be used to treat a number of health issues (Forrest et al., 1997).

Miscarriages

In literature, miscarriages are also referred to as spontaneous abortions or early pregnancy loss. These terms refer to the natural loss of pregnancy before twenty weeks of gestation. The first trimester is when most spontaneous abortions occur (Griebel et al., 2005, as cited in Alves et al., 2021).

PAC

MVA is also used for carrying out Post Abortion Care. Post-abortion care is an emergency treatment for complications as a result of spontaneous and induced abortions. However, PAC can refer to a larger package of actions which can include family planning counselling, provision of family planning methods, prevention of future unplanned pregnancies that may lead to more induced abortions and services for evaluating sexually transmitted diseases (USAID, 2014).

Endometrial Biopsy

Another application of MVA is to carry out an endometrial biopsy. This refers to the extraction of samples of the uterine lining which can be achieved with a suction device, named an IPAS aspirator. (Womancare, 2022).

The Chloe SED users

An MVA procedure can be provided by any trained healthcare professional. This includes specialists (doctors), general care providers, nurses, and midwives (Womancare. 2022). The procedure is straightforward and easy to learn.
As explained by the head of the sterilisation department at Erasmus Medical Centre, the theatre room in a hospital is the supplier of the sterilisation department and vice versa (J. Buijs-Hegeman, personal communication, March 17, 2022). In this report, the staff who are in charge of reprocessing the medical device are considered users too.

1 CHAPTER

Project Assignment and Scope

The aim of this master thesis is to give recommendations on the next steps for the Chloe SED project to boost the device's acceptance in the Kenyan market. There are a variety of aspects that can contribute to the acceptance. In this research, the focus lies mainly on the certification process because it is a journey the device is required to undergo very soon. Additionally, two non-legal aspects were researched, the reprocessing and procurement process, to ascertain how these may contribute to Chloe SEDs market acceptance. The reason for focusing on procurement is because it can be closely related to the certification of a medical device. The reason for investigating reprocessing of medical devices is because reusability is an important aspect of the Chloe SED. The following questions have formed the backbone of the research:

Question 1
What next steps should the Chloe SED project take regarding the certification process to introduce the device to the Kenyan market?

A literature study has been carried out to provide an underpinning to the comparative research on the certification of medical devices. The following sub questions were used to understand the context of medical device certification:

A. What is a medical device?
B. What is medical device certification?
C. Why do we need medical device certification?
D. How is medical device certification organised in specific parts of the world?

To determine the next steps for the Chloe SED project to obtain certification so it can introduce the device to the Kenyan market, certification choices of other medical device manufacturers in the EU and Kenya context were explored. This exercise helped to better understand the certification processes. The following sub questions have been investigated:

F. What certification path do medical device manufacturers from the Global North choose and why?
a. Who is involved in the CE process?
b. What does the CE process look like?
c. What challenges are medical device manufacturers from the Global North facing when certifying their medical devices for LMIC?
d. How do medical device manufacturers from the Global North bridge the regulatory discrepancy between the Global North and South?
e. What are the advantages and disadvantages of the EU certification process?
f. What do the manufacturers know about Kenyan certification?

G. What certification path do Kenyan manufacturers that design medical equipment for Kenya choose and why?
a. Who is involved in the Kenyan certification process?
b. Is it possible to obtain a national Kenyan certification for medical devices without prior approval from abroad and what does this process look like?
c. What are advantages and disadvantages of the Kenyan medical device certification process?

H. What are the opportunities and challenges in bringing Chloe SED to the Kenya?
a. Where is the Chloe SED project currently in the certification process?
b. What are the next steps for the Chloe SED in the Kenyan certification process? Add EU process?

Question 2
What non-legal prerequisites can be derived from relevant stakeholders for the acceptance of Chloe SED regarding its design and application?

A. What prerequisites can be derived from relevant stakeholders regarding the procurement process of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?

a. How are medical devices procured?
b. Who are relevant stakeholders that are involved in the procurement of medical devices in the Kenyan healthcare sector?
c. How do relevant stakeholders procure their medical devices?
d. How is MVA equipment procured?

B. What prerequisites can be derived from relevant stakeholders regarding the reprocessing of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?

a. What reprocessing methods are described by the Chloe SED project and the WHO that are relevant to the Chloe SED?
b. How do Kenyan healthcare facilities reprocess their medical equipment/MVA kits in practice?

1 CHAPTER

Research Method

This research was highly exploratory in nature. Reflective practice lends itself to exploratory research because it involves continuous learning and adaptation.

As explained by Donal Schön (1983) reflective practice requires a researcher to adopt a critical stance towards what has been experienced in practice by paying attention to past actions, events, emotions and responses. This method involves continuous learning and adaptation because reflecting on past experiences leads to developmental insights which facilitates forward-thinking. Schön suggests there are two types of reflective practice; reflection-on-action and reflection-in-action. The former involves reflecting on actions that have happened in the past and the latter involves reflecting on actions while they are happening. Learning researcher Graham Gibbs (1988) has suggested a model that structures reflection (see figure 6).

In this research, the general approach to the research questions consisted of three phases: context exploration, qualitative (field) research and an analysis. This however, is not a linear process because of reflective practice. By fully immersing myself in an environment full of experts, I was educated on the topic while I was also searching for interesting directions that could lead to useful recommendations for the project. Looking back at experiences and adapting on the basis of developmental insights during the process helped me reach a higher level of understanding of the topic and make informed decisions. Not only insights but also personal ideas or judgements influenced the decision making process. For example, on occasion I decided to engage theory into the process again because I acquired new information from an interview which I did not yet understand.

In this project, information was acquired through literature study, in depth interviews with relevant stakeholders, a focus group discussion, field research and observations.
The tools I used were flexible so to facilitate the co evolution of my understanding of the topic and insights generated. By reflecting-on-action, the tools were continuousely adapted based on the effectiveness of the questions from previous interviews, the expertise of the interviewee and new insights gained from previous interviews or literature study.

Reflection in action helped me maintain an agile position towards (unexpected) information that I acquired instantaneously. Improvising enabled me to respond to new information. For example, when interviewing a nurse from AMREF, it was difficult to find beforehand whether the NGO is involved in projects where they provide MVA procedures. Also, in the focus group discussion the materials and plans were adjusted based on the actions of the participants to collect the most relevant information possible. It allowed me to make best practice through out the process.

Conducting research on the reprocessing of medical devices is less related to the main theme about medical device certification but because of the opportunity of visiting Kenya to carry out field research, addressing the reprocessing allowed me to collect valuable information that online sources would not provide.

An important analysis technique in this process that has assisted in organising, selecting and synthesising information acquired from in in-depth interviews was ‘On the wall’ technique (Sanders & Stappers, 2012). It has been slightly adapted to suit this research. In stead of clustering statements from interviews to generate insights, information from the interviews were mainly clustered into categories which became a sort of library of insights through out the process.

Within this self-regulated process, the validation of ideas and conclusions has been kept to a minimum. When I was unsure of information and when possible, I asked interviewees if they agreed on the notes I made.

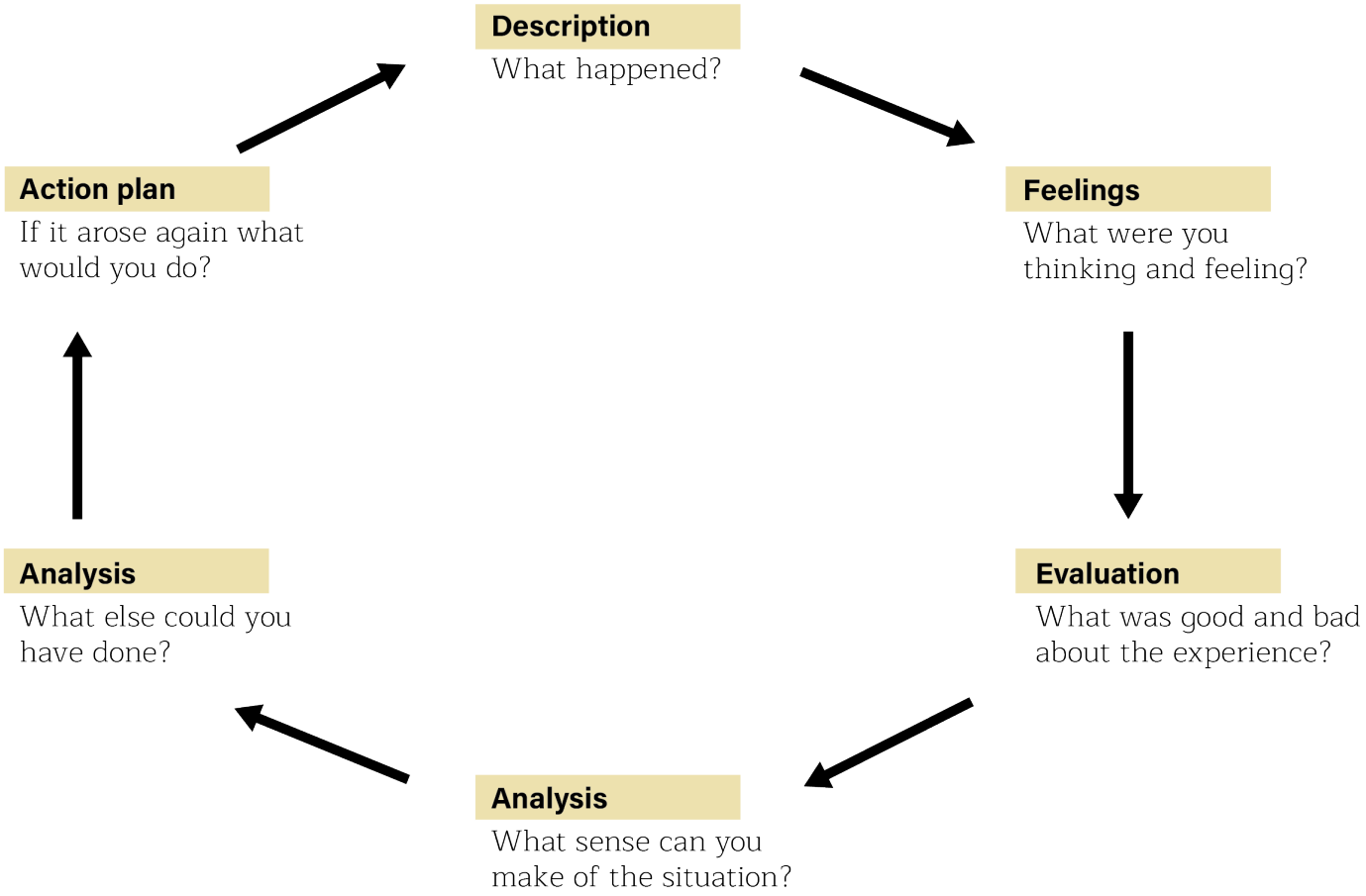


Figure 6: Adaption of the suggested model for reflective practice by Gibbs (1988)

2

INTRODUCTION TO THE REPORT

This chapter outlines the report followed by an overview of abbreviations and definitions of words that frequently occur in the report.

2 CHAPTER

Outline of the Report

Chapter 1 reviews the start of the project. It introduces the Chloe SED project and the stakeholders involved. It provides a problem description and the aim of this thesis and describes the research method.
Chapter 3 introduces the topic of medical devices, defines medical device certification and how this is organised in specific parts of the world. The chapter demonstrates the problems manufacturers from the Global North face when obtaining certification to introduce their medical devices in the Global South.
Chapter 4 sheds light on the certification process in the EU, including its advantages and disadvantages. The chapter also shows how organisations based in the Global North try to overcome the challenges of obtaining certification for the Global South.
Chapter 5, takes a closer look at the certification process for Kenya and how Kenyan based medical device manufacturers obtain certification to sell their devices in the country. This chapter provides a framework for the Kenyan certification process.
Chapter 6 investigates the steps that the Chloe SED project has made in their journey towards certification and projects this journey onto the framework provided in Chapter 5, pointing to future steps for the Chloe SED in the Kenyan certification process.
Chapter 7 focuses on non-legal aspects that may contribute to acceptance of the Chloe SED in the Kenayn market. The chapter focuses on reprocessing and procurement.
Chapter 8 presents a synthesis of research findings, a conclusion accompanied by recommendations for the Chloe SED project.
Lastly, Chapter 9 presents an evaluation that consists of a discussion, recommendations for further research, a reflection on the project and a list of references.

Figure 7 provides an overview of the chapters, how they correspond to the research questions and where in which phase of the research these questions have been explored.

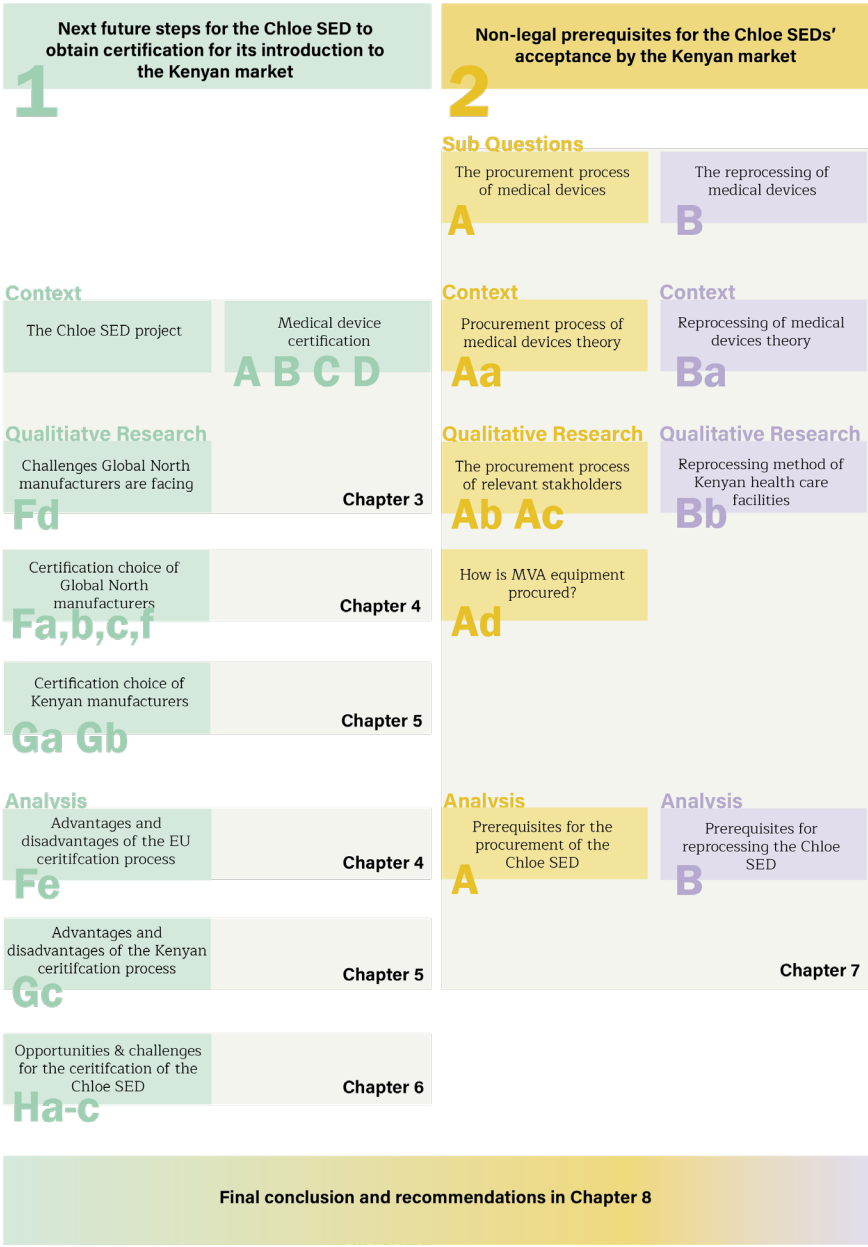


Figure 7: An overview of the (sub) research questions investigated in the chapters of the report

Abbreviations

The Chloe SED	The Chloe Syringe Extension Device
SSA	Sub-Saharan Africa
LMIC	Low- middle- income countries
LRS	Low resource settings
MVA	Manual vacuum aspiration
PAC	Post abortion care
EU	European Union
MDR	Medical device regulations
CE	Conformité Européenne
FDA	Food and Drug Authority (USA)
WHO	World Health Organisation
ISO	International Organistion for Standardisation

Definitions

Focus Group Discussion	Focus group discussion is frequently used as a qualitative approach to gain an in-depth understanding. The method aims to obtain data from a purposely selected group of individuals
Framework	A basic structure underlying a system, concept, or text
MVA	A procedure in which uterine contents are removed with the help of a vacuum suction device (Ipas, 2014)
Analgesia	Medication that acts to relieve pain
Reusable	Able to be used again or more than once
Autoclave	Autoclaves are also known as steam sterilizers, and are typically used for healthcare or industrial applications. An autoclave is a machine that uses steam under pressure to kill harmful bacteria, viruses, fungi, and spores on items that are placed inside a pressure vessel
Global South	Generally refers to regiouns outside Europe and North America, that are mostly (though not all) low-income and often politically or culturally marginalized
Low-middle-income countries	lower middle-income economies are those with a GNI per capita between $1,086 and $4,255
Low resource settings	Low resource settings refer to settings where health care systems do not meet the minimum standards set by the World Health Organisation (WHO) or any other quasigovernmental organisation

3

CERTIFICATION OF MEDICAL DEVICES

The aim of this chapter is to introduce the topic of medical devices and their certification process, and describe the regulatory discrepancy between the Global North and South. It especially focuses on the challenges medical device manufacturers from the Global North are facing in bridging the regulatory discrepancy in order to introduce their devices to the Global South. This chapter will explain what a medical device is and why it is important to look at the class of a medical device. This will be followed by an explanation of what certification is and why medical device certification is necessary. Then this chapter will shed light on the discrepancy between certification of medical devices in the Global North versus the Global South and describe how this challenges manufacturers. In this chapter, appendices are refered to as [Appendix number]. insights that are taken from interviews will be referred to as [Appendix number, Insight number].

3 CHAPTER

Method

This chapter aims at exploring the context of the medical device certification. The following sub questions that have provided a substructure to the research on medical device certification are:

A. What is a medical device?
B. What is medical device certification?
C. Why do we need medical device certification?
D. How is medical device certification organised in specific parts of the world?
Fe. What challenges do medical device manufacturers in the Global North face in obtaining certification for medical devices for LMIC?

To answer questions A-D, a literature study was performed to build a theoretical foundation to explore the context of medical device certification. For question D, published articles about medical device regulations (MDR) in the EU, Africa and Kenya were examined. Insights for question Fe, were derived from in-depth interviews with six medical device manufacturers and one distributor based in the Global North about their choice for certification and coexisting challenges. The manufacturers were mainly start-ups or small and were in the process of figuring out the certification. See [G] for the first version of the interview guide used and [B] for more information on the interviewees, the insights and information acquired from the interviews.

What is a medical device?

Before diving into the world of certification, it is important to understand there are more devices considered to be medical than one might initially think. The definition of a medical device according to the EU-MDR (2017/745) is stated as follows:

Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- **diagnosis, prevention, monitoring, treatment or alleviation of disease**
- **diagnosis, monitoring, treatment, alleviation of or compensation for an injury investigation, replacement,modification, or support of the anatomy or of a physiological process**
- **supporting or sustaining life, control of conception, disinfection of medical devices, providing information by means of in vitro examination of specimens derived from the human body;**

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

(Consolidated text: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. EUR-Lex, 2007)

With such a broad definition, many devices can be regarded as medical. So what about the Chloe SED? Statements about the definition of medical devices in this industry are debatable. While interviewing a quality manager, the interviewee argued whether the Chloe SED could be considered an accessory rather than a medical device [B1, 43]. Generally, in the EU, the Chloe SED is seen as as a medical device due to the following definition from EU-MDR (2017/745): It is an instrument intended by the manufacturer to be used in combination with (another device), for human beings, for the medical purpose of treating or alleviating an injury without achieving this by pharmacological, immunological or metabolic means.

Kenya and the EU refer to the same definition of medical devices [C]. For this reason, it seems safe to assume that if Chloe SED is considered a medical device in the EU, it will likely also be seen as such in Kenya.

The Importance of Classification

The EU divides medical devices into 4 classes based on the risk of harm they can cause to patients and users. The EU refers to the 4 classes as classes I, IIa, IIb and III where I is low risk and III is high risk. Kenya also divides their medical devices into 4 classes based on risk but they refer to the classes as classes A, B, C and D, where A is low risk and D is high risk. The reason for this similarity is that Kenya has adopted recommendations from an organisation named the Global Harmonisation Task Force (GHTF) [C]; see section 'Efforts for Harmonisation' for more information. Figure 8 provides an overview of the medical device classes in Kenya and an example of the devices that they allocate to each class.

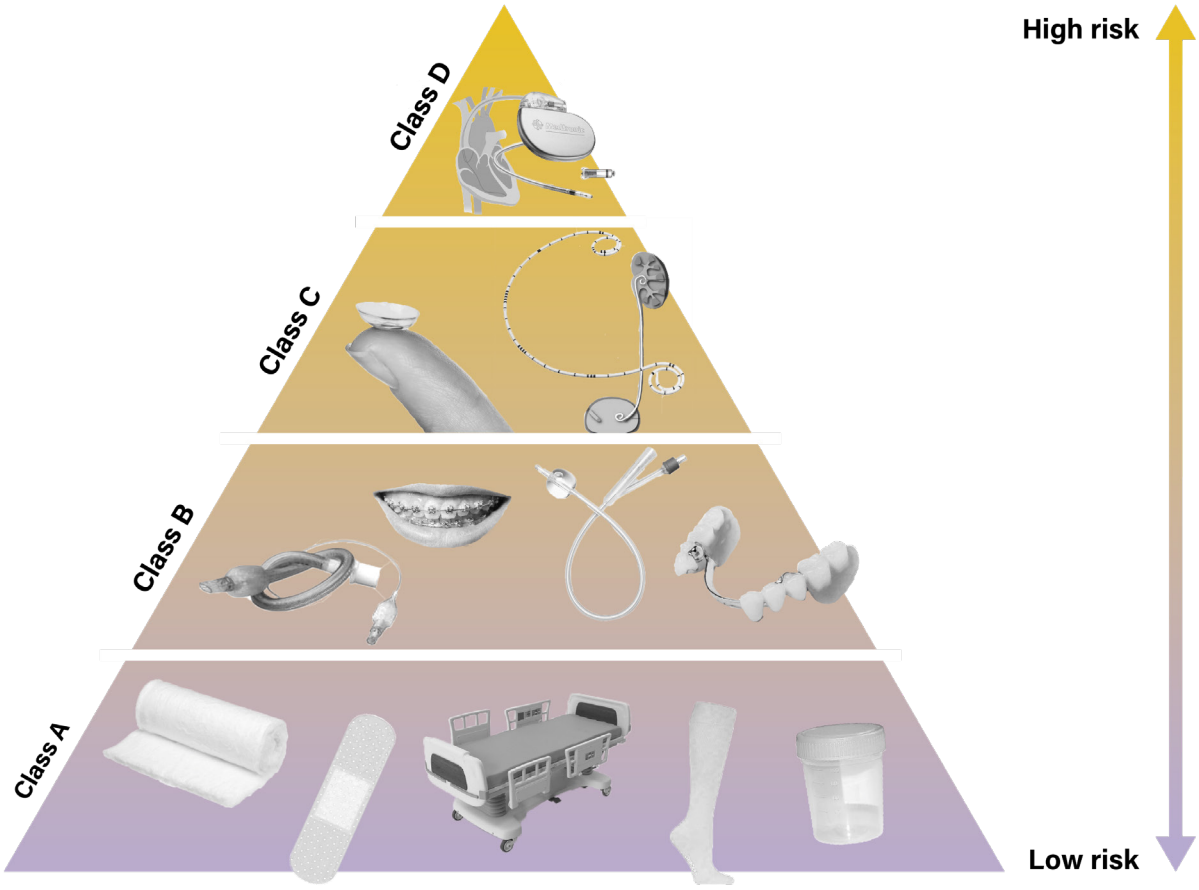


Figure 8: An overview of the risk-based classification system of medical devices in Kenya. This is a visual presentation of the information in 'Guidelines on submission of documentation for registration of Medical Devices including In-Vitro Diagnostics (IVDs), written by the Ministry of Health, Pharmacy and Poisons Board (2018).

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How smoothly a manufacturer can navigate the certification process largely depends on the complexity of the medical device in question and the level of risk that patients are exposed to when coming into contact with the device. The quality manager from organisation A, explained that it is not necessarily the classification itself that has a great influence on the certification process but the costs of the paperwork, standards and audits that come with it [B1, 25]. In the case of organisation A, manufacturers experience a less complex certification process in some regards because they are dealing with a class I medical device. This saves them from approaching a notified body, carrying out a clinical trial and setting up a Quality Management System (QMS) [B1, 26]. See Chapter 4 for more information on notified bodies and see [E] for an explanation of a clinical trial and a QMS.

A manufacturer can allocate a medical device to a certain class by going through regulation guides or annexes of the EU directives. These are lengthy documents that state rules that may or may not apply to the medical device with the corresponding class for each rule and exception, see [D] for an extract of this document listing the rules. There is also online guidance and tools to support manufacturers. One example is a document named Guidance on classification of medical devices, created by the Medical Device Coordination Group (MDCG) , composed of representatives of all EU Member States and chaired by a representative of the European Commission (MDCG, 2021). Another example is the Oxford Guide Tool (Reg-metrics, 2022). Manufacturers can also look into the declarations of conformity (DOCs) of similar medical devices to see what class may apply to their own medical devices [B1, 38]. The DOC is a document with information about the medical device which has been approved by the EU legislation, for more information on DOC see [E]. Despite the documents, guides and other tools, the classification of a medical device is subject to interpretation as is the case for the Chloe SED.

Classification rationale for the Chloe SED

In the case of the Chloe SED, classification may vary subject to interpretations on the level of invasiveness to the patient during specific usage. Some of the interviewees from medical device manufacturers in the Global North indicate that the Chloe SED may belong to class I, while another suggests class III depending on the level of invasiveness. Below are some quotes from interviews with experts.

Founder of organisation B:

“I expect that Chloe SED is still regarded as invasive under Kenyan rules. I suspect it will be class B because it enters a body orifice. For Chloe SED, the position of the patient in use is critical.

Business Unit Developer of organisation C:

“I expect Chloe SED to be class III because it is an in-vitro device (devices used for testing biological samples to determine a patient’s health), even though your device is not since it is intended for syringes. It will be the first question a certification committee will ask you. In-vitro is the toughest certification process to go through, the most difficult part to get.

Quaality Manager of organisation A:

“Is it even a medical device? Because if it is not used in combination with another device, it does not achieve its purpose. Could it not be an accessory?

Based on the EU-MDR (2017/275) classification rules in Annex IX [D], it can be argued that the Chloe SED is a class I device or a class IIa device, depending on whether the medical device comes into contact with skin or mucous membrane that is perceived as injured and for how much time. Generally, a non-invasive device belongs to class I, according to the rules. However, the Chloe SED in practice might touch the vagina very briefly and so rules 4 and 5 from Annex IX become relevant;

- Rule 5 [D] states: 'Devices that are invasive regarding entering body orifices (so not surgical in nature) belong to class I if they are used for transient use' where transient use refers to continuous use of the device for less than 60 minutes. These devices belong to class IIa if the same situation applies, but for short-term use where short-term refers to continuous use of the device for less than 30 days.

- According to rule 4 [D] if the Chloe SED does not come into contact with injured skin or injured mucous membrane, it remains class I, otherwise it is a class IIa medical device.

The Chloe SED can be assigned to class IIa, according to other expert opinions [G ,14 and F, 10]. This was ultimately determined by the engineer who designed the Chloe SED. The reasoning behind this is that comparable devices such as the speculum, MVA kit, and syringe are allocated to class IIa devices and that there is a chance that the Chloe SED is perceived as an invasive medical device because it enters a body orifice.

Based on the similarities of the classification system of the EU and Kenya. The Chloe SED will likely fall under class B medical devices in Kenya. However, the classification also depends on the level of invasiveness from a Kenyan point of view. The founder of organisation B, predicted the Chloe SED will likely be regarded as invasive under Kenyan legislation [G, 14].

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What is Medical Device Certification?

Certification in a business context refers to 'the process of giving official or legal approval to a person, company, product, etc. that has reached a particular standard' (Cambridge Dictionary, 2021). ISO (2022), an organisation that develops international standards for various industries refers to certification as 'the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements'. According to an official EU website, CE-marking indicates 'that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements and that this is required for products that are marketed in the EU regardless of where it has been manufactured (Your Europe, 2021).

In the medical device industry, DEKRA (2022), a body that issues certifications for medical devices, refers to certification marks 'as a clear sign that the products have been thoroughly tested and that they meet all the required safety or performance standards, nationally and internationally, in multiple markets across the world'. Within the medical device industry, certain certificates can be prerequisite to obtain another certificate. To sell a medical device within the EU, a manufacturer must comply with the EU Medical Device Regulation 2017/745, the EU legislation for medical devices. Manufacturers can also certify their medical devices to an ISO standard. ISO. In this case, ISO warns manufacturers not to use the label 'ISO certified' but e.g. 'ISO 9001:2015 certified' (ISO, 2022). The following example demonstrates the different layers of certification in the medical device industry: medical devices from classes II and III may require an EN/ISO 13485 certificate for the Quality Management System, to complete the EU certification process. When they have completed the process successfully, the manufacturers are permitted to place a CE mark on the device as proof of compliance (Landini, 2019).

For the sake of the thesis, I will refer to the 'certification' as legal proof that the medical device complies with all regulatory requirements set by the country (or countries) in which a manufacturer intends to market this device. This thesis will include other certificates that are necessary to complete the certification process and will mention these by their specification such as 'ISO 13485 certificate'. I will refer to the 'certification process as the journey in which a manufacturer obtains legal proof that a device complies with the country's medical device regulations which allows him to sell to the country.

Why do we certify medical devices?

Medical devices can save lives but they can also destroy lives when they are unsafe and used on people (McAllister et al., 2003). Manufacturers must certify their medical devices to protect patients and the users. It also protects the medical device manufacturers [O4,X]. Therefore it is of utmost importance that medical devices are compliant with the regulations that ensure patient safety and avoid risks that cause harm to anyone surrounding the device (De Maria et al., 2018).

Medical device regulations are the legislation put into place to safeguard the quality of medical devices (De Maria et al., 2018). Generally, in the regulation process, manufacturers must register devices with the regulatory authorities of the country in which they intend to bring the devices to the market. They must follow the regulation on medical devices in the country and comply with the corresponding requirements (Dusabe, 2020) [H]. If a manufacturer has proven to be compliant with the medical device regulations of the country, the device receives a certificate and the manufacturer is now permitted to market the device in the country.

However, worldwide, regulatory systems for medical devices can differ per continent, nation and even country (Dusabe, 2020). In an effort to reduce regulation diversity, numerous harmonisation groups are in place that stress the necessity for a uniform technical document for manufacturers to allow for widely accepted approval to simplify introduction and marketing of medical devices in multiple countries (Lamph, 2012). For manufacturers, certification can be a 'useful tool to build credibility because it is proof that the device meets the expectations of its customers' (ISO, 2022).

Efforts for harmonisation

Efforts for harmonisation on a global level can aid two types of manufacturers: those who are selling a device in multiple countries, and those who are selling to countries that are in the process of establishing or developing medical device regulations. Harmonisation initiatives aim for medical device manufacturers to be able to produce one set of documents that will fulfil the requirements of all regulatory authorities (Lamph, 2012). This reduces the time and costs to market the device, expands market access and facilitates trade while improving government efficiency and public health protection (Kaushik, 2010). Globally, there are numerous collaborations and initiatives to prompt regulatory harmonisation (see figure 9).

The World Health Organisation (WHO) is a UN agency that consists of 194 member states that make global efforts to encourage harmonised regulations for medical devices (WHO, 2022). In 2007, the WHO advised her member states on the regulation system of medical devices through resolutions 67.29 'and 60.27 'regulatory system strengthening for medical products' and 'The WHO global model regulatory framework for Medical Devices including In-vitro diagnostics (IVD's)' respectively. Such initiatives aim at guiding WHO member states that plan on establishing a regulatory framework or improving the current structure. In Kenya, a WHO member state (WHO, 2022), the national regulatory authority adopted the two resolutions in their guidelines. (Ministry of Health Pharmacy and Poisons Board, 2018 - B).

The Global Harmonisation Task Force (GHTF), now re-named the International Medical Device Regulators Forum (IMDRF) (Dusabe, 2020), works to harmonise the regulation of medical devices. It is a collaboration between representatives from medical device regulatory authorities from the founding members Canada, Japan, the United States of America and the EU (Lamph, 2012). who discuss future harmonisation efforts for medical device regulations (Dusabe, 2020). They have expanded to include ISO, Internation Electrotechnical Commission (IEC) (Lamph, 2012) and the Asian Harmonisation Working Party (AHWP) and Pan American Health Organization (PAHO) (IMDRF, 2022). This body has proposed a general classification system where medical devices are divided into four classes based on risk and a uniform definition of medical devices [L] (Lamph, 2012).

The International Organisation for Standardisation (ISO) takes effort into keeping industrial standards consistent on an international level. For manufacturers, it is worth considering conformity with ISO standards because nowadays ISO is the largest developer and publisher of international standards on the planet. Its standards are widely adopted and form the basis for health, safety and environmental requirements. On a global level, these standards help form a basis for transferring practice and knowledge to developing countries (Lamph, 2012). There are numerous standards regarding medical devices but according to Lamph (2012), the most relevant are:

ISO 13485: Medical devices, quality management systems, requirements for regulatory processes
ISO 10993: Biological evaluation of medical devices
ISO 14155: Clinical investigation of medical devices for human subjects
ISO 14971: Medical devices: Application of risk management to medical devices.

Manufacturers can purchase these standards from the ISO website for a large amount of money [B1, 6]. Regulatory systems can even require that manufacturers use ISO standards, named harmonised standards, to prove their compliance with certain requirements [B1, 30] [B4, 18]. In practice, medical device manufacturers need to think of the claims themselves and then look for an ISO standard that is applicable to the claim, the ISO standards do not always include requirements [B4, 17].

There is a voluntary working group that facilitates harmonisation initiatives across Africa, named the Pan African Harmonisation Working Party (PAHWP) (McNerney & Peeling, 2015). They are making an effort in generating a uniform regulation for the continent by reviewing the different regulation aspects: classification, the format for technical documentation, medical device functionality studies, quality management system (QMS) inspections and Post-market surveillance (PMS) (Dusabe, 2020). For an explanation of these requirements see [E]. Unlike the AHWP (Asian Working Party), the PAHWP is not an affiliate organisation of the IMDRF currently. Neither is any African country currently a member of the forum.

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Despite various efforts, global regulatory harmonisation still has a long way to go. For instance, the IMDRF (2022) has only expanded from 5 to 11 members since its existence. In the meantime, the number of non-members that have started manufacturing medical devices has increased and these may not have the potential to conform to harmonised standards/requirements. Consequently, the IMDRF may not have the desired influence on harmonisation on a global level. The next sections will take a look at the challenges Global North manufacturers are facing when introducing their medical devices to the Global South.

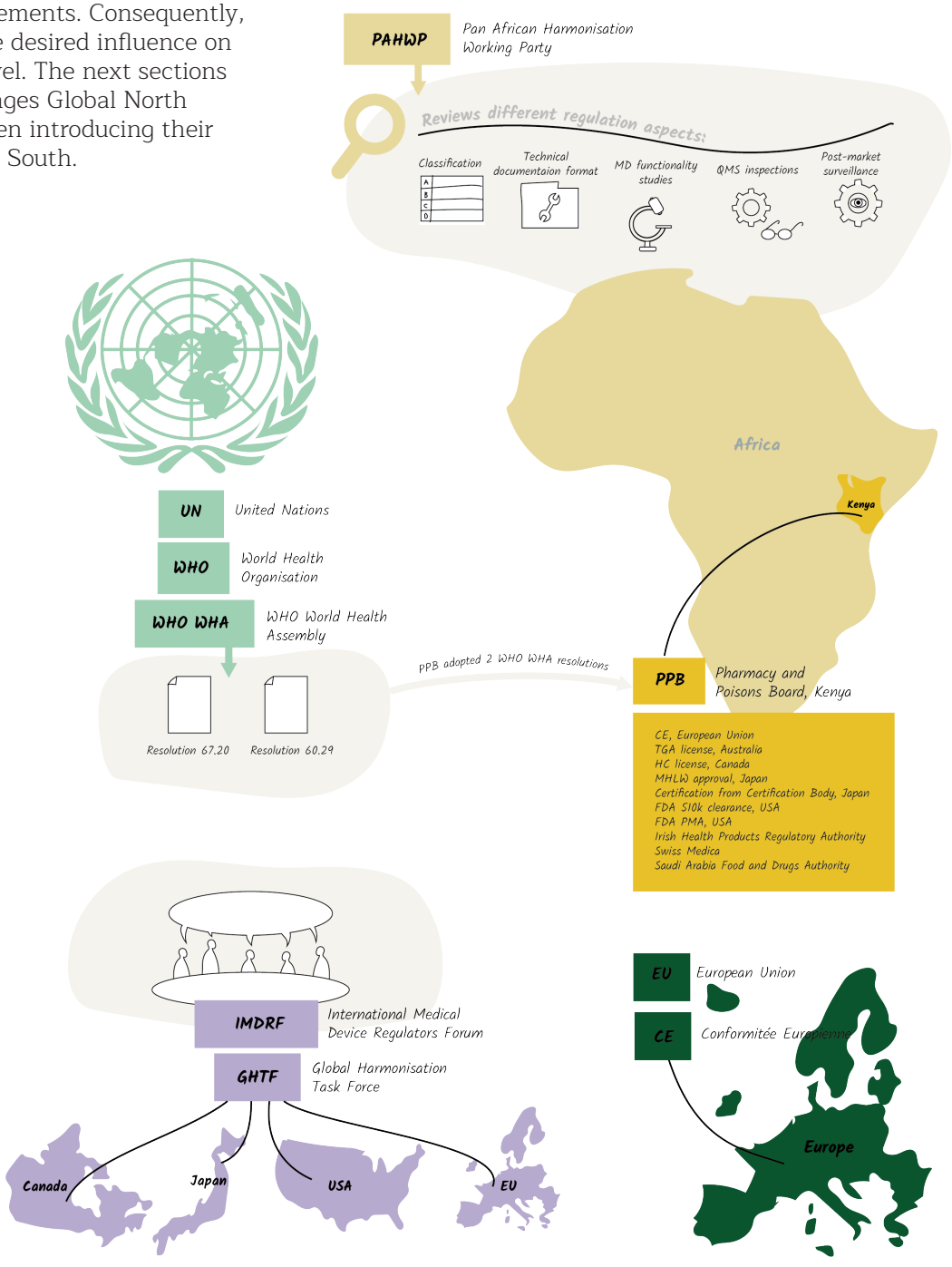

Figure 9: Overview of a several parties that aim for regulatory harmonisation

The Global North vs. South

The Global North and South (see figure 10) vary in regulatory systems regarding scope and definitions. (Kaushik et al, 2010) This poses a variety of challenges for medical device manufacturers.

Mismatch in Requirements

Countries where regulations are not well defined, such as in Africa, (Kedwani et al, 2019) rely on clearance from other unions or nations such as the CE marking of the EU (Hubner, 2021). According to the founder of organisation B, this reliance poses a problem for the safety and quality of medical devices. Global North requirements and international standards do not reflect the requirements of LMIC. Manufacturers must take into account the difference in the operating environment such as the heat and humidity of the area, the available human capacity/ skills and cost constraints which can lead to e.g. lack of funds for maintenance and electricity (Neighbour & Eltringham, 2012)

Reusability

Other challenges manufacturers face is that single use or disposable devices are the norm to prioritise patient safety (Neighbour & Eltringham, 2012). This has been the result of a political lobby from an endoscope scandal (Buijs-Hegeman. J., personal communication, February 10, 2022). However, medical devices in LMIC are reused even though they are not designed as such due to lack of financial resources to replace them (Neighbour & Eltringham, 2012). For this reason, it is easier for manufacturers to certify their medical devices as single-use when dealing with the CE certification process in the EU because proving reusability is a lot of work and very expensive [B4, 19]. Moreover, manufacturers must take responsibility in designing devices that can be sufficiently cleaned with the available facilities in LMIC to avoid contamination (Neighbour & Eltringham, 2012).

Cheaper Alternative

Moreover, a CE specialist from organisation E and the founder of organisation B mentions that the EU-MDR are not very fond of medical devices that are designed to be a cheaper alternative to their existing version [B4, 20] [B3, 19], however, the affordability of a medical device is usually what is of value to the Global South.

Inaccessible Information

Medical device manufacturers in the Global North are struggling with finding (up to date) information. The manufacturers mentioned the process is a very uncertain one [B7, 9), it is difficult to predict beforehand and it changes often [B1, 5]. Online information is not always reliable so that the requirements for certification of a target country are unclear. Fees are also uncertain. [B7, 10]. The CE specialist from organisation E explained that it is impossible to make a guide for manufacturers on how to navigate a certification process because it differs every time. [B4, 27].

Manufacturers have mentioned using parts for their medical devices that have been already certified. However, organisation D mentions that it is also unclear to them whether the pre-certified parts of their devices are also accepted by the country in which they intend to market their device [B7, 11]. Also organisation E is struggling to confirm whether the country of their intended market requires them to certify parts of their device or their device as a whole [B4, 7].

Figure 10: The global North vs South divided by a Brandt Line as adapted from The Global North/South Divide (The Royal Geographic Society, 2022)

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In Africa

Africa is home to countries with various political, social, religious and economic statuses. All 54 countries on the continent are members of the African Union (AU). Unlike the EU, the AU does not have a standard directive or harmonised regulatory framework in place. This hampers mandated authorities when establishing a structure for overseeing medical devices. Many of the countries in the continent have developed regulatory structures for pharmaceutical products but not for medical devices. This is not only due to the absence of regulatory frameworks but also a lack of the necessary human resource capacity to take up this task. Some countries have no regulations in place, while others have implemented (partial) medicinal device regulatory practices. These can differ from country to country (Dusabe, 2020). In 2017, the WHO stated that for the African region specifically, 40% have no regulatory structure for medical devices in place, 32% have a partial regulatory structure and 28% have no available data, see figure 11 (Hubner, 2021). The quality manager of organisation A explained that since the majority of the countries in Africa of no regulations in place or are in the process of developing these, a certification process can end up in two ways for an medical device manufacturer: 'either the countries are not very strict about medical devices or they are just as strict as in the EU but much vaguer. Although the chance is high they will accept devices with a CE mark.' [B1, 24].

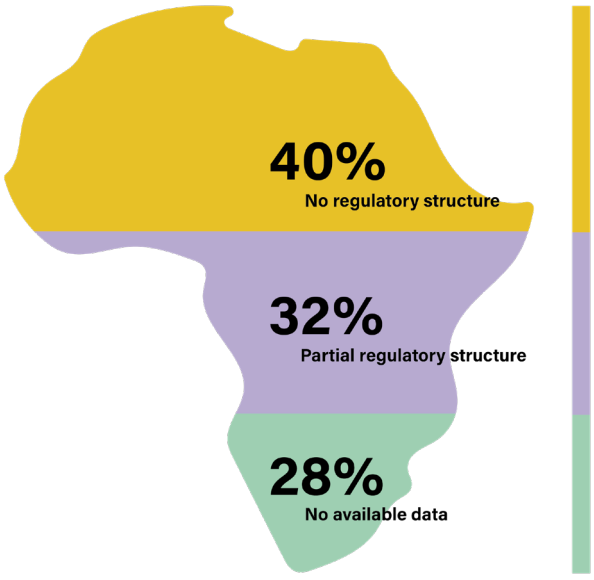


Figure 11: A visual presentation of information extracted from Hubner (2021).

In Kenya

According to Dusabe (2020), in Kenya, there are no regulations present for medical devices but there are guidelines, and there is compliance oversight, training, reporting and monitoring. Kenya has made steps in developing regulations and guidelines to serve the local context. The Pharmacy and Poisons Board (PPB) in Kenya is the national regulatory body which requires importers to show conformity certificates if they wish to register their medical devices to obtain import authorisation (Saidi and Douglas, 2019) [B5]. The PPB rely on their guidelines on the 'Submissions for Documentation for Registration of Medical Devices including In-Vitro-Diagnostics (IVD's)' when assessing these submissions by manufacturers [H]. Harmonisation efforts are evident in the sources of these guidelines since they refer to various sources from the GHTF. However, according to (Rugera et al, 2014; McNerney and Peeling, (2015) the regulation of medical devices is not a primary area of focus for the different regulatory authorities due to inadequate resources. Medical device manufacturers have indicated that Kenya accepts the CE mark [B3, 8].

Unclarities about Kenyan Certification

When interviewing a Kenyan pharmacist, the person was sure it was possible to obtain a certificate of conformity locally in Kenya but was unable to recall organisations that have done so [K].

Finding Information

Manufacturers experience difficulty in finding information. Organisation B, a medical device manufacturer that is specifically targeting Kenya mentions they are dealing with a guideline document from the PPB which states that it is a draft but is 3-4 years old. They are still figuring out what is necessary [B3, 11].

Interpreting Information

Manufacturers experience difficulty in interpreting medical device regulatory guidelines. The founder of organisation B who is now figuring out what the requirements in Kenya are explains 'The Kenyan document is frightening to read. To interpret what they mean is difficult' and at the same time 'There is also a difficulty in communication as things about the device become easily misunderstood' [B3, 8 and 9].

Extra difficulties for smaller manufacturers in the regulatory field

In the regulatory field, there is no difference between a commercial company, a start-up or an NGO obtaining certification [B1, 29]. In the EU, the requirements for medical device manufacturers are strict; tightened legislation forms a high entry barrier for especially small organisations to bring their medical devices to the market [B3].

The Chicken and the Egg

The business unit developer of organisation C mentioned that some start-ups and initiatives in the Netherlands are coming together to converse about how to build a business around a good medical device. The interviewee observed the start-ups struggle with this problem [B2, 17]. One problem manufacturers are facing when approaching a larger agency that can help bring their medical devices to the Global South, is that they are required to show their experience. This is difficult for a new manufacturer. The interviewee refers to this as 'the chicken and the egg story' [B2, 4]. Their organisation is now taking on the role of helping younger medical device organisations to pitch their ideas to a UN agency because they have managed to become part of the UN framework and have close ties with the agency [B2, 14].

Affording a certified Manufacturer

Another problem for medical device manufacturers and especially start-ups is the difficulty of finding an affordable ISO-certified contract manufacturer that can do the actual production of the device. [B1, 18].

3 CHAPTER

Conclusion

As stated in Chapter 1, the Chloe SED is a medical device that is designed to administer analgesia into the cervix prior to an MVA procedure. The Chloe SED can be considered invasive because it must enter a body orifice. In the EU-MDR and in Kenya, Medical devices are divided into 4 classes based on risk. Because of its level of invasiveness, experts predict that the Chloe SED will fall under class IIa according to the EU-MDR (or B for Kenya) In the EU, the Chloe SED must involve a notified body which checks whether the device conforms to the regulations, including proving its reusability. The device must also obtain an ISO 13485 certificate for the Quality Management System.

Medical devices require certification as proof that they are compliant to the medical device regulations in the country and thus meet quality expectations. The certification of medical devices is a complex field and the process differs per type of product. On the one hand, in some markets, medical devices are subject to strict regulations to protect patients, users and manufacturers against harm. On the other hand, neither regulatons nor certification process is consistent nor clear. This makes it difficult for manufacturers to predict the process and prepare to follow it to ensure their medical devices are compliant.

The Global North and the Global South vary in their medical device regulations. Some countries in the Global South may have partial to no regulations in place. The PAHWP that aims for regulatory harmonisation across the African continent is not a member of the global harmonisation forum, the IMDRF. The level of adherence to harmonisation policies in African countries is difficult to assess and they may set different requirements. Kenya has made steps in developing regulations and guidelines to serve the local context. The national regulatory body, the PPB, requires importers to show conformity certificates if they wish to register their medical devices to obtain import authorisation.

A great advantage of certificates from the Global North, such as the CE mark is that they are globally recognised and widely accepted by some LMIC. In the CE process, information about the certification process is accessible but a manufacturer must think of requirements themselves. Notified bodies that review their submissions are expensive and do not provide medical device manufacturers with any information about how their device must comply with regulations.

Meanwhile, they have the most accurate information about what requirements are applicable to the device and how a manufacturer can sufficiently prove its claims about the device. This makes manufacturers' submissions prone to mistakes. Resubmissions are expensive and take time.

Manufacturers of medical devices are facing challenges because of the regulatory discrepancy between the Global North and the Global South. The challenges they face also depend on their size, experience and capabilities. Generally, medical device manufacturers are forced to opt for a Global North certificate because of the reliance on these certificates by LMIC. For the CE certification, medical device features that are important to the environment of LMIC such as functionality, reusability and affordability are not a priority in the medical sector of higher income countries (HIC). Manufacturers must take responsibility for this and ship the device back and forth for proper testing. Medical device manufacturers are also experiencing challenges in communication and finding current information. Especially smaller manufacturers may not have the resources to do research into each African country they wish to market. It is a labour-intensive, time consuming process which can lengthen the time to market for devices that patients urgently need; time is of the essence [J,37].

Start-ups from the Global North face great challenges in obtaining Global North certification to market their medical devices to countries in Africa. The resources that are needed to eventually get a certified medical device on the market through the EU certification system are a high entry barrier for them. They struggle internally to organise their structure and business to be compliant with stricter requirements that are a result of tightened medical device regulations. Moreover, In the EU certification process, manufacturers must think of the claims themselves and start-ups may be more prone to making expensive mistakes because of their inexperience.

The next chapter will look at what medical device manufacturers that are based in the Global North are doing to obtain certification for their medical devices designed for the Global South and how they bridge the regulatory gap.

4

CERTIFYING MEDICAL DEVICES FOR THE GLOBAL SOUTH

The aim of this chapter is to identify factors that influence a manufacturer's choice for certification and do research into strategies that medical device manufacturers in the Global North use to bridge the regulatory gap between the Global North and the Global South. The chapter explores what certification paths medical device manufacturers from the Global North choose to market their medical devices in the Global South and aims at understanding their choices. This chapter also explores what they know about bringing medical devices specifically to Kenya. This chapter will provide information on the regulatory system in place in the EU to help understand the choices of these manufacturers. In this chapter, appendices are refered to as [Appendix number]. Insights that are taken from interviews will be referred to as [Appendix number, Insight number].

4 CHAPTER

Method

The following sub questions have provided a substructure to the research question F:
What certification path do manufacturers from the Global North that design medical equipment for LMIC choose and why?

F. What certification path do medical device manufacturers from the Global North choose and why?

a. Who is involved in the CE process?
b. What does the CE process look like?
c. What challenges are medical device manufacturers from the Global North facing when certifying their medical devices for LMIC?
d. How do medical device manufacturers from the Global North bridge the regulatory discrepancy between the Global North and South?
e. What are the advantages and disadvantages of the EU certification process?
f. What do these manufacturers know about certifying medical devices in Kenya?

The aim of question Fa and Fb was to map the EU certification process which was used to develop further understanding of the context of medical device certification and to use it as a reference for the interviews with medical device manufacturers from the Global North. The reference was a useful tool to develop an interview guide and interview more effectively. Information used for constructing the EU certification process was taken from the TU Delft course Medical Instruments B: Quality Assurance in Design was used to map the certification process and government websites from the Netherlands.

To answer questions Fc -Fe, qualitative research has been conducted. Using a holistic approach enabled me to report the complexity of the certification process and pinpoint factors that play a role in the process. The approach includes documenting multiple perspectives and sources of data (Creswell, 2014). To answer questions Fc-d, participants from a total of seven medical device organisations were interviewed. These organisations are based in the Global North and manufacture medical devices for LMIC. The participants shared their knowledge on medical device certification because they were involved in the certification process within their organisation. The interviewees have been:

- A quality manager from organisation A, a start-up based in the EU.
- The founder from organisation B.
- The business unit developer from organisation C is a small organisation based in the EU.
- The founder from organisation D. Organisation D is a start-up, based in the EU.
- The CE specialist from organisation E. Organisation E is a start-up, based in the EU.
- The founder and business developer of organisation E
- The founder of organisation F. This organisation is based in the USA and so her insights may deviate from the other organisations.

The basic form of the interview guide that has been used for semi-structured interviews, is presented in [G]. This guide has been developed with the help of the insights about the regulatory discrepancy in the literature study chapter 3. The interview guide has been developed to further understand the challenges manufacturers are facing in obtaining certification to introduce their medical devices to LMIC (question Fc), explore how organisations are overcoming these challenges (question Fd), reasons for choosing a specific certification process (question Ff) and lastly, to explore what these manufacturers know about certification possibilities in Kenya (Question Ff)

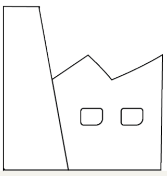
The use of the interview guide has been an iterative and reflective process. During the interviews, the questions have been adapted to either fit the background of the interviewee or improve their effectiveness as more challenges were identified during the interviews.

To answer question Fe, the collected data has been analysed with the help of 'On the wall' technique (Sanders & Stappers, 2012). Data from the interviews were used as statement cards and clustered together to generate a shared insight [T]. The process required the me to make interpretations of the meaning of the data. It is important to take into consideration that the results are generalisations and conclusions that are only time- and context-bound (Creswell, 2014).

During the research, the interviews were recorded, the insights and observations have been summarised and included in [B] with a number and corresponding time in the recording (where possible).

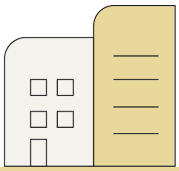
Who is involved in the EU Certification Process?

This section will provide an overview of the stakeholders in the EU certification process, see figure 12. Where certain organisations are appointed by the European Commission or EU-member states that are specific to a country, organisations in the Netherlands are taken as an example. Next to each description is a set of icons used in the visual overview of the EU certification process in [E]. The information below is taken from the Dutch government website Rijksoverheid.nl (2022).



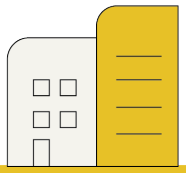
Manufacturer

The company who wishes to obtain CE-mark for their medical devices in order to market these products legally.



Inspectie Gezondheid en Jeugd (IGJ)

A regulatory body and governemental organisation in the Netherlands that monitors the notfied bodies, is involved in conducting clinical investigation, monitors notifications of incidents and corrective actions undertaken by manufacturers and also monitors the manufacturers, EC REPs and importers.

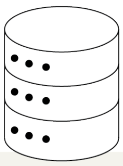


Notified Body (e.g. DEKRA)

Organisations are appointed by the European Commission to check manufacturers on their compliance with the MDR. These organisations have the mandate to issue a CE-mark if a medical device succesfully meets the requirements of the MDR. An example of a notified body in the Netherlands is DEKRA.

Centrale Commissie Mensgebonden Onderzoek (CCMO)

A national authority appointed by EU-member state, in this case the Netherlands. The national authority is responsible for validating applications for clinical evaluations. The CCMO can verify the test protocol itself or pass this on to the MREC. This was previously done by IGJ.

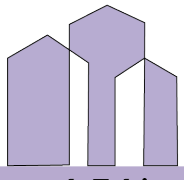


EUDAMED

European database for medical devices. This database is publically accessible and provides data about medical devices, manufacturers and notified bodies. It is still under construction.

EU REP

If a manufacturer is not located in the EU, it must appoint an authorised representative, called the EC REP, that is located in the EU. The EC REP must be qualified to handle regulatory issues (Emergo, 2022).



Medical Research Ethics Committee (MREC)

This body evaluates the plan for clinical evaluation and alter it so it fits the requirements of MDR. In the the Netherlands, it is refered to as the Medisch-ethische toetsingscommissie (METC).

Figure 12: An overview of stakeholders in the EU certification process.

4 CHAPTER

Certification in the EU

The EU member states have developed a harmonised regulatory framework for medical devices in order to trade freely across countries within the union (Kedwani et al, 2019). Since May 2021, the EU has adopted two regulations of the Medical Device Regulation (EU 2017/ 745-MDR) that will govern new technologies to ensure the protection of patients and users. The regulation (EU) 2017/745 is specific to medical devices.

The Medical Device Regulation (EU 2017/ 745-MDR) is binding for all EU member states. The EU-MDR has tightened its legislation to address the need for improving transparency about the safety and clinical performance of medical devices as a result of previous scandals related to breast implants. For high-risk devices, the medical device manufacturers must now update their published results annually (Fraser et al, 2018). Other changes include alterations in classification systems, the establishment of the EU database EUDAMED, a mandatory Unique Device Identifier (UDI), stricter requirements for notified bodies, clinical studies, performance evaluations, st-market surveillance systems, risk- and quality management and the technical documentation. (Kedwani et al, 2019). For more explanation on the different aspects see [E].

In the EU-MDR, certain organisations named notified bodies are appointed by the European Commission to check manufacturers on their compliance with the medical device regulations (MDR). According to the quality manager from organisation A, it is a commercial sector where a medical device manufacturer can approach any notified body within the EU with a large sum of money to ask them to do an audit for certification [B, 28). If the medical device successfully meets the requirements of the MDR, a notified body can issue the Conformité Européenne (CE) mark. Manufacturers receive permission to put the mark on the device as proof of compliance with the MDR of the EU (Dusabe, 2020).

How does a manufacturer choose?

CE certification holds several aspects which are taken into consideration in a medical device manufacturer's choice for certification. One general aspect is whether a medical device is destined to be sold to an existing organisation that is experienced in certifying medical devices or whether a medical device will be the start of setting up a business and adding future devices to the portfolio. Other aspects have been addressed in interviews with the organisations from the Global North that have chosen to obtain a CE certificate for their medical devices. These point out both advantages

Advantages CE certification

The organisations from the Global North who sell their medical devices to the Global South have to seek what is necessary for the countries of their intended market and balance the size and the location of the market against the costs of the CE-mark [B4, 35]. One reason for considering a Global North certificate is because it is widely accepted. Global South countries differ in their requirements and the certificate may enable a manufacturer to sell to multiple countries [B4, 36] [B7, 5]. It is also a useful option if a manufacturer is still uncertain about which country it intends to target.[B1, 3 & 4]. The CE-mark from the EU can open the door to global procuring agencies and NGOs [B4, 28] who require medical devices to have such a certificate. For example, organisation E is obtaining a CE certificate for their medical devices because it allows them to become part of a UN framework and end up on their procurement catalogue [B2, 5]. Other agencies such as the procurement departments of hospitals may also require certain standards or certificates [B6, 3].

Disdvantages CE certification

Manufacturers' experience with the EU certification process is that it takes a long time to keep up to date. The notified bodies who oversee the medical device legislation are expensive, they tie up companies for a long time with unexpected audits [B3, 31]. They also do not tell a manufacturer what to do [B1, 34] and manufacturers must think of all the claims and requirements of the device by themselves. Because of this, the process is prone to mistakes that result in resubmissions. These take time and are expensive meanwhile the restrictions of medical device regulations in the Global North are increasing [B3]. Especially for start-ups this is difficult as their inexperience with medical device legislation may lead to multiple resubmissions [B1, 35] [B6, 1-2]. Therefore, it is beneficial for manufacturers to stay on the safe side when making claims about their medical devices. For example, organisation A explains that even though an ISO is not mandatory it is too risky to come up with requirements on their own.

Moreover, claims about a device are not always to be found in an ISO standard but there may be ones that are applicable to specific claims [B4, 17 and B1, 30] oftentimes, to stay on the safe side, a manufacturer purchases the standards which are expensive [B1, 30].

What Global North manufacturers do

Medical device manufacturers may opt for the CE certificate because it offers the right advantages and it suits their future plans. However, they still need to bridge the gap between what is required in the Global South as opposed to the process in the Global North [B7, 14]. Personas are depicted in [F]. They represent the anonymised manufacturers who have been interviewed about their choices for certification, their strategies and experiences in acquiring certification for their medical devices and introducing them to markets in the Global South. Most manufacturers choose to obtain the EU certification [F]. These strategies help manufacturers to prepare for the CE certificate with a view to reducing labour and costs:

Strategies for introducing to LMIC

- It is useful to have Biomeds as contacts. Biomeds stand for biomedical equipment technicians and these are the maintenance staff at hospitals who are also sometimes involved in the procurement process [B1, 12]. They also often know who the distributor is of a hospital.
- Apart from making medical devices reusable, manufacturers are also taking responsibility in ensuring a proper design. Use risk assessment to deal/predict adverse effects in advance with the local users also [B1, 49]
- Even though reusability is a challenging aspect within the certification of medical devices, manufacturers are taking responsibility in making the devices reusable [B4, 11] [N]. A manufacturer may make a differentiation in the instruction about a feature the device is officially certified for but what may be possible in practice. [B4, 12],
- Even though online literature and medical device manufacturers state that MDR in the EU have tightened, the founder of organisation B mentions that he has to argue with the notified body and draw from his experience from the field (In the Global South) to account for product claims and other device features. [B3, 34].
- Manufacturers may send a local representative to manage the certification process for them as they can physically visit offices and be redirected to the correct one [B7, 6 & 15].
- Manufacturers may also visit the countries personally to establish contacts, engage with relevant agencies, receive feedback from their users in the local context or learn about the market first hand in terms of distribution etc. [B1, 2 and B4, 1-2]
- Manufacturers may work with local contacts; doctors, clinical bodies or a medical discipline to make a strong case for certification [B1, 11-12] [B6, 8] [B3, 38-39] and demonstrate that their medical device creates no adverse events [B6, 7] [B3]
- Designing for remote and minimal maintenance of the device. [B3, 41]
- Use pre-certified parts for their medical device. [B1, 14] [B4]
- Big companies may be quicker in getting things to the market because the internal structure (such as the QMS and PMS [E]) are there whereas smaller organisations need time to build and organise an appropriate structure. However,the certification process itself takes just as long for everyone [B1, 39 & 23].
- Look at comparable products that have gotten to the local market. [B1, 48 and B6, 9] [B4]
- Check what other local bodies who you want to sell to require [B6, 3]
- In the experience of organisation B, design modifications as a result of the certification process are about materials that may cause harm, the safety of the production method and the use of colour e.g. some colours symbolise a certain function. [B3, 30].
- Approach a procuring agency to avoid dealing with corruption in public sector [B2]

4 CHAPTER

Strategies for the EU certification

- Organisation A stated that they are deliberately leaving extensions behind during certification to reduce costs and the EU MDR allows this [B1, 17] however this is counterstated by organisation B [B4, 38]
- Read the DOC of other devices for the rationale about the classification [B1, 38]
- Be critical about the definition and scope of use: in local legislation are there things that can be left behind? [B4, 24 & 25)
- Since the classification of medical devices has an influence on the certification process, it may help to keep the device to a lower class. Organisation D, for example, is downsizing the diagnostic function of their device to a screening function to limit the responsibility the device has [B1, 35 and B7, 12]

What manufacturers know about Kenya

Targeted trading countries in the Global South may require a manufacturer to obtain their local certificate(s) [B7, 3]. Organisation D states that for them, the CE mark is currently a waste of time and resources because their Global South target country [B7]. Organisation E states that there is also value in arranging certification locally in the country. Certifying the Chloe SED locally in Kenya may allow her to skip some very expensive and complicated stages that are inherent to the journey for an EU CE-mark [B4]. Other benefits for certifying locally will be discussed in the next chapter.

When inquiring these manufacturers about what they know of medical device legislation in Kenya and the possibilities of obtaining a Kenyan certificate, organisations were mainly familiar with the PPB as the regulatory board [B1] that dealt with medical device registration [B5][B4] and that the CE mark usually suffices [B6] [B3]. The founder of organisation B, was familiar with the PPB and knew that they based their classification on the risk of the device. The founder also mentioned that the PPB is very disjoint in some places. [B3]. The founder of organisation F was unfamiliar which regulatory approval method was used in Kenya, but told that FDA approval is okay in many countries across the world [B6, 5]

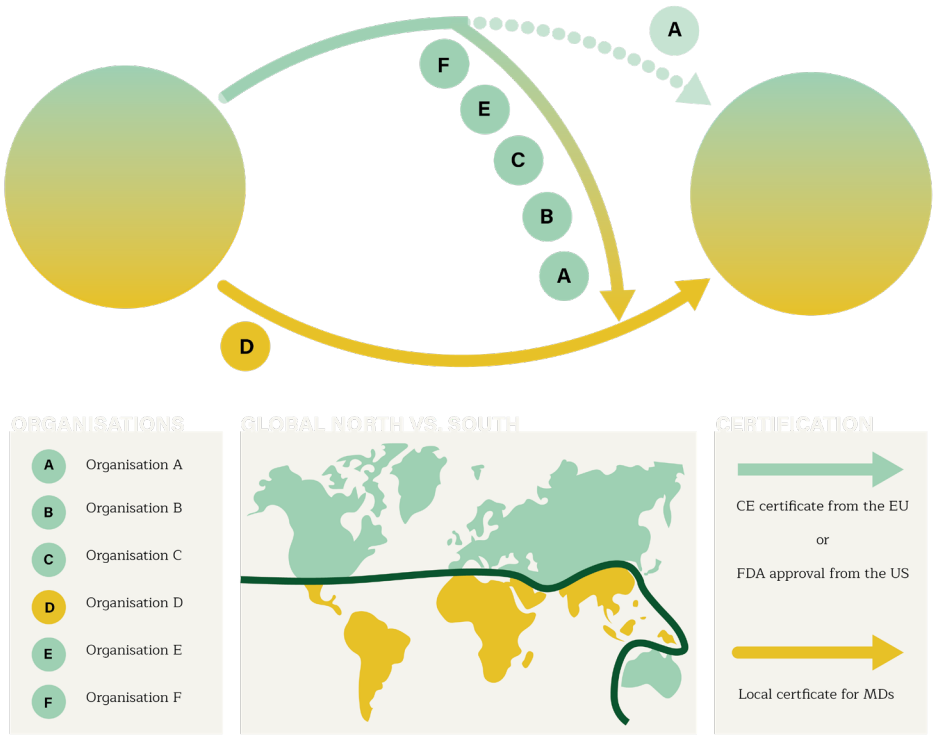


Figure 13: An overview of the certification paths Global North based manufacturers of medical devices have chosen to take. Yellow represents certification from a Global South country and blue represents certification from a Global North Country.

Conclusion

Figure 13 provides an overview of the medical device manufacturers and whether they have chosen to obtain a certification from the Global North or one from the Global South. Generally, the manufacturers that have been interviewed chose to obtain Global North certification, namely the CE certificate of the EU. The biggest advantage is that the CE certificate is widely accepted by target trading countries, (international) procurement agencies and other relevant entities. It is also a useful certificate when a manufacturer is still unsure which country to market to, including the European market.

However, the CE certificate also has disadvantages. The certification process takes a long time to keep up to date due to tightened regulations. Notified bodies are expensive and can keep the organisation occupied for a long time with unexpected audits. Manufacturers have to think of the requirements themselves, as mentioned in Chapter 3, and consequently, they must play safe by e.g. purchasing expensive ISO standards which are not mandatory but can help reduce the risk of making a mistake or leaving something out. For smaller organisations, startup costs in this field are high and their inexperience makes them extra prone to mistakes, while they have fewer means to account for them.

There is a close relationship between the business case for the medical device and the certification a manufacturer chooses to obtain. The choice depends on the trade-off between the market size, where the market can be found, the requirements from relevant (procuring) entities and the time and costs of the certification process. Manufacturers also must take into account how much they need to invest in bridging the gap between North and South and whether they have the right capabilities and network.

How manufacturers are bridging the gap between the two halves of the world, is mainly their responsibility. They may argue their choices in the certification process with a notified body in the Global North as they draw from their experience in the field. They may compensate for the discrepancy by providing extra information in the instructions about what a device is certified to do versus what it can do in practice. They may invest resources in visiting the target countries and/or establish local contacts that can help them find the right information. Manufacturers also carry out clinical trials in the Global South and ask for feedback from the users in the local context to achieve a proper design. It also seems their responsibility to ensure their device is reusable and requires minimum maintenance.

A reason for medical device manufacturers to avoid Kenya as a (first) target country, was because they were deterred by the bureaucratic medical device legislation of the country. Medical device manufacturers from the Global North who were marketing to Kenya chose the CE certification and were mainly aware of the PPB as a body that facilitates the registration of medical devices to obtain approval from the country. They were unsure about any possibilities of obtaining certification locally.

For Chloe SED, however, it is interesting to look at local certification possibilities. The Chloe SED can bring economic value to Kenya when the certification, as well as the manufacturing process, are done locally. As stated in Chapter 1, the Chloe SED project aims to offer the device at $5 or less and certifying and manufacturing locally helps keep the costs of the Chloe SED low because it can skip some complicated expensive stages of the CE certification process, however, it is of utmost importance that patient safety and quality assurance may never be called into question.

5

CERTIFICATION OF MEDICAL DEVICES IN KENYA

In the previous chapter, research was carried out to identify factors that influenced a manufacturers' decision to choose or not to choose a Global North clearance for marketing its' devices in the Global South. Even though the majority chose a clearance from the Global North, it is interesting for the Chloe SED project to certify and produce the device locally because it can reduce costs. The Chloe SED project is an initiatve with a device that is still under developement and operating on a local scale can simplify the collection of data and feedback from the market and accelerate further developement of the device. Other good reasons for local production is contributing to the development of Kenya's medical device industry and the promotion of the innovation capacity within. As a result, medical devices can be developed that are more affordable, sustainable and can more effectively cater to the need of the local context, which ultimately inceases access to health care (WHO, 2012).Until now, it remains unclear whether the PPB only facilitates the registration of pre-certified medical devices to issue certification or whether it is possible to obtain a Kenyan certificate locally. In this chapter, research is carried out into the Kenyan certification process to understand what Kenyan medical device manufacturers are doing to obtain a certification which allows them to sell within their country. In this chapter, appendices are refered to as [Appendix number]. insights in the appendix are reffered to as [Appendix number, insight number].

5 CHAPTER

Method

The following sub questions have guided the qualitative approach to research question G: **What certification path do Kenyan manufacturers that design medical equipment for Kenya choose and why?**

a. Who is involved in the Kenyan certification process?
b. Is it possible to obtain a national Kenyan certification for medical devices without prior approval from abroad and what does this process look like?
c. What are advantages and disadvantages of the Kenyan medical device certification process?

For questions Ga and Gb, a literature study was conducted to find articles about whether and what kind of certification path is in place in Kenya. It was difficult to find relevant information because articles were about the general presence of medical device regulations in African countries. Moreover, what is stated on paper may not be in line (anymore) with what happens in practice, especially in countries that might still be developing these systems [B2]. Consequently, information taken from online sources is mainly used to understand who the stakeholders are that are involved in the Kenyan certification process.

To collect more topical information about certification possibilities in Kenya (Question Gb), in-depth interviews were conducted with an employee from the PPB and a Kenyan pharmacist who had experience with the PPB. While visiting Kenya, in-depth interviews were conducted with an employee of KEBS and five Kenyan medical device manufacturers that were mainly start-ups. The notes and the insights can be found in [O]. Insights from the interviews were transformed into personas [V] to improve my understanding of the certification possibilities in Kenya and to create an overview of each interviewees' certification process. Creating personas allowed me to plot their certification process on a timeline, add missed information from the recordings, highlight important learnings and provide context for their journey by using a quote and stating the class of their medical device.

The interview guide that was used for interviewing Kenyan manufacturers is presented in [I]. The questions in the guide differed per manufacturer based on the amount of information accessible before the interview.

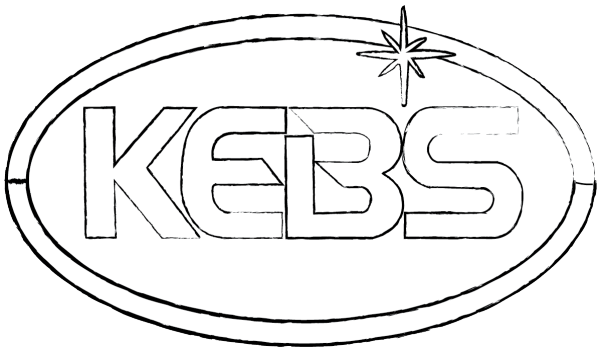
To complement the data collected for question Gb, a focus group discussion was held with entrepreneurs in the medical device industry. They were first given the task to map out the certification process in Kenya based on their experiences. The participants were then asked to write down who were involved in each step of the certification process, what they needed to prepare and the challenges they had experienced. The focus group discussion was a useful tool to receive information in an organised way and helped understand the phases of the process, the possibilities and challenges for manufacturers. Materials that were used for the focus group discussion and the outcomes are presented in [U]. The outcome of the focus group discussion was used to map the Kenyan certification process (for a device that has no prior approval from abroad) and the information was complemented with the insights from the personas.

Once again, an 'on-the-wall' technique (Sanders & Stappers, 2012) was performed similar to chapter 4, to generate insights about advantages and disadvantages of the Kenyan certification process [T]. The data sources were statements and insights from the interviews with Kenyan medical device manufacturers on the certification process (Question Gc).

Certification in Kenya: who is involved?

The two main bodies that are involved with certifying and overseeing medical devices in Kenya are the Pharmacy and Poisons Board (PPB) and the Kenyan Bureau of Standards (KEBS) [O1,2]. The PPB is responsible for regulating the 'Practice of Pharmacy and the Trade in Drugs and Poisons'. The Kenya Bureau of Standards (KEBS) is mandated to offer quality inspection of imports based on Kenya Standards or approved specifications. According to a notice by KEBS and PPB, the importers of medical devices and medical cosmetics amongst other things must obtain Certificates of Conformity (CoC) for their cargo before applying for Import Permits from Pharmacy and Poisons Board (KEBS, 2022) [O1, 4]

For medical devices manufactured in Kenya, the PPB handles applications of medical devices, checks manufacturers' technical documentation and approves clinical trials [O1, 1] and KEBS checks on the medical device production and tests the device against the standards to give out a Standardisation Mark (SM) [O1,1 & 3]. Other bodies involved in the certification process are the Kenya Industrial Property Institute (KIPI), and the Ethical Research Committee which are involved in administering intellectual property rights (KIPI, 2017) and approving clinical trial protocols respectively [O1] [O2].



5 CHAPTER

Certification in Kenya

In 2020, KEBS initiated an effort for local certification of medical devices with the PPB [O7] when the outbreak of COVID resulted in a lack of domestic capacity to produce more ventilators. It pushed people from the medical device industry to come together and pave a path for local certification possibilities. The Pharmacy and Poisons Boards' guidelines (2018 C) on 'submission of documentation for registration of medical devices including in-vitro-diagnostics', shows four evaluation options which manufacturers can choose in order to receive the national market authorisation. These options are referred to as the immediate, abridged, expedited and full evaluation route [H].

Which route a manufacturer is able to take, depends on whether the device has already obtained prior approval from 'Reference Regulatory Authorities'. It is a confidence-based approach where prior approvals from elsewhere, enlisted in the PPBs 'Reference Regulatory Authorities', may qualify for a shorter evaluation route. This reference list includes the EU-MDR's CE-mark and the FDA approval from the US. See figure 14 for an overview of the four different routes accompanied by the certificates they require.

Basically, the more prior approvals a medical device has obtained, the more credibility a manufacturer builds with the PPB and the shorter the evaluation process is. However, there are some certificates that the PPB trusts more than others. The trust in the EU-MDR clearance is high and desirable and will suffice for an abridged evaluation route, according to an employee at the PPB [J, 9-13].

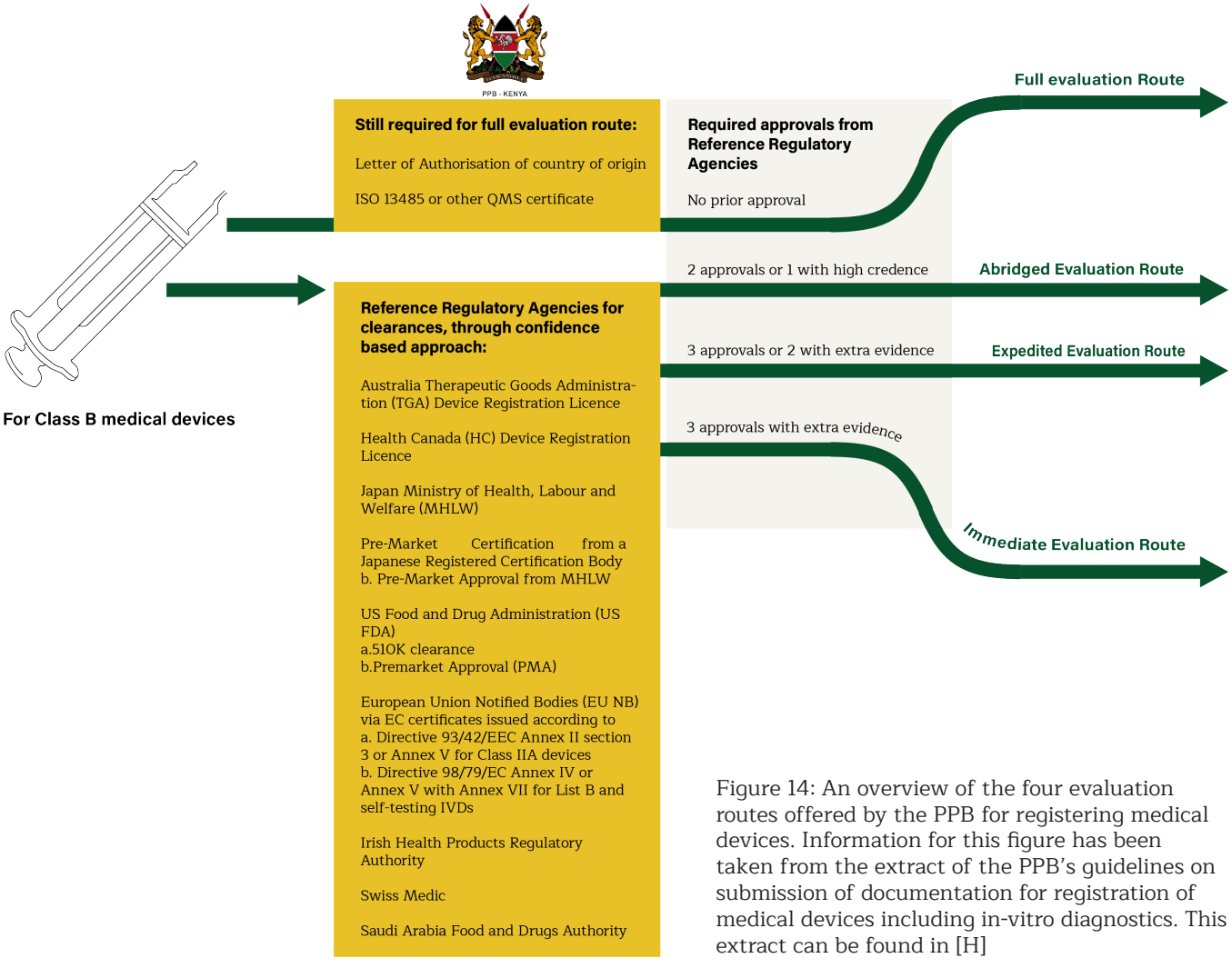


Figure 14: An overview of the four evaluation routes offered by the PPB for registering medical devices. Information for this figure has been taken from the extract of the PPB's guidelines on submission of documentation for registration of medical devices including in-vitro diagnostics. This extract can be found in [H]

However, if a medical device has not obtained any prior approval from the Reference Regulatory Agencies at the point of application, it will be subject to the full evaluation route' (Ministry of Health Pharmacy and Poisons Board, 2018 C). After interviewing an employee at the PPB, it became apparent that a manufacturer still needs to show a letter of authorisation from the export country to assure the safety of the device [J, 14-17]. If the medical device has successfully gone through one of these evaluation routes, the device will receive a certificate from the PPB and a manufacturer needs to make sure that it obtains a certificate from KEBS as well and make sure he has arranged the Intellectual Property at KIPI [J, 22 & 24].

PPB employee:

"Even if there is no prior certification, I still need a letter from your PPB telling my PPB that the medical device is okay for use [L,16].

The PPB employee explained that she has only dealt with medical devices that had received clearances elsewhere and that ideas generated locally usually seek the (financial) support of NGOs, are then manufactured and certified abroad and imported back to Kenya again. She also mentions that there are other ideas that do not manage to get funding to execute any plan [J, 19-20]. However, the PPB employee thinks it is possible to bring a medical device to the Kenyan market without having a CE or FDA certificate [J, 22]. A Kenyan pharmacist who worked for multinational organisations and often registered borderline products and medical equipment at the PPB explained he was only used to dealing with products that were CE-certified. However, he also believed it was possible to obtain a certification locally but did not know who achieved this [K].

To do research into local certification possibilities for medical devices without prior certification, I visited Kenya and spoke to 5 medical device manufacturers, an employee from KEBS and facilitated a focus group discussion to collect information on the Kenyan certification process. Information about the Kenyan certification process was based on their experiences.

In the next section, I will depict the certification process each interviewee has gone through, followed by insights about the advantages and disadvantages of the process.

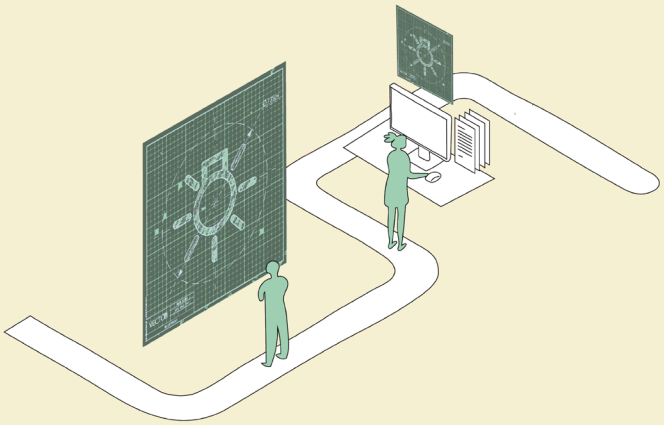
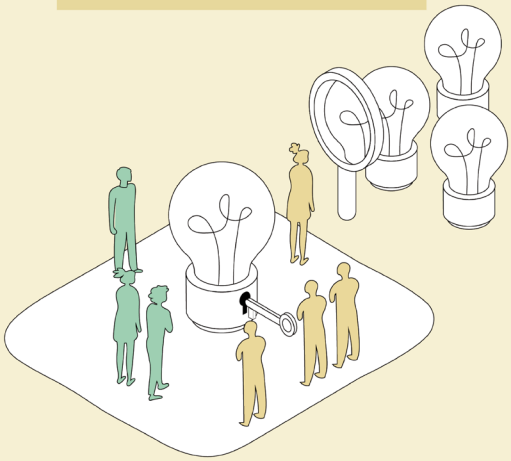
What Kenyan Manufacturers do

In this section, the certification process based on the experiences of Kenyan medical device manufacturers, a KEBS employee and the focus group discussion are presented in the form of personas. Manufacturers have experienced phases in the process in different order and have not always completed the process until receiving national market authorisation. The personas are presented with an illustrative quote, the certification process they have experienced based on insights from the interviews and the most important learnings about the Kenyan certification system.

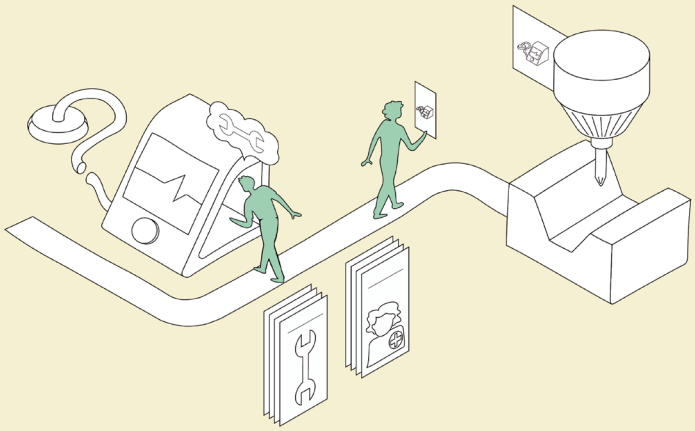
A framework based on the Focus Group Discussion and Interviews

The particpants in the interviews and the Focus Group Discussion have not all successfully passed through the local certification system in Kenya. However, information about this process has come to light with the help of the personas [V] that were created from the above-mentioned interviews and the results of the Focus Group Discussion [U]. The latter has formed the basis for defining different phases of the Kenyan certification process in the form of a framework. See [U] for the outcome of the Focus Group discussion. The insights from the interviews were used to complement this framework.
The lines in the framework represent the certification journey of each interviewee above, including the focus group discussion. The numbers plotted a line demonstrates the order of the phases in which the manufacturers have gone through the certification process until the point they have reached so far. The reason for showing different sequences of the phases in each certification process is because information overlapped in some places but also conflicted. See figure 15 for the framework.

A picture of the Focus Group Discussion

	IDEATING	INTELLECTUAL PROPERTY
ACTION		
DESCRIPTION	Design iteration Documentation	Check originality idea Approach KIPI and receive patent(s) Ownership of device
OUTCOME		Legal agreements on the idea and roles in the collaboration
STAKEHOLDERS	Design team/ Manufacturer	Design team/ Manufacturer Funders and other stakeholders Kenya Industrial Property Institute (KIPI)
REQUIREMENTS		Idea Manufacturing facility for prototype
PERSONAS JOURNEYS M	1	
N	1	
KEBS		
FG	1	
O	1	6
CHLOE	1	3
NOTES		

PROTOTYPING



Prototype and make iterations

Fabrication of device

Drafting User manual

Drafting Technical manual

User manual

Technical manual

Documentation

Working device

Design team/
Manufacturer

2

2

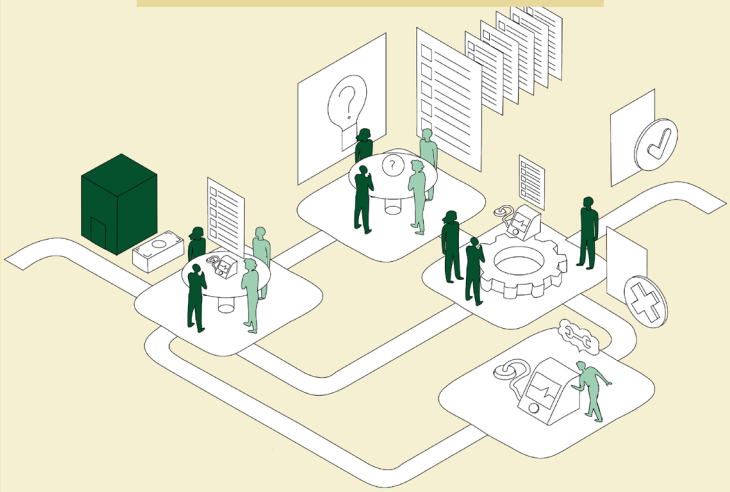
2

2

2

In the next stage, approaching KEBS and obtaining their two certificates is sufficient for medical devices of class A (no PPB involved). Manufacturers of higher risk-class medical devices must approach KEBS and the PPB.

TESTING AGAINST STANDARDS



Approach KEBS and show device

Pay fees and agree to standards

Facility inspection by KEBS

SM

CC

Test device against standards

Recieve KEBS report

If report states failure:

Make changes to device

Pay fees

Testing on previous standards

KEBS calibration certificate (CC)

Optional: KEBS SM Permit (SM)

Engineers from
the design team

(Chief Engineer)
KEBS

User manual
Technical Manual including indication of class
Sample device for testing

3

2

3

3

KEBS calibration certificate
= The performance report
of the device

KEBS SM Permit =
Standardization Mark
Permit (incl. QMS)

CLINICAL TRIAL PROTOCOL APPROVAL, PPB

Draft protocol and documents

Approach the PPB

Apply for clinical trial

Apply to stage of clinical trial

Answer questions from the PPB

Possibly make resubmissions

Make the PPB understand

Recieve approval from the PPB

The PPB ECCT Initial approval letter for clinical trial

Design team/ Manufacturer

The PPB

Techincal Documentation
[KEBS calibration certificate]
Training and User manual

Technical manual
Internal testing & Trial Protocol
Medical Device samples fabricated

4

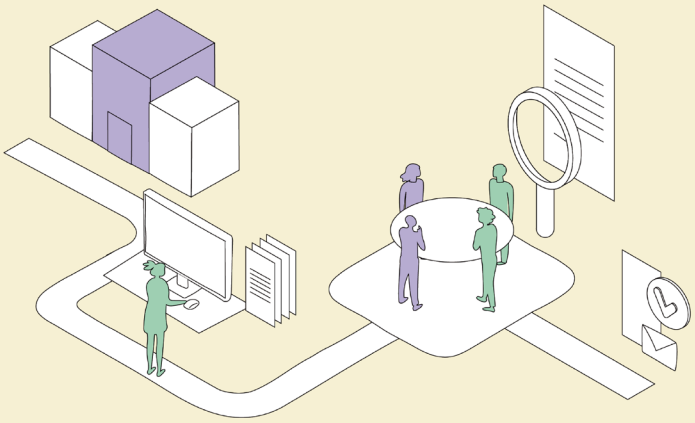
1

3

The PPB ECCT = The Pharmacy and Poisons Board Ethics Committee of Clinical Trials

KEBS certificate(s) is required if device has not been tested to relevant ISO standards

CLINICAL TRIAL PROTOCOL APPROVAL, REC



Apporach Ethical Review Committee

Submit Protocol

Review by Ethical Review Committee

Recieve approval from Ethical Review Committee

Ethics Review approval letter

(Doctors) from the design team

Research Ethics Committee (REC)

Techincal Documentation
[KEBS calibration certificate]
The PPB ECCT approval letter
Training and User manual

Technical manual
Internal testing & Trial Protocol
Medical Device samples fabricated

5

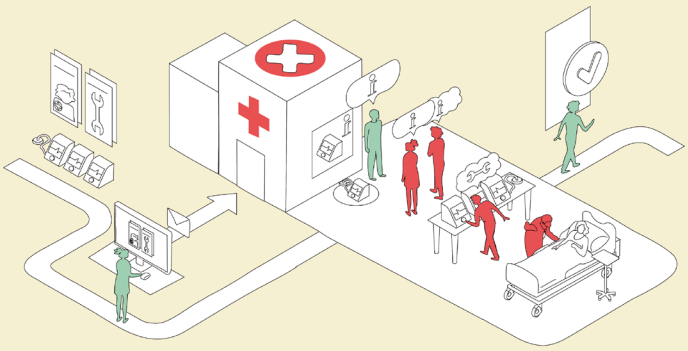
4

4

4

The REC review research applications and decide whether the research is ethical

CLINICAL TESTING



Prepare Samples and Manuals
Approach Hospital
Submit Manuals/Documents
Train Nurses and Biomeds
Set Launch Date
Handover Materials
Clinical Testing
Recieve clinical trial report

Clinical validations

Engineers from the design team

Hospital staff: Biomeds and Nurses

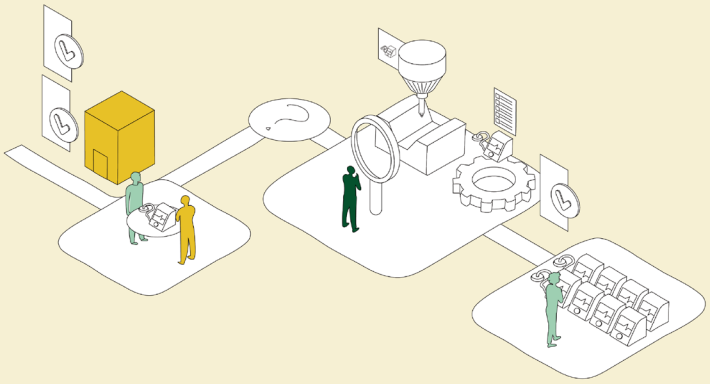
KEBS certificate(s)
The PPB ECCT approval
Trial Protocol
Training, User and Technical Manual

Training nurses and biomeds
Internal testing done
Medical Device samples fabricated
Launch Date for start of testing

6
5
5
5

The hospital writes a report with validation data

LICENSE TO SELL



Approach the PPB with reports
Decide ownership of device
?
Recieve PPB DPER certificate
No SM Permit? Approach KEBS
Inspection by KEBS
Recieve SM Permit
Manufacture (ISO)

The PPB DPER Registration Certificate

Optional: KEBS SM Permit

Design team/ Manufacturer

The PPB

KEBS

(Contract manufacturer)

Clinical trial report
Information on ownership of device
KEBS ccalibration certificate and SM Permit

3
6

The PPB DPER = Drug Product Evalaution and Registration. It is only issued after completion of phase 3 clinical trial

The KEBS SM Permit must be obtained for class B-D medical devices.

LEGEND

- The Pharmacy and Poisons Board (The PPB)
- The Kenyan Bureau of Standards (KEBS)
- Designers, engineers or other people from the design team
- Doctors, nurses, biomeds or other staff from a hospital
- Review Ethical Committee
- Other stakeholders e.g. funders, NGO's
- M — The certification process of organisation M
- N — The certification process of organisation N
- KEBS — The certification process according to KEBS
- FG — The certification process according to the Focus Group Discussion
- O — The certification process of organisaion O
- CHLOE — The certification process of the Chloe SED
- 4 — The number of the phase in the order it occurred
- An empty circle means the corresponding phase has not been mentioned or has not occurred (yet).

EXTRA NOTES

- KEBS will look into East African Standards (EAS), then into local standards (KS), then into ISO standards. If the device is too novel, customer specifications are developed.
- In this stage NACOSTI is involved. NACOSTI oversees and regulates all research and they must be informed of the clinical trials for quality assurance purposes. They can also act as a link with the organisations a manufacturer needs to consult and involve in the clinical trials.

5 CHAPTER

Notes about the Framework

Manufacturers mentioned that one needs approval from KEBS in order to approach the PPB. After the Focus Group Discussion, one manufacturer informed that this concerned the KEBS Calibration certificate.

Information has been conflicting: It has been mentioned that the PPB approaches KEBS for testing medical devices against standards, however, manufacturers have often mentioned that they were the ones to approach KEBS and that this happens before approaching the PPB.

Information was also conflicting about whether the KEBS SM Permit including the QMS, must be obtained before or after registration at the PPB. People have differed in the sequence of the phases they completed.

A manufacturer must approach an Ethical Review Committee for protocol approval for the clinical trial.

It has been difficult to find an organisation that has done certification fully locally. Revital Healthcare until now has mentioned as the only one.

It is mentioned by manufacturers that class I medical devices do not require a manufacturers to approach the PPB

The length of the phases have differed per manufacturer.

There are social factors involved in the process e.g., the context of the manufacturer can create trust or distrust at the PPB and it helps to have certain contacts at the PPB and KEBS.

Advantages of the Kenyan Certificate

A manufacturer can sit together with KEBS for novel devices such as the Chloe SED to agree on standards for the test. A manufacturer then knows how to prepare itself for inspection.

The fees may be less than those of the CE certification process

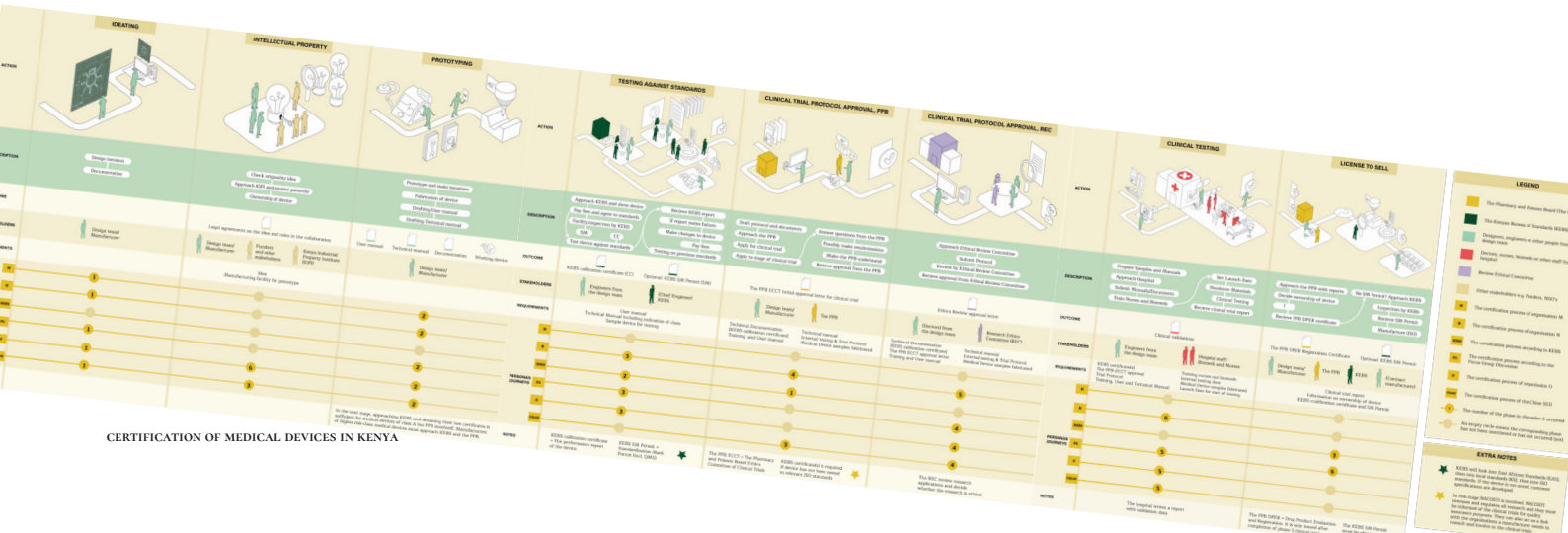
Disadvantages of the Kenyan Certificate

KEBS and the PPB certificates are not recognised broadly. For now, it is known that it only gives market authorisation in Kenya and it is the question whether it is recognised by other countries in East African Area.

Few have completed the certification process before and progression can be uncertain. There are tricky factors that the PPB depends on such as social contacts.

Manufacturers in the Focus Group Discussion and in-depth interviews have mentioned that in some cases, the time it took to await results was frustrating and that the inexperience of KEBS and the PPB can be a hindering factor. It was mentioned that their experience lies most with higher class medical devices.

Until now, only Revital Health care is known to hold the ISO 13485 certificate for their production of medical devices (with injection moulding). Generally, for manufacturers it is the question whether there are ISO-certified manufacturers for the production of medical devices.



Conclusion

The PPB and KEBS are the two main bodies in the certification of medical devices. They rely on each other's approval. It is even mandatory to obtain certificates from both before introducing a medical device to the Kenyan market if it does not have prior approval.

The framework in the chapter demonstrates that the Kenyan certification process should be possible but few have completed the certification process, by which they have received a Calibration Certificate and the SM Permit from KEBS (or have found an approved subcontract manufacturer) and a DPER Registration certifcate from the PPB. The phases in the process are not fixed in a chronological order and reflect that there is no straightforward way in which medical device manufacturers can receive a Kenyan market authorisation. The process can be unclear to manufacturers and those who are currently in approach it in an ad hoc manner. Manufacturers have also shared that the process is known to be untransparent and lengthy but that it can depend on the complexity and class of the medical device. These aspects may be the result of lack of communication, lack of protocol but most logically, lack of experience in the field of medical device certification.

Until now, KEBS has mainly been involved with class I medical devices and higher class devices are still new terrain. Unlike in the EU certification process, medical device manufacturers can establish standards together and agree with KEBS when it concerns a novel device. However, medical device manufacturers have indicated that KEBS relies on their expertise in practice as they needed to show KEBS what standards were applicable.

Some aspects seem certain about the Kenyan certification process: registering at the PPB is the last step in the process before marketing the devices unless the Standardization Mark Permit from KEBS for the QMS is still required. Another certainty is that manufacturers that are producing medical devices that are lower than class A, do not need to involve the PPB before marketing their devices. Lastly, from the experiences of medical device manufacturers, going through the process depends on a lot of human factors such as the contact person at KEBS or the PPB, the context of the developer which can either create trust or distrust with the PPB and the corruption that may occur during the process.

Furthermore, the medical device industry in Kenya seems to be complex to such an extent that good ideas generated locally seek support from organisations abroad and be certified and manufactured there to be imported back to the county again. Even though manufacturers can see the value in doing things locally, it is difficult for them to find funding for the clinical trial and to find ISO-certified contract manufacturers that can take care of the production of higher-class medical devices. Currently, Revital Healthcare seems one of the few manufacturers in Kenya with an SM Permit that can do injection moulding. According to organisation O, there are more certified manufacturers in South-Africa but the prices can hardly compete with those in India, which is regarded as the hub for medical device production. Another reason for seeking help abroad regarding certification is that the Kenyan certification seems only useful for marketing in Kenya. Meanwhile, the PPB accepts the CE mark of the EU and other Global North clearances which allows medical device manufacturers with these certifications to follow a shorter evaluation route.

In the next chapter, we will take a look at Chloe SEDs certification journey until now and what the next steps would be for the device in the Kenyan certification process according to the framework.

6

THE JOURNEY OF THE CHLOE SED

This chapter takes a look at what the Chloe SED project has done in the certification process until now and project her journey on the framework in the previous chapter. The aim of this chapter is to identify what the next steps are for the Chloe SED to obtain certification locally in Kenya.

6 CHAPTER

Method

This chapter is conclusive in nature and insights obtained from the previous chapter have been used to answer research question H:
What are the opportunities and challenges in bringing the Chloe SED to Kenya?

a. Where is the Chloe SED project currently in the
b. certification process?
   What are the next steps for the Chloe SED in the Kenyan certification process?

While conducting this research, the Chloe SED project has made progress and with their help, the current journey was determined to answer question Ha. For question Hb, insights about the advantages and disadvantages from the EU and the Kenyan certification process were taken from chapter 4 and 5 respectively, and were compared in this chapter. On the basis of this deliberation, next steps for the Chloe

In the Chloe SED's case, the journey started with an idea and prototyping it. The Chloe SED project has approached KIPI for their intellectual property rights. Instead of approaching KEBS, the Chloe SED project has already tested the device against standards at TU Delft, an ISO 13485 certified faculty. The Chloe SED project approached the PPB, received the news that the test against standards at TU Delft suffices and did not need to approach KEBS. KEBS namely, looks into ISO standards too. Currently the Chloe SED project is undergoing a clinical trial at a hospital in Kisumu after having received approval from the PPB for the clinical trial protocol. Training the nurses and biomeds took place at the same time as awaiting the approval from the PPB.

Until now, the Chloe SED project has not approached KEBS and will likely not as they are in search of a sub contract manufacturer that holds a KEBS SM Permit and can produce the Chloe SED through injection moulding (or 3D printing).

The Chloe SED's journey also differs from the journeys discussed previously. In the framework the Chloe SED's journey for the Kenyan certification process is labelled as 'Chloe'. The phases of the certification process differ in some respects from the phases experienced by other medical device manufacturers. For example, the Chloe SED project was able to train nurses and biomeds at the hospital without receiving the ECCT approval from the PPB., while it was specifically mentioned by another manufacturer that this was not possible.

Next steps for the Chloe SED in Kenya

According to the framework, the next step for the Chloe SED is related to the last two phases (figure 16). It is to await the clinical data and incorporate this in their documents. After that, the project can approach the PPB for the PPB Drug Product Evaluation and Registration (DPER) certificate to receive market authorisation. Since it is unlikely that the Chloe SED project will become a start-up and develop their own production faculty, the project must find a sub contract manufacturer that holds a Standardization Mark Permit (includes QMS certificate) and can provide the right production method. The Chloe SED project must also do this to keep the whole process as local as possible and with that, maintain the value of the Kenyan certification. Until now, Revital Health care may seem able to injection blow mould the device.

The Chloe SED project also must keep in mind that even though they have arranged a patent at KIPI, the project must also decide on its business strategy before approaching the PPB and indicating who has ownership of the device [O3].

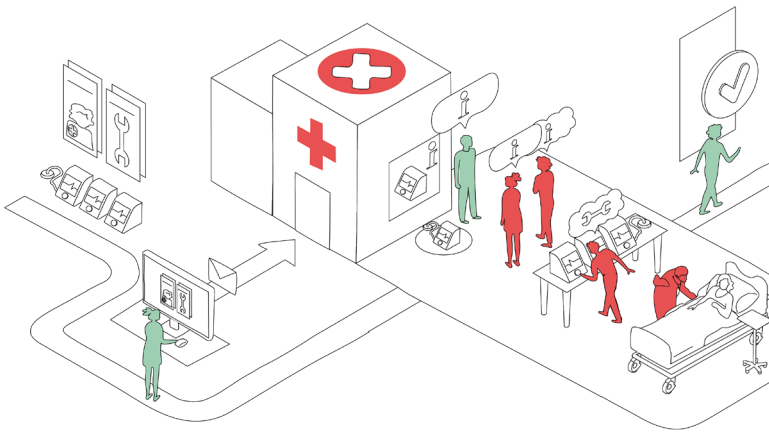
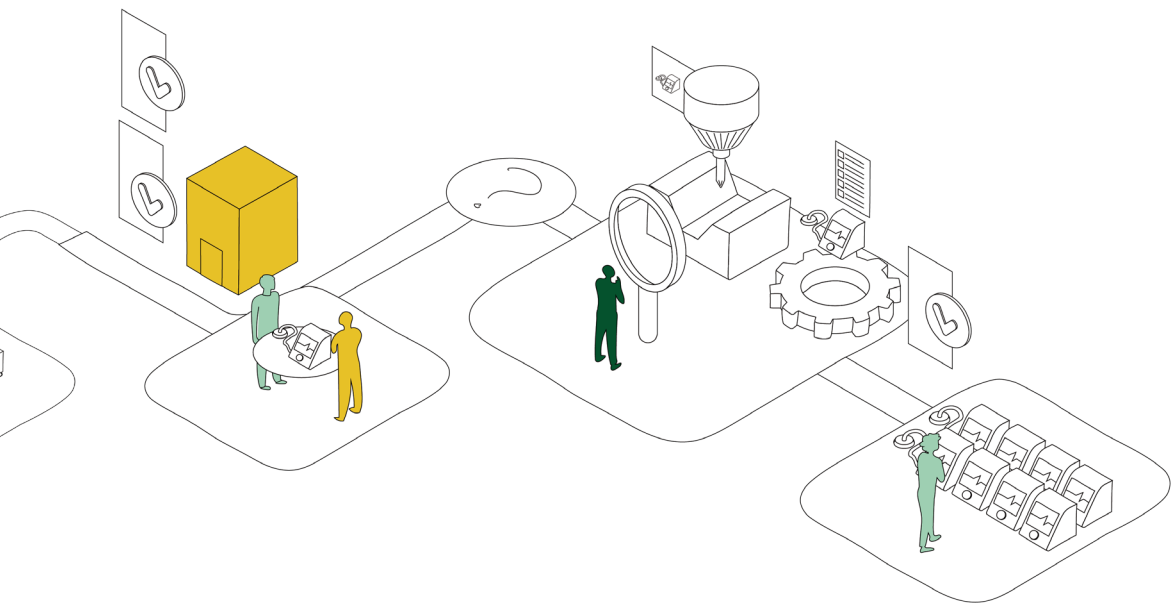


Figure 16: The last two phases of the Kenyan certification process for medical devices without prior approval.



7

BOOSTING THE CHLOE SEDS ACCEPTANCE

Certification is only one part of the many aspects related to bringing the Chloe SED successfully to the Kenyan market. The aim of this chapter is to identify factors within two aspects, namely the procuring and reprocessing of medical equipment, that can contribute to the Chloe SEDs acceptance. The chapter first discusses the research carried out into the procurement process of medical devices, followed by the research on the reprocessing of medical devices. In this chapter, appendices are refered to as [Appendix number]. Insights taken from interviews are refered to as [Appendix number, Insight number].

7 CHAPTER

Research Questions

This section sets out to answer research question 2A: **What prerequisites can be derived from relevant stakeholders regarding the procurement process of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?**

a. How are medical devices procured?
b. Who are relevant stakeholders that are involved in the procurement of medical devices in the Kenyan healthcare sector?
c. How do relevant stakeholders procure their medical devices?
d. How is MVA equipment procured?
What prerequisites can be derived from relevant stakeholders that procure medical devices?

A literature study was done to explore the context of the procurement of medical devices by researching the general supply chain of medical equipment to LMIC.

The research in Chapter 4 provided an understanding of the procurement process in the public sector. Further research was conducted to investigate how other sectors procured and who could be interesting to the Chloe SED project. In-depth interviews were conducted with two doctors, a nurse and a staff member from the procurement department, who each worked for NGOs that operated in Kenya. They shared valuable information about how MVA equipment is procured and who is involved in supplying medical device equipment in Kenya.

The Procurement of Medical Devices

According to Pharmacces (2016), about 52% of the hospitals in Kenya are public and operate under the Ministry of Health, 37% are private hospitals and 11% are faith-based health services. Generally, healthcare facilities set high fees for abortion procedures, which are unaffordable to the majority of women [N, 15]. The high service charges are problematic because women seek illegal help in unsafe environments which can lead to complications (The Conversation, 2020). NGOs can be involved in providing health care services related to sensitive topics. They can be less involved in national politics [N,12]. They can also come into places that are difficult to reach [B3, 24] and may sometimes have experience in locally registering medical devices [B3, 25]. Currently, the Chloe SED project is an initiative and it must consider the market it wants to reach and the stakeholders that can bring the Chloe SED to these markets. These stakeholders may have certain requirements to accept the Chloe SED, including the certification of the device.

There are many parties that can bring a medical device from a manufacturer to the patients. Figure 17 (Accelerating Slab, 2022) shows similarities to publications by the WHO (2017) on the health product supply chain in LMIC. The figure shows that distributors play an important role in the supply chain as they can cater to different sectors. It is also interesting to note that NGOs can have their own clinics and warehouses and can have a relatively isolated supply chain. Approaching a procurement agent can enable a manufacturer to approach the public (and NGO) sector.

The Public Sector

The public sector is the largest. Hospitals in the public sector set out public tenders if they are in need of medical equipment. As mentioned in Chapter 4, the difficulty in this sector is the corruption that is involved in the tendering process [B3] [B4]. In this sector, (international) procurement agencies are an important stakeholder that can save manufacturers from dealing with corruption. [B2] [B3] [B4]. Such agencies can be a UN procurement agency. The UN framework requires medical devices to be CE-marked. They incorporate these medical devices to a catalogue from which they can directly procure the medical devices from the manufacturers.

The Private Sector

In the private sector, hospitals may purchase their medical equipment in pharmacies, chemists or other smaller outlets [M, 3]. They can also set out requisitions for the quality assurance and pricing control of the medical devices [M, 4]. Health care facilities in the private sector procure their medical devices from distributors that purchase from private medical companies. These manufacturers can do their own marketing directly to these health care facilities by organising seminars and providing the facilities with samples [Q, 5]. A healthcare facility can procure medical devices through the distributor connected to the medical device manufacturer.

The Faith-based Sector

Faith-based health care facilities can be interesting to a manufacturer if he/she is dealing with more expensive devices. Organisation E mentions that they can afford more because they receive extra funding from the church in addition to funding from the government [B4, 10].

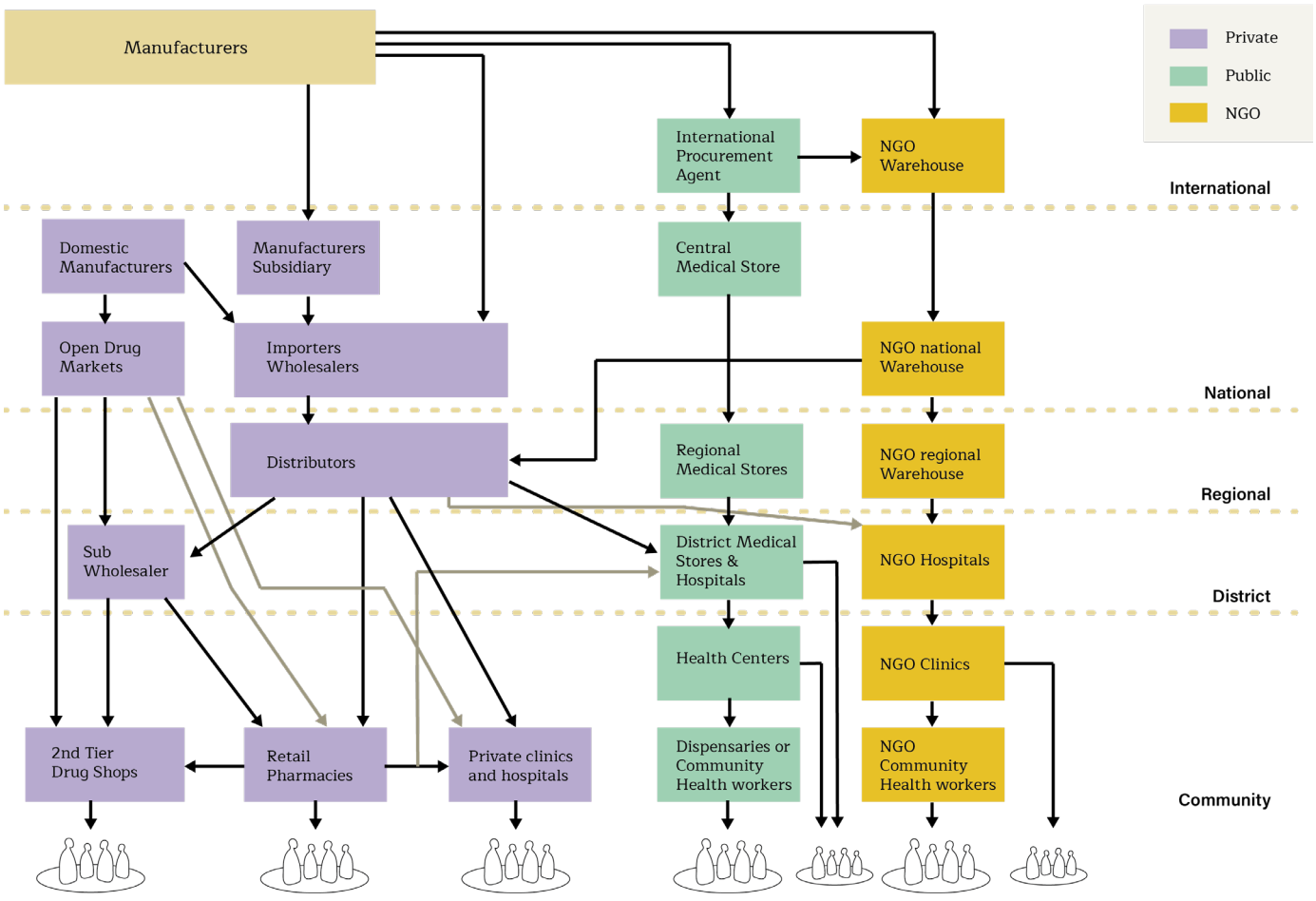


Figure 17: Health Product Supply Chain in LMIC (Accelerating Slab, 2022)

7 CHAPTER

The NGO Sector

NGOs can differ greatly in how they organise their supplies and procure their medical devices [N, 2]. NRHS is a Kenyan NGO that provides circumcision procedures (not MVA) and it is tied to a public hospital. A staff member of the procurement departmant explains that the NGO sets out yearly tenders and makes a short list of about 6 suppliers that have done a bidding and have been approved by the NGOs evaluation committee. When the NGO needs new medical equipment, they approach 2-3 suppliers on the shortlist with a request for quotations and then compare the offers these suppliers have made. The next time the need arises for new medical equipment, the NGO will approach the other suppliers on the short-list to give all the suppliers a fair chance to make an offer. This means that as a supplier, even if you have been placed on a vendor's short-list, you may not supply every time there is a need for new medical equipment because you are also not approached every time [R, 3-13].

AMREF is an international NGO that also has headquarters in Kenya puts out public tenders. Suppliers reply and the NGO tests the devices on the quality and then selects the supplier they wish to procure from. [Q, 21]. They can also have an agreement with suppliers to work with over a longer period of time [Q, 22].

MSF is also an international NGO active in Kenya. Depending on the project, they can supply to public hospitals but do not supply to private hospitals [N, 8]. MSF uses a green list, which refers to a list of medical devices that are approved by the NGO that can be procured through their projects. Principally, MSF does not procure devices outside this green list. The NGO deals with devices that are CE-marked and imports them [N, 7]. It does not procure them locally, but the devices must be approved in the country itself [N, 2]. MSF has their own distribution channels and do not react to tenders to maintain their neutral stance and avoid being involved with politics [N, 12]. The NGO has a warehouse within e.g. IDA group, a distributor in the Netherlands that brings medical equipment to LMIC [N, 4], but also has their own warehouses [N, 13].

Marie Stopes

Two gynaecologists with experience in East Africa, one Kenyan, mentioned that Marie Stopes is an international NGO that aims for reproductive health for women. They offer health care services for miscarriages, abortions and family planning [N, 5]. They are the largest provider of MVA and they have their own clinics in Kenya [M, 1]. Other providers of MVAs mentioned are Family Health options Kenya and Centre for reproductive Health rights [Q, 10 & 27]. Unfortunately the opportunity did not arise to interview them about their procurement process.

Medical Equipment Distributors in Kenya

In Kenya, the largest distributors of medical supplies are KEMSA and MEDS (Mission for Essential Drugs and Supplies). Both reach the public, private and faith-based healthcare facilities throughout the country [R, 14 & 16-18] [B4, 10] [Q, 4] (Ministry of Health Kenya, n.d.). It remains uncertain however if KEMSA and MEDS also offer MVA kits. It is possible that they offer 2-3 brands for example [Q, 7]. Another large distributor of medical equipment mentioned in interviews is Crown Healthcare [R, 19] [O4], Harleys, Cidifarm and Kentons [R,19]

How MVA Equipment is procured

The equipment that is used for MVA procedures are procured as MVA kits [N]. Figure 18 shows an MVA kit that was procured in Kenya. As the Chloe SED is designed to improve MVA procedures and designed to be reprocessed in the same way, it is interesting for the device to become a standard component of the kit. In Kenya, the most common MVA kits used are from IPAS, a supplier that has partnered with the worldwide distributor DKT [M, 2 & 5]. They have a big regional shop that sells to distributors who bring the kits to outlets such as chemists [M, 3]. IPAS instruments are US FDA-listed, CE-marked and ISO 13485 compliant (Ipas, 2022).

Marie Stopes have their own brand of MVA kits [R, 1]. Their website shows that their MVA equipment has also been CE certified, ISO 13485 compliant (Marie Stopes International, 2022).

Figure 18: An MVA kit used in Kenya

Number of MVA kits

When estimating the Kenyan market size based on the demand for MVA kits, data on the annual number of MVA procedures in Kenya is hard to find. However, to give an idea of the number of MVA kits available in a health care centre, a reprocessing staff member at a Kenyan hospital explained that there were 5 kits available per nurse per day to ensure a sufficient supply and flow of equipment used. On average, the number of MVA procedures could vary between 3-10 (mostly 5) per day [S]. Regarding the number of Chloe SEDs, the founder of organisation B explained that even though one might estimate a health care centre needs less Chloe SED devices because the device is reusable, health care centres may need a large number in inventory because the device is relatively small and parts will go missing [B3, 21].

Chloe SED as part of the Loop Electrosurgical Excision Equipment

One expert opinion saw an opportunity for Chloe SED to become part of the equipment used for a Loop Electrosurgical Excision procedure. This procedure also requires the injection of pain relief medicine in the patients' cervix. However, the interviewee was unsure whether the equipment came as a kit in both Kenya and the EU. She mentioned that the equipment might also be collected separately from different suppliers and then assembled for use [N, 14].

7

Conclusion Procurement

Public health care facilities make up for the largest sector. They procure medical devices by tendering but the process is rife with corruption. Organisations from the Global North that are designing medical devices for the Global South have indicated that they are selling to an international procurement agent when targeting public hospitals to avoid dealing with corruption but that these can require certifications such as the CE-mark.

Private facilities may set out requisitions for quality assurance and pricing control of medical equipment and also procure from the same distributors. These are interesting because they can have different standards.
.
Faith-based health care facilities are the smallest sector. They can be interesting for manufacturers because they might afford more (according to a Global North manufacturer).

The largest Kenyan distributors of medical equipment that reach all the sectors are KEMSA and MEDS. It would be interesting to research how they procure their medical equipment, wether they offer MVA kits and which brands.

The equipment that is used for an MVA procedure comes in a kit. It is interesting for the Chloe SED to become part of this kit because it is designed to be used before an MVA procedure and can be reprocessed in the same way. In Kenya, the most common MVA kits used are from IPAS that has partnered up with distributor DKT. There is also a large international NGO in Kenya, named Marie Stopes, that provides MVA. Marie Stopes has their own brand of MVA kits. The MVA kits from IPAS and Marie Stopes are both CE certified and comply with ISO 13485.

There might also be an opportunity for the Chloe SED to become part of the equipment used for a Loop Electrosurgical Excision Procedure as this procedure also requires the injection of pain relief medicine in the cervix. Further research can be done into the procurement of this equipment and how it is reprocessed.

Reprocessing of Medical Devices

Two previous TU Delft student research reports on the Chloe SED project mentioned the reusability of the Chloe SED as an important aspect. How hospitals reprocess their medical devices is of great significance for the durability of a device, its effectiveness and its safety. However, what is stated on paper does not always have to happen in practice [B2]. I had planned to visit Kenya to carry out research on the certification of medical devices and the visit to Kenya was a good opportunity to carry out field research to collect information on how reprocessing is done in practice by interviewing and observing stakeholders in the local context. This would bring more valuable information than relying on online sources. The aim of this section is to investigate whether there are important factors for the Chloe SED project to consider regarding how MVA kits are reprocessed in practice in Kenyan health care facilities. This can lead to recommendations that contribute to the Chloe SEDs acceptance by the Kenyan market.

Method

This section set out to find an answer to research question 2B:
What prerequisites can be derived from relevant stakeholders regarding the reprocessing of medical devices that can contribute to the Chloe SEDs acceptance by the Kenyan market?

a. What reprocessing methods are described by the Chloe SED project and the WHO that are relevant to the Chloe SED? (MVA kits)
b. How do Kenyan healthcare facilities reprocess their medical equipment in practice? (MVA kits)
c. What prerequisites can be derived from the reprocessing method of Kenyan health care facilities?

In the first phase, a literature study was conducted to explore the context of medical device reprocessing that was relevant to the Chloe SED. Research was conducted into reprocessing methods recommended by the WHO. Information was also derived from the Chloe SED project and used as a reference.

In the second phase, field research was conducted. Together with the Chloe SED project, I visited the reprocessing department in 5 different healthcare facilities from different levels in Kisumu, Kenya. Health care facilities in Kenya are divided into six levels of preventative and curative services based mainly on functionality. Level 1 refers to preventative measures in the community. For this reason, level 2 is considered to be the lowest level of curative care, referring to dispensaries and clinics. Level 6 is the highest level of care and can include national referral hospitals (Ndavi et al., 2005, as cited in Mutua et al., 2017). In the research, the reprocessing staff were asked to demonstrate how they reprocessed their medical devices. While the staff demonstrated the process, the steps were drawn on paper. The outcomes are presented in [S]. This was also an opportunity to observe their reaction to the Chloe SED. The outcomes are presented in a table in [S] and an analysis of the results have led to recommendations for the Chloe SED project in Chapter 8.

What is reproceessing of medical devices?

Reprocessing refers to 'All steps that are necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilisation'.

In this section, we will focus on the phases: cleaning, disinfection and sterilisation. Figure 19 presents an overview of the decontamination cycle and the phases that are outside of the scope in this section. Cleaning refers to 'The first step required to physically remove contamination by foreign material, e.g. dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a medical device for disinfection or sterilisation'. Disinfection refers to 'A process to reduce the number of viable microorganisms to a less harmful level. This process may not inactivate bacterial spores, prions and some viruses.
'Sterilisation refers to 'A validated process used to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.' (WHO and PAHO, 2016a).

7

CHAPTER

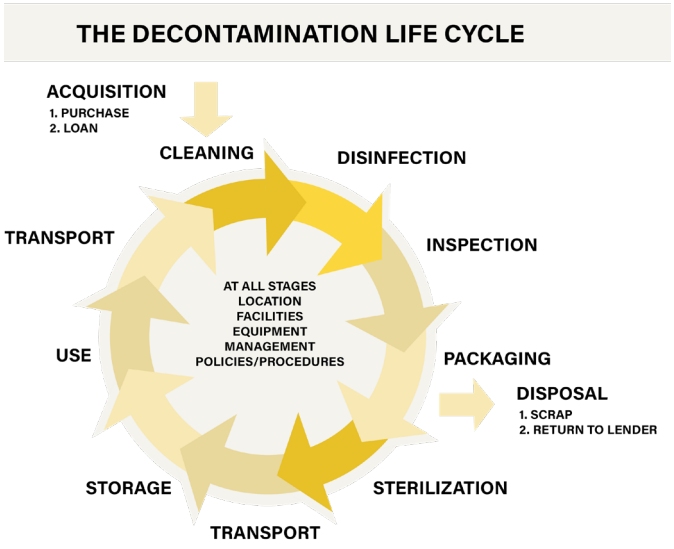


Figure 19: The contamination life cycle adapted from the UK Department of Health (2004)

Reprocessing Method by the WHO

In collaboration with the Pan American Health Organisation (PAHO) and international experts, the WHO guides reprocessing methods for medical devices. Since the guide provides reprocessing methods for medical devices made of different materials and components (e.g. electrical), the thesis will only refer to the methods that may apply to the Chloe SED. The relevant techniques are described as follows:

Step 1: Decontamination:

Right after using the device for the MVA procedure, soak in 0.5% chlorine (bleach) solution for 10 minutes, and rinse with cool water. Information about this step was provided by the Chloe SED project.
According to the WHO and PAHO (2016b), soaking instruments in 0.5% chlorine or any other disinfectant before cleaning is not recommended because (a) it may damage the device, the disinfectant may be inactivated by organic material (e.g. blood) which could become a source for microbial contamination (c)ransportation of contaminated devices soaked in the chemical disinfectant to the decontamination area mat pose a risk to health-care workers and (d) may contribute to the development of antimicrobial resistance to disinfectants.

Step 2: (Manual) Cleaning.

Make sure the device is disassembled.
Fully immerse the device in lukewarm water with detergent.
Wash it by removing soils with a brush or single-use cloth.
Rinse all parts with clean purified water and dry by air or with a clean disposable towel (WHO and PAHO, 2016c).

Step 3.1 High-Level Disinfection (HLD)

Soak in 2% glutaraldehyde for 20 minutes
Remove with sterile gloves or forceps.
Rinse under running sterile water. Air dry, or dry with a sterile cloth.
Follow manufacturer instructions for changing HLD solution, (usually, 14-day shelf life once activated, and 1-day for Chlorine) (WHO and PAHO, 2016d).

Step 3.2: Chemical sterilisation

Soak in 2% glutaraldehyde for 10 hours.
Remove with sterile gloves or forceps.
Rinse under running sterile water.
Air dry, or dry with a sterile cloth.
Follow manufacturer instructions for changing glutaraldehyde, (usually 14-day shelf life once activated.)(WHO and PAHO, 2016e)

OR

Step 3.3: (Steam) Sterilisation using autoclave

Reprocessing in Practice

In practice, hospitals in LRS have to work with the resources that are available which often results in deviating from the methods recommended by the WHO. In Kenya, 5 health care centres from different levels in the healthcare system were interviewed and observed about the reprocessing of their MVA kits (one about their circumcision kits). These facilities often had a protocol similar to the method described by the WHO. The protocol was sometimes displayed on a paper on a wall or in a folder in the room where reprocessing took place.

The majority of the health care facilities chose to follow reprocessing steps for high-level disinfection rather than chemical sterilisation after taking care of decontamination and cleaning. Even Though the reprocessing staff was aware of the protocol, reprocessing steps in the healthcare facilities deviated from the prescribed methods. The reprocessing methods differed in detergents, solutions and time per facility. The medical devices were bathed in detergents that were used for cleaning instead of decontamination, the solutions were sometimes stronger or not as strong as prescribed and the medical devices were placed in the containers with the solution for longer times than prescribed in different phases of reprocessing. See [U] for a table presenting the health care facilities that I have visited accompanied by information about how these facilities deviated from the WHO recommendations.

[The reprocessing staff that owned an autoclave were also asked whether they would put the Chloe SED in the autoclave to which they reacted that generally, they would not dare take the risk and will have to see it first before believing it.

Conclusion

In practice, hospitals in LRS have to work with the means they have. This often results in deviating from the methods recommended by the WHO, even though the reprocessing staff was aware of the protocol. In practice, most health care facilities chose to reprocess the MVA kits through decontamination, cleaning and then stop at high-level disinfection (so no chemical or steam sterilisation). The reprocessing steps differed in the type of detergents, the solutions and the time taken for different steps per facility. These aspects should be taken into consideration for the Chloe SEDs choice of material to ensure its durability when undergoing these reprocessing methods. In detail, most extreme cases were: MVA kits could soak in 0.5% chlorine (decontamination) until the end of the day when the equipment is collected by the staff to be reprocessed further. Another case is that a solution such as JIK (chlorine) was used for high-level disinfection if there was no 2% glutaraldehyde solution available.

8

FINAL CONCLUSION AND RECOMMENDATIONS

This graduation project aims to provide recommendations for the Chloe SED project on ways to boost its acceptance by the Kenyan market regarding one legal and two non-legal aspects. This chapter consists of three conclusive parts: the certification for the Chloe SED, the procurement of the Chloe SED and reprocessing of the Chloe SED. These parts form the foundation for the recommendations for the Chloe SED project in the chapter.

8 CHAPTER

Final Conclusion

Certification

The choice of certification depends on factors such as the market size, the location of the market, the requirements of procuring entities, the (estimated) costs of the certification process, the network and capabilities of the organisation and the (estimated) time of the certification process. The choice of certification for the Chloe SED also greatly depends on the future business plans of the Chloe SED project. Currently, the Chloe SED is an initiative designed for Kenya. Do they wish to become a start-up, approach a procurement agent or an NGO or, be taken over by a medical device company?

There are three important things to take into consideration about the Chloe SED project: (a) Their geographical strategy entails their focus on Kenya, (b) the supply chain of medical equipment in the local context and (c) the size of the project. Currently the Chloe SED is very small with a limited network and resources. There is no primary interest in the certification and achieving requirements on a local level can be a more comfortable space of operation.

This research has shown that obtaining certification in Kenya locally without prior approval from abroad is possible, though challenging. The Chloe SED project has invested time and resources in establishing contacts at hospitals, the PPB and KEBS and training clinicians in Kenya. The Chloe SED project aims at offering the device for no more than $5 to keep it affordable. This may be achieved by doing certification, manufacturing, and transport locally. Another benefit is that targeting Kenya as a first market, allows the Chloe SED project to generate valuable knowledge and collect data about the device to accelerate its development. The tricky thing for the Chloe SED project is that the device is novel in its category alongside its reusability. Some aspects of the Chloe SED are difficult to research in advance such as the availability of analgesia or the number of MVA kits that are procured by facilities yearly. These aspects also influence the need for and the acceptance of the Chloe SED.

There are more benefits to doing things locally in Kenya. The project is pioneering in this field and will generate new knowledge about local certification possibilities that serve the local context. It can invite other medical device manufacturers to start acting locally, which is a good lever for the environment. It can also allow manufacturers to reduce costs, sell them at a more affordable price and thus increase the accessibility of certain treatments. Acting locally can boost Kenya's economy because of increased innovation capacity and productivity in the medical device industry which in turn facilitates the developement of medical devices that can effectively cater to the need of the local context. Moreover, local certification saves a medical device manufacturer from contributing to the reliance on Global North certificates and dealing with complicated matters interlaced with this regulatory discrepancy.

One disadvantage is that it is difficult for manufacturers to find a subcontract manufacturer in or near Kenya that holds an SM Permit (which includes ISO 13485 certificate). If a manufacturer's motive is to act locally because it reduces shipping costs, then it is important to seek a manufacturer with an SM Permit to establish added value. Until now, there seems to be one Kenya based manufacturer that might be relevant to the Chloe SED project.

On the other hand, the KEBS certificate limits the acceptance of the Chloe SED to the Kenyan market only. It is questionable whether the certificate would be accepted by other African countries. MVA procedures happen worldwide and there might be a need for this device in other countries. The number of MVA kits needed globally may be a good reason for the Chloe SEDs project to opt for a certificate that allows them to enter multiple markets. The CE certificate can open doors to many markets in LMIC as these sometimes rely on such clearances from the Global North. It can also give the project access to larger organisations that can distribute the device globally. Though, this certificate is expensive and time consuming for organisations, especially start-ups, to complete. In the future, it could be interesting for the Chloe SED project to sell their product to or partner with an established manufacturer that has experience in dealing with the CE certification process.

On a global level, Africa must tackle the variance in regulations across countries and make strides in harmonisation. One key step would be for the PAHWP to become a member of the IMDRF. This way, new initiatives can be prompted that concern aspects that are important to LMIC environments that can be used as a guide by both manufacturers from the Global North and South, and regulatory bodies in African countries. This would improve product reliability and significantly improve patient safety.

The procurement Process

The Chloe SED is designed for MVA procedures and it is valuable if the device can be procured as a component of the MVA kit. A global supplier of MVA kits is IPAS that has recently partnered with DKT to enlarge their reach. In Kenya, most MVA kits that are used are from IPAS & DKT. One of the largest MVA providers is Marie Stopes, an international NGO that has health clinics in Kenya. They have their own brand of MVA kits. The MVA kits of both IPAS and Marie Stopes are CE certified and ISO 13485 compliant. The Chloe SED will require a CE mark and ISO 13485 certificate to be integrated in an MVA kit.

Even though, NGOs can have a more isolated, distribution channel, they can still differ greatly in how they procure and sitribute medical devices. Next to Marie Stopes, other MVA providers in Kenya mentioned were Family Health Options and Centre for Reproductive Rights. Unfortunalety, it remains unclear how these organisations procure medical devices.

This research has shown that there are two main distributors of medical devices in Kenya, KEMSA and MEDS, that both cater to the public, private and faith-based sector. Crown Healthcare was also mentioned as a large distributor of medical equipment.

Lastly, the Chloe SED might be interesting to become part of Loop Electrosurgical Excision equipment but this requires more investigation.

Reprocessing

Kenyan healthcare facilities often decontaminate the used medical devices by soaking them into a solution of 0.5% chlorine. The devices can even lay in the solution for approximately a whole working day. The facilities that were interviewed use high-level disinfection but do not sterilise MVA kits. Even if there is a lack of appropriate solution, the facilities may turn to less appropriate but available options such as the 0.5% chlorine. To defend product claims of the durability of the device and to guarantee its safety in use, the Chloe SED project must look into how current materials PP, PEEK and aluminium react to the worst-case scenarios of the deviations of the reprocessing methods observed in the practice. The materials and level of contaminsation should be tested to check the level of contamination which may lead to necessary design modifications.
The Chloe SED project must focus on cycle times that includes long soaking times for decontamination. One may argue that high-level disinfection might be sufficient to obtain certification and the project might also want to reconsider materials that were cancelled because they were unsuitable for autoclaving. This is because the reprocessing staff had difficulty trusting there is a plastic that is autoclavable and they do not reprocess MVA kits by steam sterilisation. However, this of course can be susceptible to changes in the future, if e.g., hospitals own autoclavable MVA kits and are used to the idea of reprocessing plastics this way.

8 CHAPTER

Recommendations for the Chloe SED

Insights from chapters 4, 5, 6 and 7 have led to the following recommendations for the Chloe SED. The recommendations are presented below in three sections again: certification, procurement and reprocessing. These recommendations may also require further research, which is presented in Chapter 9

Certification

Current resources of the Chloe SED project are focused on Kenya. The Kenyan certification process that can be completed locally seems doable but it is still in development and therefore unpredictable.

There are several advantages of obtaining certification locally in Kenya. For the Chloe SED project specifically, it helps reduce costs because the Chloe SED project is an initiative and it helps them offer the device at a more affordable price and in conjunction with this, a KEBS certified manufacturer that can produce the Chloe SED is a prerequisite to sustain cost reduction. Otherwise, the device is likely to be manufactured in India or South Africa which will increase costs. The Chloe SED is still in development. Focusing on Kenya as a first market facilitates easier data collection about e.g., durability and sales, which can accelerate its development. The Chloe SED project will receive feedback on a larger scale than research has provided thus far. For these reasons, it is recommended that the Chloe SED project continues investing in the Kenyan certification process and see it through until the PPB DPER Registration certificate is received. For approaching KEBS, it helps if the device has been tested against ISO standards as KEBS relies on these for testing the device against standards and also offers them for purchase on their website.

Next steps for the Chloe SED project in the Kenyan certification process is to await their clinical data and if successful, incorporate them into their documents before approaching the PPB. The Chloe SED project must also find a local manufacturer with a KEBS SM permit. It is recommended that the Chloe SED project approaches Revital Healthcare.

In the long run, obtaining the CE certificate or any other widely accepted certification is highly recommended. It can bring more options to the business case of the Chloe SED on both local and global level. Eventually, the aim should be to increase access to health care for as many people as possible and reach the people in need of this device to improve current procedures. Since it concerns any female patient that is in need of analgesia prior to procedures related to pregnancy issues such as MVA, the market is vast and global. It also seems a logical step to pursue when the device has been further developed and its performance has been rooted. It may not be necessary to confine the project to LMIC as the device may also bring added value to markets in the Global North. Obtaining the CE mark and the ISO 13485 certificate enables a manufacturer to introduce their device to the European market. Whether there is an interest for the Chloe SED in Global North markets is an aspect that requires further research.

Procurement

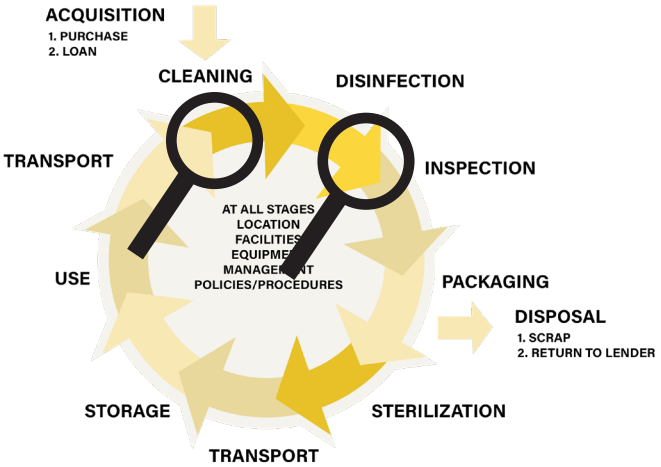
It is also recommended that the Chloe SED becomes part of an MVA kit. The global supplier of these kits is IPAS and DKT and they are the biggest suppliers of MVA kits in Kenya. Marie Stopes is recommended to be considered too as they are an NGO that is well-known for providing healthcare for pregnancy related issues and offer MVA procedures. Both IPAS and Marie Stopes have MVA kits that are CE-certified and ISO 13485 compliant. In order for the Chloe SED to be incorporated in these kits, the device likely needs to obtain these certifications too.

Since an NGO can have their own channels and can cater to different patients than public, private and faith-based hospitals (e.g. reach more difficult locations or isolated people), it is worth considering both an NGO and a global supplier such as IPAS. Further research is also recommended for identifying (smaller) NGOs that may be interested in procuring medical devices locally and accept KEBS certified medical devices.

In Kenya, the main distributors of medical devices are KEMSA and MEDS who both cater to the public, private and faith-based sector. Another large supplier of medical equipment that was mentioned is Cown Healthcare. However, further research is required to investigate whether they offer MVA kits and which brands these are.

Reprocessing

It is recommended that the level of contamination of the Chloe SED is tested for the method used in practice: decontamination, cleaning and high level disinfection to see if this leads to any necessary modifications. It is also recommended to ensure the material is resistant to longer soaking times to be able to offer more accurate information on the durability of the device. An idea would be to adjust the cycle times of this device or include extra information in the instructions e.g., what a device is certified to do and how this changes with the methods in practice.



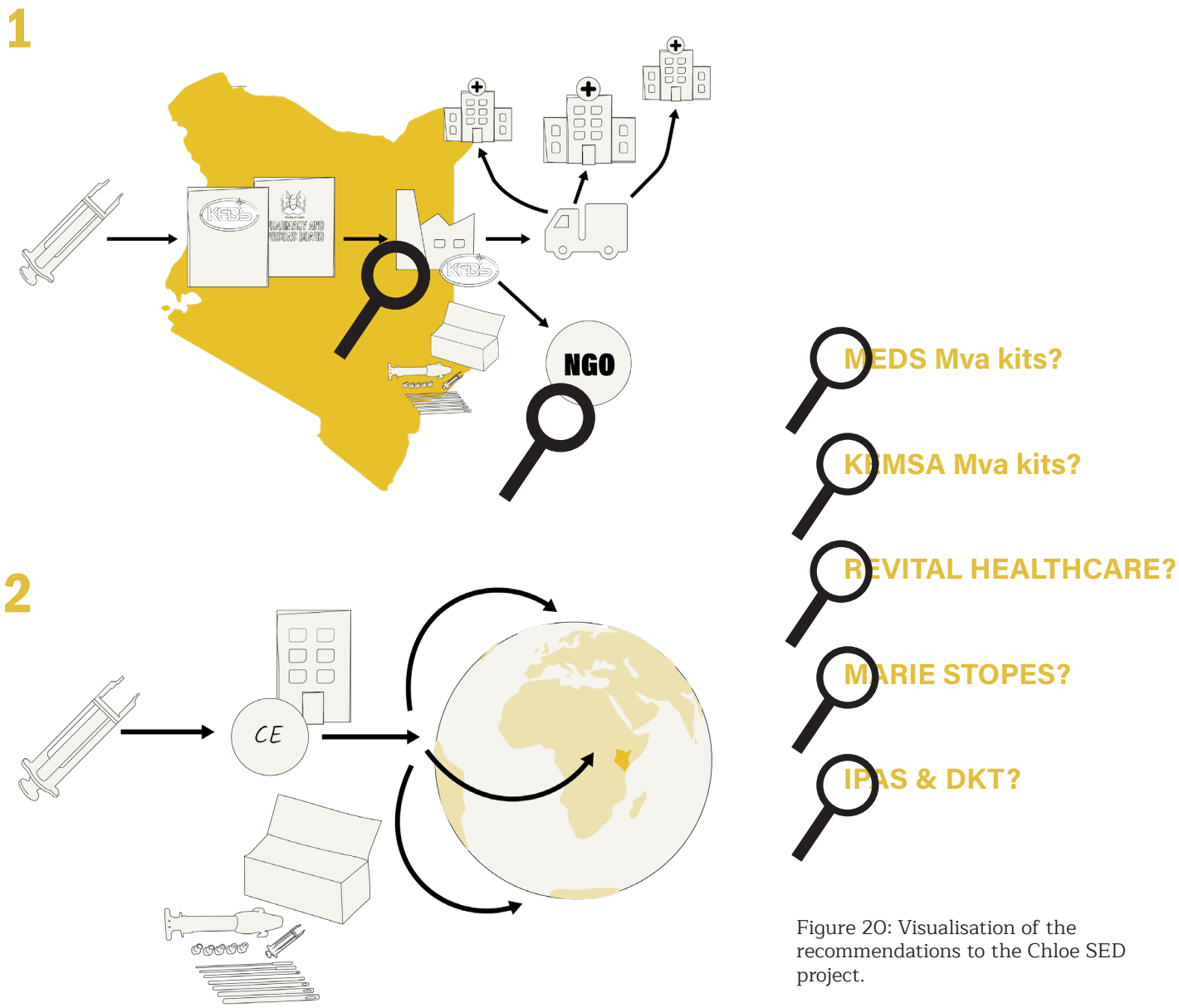


Figure 20: Visualisation of the recommendations to the Chloe SED project.

9

EVALUATION

This chapter provides a discussion, recommendations for further research and a reflection on the project. Lastly, this chapter includes a list of references.

9 CHAPTER

Discussion/Limitations

This thesis aims at answering the question: What next steps should the Chloe SED project take for introducing their device to Kenya regarding legal and two non-legal aspects? The research has focussed on next steps for the certification of the Chloe SED and prerequisites regarding the reprocessing and procuring of medical devices. This chapter will provide a discussion of the results and the limitations that have been encountered during the research.

The Scope

As mentioned in Chapter 1, other widely accepted Global North certificates were left out of the scope due to the limited time available. Accordingly, the report does not recommend the CE certification as the best certification option but merely recommends this based on the qualities compared to the Kenyan certification. The CE certification has not been compared to other widely-recognised certificates that can be interesting to the Chloe SED project.

Exciting insights

Before visiting Kenya, insights from interviews pointed out that the registration of medical devices was possible at the PPB and that a medical device with no prior approval always required a letter of approval from the country of origin. Based on this information, it remained unknown whether Kenyan based manufacturers could even obtain certification locally in order to introduce their medical devices to the market. Visiting Kenya and interviewing people from the medical device industry clarified much regarding the Kenyan certification process and showed that certification is possible but the process is still under development.

Academic relevance

Online literature stated that Kenya has been developing regulations and guidelines to serve the local context. In the beginning of the research, it was difficult to find information about these regulations and guidelines for devices that have no prior approval from abroad. Visiting Kenya, and interviewing people from the medical device industry has provided topical information about the Kenyan certification process for locally developed medical devices (with no prior approval). Based on this information, this research has proposed a framework that depicts the phases of the process, the stakeholders involved, the requirements and the certificates that are obtained. This framework may support studies that wish to investigate variances in medical device regulations and certification practices across the African continent.

Practical relevance

The framework may give direction to Kenyan based manufacturers in obtaining certification locally. It may also support initiatives that are considering bringing the process from design to sales in Kenya. However, this framework has been constructed through a qualitative research approach. This makes the result very time and context-bound. Its value depends on further developments in the Kenyan regulatory field. Meanwhile, the level of detail and accuracy can be improved by continuing to collect timely feedback from Kenyan medical device manufacturers.

Validation

The framework was constructed on the basis of the focus group discussion where people from the medical device industry in Kenya have come together to construct the process based on their experiences. Information in the framework has been complemented with information from the in-depth interviews. This leaves some freedom of interpretation. I have linked information that seemed logic to me (e.g., manufacturers used different names when seemingly refering to the same certificate which required me to make a choice). The level of validation has been low because the opportunity did not arise to formally review and revise this framework with experts. This framework therefore is merely a suggestion and may form a basis for approaching other manufacturers to be further constructed.

The detail of recommendations

It is difficult to achieve a certain level of detail for recommendations regarding the certification process because the certification process differs greatly per type of device. Every interviewee's answer depended on contextual factors that differed from the Chloe SED (e.g. different class medical devices). Additionally, this research has had an exploratory approach. Consequently, recommendations regarding the certification of the Chloe SED are also closely tied with recommendations for further research, which are mentioned in Chapter 9.

More non-legal prerequisites

Once again, the scope of the research has confined the research to two non-legal aspects. However, there are other important non-legal aspects that can contribute to acceptance of the Chloe SED by the Kenyan market. Such an aspect is the availability of analgesia and this is important as it is the substance that is administered with the help of the Chloe SED.

High-level disinfection

Observing how Kenyan health care clinics reprocess their medical devices has shown that decontamination and ending the process with high level disinfection is common practice. It is important for manufacturers to keep in mind that also the steps of high level disinfection can deviate from prescription, as chlorine solutions can be used if there is lack of solutions for high-level disinfection.

Procurement

This research has demonstrated that the way NGOs procure medical devices can differ greatly and that they can have their own distribution channels. Marie Stopes, an NGO that might be interesting for the Chloe SED project, has their own clinics and brand of MVA kits. Unfortunately it was difficult to get in touch with this NGO and inquire about their opinion on the Chloe SED.

9 CHAPTER

Recommendations for Further Research

The recommendations for further research are directly derived from the previous section and may seem obvious. To avoid repetition, these recommendations have been summarised.

Other certifications

It is recommended to consider other certifications that are widely accepted that may offer more advantages (such as the type and amount of countries that require this certificate) than the CE certification.

In conjunction with the recommendation for a Global North certificate, further research can also help consider whether the European or other Global North markets are interested in and also interesting for the Chloe SED.

Investigating what the capability of KEBS is to facilitate certification for higher class medical devices is an interesting direction for further research that may lead to insights on expected developments or provide suggestions on how to accelerate this development This information might be interesting to other manufacturers who wish to introduce their higher class medical devices to the Kenyan market.

Availability analgesia

It is recommended to conduct further research into the availability of analgesia because it is a confining factor for the need for the Chloe SED, not just in Kenya.

Marie Stopes

This research has investigated interesting stakeholders for the Chloe SED project. The research recommends inquiring Marie Stopes on their opinion of the Chloe SED and its adoption into their kit.

Also investigate how Family Health Options and Centre for Reproductive Rights, procure MVA kits and from which supplier.

KEMSA and MEDS

This research has also identified large medical device distributors in Kenya, KEMSA and MEDS, that both cater two the public, private and faith-based sector. There are also other distributors, of which Crown is mentioned to be large too. It is recommended to further investigate whether these distributors offer MVA kits and from which supplier.

Loop Electrosurgical Excision Equipment

It is also recommended to investigate whether the Chloe SED could be part of the Loop excision equipment. It is necessary to understand whether the equipment comes in a kit and whether it is desirable, feasible and viable to incorporate the Chloe SED.

Reflection

In the beginning of the project I listed competences I wanted to improve and stated personal learning ambitions. In this section I will comment on these learning goals:

- Work on analytical skills (processing a lot of information)
- Critical reading/thinking
- Improve speaking: being able to formulate thoughts clearly even when you do not know everything,
- Learning more about implementing a product
- Learning more about how certification processes influence business propositions
- Being able to pave the way within a new reference frame
- Working for a different culture: new aspects you need to take into consideration

This has been the first time that I have encountered a research topic that has been a practical problem at the same time. Research has taken place parallel to the progression of the Chloe SED project. This required me to link insights from academic research rapidly to insights from the field.

It has been challenging to interview participants about a process such as certification. Trying to grasp what the process is like while understanding the practical problems they were experiencing was a big challenge. It started out at a very detailed level while I was yet unable to grasp the bigger picture. Throughout this research, I have looked at two certification processes through the eyes of experts and insights are often based on what the participants have experienced. In accordance with this, I have received information that was sometimes conflicting. I have received essential help from my mentors not to search for a single 'truth', or a process that fits all experiences. It is not necessary to misjudge/downsize the value of information simply because it does not overlap with previous information.

Also practically, it is difficult to interview about such an extensive process within a limited time frame in an interview. it can remain uncertain whether some phases of actions were not mentioned because they were not experienced or because the information did not come up instantaneously.

Since each interviewee was nearly its own case study, their answers were surrounded by a context that was not comparable to the Chloe SED. It showed me the importance of conducting preliminary investigations and collecting information about their context.

I have learnt that a focus group discussion is very useful to receive information in an organised way and listening back to the recording gives an extra dimension to the meaning of their words. It also allows experts to construct the process instead of me as a researcher to do the puzzling which leaves gaps for interpretation. It has also been a part of the research that I immensely enjoyed.

Finally, I also learnt the importance of visiting the context you are researching. My visit to Kenya helped me better understand the healthcare environment, the people, and the regulatory challenges first hand. Being part of the Chloe SED project has been a privilege and made me realise the Chloe SED's potential to contribute to improving health care for women. I sincerely hope the Chloe SED will be successful and wish the team all the best along its journey.

9 CHAPTER

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APPENDICES

APPENDIX A: SUMMARY STEPS OF AN MVA PROCEDURE

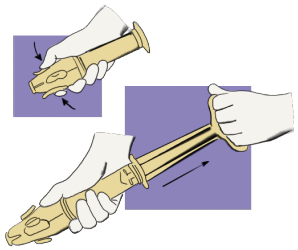
An adaption from a pdf published by the University of Washington, depicting an MVA procedure

Summarised steps for performing MVA using the Ipas MVA plus® and Ipas EasyGrip® Cannulae

Source: Ipas (2014), *Steps for Performing Manual Vacuum Aspiration (MVA) Using the Ipas MVA Plus® and Ipas EasyGrip® Cannulae.* Fot the sake of this thesis, this overview is a summary and not a complete overview of the steps provided by Ipas. Please consult source for a full overview of the procedure. Do not use this as a manaul for medicational purpose.

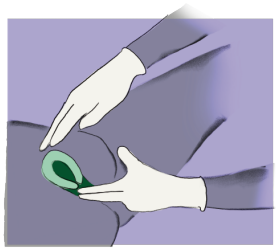
Step 1: Prepare the aspirator

Position the plunger inside the cyinder.
Push valve buttons until they lock.
Pull plunger back until arms snap outward and catch on the cylinder base.



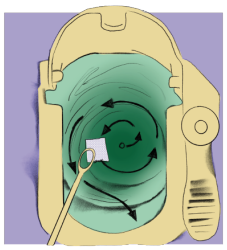
Step 2: Prepare the patient

Administer pain medication.
Give prophylactic or therapeutic antibiotics
Ask the woman to empty her bladder
Insert speculum and observe for signs: infection, bleeding, incomplete abortion



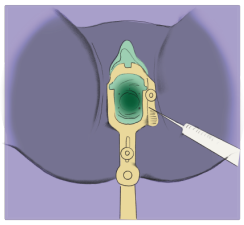
Step 3: Perform Cervical Anitseptic Prep

Use anticeptic-soaked sponge to clean cervical os. Start at os and spiral outward without retracing areas. Continue until os has been completely covered by antiseptic.



Step 4: Perform Paracervical Block

Paracervical block is recommended when mechanical dilation is required with MVA. Administer paracervical block and place tenaculum. Use lowest anesthetic dose possible to avoide toxicity.



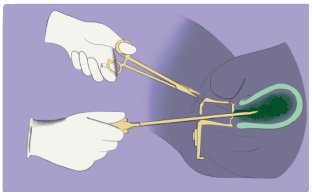
Step 5: Perform Paracervical Block

Observe no-touch techniques when dilating the cervix and during aspiration. Instruments that enter the uterine cavity should not touch your gloved hands, the patient's skin, the woman's vaginal walls, or unsterile parts of the intrument tray before entering the cervix.

Use mechanical dilators or progressively larger cannulae to gently dilate the cervix to the right size.

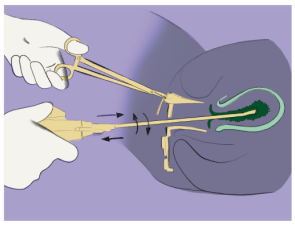
Step 6: Insert Cannula

While applying traction to tenaculum insert cannula through the cervice, into the uterine cavaty until it touches the fundus and redraw it slightly. Do not insert the cannula forcefully.



Step 7: Suction Uterine Contents

Attach the prepared aspirator to the cannula if they are not yet attached. Release the vacuum by pressing the buttons and evacuate the contents of the uterus.
After the procedure, depress the buttons and disconnect the cannula from the aspirator.



Step 8: Inspect Tissue

Empty the contents of the aspirator into a container. Strain matieral, floart in water or vinegar and view with light from beneath. Inspect tissue for products of conception, complete evacuation and molar pregnancy. Reatspirate or do another evaluation if inspection is inconclusive.

Step 9: Perfrom Any Concurrent Procedures

When the procedure is complete, procede with contraception or other procedures.

Step 10: Process Instruments

Immediately process or discard all instruments, according to local protocols.

APPENDIX B: INSIGHTS FROM INTERVIEWS WITH MEDICAL DEVICE MANUFACTURERS IN THE GLOBAL NORTH

B1: Organisation A, 07-03-22

1. Organisation A is currently looking into CE certification for their medical device. They are not looking into local certification possibilities of the intended market nor the FDA approval. The manager stated that some companies are doing both but it will take twice as much time as well as money and maybe even more. For now, the organisation is interested in the CE process only. [5 mins]
2. Regarding their medical devices, they have gone often to Egypt to establish contacts and do market research.
3. They do not know exactly to which market they want to sell. Sometimes they have their eye on one but then it shifts to a different country because the dutch government has made funding available specific to that country.
4. They are also considering entering the European market even though the intended market is Global South. They are keeping the option open to sell to the EU. [25 mins 30]
5. Decisions on the classification of the MD and which turn to take within the certification process are very on the go. It is difficult to predict beforehand. [55 mins]
6. The cost of the standard for electricity was very high but testing how to comply with the requirements costs more. It cost them 60.000 euros. [55 mins 20]
7. Halfway through the design phase, they discovered that they had to consider the certification process and learned about its influence on the embodiment design. [15 mins 40]
8. They are now in conversation with distributors and the intended market to gain feedback from them on the medical device. My interviewee is not involved in market research. [56 mins]
9. Currently, they are busy with a mannequin study (in march 2022) within 4 hospitals with anaesthesiologists and that will be compared to an existing alternative device. According to the interviewee, it involves a lot of creativity in how to generate evidence. They are now thinking about which claims they want to make and prove. For example: 'It is intuitive or as easy as similar devices'. This is shown from the risk analysis that they have done a time ago. [60 mins 30]
10. The organisation has its prototype manufactured with 3D printing but the definite product will be injection moulded. [71 mins 35]
11. The organisation has contact with a doctor in Kenya.
    Most contacts in these countries are doctors and biomeds. Where biomeds stands for biomedical equipment technicians. This is a position in hospitals for the maintenance and sometimes also procurement. Most of them are educated abroad, in the West. Biomeds from hospitals can indicate who the distributor is of a hospital. [6 mins – 10 mins]
12. Currently, the organisation is busy with setting up the quality management system and appointed a quality manager who now consults an expert for this.
13. The organisation purchases parts that have already been certified. Only the housing of the device is what they need to obtain certification. Next to this, there is also an application which is meant for assistance and does not play a decisive/ big part so the certification process does not seem too complicated for them. [16 mins 30]
    The medical devices of organisation A belongs to class I. Even though it is reusable, their device still remains class I because it is not surgical and because it can be sterilised as class I. [19 mins 30]
14. The organisation is not necessarily considering selling to WHO but it would be a very possible direction for start-ups once they decide to mass-produce. [22 mins 10]
15. Extensions for the device are deliberately left behind when approaching the Notified Body to reduce costs. [24 mins]
16. It would have been easier if the organisation had found a production partner or a supplier who already has been ISO certified but they are not easy to be found and in their case, they have a financial reason to look for partners who are up for a collaboration against a certain amount of money or even help them as a start-up or let them be part of a project. Even so, you actually always need a quality manager who knows what it is about and who is able to audit during production on the production plant to see if everything is done correctly according to relevant aspects in the standard. [40 mins 20]
17. Depending on the medical device classification, it might be required to do a clinical trial, usually a big trial with a very small group of people if the device has not been certified yet. Organisation A does not have to do this and can just keep it to the prop/mannequin study. [29 mins 30]
18 It is important for the organisation to have a very good post-market system in place because they have not done a pilot (this is always the case but especially for products that have not been piloted). [29 mins 54]
19. It really helps that there are no electrical components in Chloe SED because this has been a hassle for the organisation regarding their medical devices. For example, the colour of the lights and the thickness of the wires depend on the class and the standards that are applicable to electronics. You need to purchase the ISO standard for it, a 500-page document. [38 mins 20]
20. What one strives for with a clinical evaluation (the protocol), what the device looks like, how it is maintained, and who has what responsibility according to procedures is a huge task to set up. If a new product arrives/is purchased by an experienced company, it is only a matter of filling things in. Now it takes a lot of effort to set this up. An initiative that approaches an organisation that has an internal system in place already does not take so much time to go through this. [66 mins]

21. If you are a class I medical device manufacturer, you do not need a QMS. You must have one in place but you do not have to show it. Organisation A is setting up a QMS because they want to manufacture other medical devices in the future and because the structure of the technical file is now completely organised (structures for procedures, maps and documents) according to the quality management standard for medical devices (ISO 13485). This ISO states what the steps are for the company (though not necessarily a route) and what needs to be included in each step and the factors it depends on E.g. The clinical evaluation should include X and this and depends on Y. [73 mins]
22. Many countries in Africa (60% have no regulation and the other 40% either do or there is no data available) ask for CE or FDA even though it may not be mandatory but then there is trust in the quality. If you are dealing with countries that have no or partial regulations, it can end up in two ways: either they are not strict or they are just as strict in the EU and above all vaguer. However, the chance is high they will accept CE. [26 mins 30]
23. The biggest influence/difference is not the class of the device but the cost. It is true that the higher the class of risk is, the stricter the checks and the more expensive the process. [23 mins 10]
24. If you are able to do certification yourself and you are able to put an experienced person in this position then you are done quickly. However, if you need to approach a Notified Body you will end up in a very long queue which is not very full because of the new MDRs and companies who had products in the market need to recertify. Organisation A is happy they can avoid this because they are class I. [24 mins 15]
25. Waiting time is 6 - 9 months and in eastern Europe, it is less than in the Netherlands. The interviewee knows of people who are approaching Notified Bodies there e.g., Polish. For this, the company had to hire a Polish Quality Manager. It is a commercial sector so you can approach any Notified Body with a large sum of money and ask them to do an audit
26. for certification. This is the reason why it is so difficult to obtain information from them. [25 mins]
27. In the regulatory field, there is no difference between a commercial company, a start-up or an NGO that needs to surpass the certification process (in the EU. [34 mins 30]
28. Basically, an ISO standard is not mandatory in itself but it is a method you can follow to comply with regulations. Some regulations state that if there is an ISO standard for this, then it is mandatory to comply, and then you have to find, purchase and follow the standard. For example, there is a standard for risk management and if you follow them, you know you are complying with MDR. Riskier when you make things up because you easily miss something and Notified Body will see this. [43 mins]
29. Risk analysis is: what happens in each step of use, what risk, what harm, how serious is the harm, how probable is it to happen, how acceptable is the harm/risk and, how can it be avoided. How acceptable the harm or risk is decided by the manufacturer together with the Notified Body. A Notified body checks this risk assessment. Probability disappears if it is completely solvable but a manufacturer still needs to remain careful. In the risk assessment, one can do a severity and probability calculation including the mitigation of risk and then prove the risk is reduced. A manufacturer has to show KAPA, and corrective actions (adjust or monitor), that will be carried out. [62 mins]
30. These preventative measures can be Design modification (biggest), warning or giving alarm (electronics)/feedback during use, and instructions for use (to protect the manufacturer). The interviewee has never encountered that it is required to prioritise the different methods for risk mitigation; e.g. design modifications is a prefered over changing the instructions for use. She does think this is strange. She mentions that it is mandatory by the EU-MDR to reduce the risk of harm as best as possible but a manufacturer is not allowed to lose the functionality of the device. This means there is a trade-off in this. [64 mins]
31. The PMS is part of the QMS. QMS is how you operate as an organisation such as PMS, which differs per product. QMS is the whole system including e.g. requirements for the people you hire etc. Or you show you have an intranet or drive etc for safety issues. [78 mins]
32. A Notified Body is very expensive and does not tell an MD manufacturer what to do. The organisation has not approached a Notified body yet and does not know what the costs are. exactly [23 mins 30]
33. The relationship between the Notified Body and the manufacturer is going back and forth a lot. It also depends a lot on the MD class a manufacturer wants their device to end up in. The organisation is experiencing a lot of grey areas in which they try to make choices that will enable them to end up in a lower-risk class. [37 mins]
34. A Notified Body gives you another invoice/bill if it takes a manufacturer longer to make bigger essential modifications. A manufacturer needs to resubmit documents concerning major changes and they will receive another deadline and another invoice. Minor and more unimportant modifications to the MD are allowed in a few weeks. The interviewee explains that even though a manufacturer will hear from them that the modifications are minor, they have to fix this before the next inspection but this can be very soon. [44 mins]
35. If you are considering selling to the WHO, it is wise to look into what requirements they state for products. You will not see any requirements about classification itself but a list of standards. [21 mins 40]
36. Look for a declaration of conformity (DOC) for similar medical devices because it often includes a rationale for which classification they are. [69 mins]
37. A difference in approaching a big company is perhaps the time in which they are able to bring the product to the market because it is picked up more quickly, except for the waiting line for the Notified Bodies. However, this waiting line will probably not be there in Kenya. [35 mins]
39. Unless it is very common for hospitals to have long needles in the EU, the quality manager expects there is a market for this device in the EU. And then, even so, it is appealing if there is a cheaper option. IT is the same essence organisations are trying to achieve in the Global South so it could also work for the EU, but it is then necessary to prove that it is just as effective or even more effective than the current solution. [25 mins 55]
40. Organisation A expects that connecting the device to the intended purpose of assisting in abortion/miscarriage procedures is too far but solely the injection of a pain-relief substance into the cervix. Can you achieve this injection without Chloe SED? Talk to the syringe producer to ask about this. [48 mins 10]
41. MDR states 'to be used alone or in combination makes it a medical device and ' for the alleviation or treatment' will refer to the injection of medication and not the treatment of abortion. Not a direct treatment for an illness. Look at other syringes that inject such substances for pain relief and not the overarching intended purpose. [52 mins 10]
42. The interviewee even expects that it is not a medical device if you see it without the syringe because it does not achieve

medical purposes. But it is an essential part of the syringe. If it is an accessory then you need syringe producers to certify the medical accessory as part of their device. So then you will sell it as a product plan to producers. In case it is an accessory, you need to see if you are allowed to certify it as an accessory without going to a specific syringe producer. This is something that happens a lot (e.g. phone case/holder). [49 mins 10]

43. Formulate the intended purpose of Chloe well (so exclude e.g. the miscarriage procedure but include pain-relief substance) so that it is clear what should be proved. Especially because there are a lot of grey areas. [54 mins 22]
44. Be aware of standards (ISO) that state that the device e.g. should not cover the metric scale of the syringe. Look for standards for the syringe if it is in there, or requirements for forces needed to disassemble the product or for example for the screw part or other edges to soften them against bacteria (when cleaning), it is not nice to have a lot of edges.
45. Disinfection for syringes protocol or ISO standard. This is also the responsibility of the quality manager. [41 mins]
46. A biocompatibility test is important because it checks if the device can touch people safely. You can select producers on the basis of their material (plastic) suitable for medical devices. Or find literature on the application of plastic. [57 mins 30]
47. There is a website for cheaper prices of standards (Estland). Select ISO that completely describes what is applicable to your device. The difficulty is that it has no specific name because Chloe SED is completely new so finding ISO is difficult (observation looking for it is more difficult). [46 mins]
48. Major first step! One way organisation A has done a literature study: research into complaints (database) for comparable devices. A database of complaints about syringes with long needles is useful because there may be interesting insights that are applicable to Chloe SED. For example, the long needles of the syringes keep breaking and you need to incorporate this into risk assessment. [58 mins]
49. The second way that the organisation has done this, is to interview experts, end-users/doctors (and designers) about what they think and take it through a risk assessment. For example, with infections or needs to be cleaned very well but this is for example not a well-defined requirement for laryngoscopes and the organisation had to include this as a product requirement. [59 mins]
50. If someone is allergic to the material example = biocompatibility analysis. Depends on the risk class within this standard (how long contact with the body) and the lowest risk class is 24 hours so Chloe SED will likely fall under this. [61 mins]

B2: Organisation C, 11-03-22

1. The route for certification for organisation C will differ from Chloe SEDs, because the organisation does X-ray machines and mobile clinics. They work a lot with artificial intelligence in their machines to detect certain diseases. All of these are class II (depends on which product). CAD (AI) is definitely class IIb.
2. Organisation C leads the development of devices, but manufacturing and CE-holding are done by different companies (who protect intellectual property and are in charge of CE) [7 mins 10]
3. All their products are CE-certified. Current X-ray system and portable AI software. [7 mins 30]
4. This project is financed by USA ID(EA), so it is public funding and it is procured by an intermediary agency that has very high-quality standards. Without CE certification and relevant company experience and so on, it is difficult to become accepted. It is the chicken or the egg story. You need to get projects to get experience but you need the experience to obtain projects from these entities. [8 mins 10]
5. For Kenya, organisation C does the following: they sell their medical devices through public funding from USA IDA, the intermediary agency that wants to check boxes such as the CE certificate. Organisation C is in a framework contract with the UN and so the organisation is in a couple of catalogues of the UN so the UN can procure some of the goods directly from the organisation. Getting into it is very difficult: an MD manufacturer needs to show 3 years of annual reports, financial stability, similar projects and settings, and service capabilities (maintenance). If you can show this, you get into the catalogue through which they procure. [13 mins 6]
6. Organisation C does not target the private sector. Because the organisation always has an intermediary (UN and procurement agencies). They do a lot of public funding and they make the process very transparent. They take all the possibilities of corruption out so the organisation is in a different channel. If you go as a private company directly to the government you have to go through a government agency, it is a less transparent route. In a lot of these public funding, things go through public tendering so it will be very transparent with certain specifications. [20 mins 26]
7. The products should have been transported a long time ago, but not yet. Aspects that make Kenya quite challenging: many regulations there [7 mins 50]
8. Out of the 40 countries, the majority of the work of organisation C is in African countries (25 countries). Cycles can be very long in the public funding sphere. This is a big runway for a start-up. [9 mins 40]
9. How organisation C got to this position: The CEO had a group of medical companies and sold-out part of the group and kept this company separate from TB for emerging countries. For that, he had funding from selling the other companies. Every time we have new innovations, the current products generate revenue and cross-subsidise the new innovation for as long as they do not make revenue. [9 mins 10]
10. For screening Tuberculosis (TB): It helps to bring down organisations who are active in TB and their respective customers. They found niche markets and small groups to find and build relationships with, someday they hoped to get funding & procurement and those loops. Small customer base to go through, it is not the entire private market. [22 mins]
11. Organisation C works a lot with research partners who implement clinical studies. Partners in the NLs, Switzerland, across Africa and Asia; all over the place. They organise the studies and we provide solutions for these studies (discount, free of charge) depending on what is in it for organisation C. This way they (help) generate a lot of evidence without creating evidence from scratch. [12 mins 22]
12. Organisation C has decided to do both import tracks (PVOC and PPB). The main reason: in the end, these are valuable solutions for the market and have plans and easier position if registration is completed to scale it up further. Within

PVOC, it is good to reach out to agencies for information because they have different ranges: there is a licence for which you can cover the first 20 products but there are also larger licences for over a year of continuous importing. There is no licence for perpetual importing. For registration, it is once but you need to keep up registration yearly (annual fees to keep the product registered). [18 mins] Both tracks are equally official as both are registered at the ministry. [16 mins
13. 17]
Organisation C does not sell to the European market. For these projects, they ask CE or FDA. FDA is even nowadays easier to get for a lot of cases due to using clearance of similar products (510k clearance). That is now difficult for new MDR EU regulations. Also, for clinical evaluations, one big change is to evaluate more frequently and provide more
14. evidence is very tough. [9 mins 17]
The organisation talks with start-ups especially in TU Delft and this is one of the toughest parts. Just starting a business from the start. What DI can offer is they work a lot with the UN, and have long-lasting relationships with them and that helps to pitch their current and new innovations well but that is a very long road map. All start-ups are facing
15. similar challenges, quite difficult to get the business going. [6 mins 30]
The organisation states he notices that a lot of start-ups quickly look at Kenya because it is a hub for start-ups. But
16. when you look at procurement and registration of the goods, then it is not the easiest market. [20 mins]
Kenya is a friendly environment for start-ups, to register a company locally (which you do not want to do if you are based/living in the Netherlands). If you register in NLs and then do go-to-market then organisation C is unsure if Kenya
17. is the most logical one but it depends on where your customers are. [21 mins 40 mins]
There are more in-depth conversations occurring between organisation C, D (and also with A about what kind of role an
18. MD manufacturer should have and how you build a business from a good product. [9 mins 02]
PVOC: is a specific action for Kenya. They want to do an inspection of the product before importing it to the country. It is already bought but it is an import issue. They need to inspect themselves. They can now do this remote because of COVID and you need to pay them for this. There are a couple of agencies named STS and Veritas. They both facilitate PVOC assessment, you can just reach out to them for costs and they will ask what kind of certification your products have and you need to show regular registration things like the profile and brochure and the ISO certificates at the company level are equally important. The purchasing party needs to request this PVOC from the ministry. If the ministry agrees you get the unique number and use the number you need to supply additional documentation for them to start inspecting the goods. If they say it is fine you can import. This is a separate track from registration. It does mean you are allowed to import it but it does not mean you are registered yet. You can combine tracks (register while
19. the assessment takes place) but it costs more money and time. [14 mins]
Kenya is a very difficult market when it comes to the procurement of public funding. It helps to be in the catalogues to facilitate procurement. The question is what is the market? There are different requirements per market (private vs public). If you want to get products into the country under the umbrella of the ministry, you will be asked different
20. things. 1 clinic can decide a lot more things themselves on their own. What is the route to procurement? [18 mins 37].
There is a procurement agency within Kenya that does a lot for the public entities whether it is government or other public entities related to the government. There are a lot of corruption issues around that where you do not want to get
21. involved. It makes it very tough. [19 mins]
This is not the route you want to go because you are doing something that no one has done before. So they are unable to make specifications on what you have because you are the only ones who can bid on this (difficult for Chloe SED).
22. Normally you need to build a good amount of experience for that. [21 mins 36]
The business unit developer expects our product to be class III because it is in-vitro, even though your device is not since it is intended for syringes: which will be the first question the certification committee will ask you. In-vitro is the
23. toughest certification process to go through, the most difficult part to get. [4 mins 26]
The business unit developer gets it is an accessory to a syringe that injects a substance but he wonders if a certification evaluation committee will see the same thing because at the end of the day, it amplifies something that is done for in-
24. vitro. [5 mins 10]
The organisation does not really have a strategy in the public funding sector, but public funding is very transparent and you can see in public funding streams what they are spending money on; where money is flowing to which countries and which organisations. You can track all that and that can help to determine if there is a field that is interested in your goods and if so, solely in the public finding sector. But to get into the public funding sphere, you need to have a lot of experience so not the first place to start with. [23 mins]

B3: Organisation B, 22-02-22

1. The function of the person at this organisation who is involved with certification processes is the quality manager
2. The competition of organisation B are often non-profits or NGOs. A not-for-profit company does not work in the UK because it is perceived as a company that has gone bust. In the UK there is no real legal entity that governs a non-for-profit. In America, these get all sorts of benefits and is an easier way to go (e.g. taxation) [18 mins]
3. In the UK, companies can have a charitable arm and commercial arm but they have to watch out they do not indivertibly break rules [19 mins]
4. Non-for-profit companies get away with a lot more than commercial companies do. They get funding for things. Organisation B cannot get funding. Perceived from the commercial side, these not-for-profits are a lot less efficient with the funds. A commercial company has to make a profit to remain and is, therefore, a more sustainable one for the future. A not-for-profit company has to rely on external funds to be able to keep trading [20 mins]
5. Organisation B is also concerned about wider issues on aid dependency within LRS. If they are continuously spoon-fed aid, will they ever have an incentive to trade their way out of it? E.g. Ghana had a very good internal shoe wear industry and then the charity started sending shoes and the industry collapsed. It is important to bear this in mind. [21 mins]
6. The market is complex because of legislation.

7. Quote: There is a big problem with getting equipment to LRS
8. Quote: The Kenyan document is frightening to read. To interpret what they mean is difficult. For Kenya, the CE-mark was okay but now it becomes more riddly to some countries because they are reinventing the wheel by establishing their own procedures.
9. There is also a difficulty in communication as things about the device become easily misunderstood (experienced this with their cannula device)
10. In Kenya, they also see an opportunity to make money and can hold things up if you get it wrong.
11. Quote: The PPB document says DRAFT and is 3-4 years old. So organisation B is still busy figuring out what they need. (33.40 mins)
12. Quote: The PPB is very disjoint in some places.
13. Quote: Do everything by the book where you can
14. Organisation B expects that Chloe SED is still regarded as invasive under Kenyan rules. The organisation suspects it will be class B because it enters a body orifice.
15. For Chloe SED, the position of the patient in use is critical. If Chloe SED can get away with not being invasive it will be a big advantage.
16. Chloe SED does not need to be oxygen cleaned and there is no interaction with drugs. If the product can be autoclavable but does not need to be sterilised, leave it out because otherwise a second auditor is needed who costs extra money to give this certification
17. Chloe's main risks are in the material, the finishing and how this interacts with bodily fluid. The organisation expects this to be well doable.
18. Even though Chloe may come into contact with bodily fluid it does not mean it has to be autoclaved, it can be washed and rinsed in Cidex or decontamination methods.
19. People do not like the idea that you are manufacturing a different medical device because it is cheaper. A good positioning would be that a lot of obstetric procedures in LRS often do not receive pain medications. It can be positioned as a pain relief for women and appoint the serious alternatives that would otherwise be the case.
20. Good reasons for Chloe's existence: (1) 1 of 3 areas of medicine in LRS is Obstetrics trauma and paediatrics and the area is huge: it is done everywhere and at a very low level. These places do not have access to single-use items. (2) It is a good lever for the environment: to reuse something is the flavour of the month but medical devices are slow to catch up with that. Single-use everything in the medical field is unfortunately still there and often has to do with money rather than patients' safety. [17 mins]
21. Keep in mind: even though the product is reusable, it is small and will go missing.
22. For organisation B, it was difficult for people to accept their product because the technology was different. This is luckily not the case for Chloe SED.
23. Possible routes for Chloe SED, are to approach an innovation hub in Nairobi or to approach the NGO 'Maison Sans Frontières'.
24. The advantage of approaching an NGO such as Maison Sans Frontières is that they work in probably the most difficult locations going, they are always interested in ideas that make things easier for them on the ground and are looking into how to make consumables come into conflict zones [28 mins].
25. NGOs sometimes have experience in registering medical devices. MFS have innovation units (e.g. MFS Sweden). The founder can help find these products. [29 mins].
26. A clinical evaluation is not necessarily with patients. It can be a material examination e.g. to check if there are no fellates etc). A clinical trial is with people.
27. Requirements at the PPB are mainly risk-based
28. Sterilisation depends on single vs multiple-use devices (the founder wrote a document about this): where, in practice, single-use does not mean it is used only once.
29. A clinical body that is Kenyan refers to local people doing obstetric work.
30. Usually, design modifications as a result of certification are about: (1) materials for harm (2) link to production methods e.g. injection moulding offers more options for materials. (3) colour has an impact [38 mins], (4) avoid colours that indicate something special and check international standards (caution: wrong colours can lead to patient deaths and fines).
31. The EU-MDR is a complex issue as it takes a lot of time to keep up to date, notified bodies who oversee medical device legislation are expensive (put up prices by 40%) and ties up the company for a long time for unexpected audits.
32. Quote: It took the organisation 5 months to re-evaluate their device and it cost 50.000 pounds to eventually change the colour of the on/off button in order to be compliant.
33. The competent authority of the UK named 'MHRA' (medicines and healthcare regulation authority) put a statement: it takes 4-7 years to put a product on the market.' ''No company can do that''.
34. What the device does and what is required for it. Usually, organisation B has to argue this with the notified body. They know the directive and the standards but their interpretation of them is not provided by experience in the field so organisation B can argue the case in their way [46 mins]
35. Generally, products that organisation B sells are CE-marked before entering the market [24 mins]
36. They also sell products that are not CE marked and are sold widely. They have to be careful in how to describe them. It can work but it makes it a bit difficult on the marketing side.
37. In Kenya, it is difficult to get products to the market that are not CE-certified. The organisation usually goes through CE-route.
38. It helps if you come in touch with clinicians in Kenya (have one of the medical bodies work with you). For Chloe SED, get in touch with Kenyan obstetricians or obstetric groups or obstetric charities. In the founders' experience in the past, if you have evidence of it being used then it can remove some barriers (12:00 mins)
39. Getting a medical discipline on board would also make a strong case/promote why the device is a good alternative.
40. How to keep things going: The NL government which has representatives in EA/Kenya can really help [31 mins]. A couple of companies in the NLs who are heavily involved in this type of work can help such as Hospitainer which does

some good work.
41. Organisation B designs products that are close to minimal maintenance and a lot of commonalities in parts. This way, maintenance can be done remotely through video training packages and work through issues e.g., through WhatsApp (which allows them to see and hear what is going on).

B4: Organisation E, 25-02-22 & 02-03-22

1. The market strategy of organisation E is to get to countries where there is no regulatory system in place to at least penetrate the market and then receive local approval. Getting a CE mark in the EU and then selling to countries in Africa costs too much time, money and energy.
2. Organisation E works together with local, governmental organisations and they consider the following per country: what is the market like and how does it work? Who is important? (e.g. NGOs can also run many hospitals in a country). It helps to follow the money. The organisation has considered approaching faith-based healthcare centres but the governmental ones have the biggest impact in terms of a successful adoption. To sort things out per hospital takes too much time and sometimes some hospitals accept equipment that other hospitals have accepted (trust in their expertise). [40 mins]
3. Currently not ready to sell. Next year they will certify their products and are now setting up contacts and partners before entering the certification process.
   The company has done research into all the countries in SSA and selected ones that are interesting to organisation E, based on the number of inhabitants and safety.
4. Entering Nigeria is difficult. The organisation is considering working with distributors or agents because of poverty and corruption.
5. They have visited the countries to which they intend to sell and mapped out what regulatory path there is, what distributors they need to partner with, what hospitals to target, how hospitals react to the product and what competitors there are in the field.
6. They decided that Kenya is a bit too big and too complex as a first market (first Rwanda and Malawi). Kenya is too complex and is a relatively richer and bigger country, that is why the majority of health care innovators of Africa are in Kenya and that is why there is not a lot of attention from regulation authorities or the government for flexibility for those innovations to test properly. They have a strict bureaucratic system which is logical for them but very difficult for start-ups. You have to cross a lot of stages and wait a long time. Their product is relatively complex and they have to talk a lot with regulatory bodies about whether to certify parts separately or the device as a whole together.
7. The organisation has chosen to do the CE process in the EU before marketing to Kenya [5 mins].
8. Define the device class A,, B, C and D and it is necessary to appoint a technical local representative who will do this for you, and pay a fee. [7 mins]
9. Their go-to-market-strategy for Kenya: (1)obtain CE-markering, (2) Work with a distributor that is currently in Rwanda who is starting to go to Kenya, (3) Also find a distributor who supplies all faith-based hospitals, called MEDS (4) There are 3 categories: faith-based hospitals (established by the church), public hospitals who belong to the government and private hospitals. (5) faith-based hospitals are better generally than public ones because the government usually pays the personnel but the faith-based hospitals get extra money from the church to better the hospital. (6) Private hospitals are also interesting; they have private clinics and the company organisation E works with is Ilara Health (the quickest growing start-up in Kenya). They are modern, mobile-based and invented in private clinics in Kenya.
10. Reusability: in Africa, everything is reused even though it is not intended to do so. So make things reusable!!
11. Organisation E is making things reusable but does not need to certify these reusable parts. [20.30 mins]
12. The organisation is struggling with certifying their reusable mattress of which there is an alternative in the market. The EU would say it needs to be replaced in 2 years but Africa will not do this. So do you choose to approve that they use it differently than intended or do you try to control the use duration? So the manual says: actually 5 years but the EU says 2. And implement a test system for software. In the mattress are sensors and the organisation works with sensors that are already certified. [23 mins]
13. Kenia is home to the largest government agency in the world. You need to fill in a lot of documents and therefore it has a bigger entry threshold for organisations.
14. It is difficult because there are a lot of choices in Africa. What is stated on paper is usually what happens in practice in the West, but this is not the case for Africa. However, there is a way of doing things. [4 mins]
15. NGOs never put their own medical devices on the market. They usually procure them from manufacturers at a certain price and then manufacturers deliver the devices to them.
16. It is important to decide who is the owner of the device; someone has to be the owner of the device and the production process who is licensed to sell these devices to NGOs.
17. The requirements are not always stated in the ISO standards. As a manufacturer, you need to think of the claims and requirements of the device yourself, and it is possible that there are ISO standards applicable to this.
18. Requirements that refer a manufacturer to an ISO standard are called harmonised standards. There are not a lot of them, but there is a set that is usually common practice (even though not mandatory). [36 mins]
19. The European market is not very keen on reusable medical equipment because of sterility issues concerning scandals with contaminated endoscopes. Proving reusability is also a lot of work. For this reason, it is very attractive to make equipment disposable. It is difficult to estimate if what you as a manufacturer have thought about claiming and proving about reusability is sufficient. [21 mins].
20. Regulations are not fond of stories that claim it is a cheaper alternative [22 mins]
21. Certification is closely tied to business cases because it concerns the risk a business is taking and what major amount of money has to be paid.
22. The class of your medical device is an indication of how much paperwork there is and how detailed it has to be.
23. Formally, you need to submit the same kind of papers despite the class.

24. There is a movement/lobby going on for reusability regulations in Africa because it happens anyhow and the EU does not look at this per se. There should be rules for proper reuse design guides. Organisation B is busy with this. Kenya and
25. Rwanda are busy with their own rules but unclear what they say. South Africa, they have regulations for reusability. Does the local legislation regard the product as a medical device? Go through the definition word by word and look into where it does and does not apply to the product [9 mins].
26. Look at the intended use: be critical about the scope of use. Are there things you can leave out and is it possible to talk your way out of this? This step requires some tact and depends on the organisations' competences and contacts to see if it is possible to take a risk [10-11 mins]
27. You need to have a good story surrounding the medical device. The less competent a reader is, the more effort it takes to persuade the reader. [28 mins]
28. It is impossible to make a guide. The process differs every time.
29. NGOs can sometimes require that the medical device is certified e.g., FDA approved or CE-marked, especially if it is involved in tenders.
30. See into it if there is enough need for Chloe SEDs to go through the CE route.
31. As the CE route is established from a European point of view, you can tell a different story when going through the CE process (compared to Kenya). For example, you could leave out the fact that it has a gynaecological function. Everything you tell, you need to prove and that is difficult when the story is complex. However, you must ensure not to deviate from the original story too much. [19 mins]
32. Also, look at worst-case scenarios when making claims and make credible claims because it all needs to be proven. Chloe SED may be too innovative for massive tenders. The order amounts in tenders may also not suit Chloe SED's business proposition.
33. Certifying it locally is interesting because you will skip expensive, complex steps and time. [9 mins]
34. There is a call for collaboration in developing medical devices in African countries, an initiative from the Dutch government named SBIR-subsidy. The government has different subsidies and projects to develop local products together with African companies in the healthcare sector. You can submit a project suggestion/plan for researching the validation of developing your product there with a local partner. You can get 10000-20000 for this. [11 mins]
35. Chloe will be in the consumable low market value category; everything will go through distributors. There is no point in direct sales because of the low price. [19 mins]
36. Make a choice in the ownership of the product: do you wish to make a start-up and produce more products in the same portfolio or are you going to approach an organisation that can do everything and make a deal? Usually, this is an entry barrier in the medical world because you need a CE mark which is worthwhile if you need access to a big market.
37. It is very labour-intensive to go through the certification process per country in Africa as you need to work locally and analyse/understand the system of the country separately. Each time you need to consider: how much does the approval cost and to what markets does it access, for how much can I sell it and is it worthwhile? [17 mins]
38. Disadvantage: It is not allowed by the EU to get a CE-mark for a basic system and then produce varieties of this system.

B5: Organisation G, 25-02-22

1. Orgnaisation G is an importer and has just started in Kenya. Organisation G registers American products such as sunscreen and equipment for hospitals which they sell to the Kenyan market.
2. The PPB is the regulatory board in Kenya and stands for the Pharmacy and Poisons Board.
3. On one occasion, a product had already been registered due to corruption (as this is only possible with official documents from the manufacturer). Registration is necessary because it should help against corruption.
4. There is also an unofficial route possible, which happens without registration: it is possible to import samples as long as the official route (through the PPB) is completed.
5. Registering equipment for hospitals went smoothly but this largely depends on the contacts at the PPB. Quote: On one occasion the contact at the PPB had moved and the organisation had to go through the process again.
6. The process in Kenya is automated. You need to make an account and submit documents. However, after this, it is stored in a drawer and you do not get any answers.
7. The process at the PPB takes a long time but the office, the location and the structure look good to them.
8. However: there is not enough priority in the ministry to organise this better. The ministry has the capability as this is evident in how smoothly visas are arranged for tourists. There is a lack of supervision.
9. For manufacturers outside of Kenya, there is also a different route that is partly parallel to the PPB: it is possible to obtain an export declaration ('Export verklaring') for medical devices. This allows you to sell outside of Europe as well. You can get there through Hulpmiddelen.farmatec.nl
10. There is a lot of corruption at the PPB. What the PPB is doing is crucial but it is very untransparent. You can drink 'a tea' with them or you can complain at the embassy of the country of origin (where the manufacturer is located) and use them to put pressure on the PPB. The latter however is not beneficial for the long term as you are building a negative relationship with the PPB. This is why you usually contribute to the corruption culture instead of the confrontation culture because of the long-term beneficiaries.

B6: Organisation F, 03-03-22

1. Organisation F chooses FDA because the CE process takes longer and you have to indicate with which requirements you need to comply by yourself which is difficult and prone to mistakes.
2. Other people in the same medical device field state this about the CE process.
3. They do not only look into what a regulatory body such as the PPB requires but also look into what the procurement

department of hospitals requires. It does not necessarily have to be a department as it could also be one person in charge.
4. Which certification you eventually go for depends on where you would like to put your product on the market.
5. To organisation F it is unclear which regulatory approval method is used in Kenya, but does know that FDA approval is okay in many countries across the world.
6. Before going through the certification process, also think about transportation: how do you package them to avoid damaging the devices and what are all the actions surrounding the device from beginning to end and who is involved?
7. It helps if a manufacturer can show there are no adverse events when the medical device is used.
8. It is important to look for doctors, health care workers who can use the device.
9. Look at comparable products that have gotten into Kenya: simple ones that are in need of sterilisation, are not invasive but come into contact with the body.
10. Organisation F estimates that Chloe SED will fall under class 2 medical devices under US regulation. Classes in the FDA approval system are based on invasiveness and since Chloe SED touches the body for a very short amount of time, it might be considered non-invasive.
11. Watch out for the material and the finishing that comes into contact with the skin. It should not cause irritation.
12. Be very careful with a claim in the certification process. What you say is what you need to prove. If you say it is autoclavable 100 times, then you need to show this. It helps to include an infographic on the label or include a manual on how to use the device.
13. For reprocessing, look at what hospitals have (autoclaves and/or chemical baths) and look at what your product is designed for and what you have to pay to prove the methods.

B7: Organisation D, 21-02-22

1. Organisation D is figuring out what is needed to acquire certification in Nigeria. While figuring out the certification process, it became clear that Nigeria is outsourcing a part to Intertek.
2. The Nigerian certification process is known to be complicated, difficult and tedious in Nigeria.
3. Certification is mandatory for Nigeria, otherwise an organisation receives fines
4. Nigeria has made a SONCAP certificate mandatory for manufacturers.
5. Because Nigeria demands this particular certificate and is the organisation's first market space, they need to put the product on the market without fines. After things are running, the device will probably need a CE mark in order to sell to other countries but this is for a later stage because the process is too expensive and extensive.
6. Their Nigerian partner visited NAFDAC in Nigeria and mapped the certification process. This person was redirected to SON and finally to the legitimate portal named SONCAP.
7. The portal SONCAP is from Intertek. They ensure products meet standards for any markets around the world. They are highly accredited and recognised. They have 1000 locations in 10000 countries. They stand for guarding quality, health, environment-friendly, safety and social accountability standards. Nigeria has outsourced this and is not done governmentally.
8. Generally, the process consists of 3 steps: 1) checking product compliance, 2) choosing a route and 3) paying fees. Organisation D is very uncertain about the process. They are clueless about doing things online and were only able to know what to do by establishing a contact person who visited the NAFDAC office in Nigeria.
9. Fees for Intertek still remain unclear.
10. Organisation D uses parts in their microscope that are already partly certified, but whether these parts are already certified in Nigeria is unclear.
11. A strategy for a more doable process to gain certification is calling their device [name organisation D] Assistant. The organisation calls their medical device a screening tool in order to keep it in a lower risk class. They have designed the device in such a way that the final authority lies with the human and not the device. So it does not have a diagnostic function but a screening function; the device holds less responsibility. This allows for easier certification protocols.
12. Their strategy for pricing: the organisation is establishing channels to clients that can pay more expensive prices (hospitals) and use these extra financial resources to distribute to places for a cheaper price.
14. Organisation D does not have a lot of money and the CE mark will not provide what is necessary at the moment. Currently it is a waste of resources and energy.
15. The organisation will approach Marokko the same way as they did with Nigeria. The organisation will go there physically and make connections.

APPENDIX C: DEFINITIONS OF A MEDICAL DEVICE

The definition of a medical device according to the EU vs Kenya. For the EU: extract from Article 1 in the Council Directive 93/42/EC/ and for Kenta: extract from 'Guidelines on Submission of Documentation for registration of medical devices', from the Pharmacy and Poisons Board in Kenya.

The EU

Article 1

Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) ►M5 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: ◄

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

(c) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations,

derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or

— concerning a congenital abnormality, or

— to determine the safety and compatibility with potential recipients, or

— to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

Kenya

Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

a. diagnosis, prevention, monitoring, treatment or alleviation of disease,

b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

c. investigation, replacement, modification, or support of the anatomy or of a physiological process,

d. supporting or sustaining life,

e. control of conception,

f. disinfection of medical devices,

g. providing information by means of in vitro examination of specimens derived from the human body;

h. disinfection substances,

i. aids for persons with disabilities,

j. devices incorporating animal and/or human tissues,

k. Devices for in-vitro fertilization or assisted reproduction technologies.

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

References

1. *Global Harmonization Task Force (GHTF)-/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices.*
2. *GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.*
3. *GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.*
4. *GHTF/SG1/N41:2005 Essential Principles of Safety and Performance of Medical Device.*
5. *The Global Harmonization Task Force (GHTF)which is now The International Medical Devices Regulatory Forum (IMDRF)*
6. *The Asian Harmonization Working Party (AHWP)*
7. *British Standard Institute*
8. *Health Safety Authority*
9. *Global Medical Devices Agency*
10. *ISO Standards*
11. *World Health Organization (WHO)*

APPENDIX D: EXTRACT FROM THE EU-MDR (2017/275) CLASSIFICATION RULES

EU-MDR (2017/275) classification rules. An extract from Annex IX.

III. CLASSIFICATION

1. **Non-invasive devices**

1.1. *Rule 1*

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in Class I.

1.3. *Rule 3*

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

1.4. *Rule 4*

All non-invasive devices which come into contact with injured skin:

— are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

— are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,

— are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

2. **Invasive devices**

2.1. *Rule 5*

►**M5** All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: ◄

— are in Class I if they are intended for transient use,

— are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,

— are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

APPENDIX E: THE EU-MDR CERTIFICATION PROCESS (1/3)

An overview of the steps in the EU certification process including short descriptions

Design process of the medical device

Document the design and modifications during the design phase. Gather technical information about design; e.g. material selection

Decide:
Is it a medical device according to EU-MDR (2017/275)? Do you want to sell and/or manufacture abroad?
Is the CE-mark the right certification?
Do you need an EC REP?

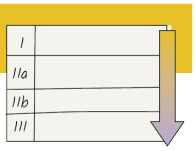
Design in advance:
Labels & Instructions (for class IIb or III).
Check sterilisation methods. Tip: be aware of impact of pigements

Before setting up clinical investigation, think of the exact scope of the function of the medical device (What can your device do?). [J,25]

Tip: perform risk analysis/assessment for feedback from stakeholders. [B,49]

(W. Nerkens personal communication, March 3, 2022)

Classification



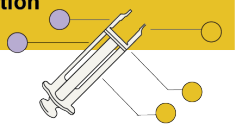
Deicde which class the medical device belongs to with the help of annex VIII of the EU-MDR (2017/275):

Class I, Class Ir, Class Im, Class Is
Class IIa, Class IIb, Class III
(KVK Ondernemersplein, n.d.)

Medical devices of class IIa, IIb and III needs to be checked by a notified body. The higher the number of the class, the more risk the medical devices hold and the stricter the checks by the notified body will be. (P.Koster, personal communication, Febreuary 17, 2022)

If the medical device belongs to class I (with no sterile or measuring function) and it complies with the EU-MDR, then a manufaturer may self-certify the device and does not need to approach a notified body. [B,26] (Rijksdienst voor Ondernemend Nederland, 2022)

Arrange production partners



Arrange suppliers for devices and for the packaging.
Arrange distributors.
Arrange Service Level Agreements with sub contractors

Tip: think of selecting sub contractors on the basis of good and fast communication

(W. Nerkens personal communication, March 3, 2022)

Prepare requirements and documentation

Prepare:
Quality Management System (QMS) in accordance with EU-MDR:
Most organisations use ISO 13485 for this. A QMS includes a Post Market Surveillance (PMS) (plan for active engagement) [B,33] and PMCF plans (look at service level agreements and show how complaints will be traceable). (Emergo, 2022)

Prepare:
Technical documentation. It includes the following aspects of the medical device: General aspects, device description, risk management, general safety and performance requirements, usability, sterilization, software, electrical safety, packaging (and shelf life), biocompatibility, clinical evaluation, labeling, symbols and Instruction for use (P.Koster, personal communication, February 17, 2022)

For the different sections of the technical file, manufacturers can consult EU-MDR guidelines and puchase relevant ISO standards e.g., Risk Analysis ISO 14971 and Biological Evaluation EN ISO 10993-1:2009/AC:2010) (P.Koster, personal communication, February 17, 2022)

Clinical evaluation and/or Clinical trial

A clinical evaluation is mandatory but a manufacturer needs to decide whether clinical trial is necessary. (Emergo, 2022) (Rijksoverheid, n.d. - A)

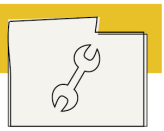
Tip: Keep claims about technical and clinical performance (and sterilisation) modest because everyhting you state you need to prove. [O,12]. [Prepare according to Article 62&74.2 CER and 74.1 PMCF (Rijksoverheid, n.d.)

Clinical Evaluation refers to laberatorium testing where e.g. performance of the material is tested. This evaluation does not include testing on humans but can include testing on mock-ups. [G,26]

Clinical Trial refers to testing the performance of the medical device on people to see if it complies with EU-MDR. Otherwise, if people are necessary check if it falls under WMO legal framework.[G,26] (Rijksoverheid, n.d.-A)

Tip: test your device in an environment that accurately replicates the environment to which it will be sold.

Complete and submit documents



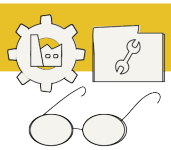
Add the reports from the clinical evaluation and/or clinical trial to the Technical Documentation. (Emergo, 2022)

Make sure to complete:
Clinical Evaluation Report and Risk Management File
Quality Management System including PMS, PMCF

Make arrangements with suppliers about unannounced Notified Body audits.
(W. Nerkens personal communication, March 3, 2022)

APPENDIX E: THE EU-MDR CERTIFICATION PROCESS (2/3)

Assessment by a Notified Body



The Notified Body will assess:
The QMS (ISO 13485)
The Technical File
The Clinical Evaluation and Trial reports
(P.Koster, personal communication, Febreuary 17, 2022)

If everything is completed succesfully, the Notified Body will hand out a CE Marking Certificate and an ISO 13485 certificate for the production faculty. (P.Koster, personal communication, Febreuary 17, 2022)

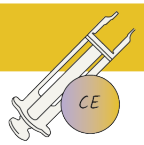
In the future, annual audits may be carried out by the Notified Body, depending on the class of the MD. Failure to pass the audit will invalidate the CE Marking certificate. you must perform Clinical Evaluation, PMS and PMCF activities to maintain certification. (P.Koster, personal communication, Febreuary 17, 2022)

Prepare the Declaration of Conformity (DOC)

Prepare the Declaration of Conformity (DOC) according to Annex IV EU-MDR(2017/275) . The DOC is a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable European requirements. (P.Koster, personal communication, Febreuary 17, 2022)

With this document, a medical device manufacturer recieves the approval to put a CE marking on the medical device. A manufacturer also recieves the ISO 13485-certificate for faculty compliance. (P.Koster, personal communication, Febreuary 17, 2022)

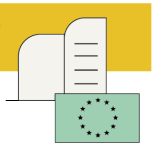
Affix CE-mark on the device



The CE-marking is usually valid for 5 years maximum, but are typically reviewed during annual surveillance audit. The ISO 13485 certificate must be renewed each year. (Emergo, 2022)

There are rules for putting the CE-mark on the medical device. If it is not possible to affix a CE-marking on the device, then the mark should be visible on the packaging. See the source for the rules. (YourEurope, 2021)

Appoint an or organise for a EC REP



If you are a medical device manufacturer that is not located in the EU, it is mandatory to appoint an EC Representative (EC REP).
The EC REP must be qualified to handle regulatory issues.

Obtain a Single Registration Number from regulators

(Emergo, 2022)

Labels, instructions and Unique Device Identifyer (UDI)

Place clear labels and instructions on the device. For medical devices from class I or IIa, intructions are not necessary if the patiënt or client can use the device safely without it.

For the labels, follow Appendix I of the EU-MDR (chapter 3, section 23.2) to see what is required on the label of the device. The label must mention a physical address of the manufacturer. If the manufacturer is not in the EU then you must also include the address of the authorized representative (EC REP) on the label, package or in the instructions.

For the instructions, it is necessary to use the language of the local market and to formulate the text that it fits with the knowledge of the user. If you are sure your device will be used by healthcare professionals that understand English well, then you are permitted to write in English alone.

Obtain a Unique Device Identifyer (UDI), You need this in order to register in the next phase. (Rijksoverheid, n.d.-B)

(KVK Ondernemersplein, n.d.)

Register at EUDAMED and FARMATEC

The medical device manufacturer must register itself, the organisation and the medical device in the European database named EUDAMED. This is mandatory before marketing the device. The device must be registered with its UDI that is associated with the regulatory documents.

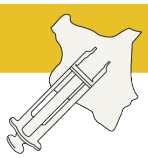
Some medical devices need to be registered at Farmatec (e.g. class I and IVD's). If this is the first time, it is also necessary for a manufacturer to register. Farmatec needs to be notified when a manufacturer decides to stop with the supply or delivery of the medical device or if it needs to modify it.

Caution: currently the EUDAMED is still under construction and for now medical device manufacturers must register elsewhere.

(KVK Ondernemersplein, n.d.)

APPENDIX E: THE EU-MDR CERTIFICATION PROCESS (2/3)

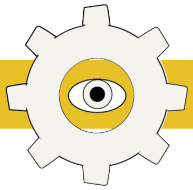
Bring the device to the market



Manufacturer is now permitted to sell the product to markets that approve of the CE-marking. (P.Koster, personal communication, Febreuary 17, 2022)

Tip: ensure sufficient financial back up in case the device is defect. (W. Nerkens personal communication, March 3, 2022)

Post Market System



Medical device manufacturer

Keep monitoring device e.g. through post-market system with the help of the UDI. UDI allows quick traceability of the device in case something turns out unexpectedly.

PMS must not only monitor but also actively set out to gather information on professionals and patients experience with the device to keep improving its quality.

Significant modifications need to be reported to the Notified Body (e.g. change in design, package or retrieval of devices).

Carry out field safety corrective actions by arranging incident report system. Incidents need to be reported to the IGJ.

Draw up a Periodic Safety Update Report (veiligheidsrapport)

(Rijksoverheid, 2020)

EU REP

Must register itself in EUDAMED and keep registration/data up to date

Must verify whether you have drawn up the Technical File and Declaration of conformity

Must verify whether a Notified Body has assessed the device

Must notify authorized body such as IGJ of incidents and complaints about the medical device and provide information about the device

EC REP, you and the importer have equal share in responsibility

(Rijksoverheid, 2020)

Inspectie Gezondheid en Jeugd (IGJ)

Must safeguard safe and sufficient care with the device (or maybe this is only for implants)

Must check manufacturers, suppliers, healthcare institutions, patients, notified bodies.

(Rijksoverheid, 2020)

Notified Body (e.g. DEKRA)

Must monitor and check the manufacturer and devices

Will keep carrying out audits.

(Rijksoverheid, 2020)

A patient

Must be able to notify complaints, information or incidents at a certain database point.

(Rijksoverheid, 2020)

APPENDIX F: PERSONAS GLOBAL NORTH MANUFACTURERS

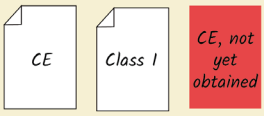
This appendix presents the personas that were created from the interviews with medical device manufacturers based in the Global North (Appendix B)

Organisation A

> *Purchasing an ISO standard is expensive but testing the compliance of the device costs even more: 60.000 euros.*

> *It is a commercial sector so you can approach anyone (Notified Body) with a large sum of money and ask them to do an audit for certification. This is the reason why it is so difficult to obtain information from them.*

CERTIFICATION & CLASS



REASONS

They are unsure which market they want to target and the CE-mark keeps many doors open. Organisation A shifts their focus to a different country when the government offers funding that is tied to a specific country.

They are still opting to market their medical device in the EU as well.

STRATEGIES

They looked into literature and the declarations of conformity of similar medical devices to read the rationale for the classification of these devices.

For Kenya, the organisation is in contact with doctors, users and biomeds for feedback on the medical device. Biomeds can also indicate who the distributor is of a hospital.

They take doctors, users and other experts through the risk assessment.

They are looking for partners that are up for collaboration against a certain amount of money or that are willing to let organisation A be part of a project and give support. This is because they are experiencing difficulties with financial resources and finding a partner that has been ISO certified.

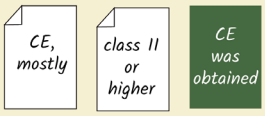
They are a class I medical device manufacturer in the EU so they do not need to show your QMS but must have it in place. The device only requires clinical evaluation instead of a clinical trial which takes longer as it involves testing on humans. It also means they do not have to involve a notified body and skip waiting time

Organisation B

> *The Kenyan document is frightening to read. To interpret what they mean is difficult. The PPB document says it is a DRAFT but is 3-4 years old. The organisation is still busy figuring out what they need.*

> *For Kenya, the CE-mark was okay but now it becomes more riddly to other countries in Africa, as they are reinventing the wheel by establishing their own procedures for medical devices.*

CERTIFICATION & CLASS



REASONS

XXXX

STRATEGIES

In their experience, design modifications that were necessary as a result of legislation, were about: (1) using materials that did not cause harm and this is closely linked to the production methods and (2) avoid using colours that indicate something special or hold meaning as this can seriously lead to fines and patient deaths.

For Kenya specifically, it is difficult to get products to the market that are not CE-certified.

It helps to come in touch with clinicians in Kenya and have a medical body work with the organisation. It can remove some barriers if an organisation has evidence of it being used.

It took us 5 months to re-evaluate their device and it cost 50.000 pounds to eventually change the colour of the on/off button in order to be compliant.

Organisation C

CERTIFICATION & CLASS

CE, mostly

Class II & III

CE was obtained

REASONS

They are part of a UN framework which requires medical devices that hava a CE-mark. This means the organisation is part of a catalogue from which the UN can procure goods direclty.

STRATEGIES

It is difficult to get into the UN framework because you need 3 years of annual reports, financial stability and show experience of similar projects in similar settings and the service capabilities. On the other hand, this catalogue allows them to sell to distributors in the UN framework that can reach the public sector without having to deal with the corruption that nestles in the public sector.

For Kenya, organisation C is registering itself at the PPB and is organising the PVOC. These are two different options: the former for mere registration and the latter for receiving approval from Kenya to import.

Organisation C leads the development of devices but outsources manufacturing and CE-holding (who protect intellectual property and are in charge of obtaining CE-marks).

Organisation D

CERTIFICATION & CLASS

Local Global South

Class B

Not yet obtained

REASONS

Organisation D finds it a waste of financal resources and time to invest in the EU certification process.

STRATEGIES

Organisation D established a contact in an African country to which they intend to sell to figure out locally what the certification process looked like. This person was redirected to several offices. The organisation remained clueless about the process when relying on online sources only.

The organisation is using parts in their medical device that have been certified but they are unsure whether this is sufficient for this African country.

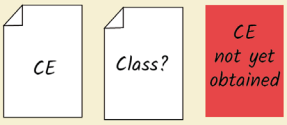
Organisation D is giving their medical device an assisting function rather than a diagnostic function where the final responsibility lies with the human and not the device. This choice enabled them to allocate the medical device to a lower risk class which results in easier certification protocols.

The organisation is establishing channels for clients that can pay a higher price for their medical devices and will use these extra financial resources to distribute to places that can afford less.

Organisation D is planning on establishing a local contact again in a different African country to figure out what the certification process looks like for this country.

Organisation E

CERTIFICATION & CLASS



REASONS

Organisation E wants to target multiple countries in the African continent. The CE-certification keeps the doors to these countries open.

STRATEGIES

A favourable strategy is to market their medical devices in certain African countries that do not have a regulatory system in place.

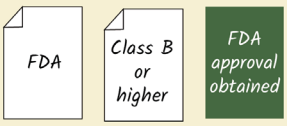
Organisation E has visited the countries in which they intend to sell to map out what regulatory path there is, what distributors they need to partner and what competitors there are.

Organisation E finds Kenya a too complex market because of the bureaucratic and inflexible system that is in place. According to them, it is logical that the system is there to regulate all the devices from medical innovatiton hubs in the country. You have to cross a lot of stages and wait a long time. Their product is relatively complex and they have to talk a lot with regulatory bodies about whether to certify parts separately or the device as a whole together.

Go-to-market-strategy for Kenya: (1) acquire CE-markering, (2) work with a distributor partner in Rwanda who is starting up in Kenya, and (3) Work with a different distributor partner who supplies to faith-based centres. There are 3 categories: faith-based, public and private hospitals. (4Faith-based hospitals are interesting because generally, they are better off than public hospitals as they gain extra money from the church to better the hospital. (6) Private hospitals are also interesting; they have private clinics and the company goal3 works with is Ilara health (the quickest growing start-up in Kenya). They are modern, mobile-based and involved with private clinics in Kenya.

Organisation F

CERTIFICATION & CLASS



REASONS

Organisation F chooses FDA because the CE process takes longer and you have to indicate to which requirements you need to comply by yourself which is difficult and prone to mistakes.

Other people in the same medical device field state this about the EU certification process.

STRATEGIES

They do not only look into what a regulatory body such as the PPB requires but also look into what the procurement department of hospitals requires. It does not necessarily have to be a department as it could also be one person in charge.

It helps if a manufacturer can show there are no adverse events when the medical device is used.

APPENDIX G: INTERVIEW GUIDE FOR GLOBAL NORTH MANUFACTURERS

The interview guide is used for conducting semi-structured interviews with medical device manufacturers in the Global North, to understand what process they have chosen to undergo to receive certification for their medical devices to sell them to markets in the Global South. The guide was used to understand why these choices were made and what organisations did or were planning to do in introducing their medical devices in the Global South.

Introduction

Welcome to the interview about the certification of medical devices. I will shortly introduce myself:
My name is Floor and I am a (dutch) student from TU Delft (in the Netherlands) of the faculty of Industrial Design Engineering. I am currently rounding off the Master Strategic Product Design with a graduation project. The graduation project is about the certification of medical devices where I will focus on Chloe SED for Kenya and who could bring her to the Kenyan market.
May I record this conversation? (explain that it helps to listen back to information).
Thank you for being here to talk about the certification of MDs.
Would you like to introduce yourself?

Certification

Now let's dive into the topic of certification:
Which certification path do you choose for your medical devices?
Are your medical devices CE-certified?
Are your medical devices also certified locally in Kenya or in the country of the intended market?
Have they certified another way?
To what countries do you market that are LMIC?
Do you market medical devices in Kenya?
How do you ensure the performance/design of medical devices within HIC also suffices for challenging environments of the LMIC?
In what ways do the regulatory requirements tighten if the class of the device is higher?
What parts of the certification process have translated (back) to modifications of the design of the device? Example?

Certification in Kenya

Do you have experience with the regulatory system in Kenya? Do you know what system is in place? How did you find out?
Do you have experience with registering at the PPB? What is your experience with the PPB?
What is your experience with bringing medical devices to the Global South regarding certification?
Marketing the medical device in the Global South
Have you considered selling your medical device to an NGO/Innovation hub?
What is your go-to-market strategy for Kenya?
Contacts for further research
Do you have any contact with other organisations that have managed to achieve this?
Do you have any contacts with organisations in Kenya that have achieved this?
Do you have contacts from the PPB or any other regulatory body in Kenya involved in the certification of medical devices?

Closing

Thank you very much for your time for doing this interview.
Is there anything you would like to ask?
May I contact you in case I have questions?

APPENDIX H: 4 EVALUATION ROUTES IN THE PPB GUIDELINES

Extract from the PPB guidelines on submission on registration or MDs presenting evaluation routes for Class B MDs.

PPB/PER/MDV/GUD/011

5 MODULE 2 - REGISTRATION OF CLASS B MEDICAL DEVICES

5.1 Evaluation Routes

There are four evaluation routes for Class B medical devices:

i. Full Evaluation Route
ii. Abridged Evaluation Route
iii. Expedited Class B Registration (EBR) Evaluation Route
iv. Immediate Class B Registration (IBR) Evaluation Route

The abridged, expedited and immediate evaluation routes are set out according to a confidence based approach, leveraging on the approvals by listed medical device reference regulatory agencies (8) and/or prior safe marketing history of the Class B devices. The types of approvals that qualify for the abridged, expedited and immediate evaluation routes are:

i. Australia Therapeutic Goods Administration (TGA) Device Registration License

ii. Health Canada (HC) Device Registration License

iii. Japan Ministry of Health, Labor and Welfare (MHLW)

-Pre-Market Certification from a Japanese Registered Certification Body

-Pre-Market Approval from MHLW

iv. US Food and Drug Administration (US FDA)

   a. 510K clearance
   b. Premarket Approval (PMA)

v. European Union Notified Bodies (EU NB) via EC certificates issued according to

   a. Directive 93/42/EEC Annex II section 3 or Annex V for Class IIA devices
   b. Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs

i. Irish Health Products Regulatory Authority
ii. Swiss Medic
iii. Saudi Arabia Food and Drugs Authority

5.2 Full Evaluation Route

5.2.1 Eligibility Criteria

A medical device that has not obtained any prior approval from any Reference Regulatory Agencies at the point of application will be subject to the full evaluation route.

1.1.1.Submission Requirements

- Letter of Authorization
- List of configurations of medical devices to be registered
- Common Submission Dossier Template (CSDT)
- Executive Summary
- Essential Principles Checklist and Declaration of Conformity
- Device Description
- Detailed Information of Design Verification and Validation Documents
- Full reports of Preclinical Studies including the detailed sterilization validation, if applicable
- Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
- Risk Analysis
- Manufacturer Information
- Name and address of the manufacturing site(s)
- Proof of Quality Management System – e.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
- Manufacturing Process – Flow Chart

For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

d. Proof of marketing history in the same independent reference regulatory agency's jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history

e. Declaration of no safety issues globally

f. Common Submission Dossier Template (CSDT) dossier approvals from the independent reference regulatory agencies

5.5 Immediate Class B Registration (IBR) Evaluation Route

5.5.1 Eligibility Criteria

A Class B medical device may qualify for registration via the IBR route if it complies with the following conditions:

(i) approvals by at least three of PPB's independent reference regulatory agencies for intended use identical to that submitting for registration in Kenya;

(ii) marketed for at least four years in two of the independent reference regulatory agencies' jurisdictions; no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years, defined as

(iii) no reported deaths;

(iv) no reported serious deterioration in the state of health[3] of any person; and

(v) no open field safety corrective actions (including recalls) at the point of submission; and

(vi) no rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) or Kenya due to quality, performance/efficacy or safety issues.

(vii) For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested post-registration to substantiate the proposed label use.

PPB's independent reference regulatory agencies are HC, MHLW, USFDA,TGA,EU-NB,SWISSMEDIC,HPRA.

APPENDIX I: INTERVIEW QUESTIONS FOR KENYAN MANUFACTURERS

Organisation S

Physical and digital platform to tie together a network of local manufacturing hubs and centralised engineering. Manufacturing with 3D technology and also offers a catalogue with parts. They do this for healthcare providers /institutions that do the public good.
Goal: To know which organisations are clients, and how the products are checked and certified as they reach the healthcare sector market.

Name and describe what kind of organisations from the healthcare sector approach and order at this company?
Do the products go through certification or an approval process in order to be used?
If so, who takes care of this and how is this achieved?
How do the products reach the market?
Does the company print medical devices that are intended to come into contact with human fluids?
How are local hubs connected to a specific order?
How large is the network of local hubs?

NRHS Dr. Gwer

Co founder of chloe sed.
Goal: What he has seen in terms of certification and procurement process and clients of Kisumu hospital.

Which MVA kits are used? Why?
How is MVA kit certified?
Who distributes MVA kits to Kisumu?
For other devices, how are they certified?
Can you explain to me what the procurement process of Kisumu hospital looks like?
Do you know procurement process is similar for other private hospitals?
Do you know what procurement process looks like,e for hospitals in public sector?

Organisation U

Provider of flexible working space, shared prototype facilities, training in manufacturing, fabrication and design such as 3d printing, electronics, metal working and automation. Also training in mentorship, investment opportunities and community development. Industry experience in healthcare, product realisation amongst other things. Provides networking with people that know how to take products to the market

Is the organisation also involved in helping individuals or ogranisations obtain certification for their medical devices?
If so, how does the certification process look like?
Who is involved and what is the company's role?
How hasthe company helped with product realisation and getting products to the market?
What kind of organisations seek help from the company's network of experts in getting products to market?

Organisation M

There are different teams working on ventilators and teams are also seeking how to certify this locally?
Goal: To know what ventilator team is planning on doing with the certification process for the ventilators. And possible contacts for organisations in Kenya involved in gynecology/MVA in Kenya.

Does Organisation M also develop medical devices for women's reproductive health?

Has medical device designed or initiated in this organisation reached hospitals or healthcare facilities?
How have these been certified or approved?
Contacts within organisations that are involved in women's reproductive health and MVA? Such as Marie Stopes or Family Planning Options.
About the ventilator teams: what is their plan for certification?
Is this organisation involved in/ facilitates clinical evaluation?

Organisation 0

Global team of designers, engineers, medical professionals and business minds working out of India, USA and Kenya. Belief is no matter where you should have access to world class medical treatment. Focus entirely on healthcare system. Design process includes sustainability, global partnerships and scaling up. You can submit proposal for healthcare innovation.

For who do you design medical devices? To what types of organisations do you sell?
How do your designs reach Kenyan hospitals and healthcare facilities?
How do your designs go through certification process or obtain approval?
Where do you manufacture devices?
What types of global partners do you have?
And to which countries do you sell?

KEBS-PPB

Official governmental regulatory body (PPB) who offers 4 routes for certification which depends on prior certificates from outside Kenya on a confidence based approach. KEBS is bureau of standards and eventually inspects and approves of device to be used in Kenya.
Goal (KEBS): Seek possibility for certification in Kenya without certification from outside of Kenya (CE or FDA e.g.). If possible use pen and paper for brainstorm.

Is it possible for medical devices to obtain Kenyan certification locally without prior approval from abroad/ country of origin?
What is required and what does the process look like?
Who is involved in the process?
Are we the first ones to come into contact with KEBS with this question?
Are there individuals or organisations succeeded to do so before? Which ones?

Revital Healthcare

What is the Revital Healthcare market?
Does Revital Healthcare develop medical devices for women's reproductive health?
Does Revital Healthcare develop medical devices that are reused?
In what order did Revital Health achieve certification for their medical products for Kenya and why in this order?
What did the certification process look like?
Revital Healthcare's experience with certifying medical devices with KEBS and the PPB if applicable? (Which KEBS certificate?)
Also how Revital Healthcare has come to supply WHO and UNICEF?
Does Revital Healthcare also supply to hospitals in Kenya directly? (What kind)
Further questions about the types of medical devices Revital Healthcare manufacturers

APPENDIX J: INTERVIEW WITH THE PPB

Insights taken from an interview with an employee at the Pharmacy and Poisons Board in Kenya, 09-03

1. The interviewee got into this field because of a mistake but also considers it a blessing. The person is an accountant and financial analyst by profession and used to work at an NGO and we used to receive a lot of public health equipment, especially from G-foundation. [1 mins 50]
2. About previous work at the NGO: In terms of doing it through donation and when there was no regulation to get the medical devices, it was easier for us to leave the clearance agent to clear the goods and then get them and distribute them to the various hospitals. But then the regulation tightened and with no experience, I had to start looking into how and why it is necessary to register. And now the interviewee is in the field for 6 years. [2 mins]
3. That is when the interviewee started to know the PPB as a regulator or governmental organisation that deals with pharmacy and medical devices. So then she started to understand the classification and why etc. [3 mins 26]
4. The NGO, the interviewee used to work for was called Centre for public Health and Development with a project to get medical devices from (3)G-foundation with topnotch products that they never sold and not the newest (second hand?) model to distribute to government hospitals as donations. It came with a donation, warranty and training for the MDs. The training was important because however good the equipment was, if there was no training it would end up in storage. [3 mins 45]
5. The NGO still contacts the interviewee for advice on the classification of their mannequins for training that fell under medical device regulations and required corresponding documents. [5 mins 26]
6. Once you register in Kenya, you get a certificate from BBP. With this certificate, you can do anything in Kenya because it has been evaluated by PPB. To supply to governmental hospitals you need a valid PPB certificate. If you do not have this valid certificate, you can not apply to the tenders. Ideally, PPB is given the mandate to do this on behalf of all the governmental hospitals [6 mins]
7. The same is for private hospitals. Not all private hospitals but the major private hospitals require certificates from the PPB. Other private hospitals do not require such because of the costs involved with registering. However, these hospitals can not go back to the PPB in case of malfunction or complications of/due to MDs, it will be their own lawsuit and deal with insurance themselves because they decided to do it by themselves. [7 mins]
8. Ideally, this was introduced because of the evaluation time it takes for class B. It comes to 60 days without weekends etc. So for more urgency and to fasten the evaluation process, if you have 2 certifications (EU, USA, Canada) the evaluation time will take shorter because you have already been approved by 2. [12 mins 42]
9. In comparison to equipment from China where they have only been certified by CE and sometimes those certification processes are not as credible because the interviewee has dealt with registrations where CE documents have been manipulated. It is not necessarily the manufacturer but sometimes if PPB asks the manufacturer for the document they say they do not have it and ask what it looks like so they can copy it and this document is necessary for the evaluation. [13 mins 33]
10. 1 credible certification is sufficient for abridged evaluation. It will take 60 days but not all 60 days. [17 mins] Others have CE and FDA, they are more credible. [14 mins 50]
11. Having CE from Europe is okay because Europe has set the standards on their MD in such a way that you can go to the website and find the document, they freely give it out and you can easily lay contact/call and get it as credible as possible. [15 mins 10]
12. Certificates from Germany and the Netherlands are like heaven for the PPB in approving MDs. Chinese certificates raise the alarm and will usually take more than 60 days. For Europeans, the PPB does not go as hard as for the Chinese. Because most European manufacturers freely give this information. [15 mins 48]
13. Leaving other regulatory references aside, You need a letter from the ministry of Health or a letter from a credible university/college. If the equipment is still under clinical evaluation, this letter can say they back up the device with qualified entities. This is allowed because CE takes a long time. [17 mins 55]
14. It is very difficult to get through the PPB without backing from the country of origin unless it is a donation. But even then the interviewee needs a certificate of an analysis of the clinical evaluation. For people from Kenya to use it, you need backing from your country. [29 mins]
15. If you have no reference regulatory agency, you need to go through the full evaluation route. The interviewee still needs a document from NLs, it is a must. She still needs backing from the country telling her the equipment is okay for use.
16. There is a PPB NLs and they must give out a document that says the device has been tested and done by this entity and so has a backing. For the PPB system, the interviewee needs to attach something and if she does not it does not generate anything fruitful and she can become suspended if she does it a bit shaky. Backing from the country of origin is very important. [26 mins 30]
17. The document stating this is from the Netherlands and it has been approved, will be used/taken as the CE (substitute the CE) but also the PPB can approve notes saying the product is undergoing clinical evaluation and will take 'this' amount of time. Though she still needs NLs PPB, telling the Kenyan PPB that this is okay. It will be very difficult without your backing [28 mins 26]
18. While the interviewee worked at the NGO, there were 2 projects: 1 that concerned a breathing machine. It was developed in the US but the clinical evaluation had to be done in Kenya because they did not have an environment that truly replicated the one in Kenya. What happened was we imported the device and we had to talk to PPB regulatory department and ask for permission to bring them in and then we were given the mandate to work with a university which also does medicine, a research institute or work with PPB to start with clinical evaluation/processes so there was a lot of data collection. The was returned back and corrections were made but never came back. At that time she left

the company and does not know what happened afterwards. The other device was an oxygen cylinder that underwent clinical evaluation in Kenya, it was designed and manufactured abroad. [19 mins 29]

19. So many people want to do it: manufacture and design locally.The interviewee has seen well-thought-out ideas but when it comes to funding……Clinical evaluation funding is expensive.You have to pay back the funding and so they find it a bit time-consuming and the element of funding. It takes time. Data collection and everything takes time, effort and resources. The interviewee has seen good ideas but usually run to NGO who can help them fund, try to reach top companies in Kenya as giving back to the community but there also so many ideas that they do not get the fund to execute the plan [22 mins 49]
20. Most of the time these companies with good ideas generated locally, manufacture devices abroad before being brought back to Kenya.[24 mins 31]
21. Now Chloe SED is undergoing a clinical trial in Kisumu [29 mins 31]
22. The interviewee thinks getting to Kenya is possible without going through CE or FDA. The interviewee asks Karl what university he is working with. Maseno University?). She is happy Karl has worked with this university before. Once clinical evaluation and reports are done, she thinks it is a matter of communicating to the PPB that this has been done and then you have to go to KEBS for certification and then you can go and mass produce. [30 mins]
23. Most of the clinical evaluations have not reached that stage and the interviewee has to be rooting for Karl but concerning certification, it should be possible and Karl needs to email/call her. [31 mins 20]
24. Karl has already had contact with KEBS. He has gone to the PPB already and is almost gone/done for clearance. Because it is a second trial, we have already done the first one. Karl asks her who in KEBS should he talk to ask what certification is necessary at KEBS. She knows a person and Karl asks her for support. [32 mins 20]
25. All you need to think about is getting it ‘to your own’. Karl states he has already gone to KIPI. [33 mins 38]
26. The interviewee has not seen the whole certification process happen in Kenya: design, manufacture, certify and register in Kenya. The idea is generated here, work with a team of engineers in the UK or USA, prototype there and go back and forth, back and forth with Kenya until they get to proper equipment. But it is never brought back and manufactured. [24 mins 58].

APPENDIX K: INTERVIEW WITH A KENYAN PHARMACIST

Insights taken from an interview with a Kenyan pharmacist who has dealt with registering both borderline products (e.g. sunscreen) and medical equipment at the PPB, 24-02-22

1. For Kenya, you have the ppb; for registration and regulation of the products (He also names other boards for other African countries). [3.40 mins].
2. Role of the interviewee is to get products registered in region EA (countries named previously). Products refer to (medical) devices, pharmaceutical products or utility and borderline products which are more cosmetic in nature (not pharmaceutical e.g. supplements). [4.10 mins]
3. The interviewee has a background in pharmacy and marketing. He has a bachelor's in business administration. master strategic management. Working for pharma business since 2006. He worked in different multinational companies. Pharmacist as side business [1.57 mins]
4. The difference between pharmaceutical products and borderline products: pharmaceutical products are more detailed and expensive to register because the ppb has to visit the site where the product is being manufactured to give certification. You have to pay for the costs; accommodation, visa etc. You need a lot of data, surveys, ISO certification, FDA approval, GMP, and stability requirements. Can all be obtained from the manufacturer. Borderline you can register yourself? [4.40 mins]
5. The difference with devices: Is not as deep as in the pharma business. For a device, they do not need a visitation, no sampling but they only need a letter from the principal company indicating the area of the country to distribute to, the authorised distributor, the documentation in terms of the production, the documentation if there is ISO certification, the specs of the particular item/device. It is quite easy however the system takes time to be effective. The operation of the system is tricky. [5.49 mins]
6. The system operation is tricky. Ordinarily registering a pharmaceutical product or medicine in Kenya can take 2-3 years of which 6 months for registration or indication extension. You can register a product for an indication e.g. if you want to adjust after 2 years to extend another purpose to increase the scope of the market. This adjustment takes 6 months for indication to be certified but it is not a new process to start or if you want to change the packaging. [6.40 mins]
7. About the PPB process: the device is more simple because there is no sampling. All you need to do is go to the PPB portal, share documentation and load everything they ask (drive through it) and it goes for approval. Then they will tell you what the regulatory fee is. Then you pay with a mobile transaction. It will then reflect on their end, you are not able to proceed to the next stage. You submitted the application and then you will go to a waiting point: pending assessment, evaluation and approval until you get approval. [7.30 mins]
8. What you need to get for the device (same for borderline products not so detailed) in terms of documentation: ISO certification, GMP, the certificate of the lease, the freeofsol, the show of good practice, letter or the company that they are the ones to produce is (basic prerequisites). To show that the product is good quality, from a reputable manufacturer and usable without any significant or minor side effects. [9.05 mins]
9. Summary: First of all there is no detailed chronological procedure but the easiest to do: (1) a registered company in Kenya which is limited (Ltd). (2) Register a company to PPB and get access to the PPB portal. (3) go and check what you want to register, what are requirements and then give all those items. Lack of documentation can hinder you to get to the next level, and loading documents into the system. Documents vary per device. (4) System will tell you the fee in the pre-approval stage. (5) You pay the fees. (6) You enter the point of evaluation and certification. [13.59 mins]
10. 1 or 2 contacts from the interviewee that are consultants from institutions do registration at a fee and they help. They tell you all that you need, ask you for all documentation and you must open a portal. For this, you must have a local company registered in Kenya (talk to the interviewee for this), after this has been registered then you need to log in to the portal (you get a login credential to the PPB, and they give you a password). The registered company must have a certificate of good cooperation, and a licence of operation (all basic business perquisites). After you have all those, you register at the PPB. The login portal becomes your portal where you can log in all your documentation. [11.48 mins]
11. From the point of view of the interviewee, there is no chronological order but depending on the product you are focusing on, requirements are different per device, check required documentation. Acquire them all and load them. [15.54 mins]
12. In most cases, the product from the mother company usually has FDA or CE marks. There are local products that need to undergo the same procedure for a mark but the registration process will be slightly shorter because the visit to the manufacturer takes less time (less lead time). [10.37 mins]
13. The rationale for producing products in Kenya and not outside [23.46]
14. The pharmacist might know what pricing could be there. Is it a basic price (or high-end)? [25.15]
15. Uniqueness and pricing are important factors for market penetration. The interviewee knows gynaecologists and knows a simple way. If it comes to the registration of products, he would like to help. [26.42]
16. The process of PPB is difficult, and the duration of time always varies. Generally, the process is tedious. Priorities, huge mandates and the amount of work overwhelm people working. Some companies even register more than 200 products and checking documentation is a lot of work. They also have to regulate pharmacies. Huge for them to chew because of all these mandates. [16.53 mins]
17. To speed things up, manufacturers can talk to friends at the PPB and push it in the corrupt or correct way: there are people who are different who either will or will not accept bribes, depending on the interaction level with him/her. [18.40]
18. What is common in Kenya in getting (gynaecological) devices to the market: The interviewee can assist because

he worked for 3 multinationals: Innotek International, Jansen (Johnson & Johnson), Mark Healthcare (the oldest pharmaceutical in the world). Mark healthcare: woman health for EA. (with products). [29.21 mins]

19. The interviewee can link us up with top gynaecologists who can be brand ambassadors for the introduction of the product. Link to people who can introduce products in the market. Thereafter use the Kenyan Gynaecological society to introduce the device and use the exhibitions to display the device with explanations of its uniqueness and its features. A cheaper, effective and impactful way to introduce and launch a new brand. [31.47 mins]

APPENDIX L: GHTF PROPOSAL FOR CLASSIFICATION

GHTF-proposed general classification system for medical devices, as is adopted by the PPB.

Table 1
GHTF-proposed general classification system

Class	*Risk level*	*General device examples*	*IVD device examples*
A	Low	Surgical retractors/tongue depressors	Clinical chemistry analyser/prepared selective culture media
B	Low-moderate	Hypodermic needles/suction equipment	Vitamin B12, Pregnancy self-testing, Anti-Nuclear antibody, urine test strips
C	Moderate-high	Lung ventilator/bone fixation plate	Blood glucose self-testing HLA typing, PSA screening, Rubella
D	High	Heart valves/implantable defibrillator	HIV blood donor screening, HIV blood diagnostic

APPENDIX M: INTERVIEW WITH DR GWER

Insights from an interview with Dr Gwer, a Kenyan gynaecologist and obstetrician, about how health care centres procure their MVA kits.

1. Marie Stopes is the biggest abortion provider in the world. They have their own brand of MVA kits.
2. DKT is partnering with IPAS, a manufacturer/supplier of MVA kits
3. DKT has a big regional shop that sells to distributors who bring the kits to outlets such as smaller chemists. Health care centres can purchase the MVA kits from these outlets.
4. Private hospitals also set out requisitions for quality assurance and pricing control. Just like with tenders, they seek the most cost-effective distributor.
5. Most used MVA kits are from IPAS and DKT.

APPENDIX N: INTERVIEW WITH A GYNAECOLOGIST (TRANSLATED)

Insights from an interview with gynaecologist who has dealt with MVA procedures in Ethiopia and worked for MSF, 25-03-22

1. The Female Cancer Foundation (FCF) facilitates the screening of cervical cancer because there is no government programme that offers this, unlike in the Netherlands. The screening is carried out by the see & treat method with the help of a smear test. FCF takes place in hospitals and health care clinics through partnerships and sometimes mobile clinics as well for improved outreach. MVA kits are not involved in the process.
2. The procurement process differs per NGO. MSF uses a green list. A green list refers to a list of products that are approved by MSF and can be ordered/procured through projects. Principally, MSF does not procure devices outside this green list. MSF imports devices and does not procure them locally, but the devices must be approved in the country itself as they have to show the papers/documents. It differs in how easy it can get through customs: that of Ethiopia is strict.
3. MSF has 5 main offices that are located in different countries.
4. IDA group is a distributor in Amsterdam that brings medical equipment to LMIC.
5. MSFdoes not use MVA kits per se but Marie Stopes does. MSF sometimes also uses MVA kits. Marie Stopes is a local and international NGO that concerns itself with reproductive health for women and their activities in health care clinics related to this. They offer treatment for abortions and miscarriages and family planning. This NGO would not only use their own purchases but would also use the national 'joint medical stores' if there is one in Kenya (there is one in Uganda). 'Joint medical stores' is a kind of department store with biomedical supplies. The government can also order/procure here (in Uganda). In Kenya, these could also be private organisations.
6. Just like Marie Stopes, there are other NGOs with local partners which would procure locally. Procuring equipment locally is very valuable for their own economy. They have also already earned from the import costs.
7. Not every country has their own equipment or a local distributor. For example, specula were imported but also procured locally but some medical supplies had to be obtained from South Africa. Usually, D&C could also be procured locally. These were very durable. AzG always imported their devices and never procured them locally and the devices were often CE-certified.
8. NGOs can also have their own hospitals. For AzG, it depended on the project or activities that had to be carried out, if they were stationed/facilitated in a public hospital. They do not supply to private organisations or hospitals.
9. The interviewee mentions that while working in Africa and at MSF (Tanzania, Uganda, Malawi), she did see MVA kits but mainly D&C was popular. The reason behind this is that D&C is made of simple materials, it is reusable, it is very durable and the users are trained for using this equipment. The MVA kit is designed as single-use which means a healthcare facility needs a big supply (costs) and the users are not always trained for this equipment. MVA is not suitable for a hospital's autoclave in order to be reprocessed.
10. In Tanzanie, it is possible to have your uterus cleaned for a small fee (as preventative treatment). There does not have to be a medical indication and there does not have to be an echo.
11. Gynaecological procedures (MVA and D&C) were also referred to as 'Polé' treatments which means 'sorry'. This is because they often took place without pain-relief medicine. Otherwise, a patient would be put to sleep with ketamine like in the Netherlands. For miscarriages in the hall, oral pain-relief medicine suffices.
12. Some NGOs react to tenders but MSF does not, to maintain its neutral stance. They choose their own channels to stay away from politics.
13. MSF has a warehouse with an IDA group but also has their own warehouses. They also have their own funding method/channel for their own projects where other NGOs have to wait for funding. They have a supply of their own products and separate funding resources which is useful for emergency projects. They differ from other NGOs in this aspect.
14. Chloe SED may also be useful for Loop Electrosurgical Excision Procedure. In this procedure, a health care provider uses a small metal hook to extract and investigate deviations in the cervix through in-vitro. For this treatment, a patient needs pain-relief medicine. Chloe SED could also be sold in a kit for this procedure Manufacturers deliver different sizes of Loops', cannula and syringes. The interviewee is not sure how these kits are sold in LMIC or in Europe. She knows that the loops are delivered separately and the cannula and syringes are used with the ampulla.
15. Public and private clinics want to earn money so treatment is expensive.
16. In the city you would find more private clinics and in the villages, you would find more pharmacies.
17. Abortion is difficult and not always legal. The pill for treatment is difficult to obtain and providing care is also difficult. Sometimes patients seek help in more traditional healthcare clinics (traditional healing methods) where the care given is not always safe. Patients would receive natural products and it does not always have the desired (or complete) effect. In hospitals and healthcare clinics, an abortion can sometimes be registered as a miscarriage or as another case. In this case, to cover up the abortion, an MVA is better than a pill (medication)..
18. Patients that have had miscarriages in health care clinics and hospitals do not always seek help from a hospital, it often happens outside the building and they do not seek treatment.
19. As a hospital, you do not want to be known for providing abortions (depending on the country's policy). NGOs are less

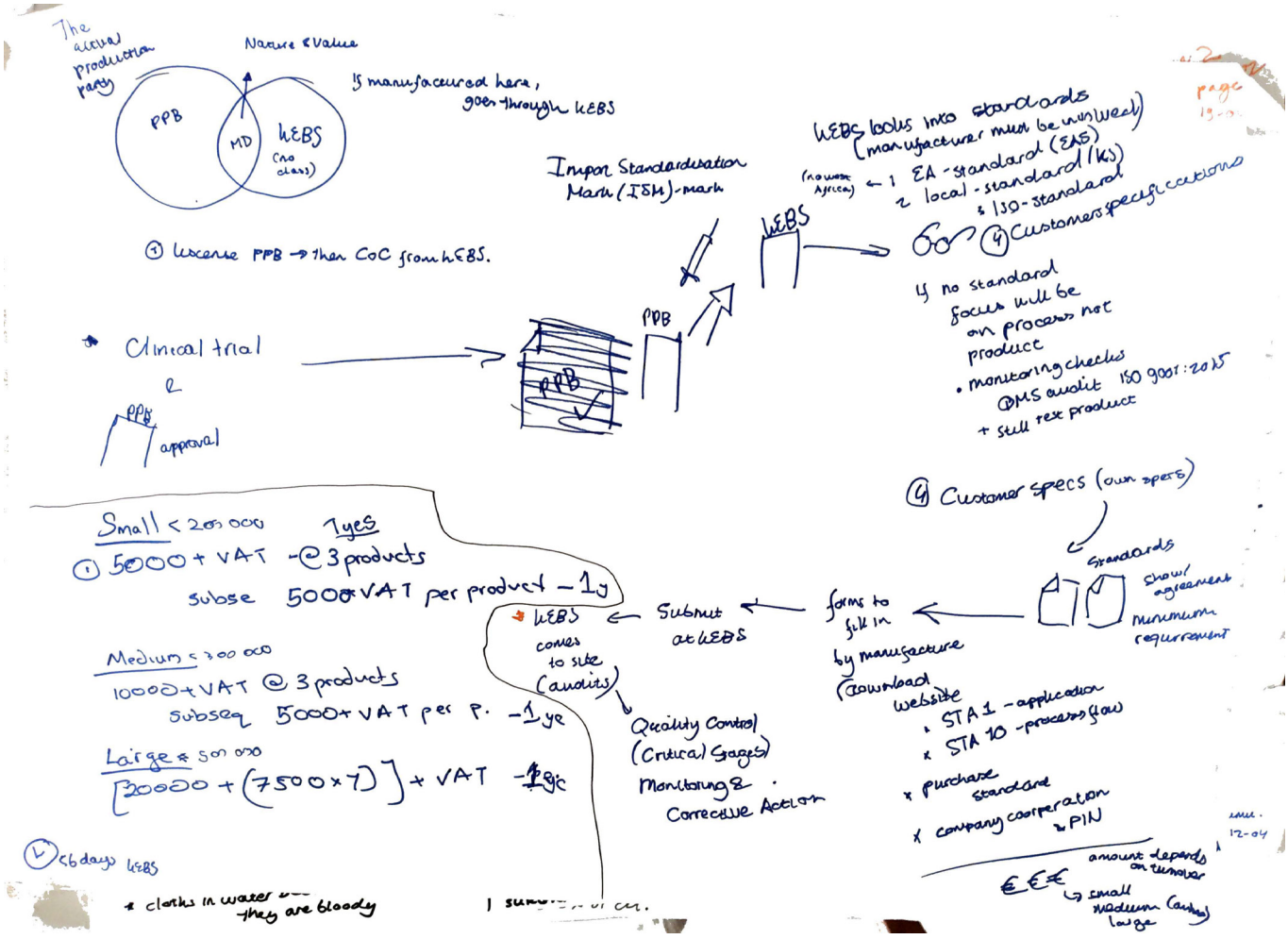
vulnerable because they are not dependent on governmental money. Patients can be for example refugees that have been sent to visit a clinic from their camps. Organisations usually know who provides treatment and Marie Stopes has this as a focus.

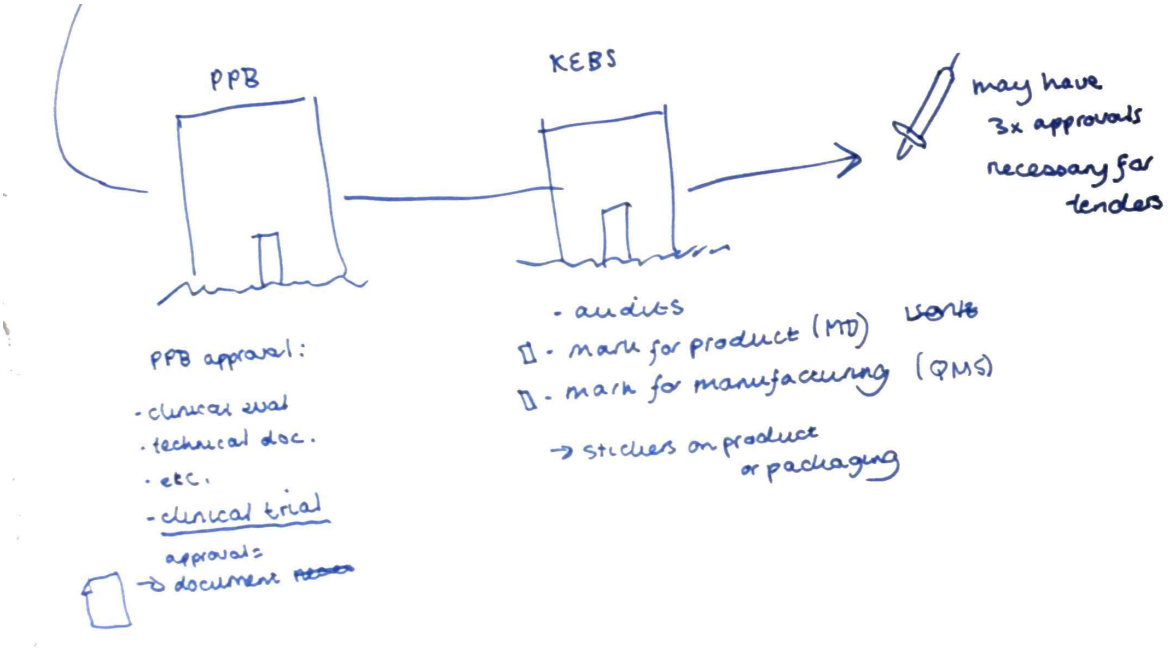
20. Marie Stopes Kenya has given training in MVA.
21. In faith-based clinics, they do procedures for miscarriages but not abortions (not openly at least)
23. The difficulty with abortion is that even though one country may approve, another one might not.
24. Contacts at the PPB are useful to avoid the bureaucratic swamp.
25. MD regulations that are disjoint, and not fully established are difficult because the country does not have to validate why something is not happening/taking place or in progress/ able to complete the process. It is very opaque.
26. These countries often see the CE as a mark of quality but a manufacturer has to show this is also a way for them to earn money

APPENDIX O: SUMMARY INSIGHTS TAKEN FROM INTERVIEWS WITH KENYAN MEDICAL DEVICE MANUFACTURERS

U1: Insights taken from an interview with an employee of KEBS, 19-04-22

1. The PPB handles applications of medical devices and checks the technical documentation and clinical trials. KEBS does checks on the device production and tests the device against the standards.
2. PPB and KEBS are involved with one other when it comes to medical devices.
3. If a device is manufactured in Kenya, it goes through KEBS for the SM (standardisation mark). If it is imported, it requires an ISM (import standardisation mark). DM (diamond mark) is for both local manufacturers and traders/importers.
4. A manufacturer first receives a licence from the PPB and then the CoC (Certificate of Conformity) from KEBS.
5. After a manufacturer approaches PPB for carrying out a clinical trial, the PPB then approaches KEBS
6. KEBS then looks into applicable standards based on the device. The manufacturer is involved in this step of the process. First KEBS will look into EAS (East-African Standards), then into KS (Kenyan standards, local standards) and then into ISO standards.
7. If there are no applicable standards because the device is novel, KEBS will look into customer specifications, where they will devise a set of standards for the devices in agreement/together with the manufacturer. This is a document with minimum requirements. The focus is on the process rather than the product and there will be strict QMS inspections (referred to as ISO 9001:2015). The product will be tested on its function.
8. The manufacturer can purchase these standards from KEBS through the website.
9. The manufacturer fills in forms provided by KEBS such as STA 1 (application form) and STA 10 (for the process flow). The manufacturer needs to sign a company cooperation document and provide a PIN.
10. After payment and submission of documents completed by the manufacturer, KEBS comes to the site of the manufacturer to do audits where they check quality control, inspect critical stages of the process and corrective actions taken.
11. KEBS picks a sample for testing.
12. If passed successfully, KEBS will hand out a permit to the manufacturer in regards to conformity to production standards and device standards. This permit can be recognised in East Africa and can act as a reference in West Africa.
13. Manufacturer receives a number from KEBS to produce the KEBS sticker.
14. The PPB will hand out and check the approval. The PPB approval also needs to be renewed each year.
15. Process at KEBS should not take longer than 56 days.



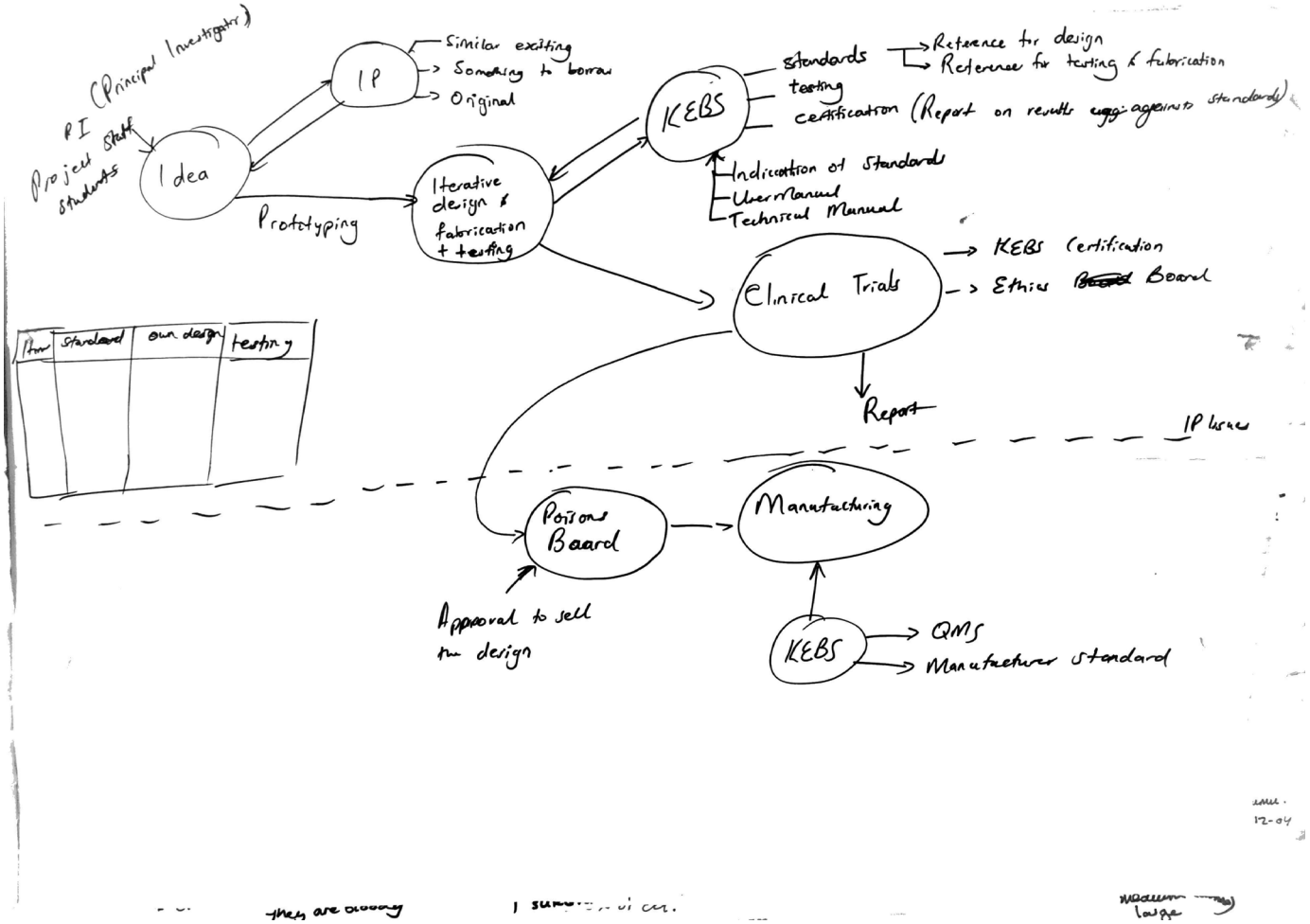


U2: Insights taken from an interview with organisation M, 21-04-22

1. Organisation M has received all necessary approvals up until the clinical trial. The process up to this stage has taken almost 2 years.
2. Their medical device has gone through KEBS for the certification of electrical components and a quality check.
3. Organisation M approached the PPB after KEBS because the PPB needs approval from KEBS.
4. The quality check (QMS) involves inspecting where the device is made: whether the facility is clean, whether all the components are there, whether there is a structure and how the prototype is made.
5. The test that took the longest at KEBS was the verification of the output; testing whether the device is doing what it says it is going to do.
6. Approaching the PPB afterwards takes a long time because the ventilator team had to make the PPB understand the device. The PPB is used to review drugs/pharmaceutical products, not medical devices.
7. While the PPB was reviewing the clinical trial protocol of the organisation and asking them questions, the organisation had to do a lot of iterations and resubmissions, which took a long time.
8. There are 3 stages of clinical trials to which you can apply. The organisation was able to argue with the PPB that the first 2 stages were inapplicable to the device and that the components were already there to act as a simulation and indicate whether it was functioning. It also took a while to make the PPB understand this.
9. A manufacturer does not only need approval from the PPB to carry out a clinical trial, but also approval from any centre that does an ethical review. Organisation M, for instance, has an ethical review committee. To this committee, you have to submit everything you have and they will review the protocol and give you approval.
10. You need to have both approvals before you can apply to the hospital for the clinical trial. This means you can not have a hospital on the side when doing the applications at the PPB or Ethical Review Committee.
11. After being refused by the first hospital, organisation 3 was approved by the second hospital. The hospital that approved, however, insisted that their own ethical review committee checked the clinical trial protocol instead of accepting the approval of the ethical review committee from the organisation itself.
12. Applying for a clinical trial at a hospital, means filling in a template and submitting the protocol.
    The project started in March 2020, and the part with KEBS was completed in August/September 2020. The PPB took long and happened in 2021
13. The OBORA platform helped the organisation document their process in such a way that their portfolio was largely ready when approaching KEBS
14. If a manufacturer wants to develop something new, KEBS will publish their own specifications which are not as long as a standard. It is a list of requirements that you need to submit to KEBS. Some of the required documents however can refer to an ISO standard such as the Risk Management Plan. A manufacturer can use these standards even in the process of developing (something). KEBS set these requirements but they do this with the help of stakeholders.
15. KEBS also provides the ISO standards.
16. The planning is to get the data from the clinical trial and submit this to the PPB for the other certifications needed.
17. From here the process is unsure.
18. The organisation's team consisted of pharmacy people, engineers (electrical, medical and computer), nurses, business entrepreneurs and doctors. The engineers are involved with KEBS, the doctor is necessary for writing protocols and submitting this, and the pharmacy people are good at assisting in the protocols and helping push at the PPB.
19. If an organisation will find a contract manufacturer for producing the medical device, this contract manufacturer will have to apply to KEBS to conform to the production quality. It would help if the manufacturer already is certified to do so.
20. Organisation M is thinking about developing its own manufacturing/production plant.

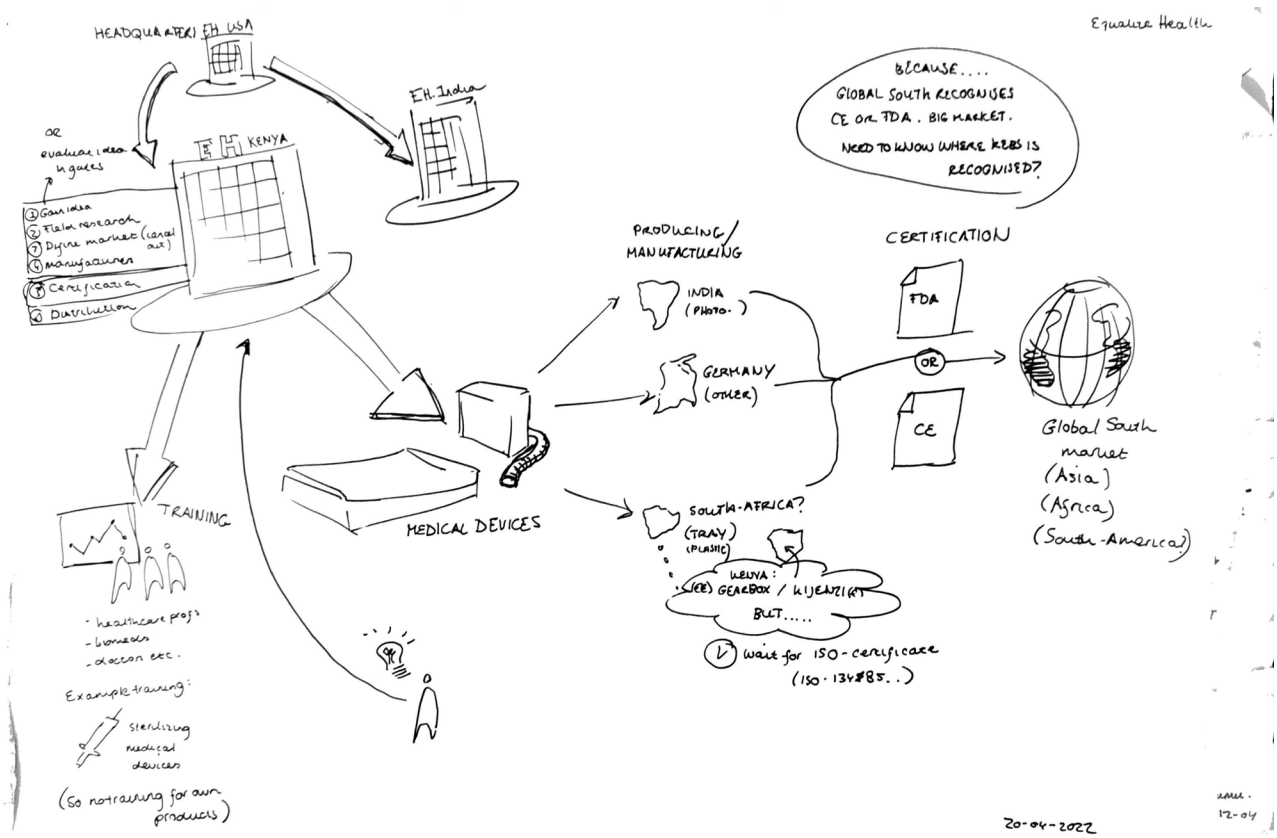
U3: Insights taken from the interview with organisation N, 27-04-22

1. Organisation N became stuck when the project team had disagreements about Intellectual Property rights. They found out about the rights just before approaching the PPB, where you show who is intending to sell and who is the manufacturer.
2. Even though the discussions took place beforehand, the team neglected this because it was new territory for everyone.
3. The disagreements were set aside and they went ahead.
4. The project was NGO funded and funds had been transferred between various organisations. More stakeholders became involved with partnerships throughout the certification process and eventually, no one agreed on to whom the design/device belonged and what should be done with it.
5. The project started out as research to see if it was possible to get a device from the design phase to the selling/manufacturing phase done locally. Since the research succeeded, the project now focussed on whether the team could truly bring something beneficial? The project was never thought out to the point after the success of the research and there was no system in place to jump from the research phase to the implementation phase.
6. MakerSpace had completed the clinical trials
7. Advice now is to check IP from the very beginning. IP also includes checking the originality of the idea and whether you can borrow something.
8. KEBS will give out a report of the check against standards, which is required when applying for the clinical trial.
9. Eventually, the QMS would have come later, but the team did not come to this point. In the future, they would have approached the PPB first and then gone back to KEBS for the QMS certificate.
10. The CE-mark from KEBS would be the report from KEBS and the corresponding sticker1]1]
    You need approval from the PPB before manufacturing. This approval you can get after completing the clinical trial.



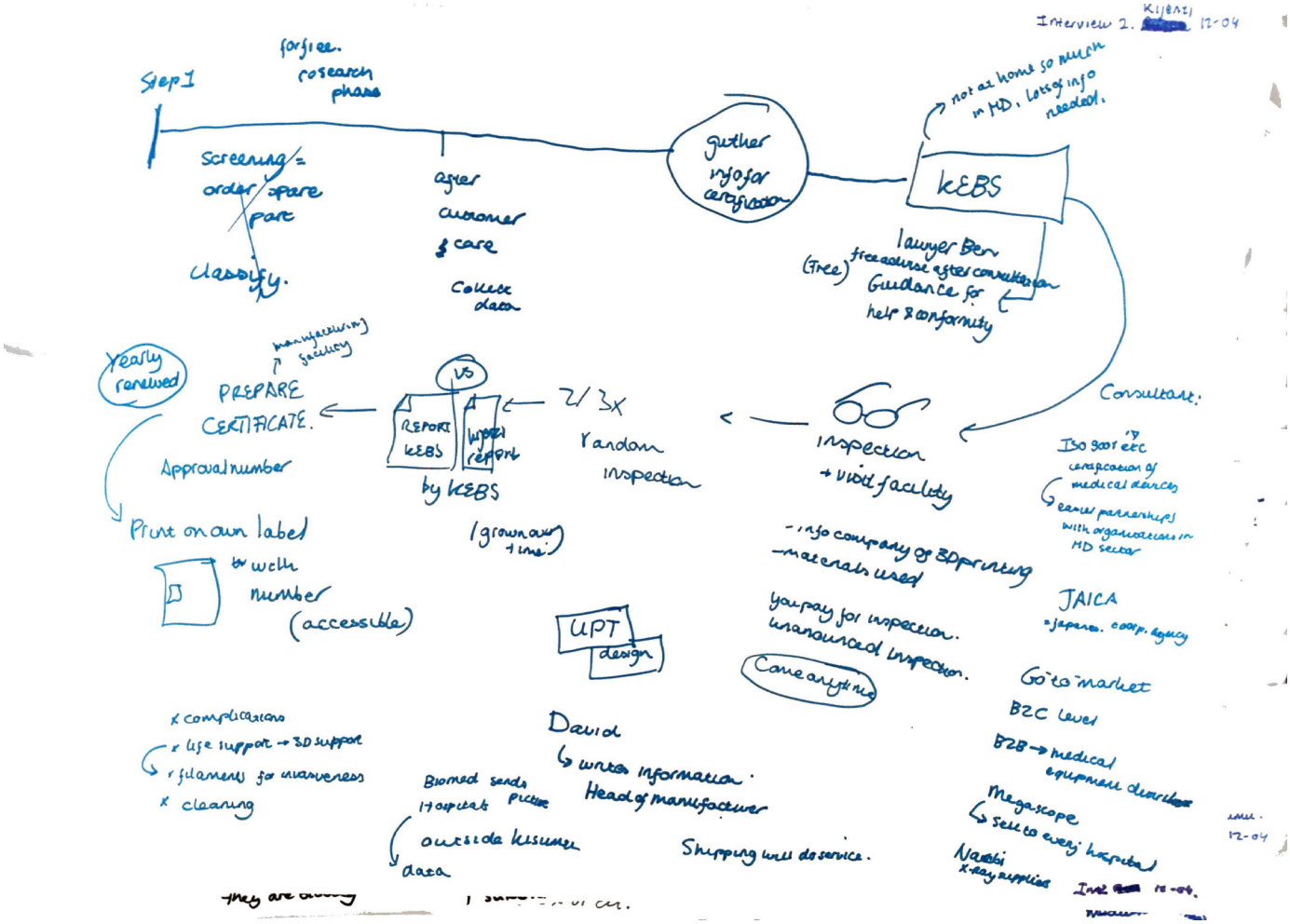
U4: Insights taken from the interview with organisation O, 20-04-22

1. Organisation O manufactures class B medical devices and also class C medical devices because it is invasive. If a device becomes invasive it goes to class C. (13 mins)
2. For one of the devices, organisation O is looking for a contract manufacturing in Africa. In South Africa, organisation O is considering one but it is more expensive than in India due to shipping costs. This is because the shipping route is cheaper as India has become a hub of medical devices (intentionally done so by the government).
3. The problem with finding a contract manufacturer in Africa, is that current manufacturers are not ISO-certified, whereas South-African manufacturers do have this certification. How this is possible is unclear, but organisation O suspects it has something to do with regulations and better financial resources.
4. All the devices are CE or FDA marked. The reason for this is that the main engineering office is in the US.
5. Before approaching a contract manufacturer, organisation O ensures they have an IP and the approval(s).
6. Manufacturing in Kenya would make the process a lot cheaper because there will be no shipping costs, no import costs and fewer government levies. The latter two can end up being 20% of the device costs.
7. The clinical trials take place in Kenya or India (not the US) even though the approvals are obtained abroad.
8. Quote: Our target market is South Asia and Sub-Saharan Africa. The first requirement will be 'Is your device FDA or CE-marked? Even in the US, the question is: Is it FDA approved? If not, does it have a CE mark? Period. It is just those two. So, you need one of those. Once you have one, you do not actually need the other one. They are both recognised.
9. It is not like KEBS because I can not take a device to Ethiopia and say it is KEBS approved. They will ask who is KEBS?' (23 mins)
10. Quote: The PPB has their own rules and that is the problem, you know, there are so many processes which is maybe not bad if it is protecting the people. (31 mins)
11. Headquarter of this organisation is in the US and two satelite offices of which one in Nairobi and one in India. The biggest in India with 11-12 employees.
12. Many distributors do not care and do not do monitoring. If a hospital does ntot pay them to do monitoring they will not come and if they come during end of warranty period for preventive maintenance, hospitals do not see the need in paying them if the devices are working. The manufacturer keeps communication line between distributor and hospitals where the device are sold but it is important to discuss why sharing information is important (8 mins).
13. The certification also protects the manufacturer. Quote: 'If the baby dies you will be sued' (17-21 mins).
14. Quote: 'If it is KEBS approved, I cannot take it to Uganda'
15. Shipment costs are usually very high because of all the taxes and you may also be exempt of value added tax. Usually levies you have to pay are 2-3% but if you add them up, you end up payinh 20% of what the device cost is. 20% is the transport and it is the only thing you can best bring down. (28 mins)
16. The cost of certification is not the biggest but not the most straightforward. You can have an estimation of the costs but it will always be higher in practice.
17. Some distributors concentrate on specific medical devices, some are doing everything because they just started, some do medical devices and even pharmaceuticals. Most big players have departments (example maternal health departments) and see which devices they sell in this (example new born devices. (41 mins)
18. Crown is an organisation (distributor) who will have many medical devices and departments for types of devices.



U5: Insights taken from interview with organisation S, 12-04-22

1. Manufacturing company whose facility is approved by KEBS to manufacture class I Medical Devices.
2. KEBS came to inspect the production processes and all the information and complications surrounding the device (production).
3. For class I medical devices, there is no board involved (such as the PPB). For organisation 1 this is because it is either about spare parts or the device is not invasive as it does not really come into contact with the patient.
4. For every order, the company screens to make sure they are dealing with class I medical devices. They sometimes consult a board for this.
5. The organisation used a lawyer to approach KEBS
6. KEBS offers guidance that manufacturers can use to make their processes conform. The guidance is free and an organisation can receive this when approaching KEBS for consultation. KEBS will advise them accordingly on what steps they need to take which you need to prepare before the inspections are done by KEBS.
7. After inspections by KEBS, KEBS will write a report on what they have observed and compare this to the documents the organisation has submitted. KEBS makes the decision to approve and hand out the certification. This certificate comes in the form of an approval number which you can put on the stickers and labels.
8. The manufacturing organisation is currently sticking to class I medical devices because of the complications that arise when expanding to other class medical devices (e.g. inappropriate material)
9. The manufacturing company is unaware of other organisations that are (certified for) manufacturing class II or class III medical devices in Kenya.
10. KEBS certification needs to be renewed yearly but there are certificates with different durations. There is one for 3 months, 6 months, 1 year, 2 years or 5 years, each with a different cost. The organisation chooses 1 year so there is enough time to improve and enough space to keep improving.
11. Quotes: They (PPB and KEBS) are just like one item. The PPB and KEBS are working closely and are now approving higher class devices.
12. Quotes: If dealing with class II devices, you communicate to KEBS and they direct you to the right board.



U5: Insights taken from interview with organisation P, 25-02-22

1. The way medical device certification is set up in Kenya, it is really set up for companies coming from outside of Kenya who are bringing in devices into Kenya and getting certified.
2. The whole cost structure is quite prohibited. Everything was geared towards multinationals.
3. The certification is quite a lengthy process; you have to go to the PPB who will let you go through the clinical trials and then you have to go through the KEBS boards as well so there is a defined process for that (1 mins)
5. What happened with COVID, when Kenya was in need of ventilators and there was little local ventilator capacity, people turned towards innovating ability within the country but the question was raised about what the path towards certification would look like. The government would create a task force where every stakeholder in that certification process will be in one room. And that was the first time it has happened for medical devices, in late 2020. (2 mins)
6. Up until mid-2021, this task force would meet once a month but with COVID going down, the need for this has gone away but hopefully, according to the interviewee, the working group will remain active. (3 mins).
7. The process in terms of building a medical process and gaining certification in Kenya is still being clarified. There is a document with a road map. (3.50 mins)
8. This task force was driven by KEBS, the initiator.
9 For software products there are multiple venues to go to, but this ecosystem did not exist for hardware and this is the foundation for organisation P: allowing innovators to go through the product development process and create a working prototype which can be leveraged for funding purposes down the road. The organisation has mechanical and electrical engineering capability for creating prototypes. (4.50 mins)
10. When it comes to medical devices, the organisation knows of a ventilator team who is preparing for submitting KEBS, who will then approach PPB for clinical trials. There were 6 teams trying to do this.
11. When it comes to certification, for organisation P it is about what is the certification in manufacturing space. For medical products that means if there is a pcb that needs to be manufactured to be put into a medical device, that needs to fall under ISO 13485. This is something that the organisation is working towards having at the end of this year or beginning next year. So anyone who is manufacturing a medical device and using this facility will automatically receive the certification as far as manufacturing is concerned. (6-7 mins)
12. When it comes to the other relevant certification, that is for the development body and they will have to do that with KEBS and the PPB.
13. ISO 13485 (Medical devices) sits under ISO 9001 which is the QMS for any organisation. So, for the organisation to manufacture products, they need to have ISO 9001 and if it is to manufacture medical devices, they also need to have
14. ISO 13485. (7.45 mins)
15. Then, is you are doing electrical products, there are other certifications that fall under that so depending on the type of product that you are making, they can fall under different classes of IPC. IPC is a body that standardises electronics manufacturing across the globe: class I, II and III (III for mission critical devices: it cannot fail under any circumstances). For manufacturing only. (8 mins)
16. Organisation P is involved in the prototyping phase and the mass manufacturing phase. For mass manufacturing phase (e.g.) injection moulding, the organisation connects designers to existing manufacturers in the existing ecosystem who can provide this. (10.50 mins)
17. If organisation P is manufacturing something, and the device is failing, they will use the data back to the manufacturing process. That is the support the organisation provides in the QMS. As the organisation is not into the distribution of the medical device, they do not provide more than that (stepping out of core business). (16 mins).

U6: Insights taken from interview with Revital Health care, 25-02-22

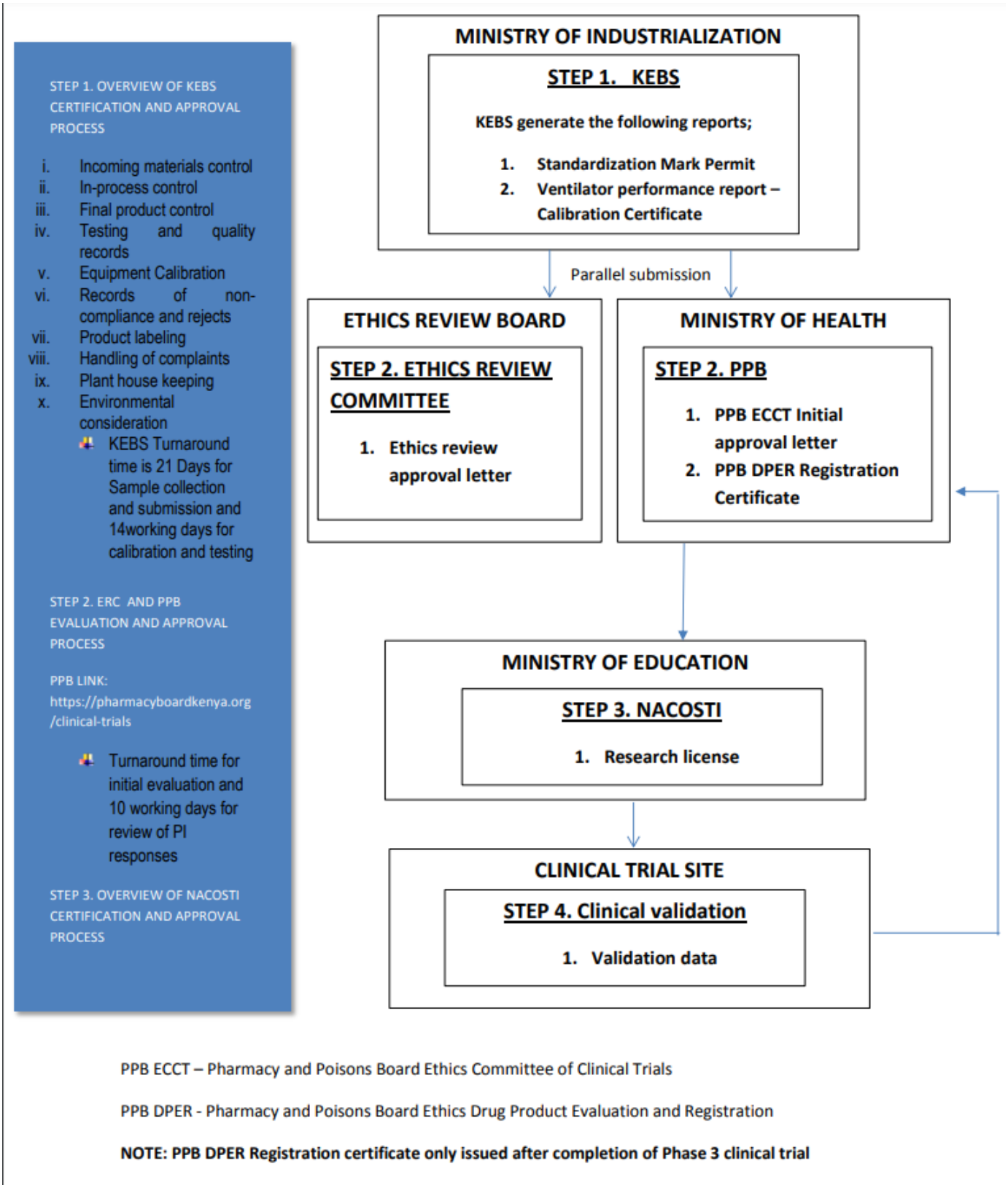
Cite: To give you a brief overview, Revital Healthcare (EPZ) Ltd (Revital) is the largest medical disposable manufacture in Africa (situated in Mombasa, Kenya). Revital has been leading the localization and manufacturing of essential Medical Disposables in Africa and has been contributing to continuously improve Africa's public health for over 15 years with the manufacture and supply of over 45 Medical Devices to over 27 countries around the world, including supply to WHO and UNICEF.

Our vision to become a global manufacturer and supplier of Medical Disposables has continued to progress exponentially. Revital Healthcare currently manufactures over 1 billion Medical Devices annually while constantly developing innovative products.

Our products all undergo stringent safety and quality management standards which has ensured our facility is internationally accredited by various certification and regulatory bodies such as CE, ISO 13485:2016, ISO 9001:2015, ISO 14001:2016, WHO-GMP and WHO-PQS, Geneva (Only manufacturer in Africa.).

APPENDIX P: ROADMAP FOR CERTIFICATES

This is a document was provided by organisation P [U5, 7]



PPB ECCT – Pharmacy and Poisons Board Ethics Committee of Clinical Trials

PPB DPER - Pharmacy and Poisons Board Ethics Drug Product Evaluation and Registration

NOTE: PPB DPER Registration certificate only issued after completion of Phase 3 clinical trial

APPENDIX Q: INTERVIEW WITH A NURSE FROM AMREF

Insights taken from an interview with an NGO employee named AMREF Flying doctors

1. The interviewee is a nurse by training, specialised in public health. She worked at AMREF for 10 years. She trains nurses and midwives and is a project manager in maternal and newborn child health within the AMREF International University setting. [1.30-3 mins].
2. How does Chloe SED fit in Kenyan gynaecology? (First, clarify the confusion about the procedure before labour because these are spinal needles). [10 mins].
3. In terms of procurement, there is a huge difference for the Chloe SED if it is meant for public healthcare facilities or private facilities. [10 mins]
4. In public facilities: their own commodities are brought in by the government to one central distributor called KEMSA. From then, each individual public hospital requests equipment and drugs from KEMSA. Then it runs from KEMSA to the facility at a very subsidised rate because it is paid for by the government. The money is actually from the central government that goes to the county government. The county government pays KEMSA but it is really subsidised [10 mins 40 - 11 mins 40].
5. In private hospitals it is different: because you find they look for drugs and equipment they will not buy anything that is really generic. They look for really good equipment. Some of the equipment comes from distributors who deal with those companies. Private companies will buy from these distributors (11 mins 40 - 12 mins 22). Each pharmaceutical or device company will work with this distributor to sell. You will also find that different companies will do their own marketing directly to doctors and hospitals through seminars and give them samples etc. If a hospital finds the device useful it will order from this company through the distributor. [12 mins 22- 13 mins 45].
6. MVA kit distributors and medical device companies? The interviewee is not aware of the private and public sectors, she will check [15 mins 37].
7. It depends on the demand if KEMSA does MVA kits but KEMSA specifically does public hospitals and can offer 2-3 brands [16 mins 30].
8. Is AMREF involved in MVA procedures? Not that she is aware of any project that is being done. She highly doubts that it is the case [17 mins].
9. Another thing that is silent (about AMREF): MVA can be used for miscarriages but also intended abortions. We have not openly engaged in projects that are dealing with abortions. She will look for contact with organisations that do so.
10. Asking for contact Marie Stopes [19 mins]
11. Marie Stopes does training and they market with safety. It is also silent but it is there. Family health options is also involved in MVA procedures and abortions. May also has a contact there. [20 mins]
    AMREF does not have any projects that utilise MVA kits. She states 'I understand that we cannot as an organisation implement projects in this area.'
12. For medical devices that are new, it has to go through an organisation, a regulatory body, KEBS (Kenya Bureau of Standards), they have to ensure anything that comes to the Kenyan market and to the Kenyan people is good for use.
13. You also have to go through the Kenya PPB for approval. [23 mins]
14. Sometimes, it also depends on what you want to do; if it is a pilot project, you still need to go through the organisations.
15. The question is, are you going into the market to start selling or are you going into the market to test its viability and use before you can produce results to say it helps people or that hospitals can use it. From your results and publications, you have evidence, now you go to hospitals to pitch for them to buy, and you have evidence. AMREF does a lot of pilots for donors about what the device is and is the go-in-between to help prove something is working for the good of the people. That is a long route and what AMREF does [24 mins]
16. If you want to bring a device to the market for a business purpose, you go through the regulatory bodies. You do a lot of hard work, training people, bringing on board different hospitals so they can buy the gadgets. [25 mins]
    You can choose both routes. AMREF works with people to work towards something that is socially good but at the end of it, all the goal is the donor/company wants to sell and now they work with those results to push for sales [26 mins 20]
17. AMREF policy: does not advertise brands, they say them with who they worked with and that this is the device. But you can use the results (proven to be useful) and start its distribution in the Kenyan market but that comes from the manufacturer as the marketer (as AMREF does not advertise) [27 mins].
18. Authentic, good for human use? AMREF decides on the benefit of the mother.. [28 mins 30]
19. [Talking about examples of obstetric ultrasound, where Ilara Health and Delft have approached them]. They collect data on its use and the results can be compared. Talk about the results and how it has benefited the people (no discrimination if two manufacturers approach them for the same device). [29 mins]
20. They even work together to develop concepts that can be used for donor funding. Funding will be done between Ilara (and AMREF), AMREF and Delft. Pilots can be 6 months, also 1 year [30 mins]
21. The device has already been approved by the country of origin and then come approved by the Kenyan way [31 mins 30].
22. AMREF works on projects. It can be a project on TB or HIV. At the project level, the project manager and staff will put up a requisition (request) through the procurement office and will put out a tender notice to the public 'if you have this equipment and these are the requirements, please provide us with it'. The project will make a budget available for the devices and will communicate what they can afford (e.g. 1 dollar per syringe). Procurement is careful and makes a selection of suppliers who meet the requirements (anything above a dollar will be put aside). They will ask the experts in the project who are keen on this gadget, they will go and check the equipment in the lab (with a laboratory expert person)

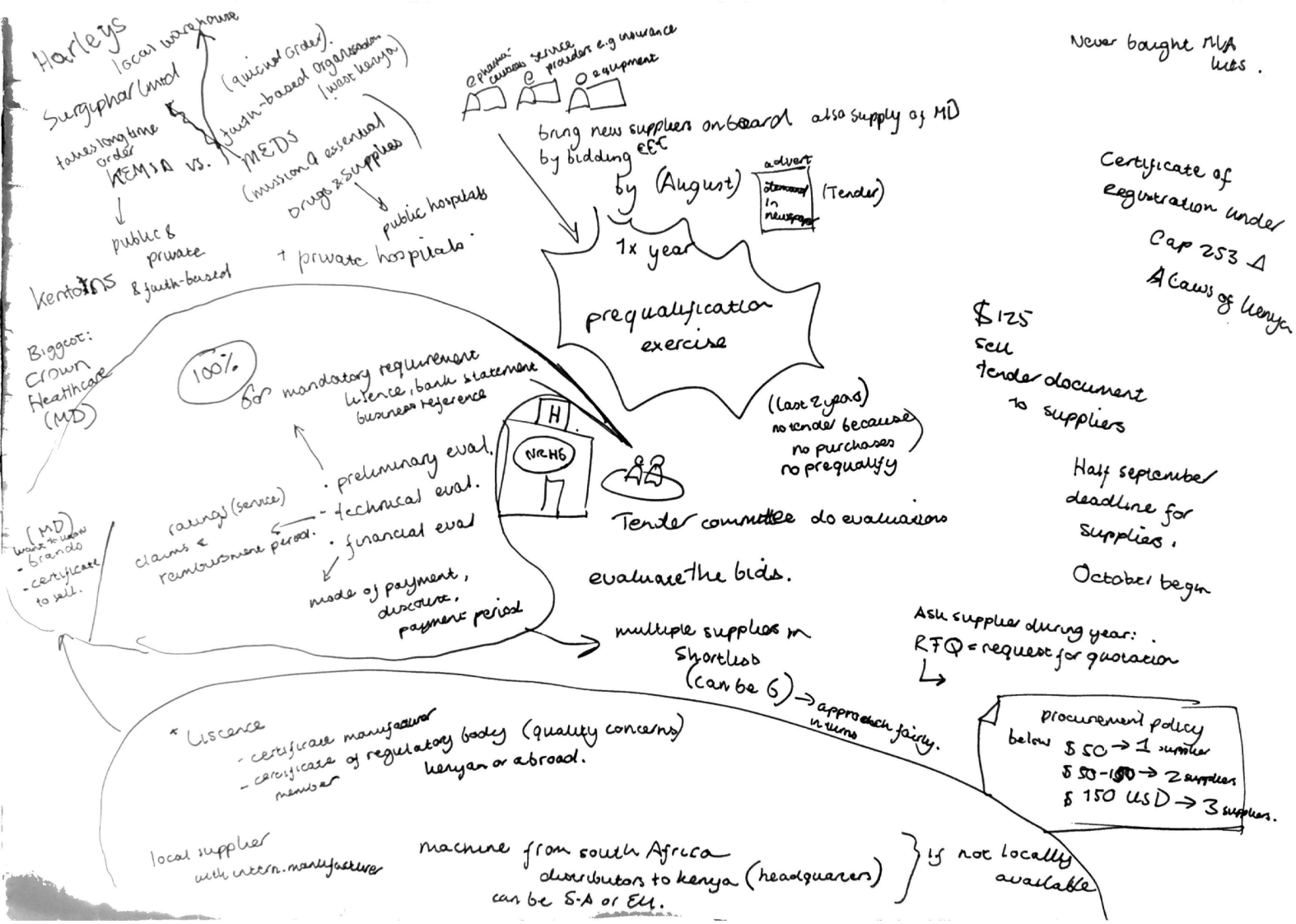
to confirm if it is useful and of good quality (drugs will go through pharmacological technologist (pharmacist). AMREF will choose the supplier and then the procurement process will begin. That is competitive sourcing. [32 mins 20 - 35]

21. They can also agree with suppliers to work with because of a very specific project. The project can source from this company and approach the procurement department showing agreement and stating this. Especially if AMREF is putting them out for testing. It can also happen if they are working for a longer time with someone. [35 mins 25]
22. AMREF is an NGO that works with a number of donors for projects. The main organisation is the NGO. There are different country offices in the North doing fundraising for the African continent. Every year, AMREF is looking for money to implement projects for different facets in health. Projects can have a lifetime of 3 months to 10 years and can be funded by big funders such as USAID. They do not have our own hospitals yet. AMREF has a small space, a clinic (not a hospital) in Nairobi. AMREF works with public hospitals mostly because they work closely with the ministry of health. [37 mins 20 - 39 mins 50]
23. AMREF is buying gadgets from a company with donor money and then we give them to this public person to approve?
24. For the county or government hospital, they are not procuring directly from the company, they mostly get the gadgets as donations from the NGO. But when someone is looking at how this county can continue purchasing gadgets from a particular company after a project for a long time of engagement. [40 mins]
25. The interviewee is unsure whether AMREF procures any kits (Malaria and TB) [42 mins 30]
26. From email contact: KEMSA tendering process
27. From email contact: Centre for reproductive Health rights is also an organisation involved in MVA procedures (including intended abortions).

APPENDIX R: INTERVIEW WITH STAFF MEMBER OF NRHS

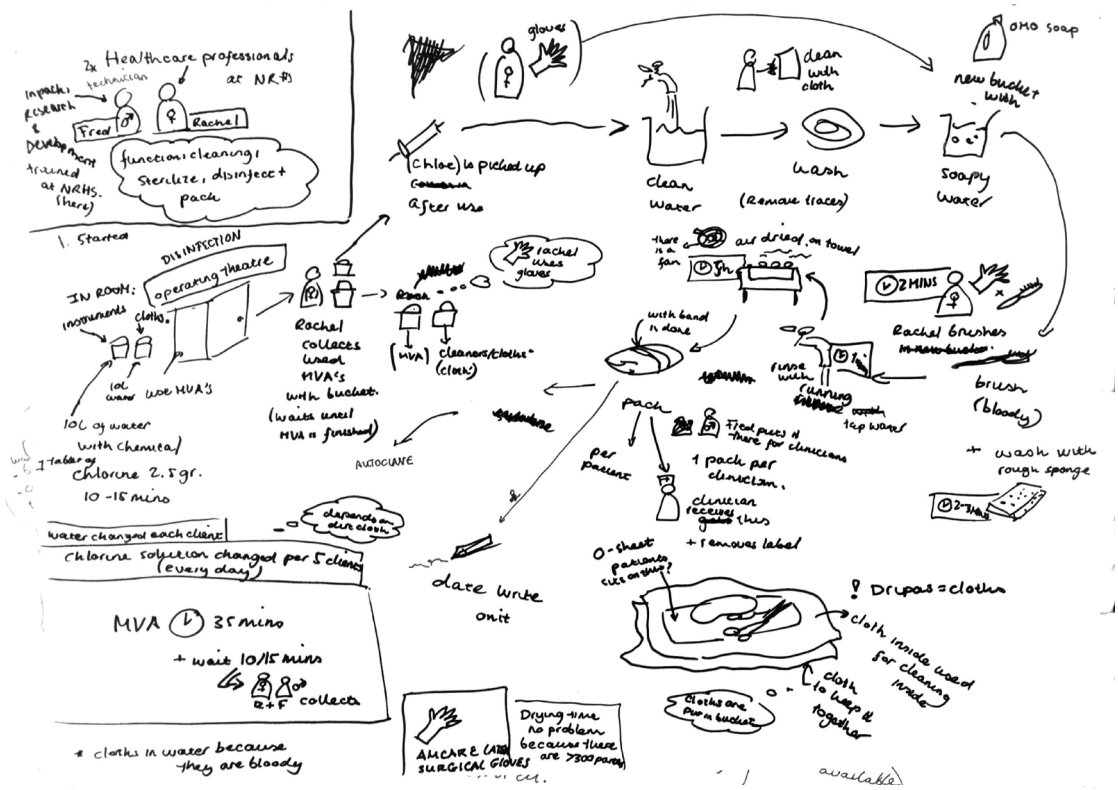
Insights from an interview from an NGO that is tied to a public hospital 14-04-22

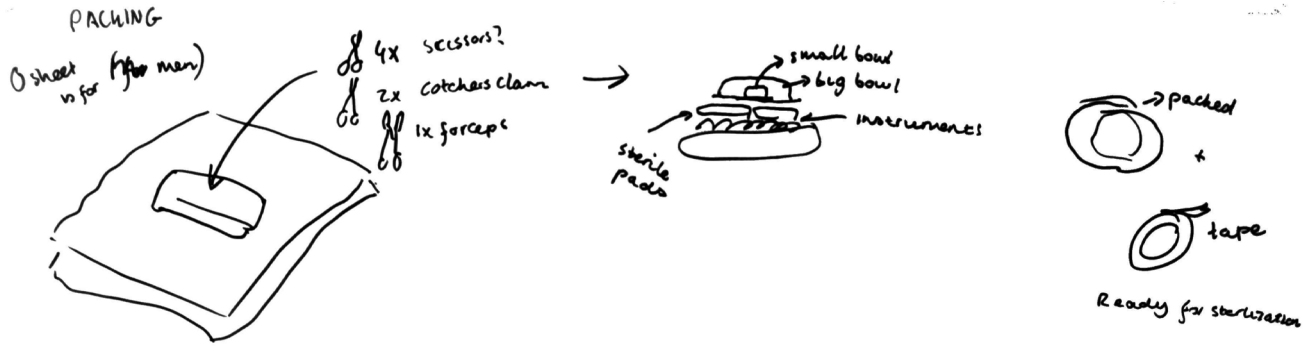
1. NRHS says that they do not procure MVA kits (as they do not carry out MVA kits)
2. The procurement process for consumables is the same as for medical equipment
3. NRHS does a prequalification exercise to bring new suppliers on board each year. For different categories for supplies and services NRHS needs, they place an advert in the newspaper which normally appears around August. Supplies examples are: pharmaceuticals, stationaries, provision of security services, supplies of drugs and medical staff
4. After the advert, NRHS receives bids that the Tender Committee of NRHS will evaluate the bids for the different categories of suppliers that have shown interest to work with NRHS (2-3 mins).
5. The bidding is evaluated on: preliminary evaluation, technical evaluation, financial evaluation. For preliminary is looking for the mandatory requirements (valid licence attached, booking accounts that have been signed, attach references from partners etc), where you have to score 100%. The technical evaluation: the committee will look at e.g. the brands of equipment that are offered for sale, licence from manufacturer for sales authorisation distributor, check if manufacturer is member of regulated body (important for quality concerns). If medical equipment is not locally available, then a letter of proof from the headquarters of the manufacturer is sufficient (e.g. Europe CE or South Africa). In financial evaluation, the committee looks at the pricing, terms of payment, discount, mode of payment. Tender committee makes a selection. (3-14 mins).
6. So long the supplier is local and is also dealing with an international supplier, there is no problem.
7. NRHS has a guide that they sell to suppliers for 25 USD which shows which info/docs they have to submit for evaluation. Suppliers collect these and pay NRHS the receipt
8. Suppliers fill in the guide and submit before the deadline. They have around a month.
9. NRHS sets up contracts with new suppliers from October 1.
10. NRHS has been working with similar suppliers over time. In any time, NRHS is in need of something they will send the suppliers a request for quotation (RFQ). A quotation is an offer for a specific order. (18 mins)
11. If NRHS in need of something, the procurement office approaches suppliers from the list and waits for their offer (Supply & Price). NRHS has a procurement policy where if order is 50 USD or bellow. If order is more than 50-150 USD, NRHS has to approach/ask 2 suppliers, if it is more than 150 USD, NRHS needs to approach 3. These suppliers are selected from their shortlist of e.g. 6 suppliers. 20 mins.
12. NRHS has to be fair to all suppliers, they will request quotation from a first set of suppliers and the next time approach a second set of suppliers.
13. Suppliers work with various distributors
14. If there is one supplier (MEDS, Mission for Essential Drugs and Supplies) who is cheapest: MEDS is a faith-based body that is dealing with supply chains solutions for public hospitals and faith-based and has a vast network. Composed of catholic and protestant churches. They are second biggest to KEMSA (27 mins). Their prices are so low.
15. NRHS informally communicates why supplier was not selected for RFQ.
16. There was a law in this country that was always limiting county governments and any governmental institution from buying medical supplies outside of KEMSA. But since KEMSA has its own issues, public hospitals are purchasing from MEDS. (30 mins)
17. MEDS also supplies to private hospitals as they have a local warehouse in Kisumu, the Interviewee went to pick items and he recognised people from private hospitals picking up equipment here.
18. KEMSA also supplies to private hospitals and faith-based hospitals. MEDS prices are much lower than KEMSA but the turn around time is longer: it takes a month to gain the equipment after placing the order. For KEMSA the turnaround time is less, around a week to fulfil an order.
19. Cidifarm, Harleys, Kentons (Kisumu), Crown Healthcare (biggest distributor for medical equipment) (34 mins).
20. The last 2 financial years, NRHS was not prequalifying for medical equipment and supplies because they did not see the need as they were not buying a lot of medical equipment. If a need arises
21. It is not allowed to go outside the list of qualified suppliers (shortlist). It is only allowed under special circumstances such as that they do not supply certain equipment.

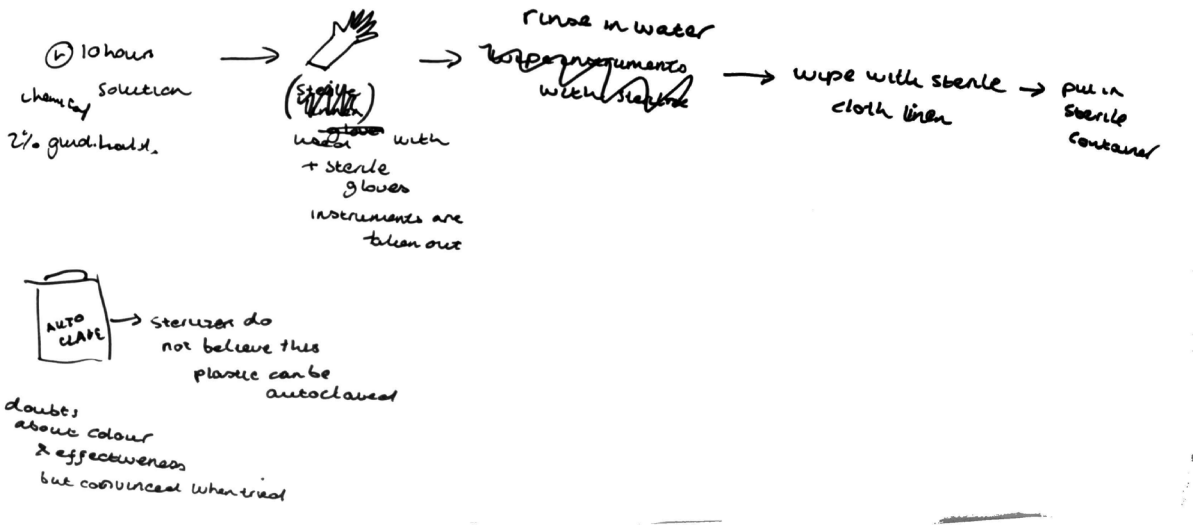

Harleys
local warehouse
Surgipharm Ltd
takes long time
order
KEMSA vs.
(quicker order)
faith-based organisation
(most kenya)
MEDS
(mission d essential
drugs & supplies
public hospitals
+ private hospitals.
Kenyatta
public &
private
& faith-based
Biggest:
Crown
Healthcare
(MD)
100%
for mandatory requirement
licence, bank statement
business reference
· preliminary eval.
- technical eval.
· financial eval
rating (service)
claims &
reimbursement period.
mode of payment,
discount,
payment period
(MD)
- brands
- certificate
to sell.
NCHB
Tender committee do evaluation
evaluate the bids.
multiple suppliers in
shortlist
(can be 6) → approach fairly.
bring new suppliers on board
by bidding
by (August)
advert
(Tender)
1x year
prequalification
exercise
(last 2 years)
no tender because
no purchases
no prequalify
Never bought MHS
kits.
Certificate of
registration under
Cap 253 A
A Laws of Kenya
$125
sell
tender document
to suppliers
Half september
deadline for
suppliers.
October begin
Ask supplier during year:
RFQ = request for quotation
procurement policy
below $ 50 → 1 supplier
$ 50-150 → 2 suppliers
$ 150 USD → 3 suppliers.
* Liscence
- certificate manufacturer
- certificate of regulatory body (quality concerns)
member
kenyan or abroad.
local supplier
with intern. manufacturer
machine from south Africa
distributors to kenya (headquarters)
can be S.A or EU.
is not locally
available

APPENDIX S: INTERVIEW WITH STERILISATION DEPARTMENT OF 5 HEALTHCARE FACILITIES IN KENYA

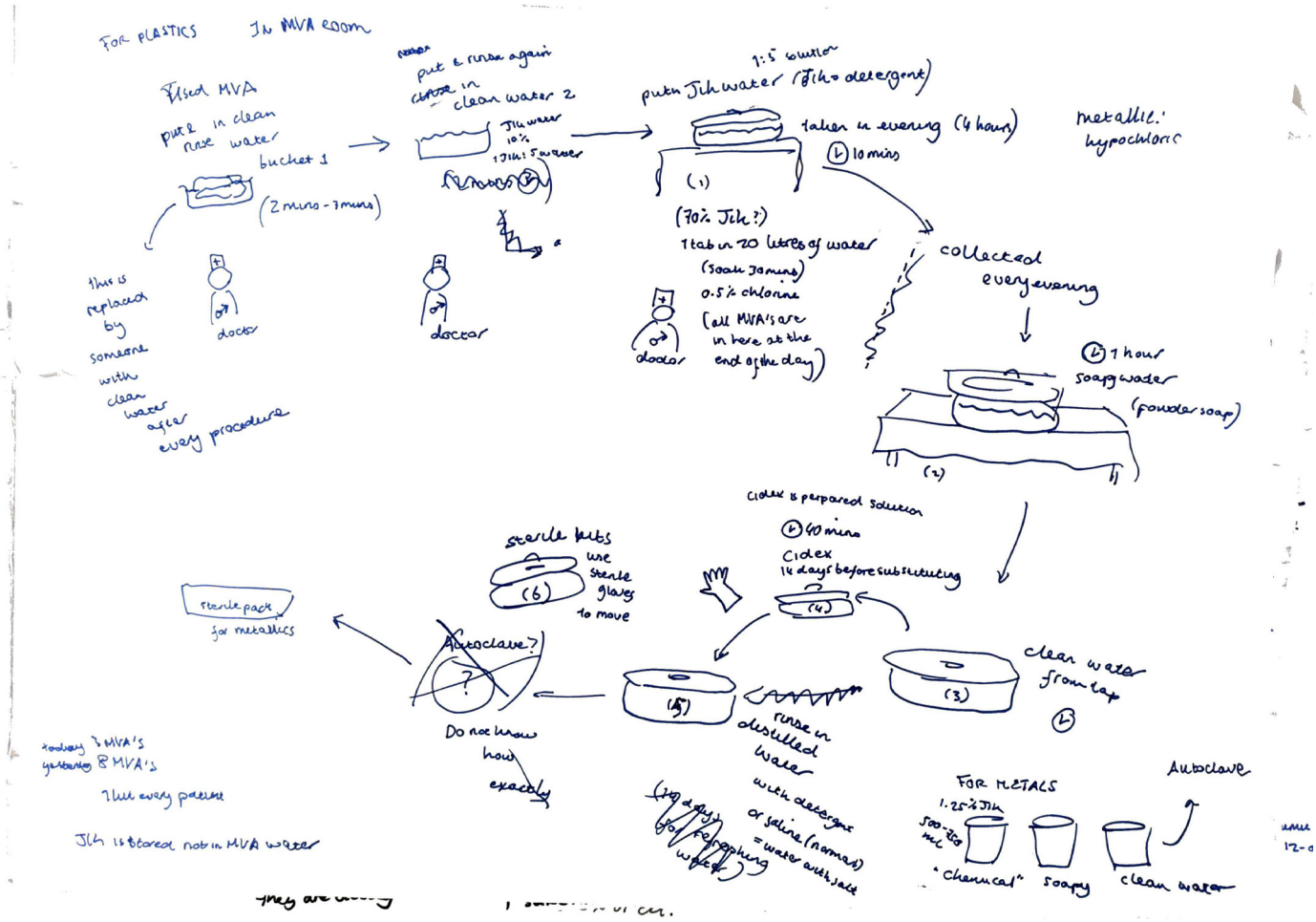
Health care facility 1



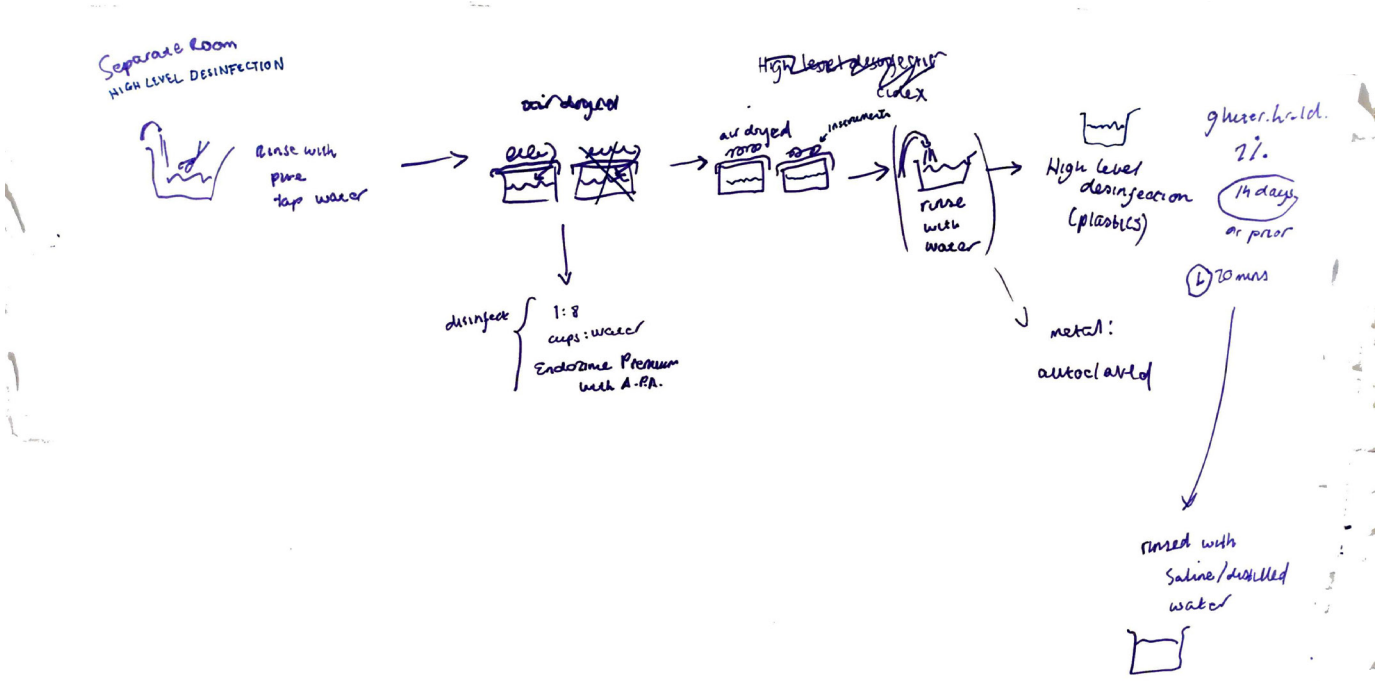




Health care facility 2



Health care facility 3

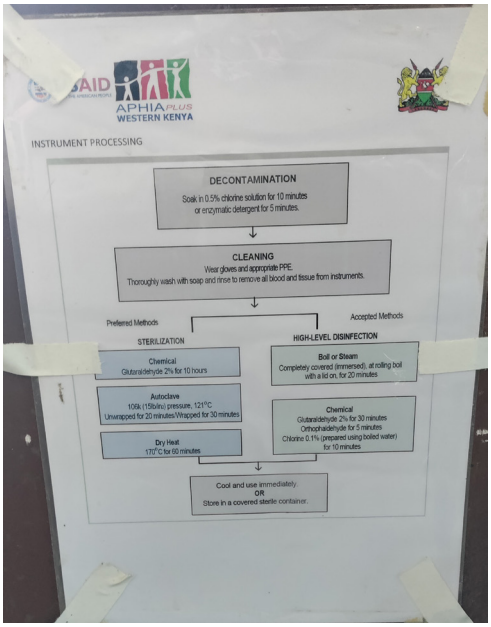


Health care Facility 4 Notes:

As observed before, this healthcare facility takes care of Decontamination, Cleaning, Chemical high-level disinfection and no Sterilisation. Similar to other health care facilities, reprocessing takes place for a large part within the theatre room and buckets with the solutions that correspond to their reprocessing steps are used.

Health care Facility 5 Notes:

This healthcare facility follows the procedures on the right (rights side of the flow chart without boil/steam). This pciture is taken from the instructions that were displayed on the wall in the theatre where MVA is performed. Their procedure is similar to the other health care facilites. The steps are: Decontamination, Cleaning, Chemical high-level disinfection and no Sterilisation.
Similar to Health care facility 4, this facility also had 3 buckets: one with chlorine for disinfection, one with soapy water and one for high-level disinfection.



Interesting Observations

1. When asked about their opinion of Chloe SED, the staff was reluctant to believe Chloe SED of a type of plastic that is autoclavable. They mentioned that they first need to see this before believing it. There is a chance that they might fall back to the high-level disinfection method they are used to for reprocessing plastics. (Healthcare facility 1)
2. The reprocessing staff of one of the healthcare facilities mentioned that there were 5 medical device kits available per nurse. The reason for this is to avoid a shortage of equipment and maintain a steady supply of kits that are ready for use. The number of MVA procedures that took place in healthcare facilities I visited differed between 3 and 10 procedures daily. Their estimation came down to 5 MVA procedures per day. (Healthcare facility 1)
3. Health care facilities can store their MVA equipment differently. An MVA kit is not necessarily stored as a kit. In a level 3 health care facility, the MVA equipment was stored together and some spare, broken parts were also stored together. (Healthcare facility 5)

Overview Deviations

Health care Facility	Level of Health care	Reprocessing Step	Notes
1	3	Decontamination, Cleaning	The (chlorine) solution for decontamination is in the theatre room. After the procedure has taken place, the equipment enter the theatre room is collect the equipment. This mmeans the equipment can soak for longer than 10 minutes. It is mentioned that the procedure takes 35 minutes so they are not soaking longaer than 30 minutes. OMO soap is used for cleaning.
2	5	Decontaminsation	In this step a detergent named JIK is used. In stead of soaking for 10 minutes MVA equipment can soak in this for a whole day (average would be 4 hours). At the end of the day all MVA kits are put in the same decontamination solution and are collected by the reprocessing staff.
3	4	Decontaminsation	They use different detergent than JIK, named Topex. Furthermore, similar to the other facilities they stop at high-level disinfection.
4	5	-	Similar to other facilities, reprocessing includes decontamination and excludes sterilisation (only high-level disinfection).
5	3	High level disinfection	The detergent JIK is used (usually used for decontamination) if there is no cidex (a solution used for high level disinfection) availanle

APPENDIX T: FLY ON THE WALL ANALYSIS OF INTERVIEWS

Clusters to which information from interviews in the Netherlands were allocated

- Steps in the CE certification process (mapping)
- Disadvantages CE process
- Pricing strategy
- Complexity medical device industry in general
- Go-to-market-strategy
- Uncertainty certification process
- Awareness of higher class medical device manufacturers in Kenya
- Strategies of manufacturers for bridging discrepancy
- Order of certification
- Advantages of commercial company for introduction
- Advantage of Global North certificate
- Global North & South discrepancy in MDR
- Disadvantage of Global North certificate
- Manufacturers figuring out certification of Global South
- International Procurement Agencies Advantage
- What Global North manufacturers know about MDR Kenya
- Complexity medical device industry in Kenya
- Advise for the Chloe SED

Clusters to which information from interviews in Kenya were allocated

- Practical information about KEBS certificates
- Disadvantages KEBS and PPB
- After sales
- KEBS does inspection for QMS (Class I medical devices)
- Process manufacturers in Kenya undergo
- Local manufacturing brings value
- Awareness of higher class medical device manufacturers in Kenya
- Function of the person in charge of certification at company
- Challenges at the PPB
- Steps & Activities in the Kenyan certification process
- Advantage of Global North certificate
- Familiarity with KEBS & PPB but not sure where to be
- Tips from manucaturers for approaching KEBS

APPENDIX U: FOCUS GROUP DISCUSSION (MATERIALS)

Who was invited?

People from the Kenyan medical device industry from the following organisations: PATH, Elara Health Innovations, Kijenzi, Maker Space, Gearbox Europlacer, Focuslense, University of Nairobi, Caracal Systems / Adix Plastics Ltd and UoN.

Not all people were experienced in the certification of medical devices or had completed the local certification process in Kenya

Their Assignment

The participants were split into two groups. Group 1 consisted of participants with experience and Goup 2 without. Group 1 had most relevant information and was tasked to:

Round 1
Draw out the process of certification in Kenya

Round 2
Write down at each step who was involved (in green), what preparations were necessary (in red) and the challenges they experienced (in any other colour).

Part of the Schedule

Participants: 15	Co-session/Focusgroup	Duration: 120 mins	Date: april 20th	
Time	**Step**	**Goal**	**Description Step**	**Time**
17:00 - 17:05	**Welcome**	× Welcome × Introduction Karl & Floor × Goal of the session/focus group × Explain outline sessions/FG × Explain groups 1 & 2 × Hand out drinks and food × Opportunity to ask questions × Consent pictures and recording (do this before hand?)	We welcome the participants and tell them who we are and why we are doing this for the benefit of Kenya and Chloe SED certification project. We want to learn from them and hopefully they can also learn from each other. Then, we will take them through the planning of the workshop and at the same time hand out foods and drinks. The planning/outline of the workshop will be hung up on the wall so everbody can see. Show that group 1 is people with (previous) experience or are in the middle of the process and Group 2 is people who has no experience. Opportunity to ask questions and at the end we will ask them for consent of taking recordings and pictures.	5
17:05 - 17:15	**Intro**	× Everybody introduces him/herself × Everybody names the company × Everybody can state one fun fact × Everybody listens closely to one another and knows who is present	Make a round and let everybody introduce themselves (name and company) and 1 fun fact. They must also introduce the people before them.	15
17:20 - 17:25	**Explanation round 1**	× Explanation: Draw timeline of experience for certification locally × Tell the amount of time and break afterwards × Explain and show available material **× Group 1: draw experience and future planning** **× Group 2: draw what they think should happen/ what planning is**	Explain the first exercise: Tell them about the materials, possible use and the amount of time and let them know you are available for questions. After this they will have a break of 10 minutes.	5
17:25 - 17:45	**Round 1: Draw Experience**	× Carry out exercise		20
17:45 - 17:55	**Break**		Replenish drinks and offer small bites	10
17:55 - 18:00	**Explanation round 2**	× Explanation: At each step show stakeholders × Highlight what was difficult and why was it difficult × What preparations were necessary to get there? **× Group 1: add on stakeholders, difficulty and preps** **× Group 2: show what they are preparing now and why?**	Show who in the company is responsible and which parties they interact with during each step of the process. Tell them that they can use a different colour or use stickers if it helps them organise. Tell them that this is the last exercise and that after this we will do presentations. Everybody has 2 minutes to present and 2 questions.	5
18:00 - 18:20	**Round 2: Stakeholders and preparations**	× Carry out exercise		20
18:20 - 18:40	**Presentations**	× Let everyone present their process	Moderate the turns. Let participants ask each other questions	20
18:40 - 18:45	**Round off**	× Thank everybody for their participation	Round off	5
	Total amount of time taken			105
	Leftover:			15

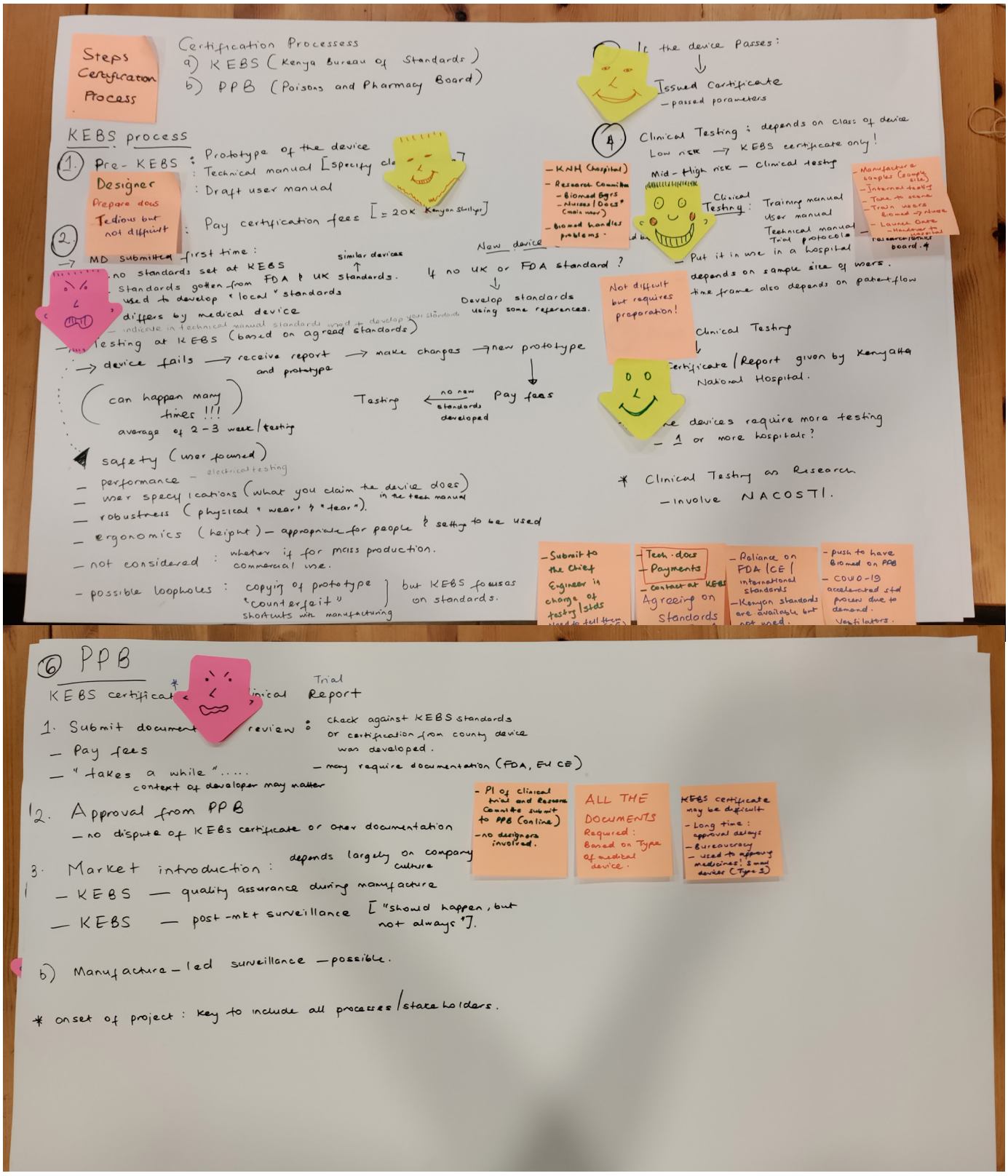
A selection of slides used (incl. exercises)

Group 2: Draw what steps you expect the process to consist of!

Group 2: Add to each step the following aspects:

- Which preparations are taken per step? RED
- Why are these preparations taken? GREEN

FOCUS GROUP DISCUSSION OUTCOMES



U2: Insights

Round 1: Steps of the process

1. Ideally, you should get the two certifications; one from KEBS (Kenyan Bureau of Standards) and the other one from PPB (Poisons and Pharmacy Board)
2. For KEBS, you have to have the prototype, the technical manual with the classification. At KEBS you specify which class the medical device is in and the draft of the user manual.
3. Take the documents to KEBS and pay certification fees which cost around 20 000 KSH (5 mins).
4. If you are submitting the medical device for the first time and if Kenya does not have medical device standards for this within KEBS, they will be unsure what parameters to check. KEBS will have to contact the manufacturer. KEBS will

work together with the manufacturer to look into British standards and the US standards for the FDA to develop standards. The FDA or UK standards will be used as reference
5. UK standards have a name.
6. The standards are different for different medical devices.
7. KEBS do their test based on these standards and different things can happen: you fail the tests/examens (7 mins) If you fail: the manufacturer receives a report from KEBS with information on the failures of the Medical Device, and what you need to iterate on and change. The manufacturer makes the changes, produces a new prototype, pays fees again goes straight to testing again because you have agreed upon the standards. You do not have to sit down again for that. (10 mins)
8. Testing as result of failed reports can happen 6-8 times. There are several categories for testing. You can fail very many times and it takes around 2-3 weeks per test depending on how much work they have.
9. What is tested? Performance (user focused), safety performance (e.g. electrical testing), user specifications (what you claim the device does in the technical manual), also aspects related to the African setting such as robustness (physical wear and tear), Ergonomics (e.g. height appropriate for people and setting of the device during use) (12 mins)
10. What KEBS did not consider during testing: whether it is for mass production and commercial use.
11. Possible Loopholes (Copying of prototype 'counterfeit' shortcuts with manufacturing. But KEBS focuses on standards.
12. It is not KEBS job to focus on the patent. Two institutions deal with protection. One used to be neighbour of KEBS. Big companies take shortcuts.
13. If you pass after you will be issued a certificate showing the parameters and how you have passed all that.
14. Depending on the type of medical device, there are some that do not require clinical testing, some which do. For class I of medical devices, KEBS certificate will suffice.
15. The other levels (class II to III) require clinical testing. Before clinical testing you need to have the certification, the sample sizes, the user manuals and you have to do the trainings and you need the technical manual for the biomeds. Clinical trial involves going to the hospital and test it by putting it in use. Depending on the sample size and influx of patient this testing can take either a month or a year. It took 1 manufacturer 3 months for clinical testing. (18 mins) Manufacturer receives the certificate for this and is now ready to approach the PPB. Quote: So we are lucky that clinical testing passes, and we get the certificate for this and now we go to the big monster, PPB (in phase 2)! (19 mins)
16. KEBS does not issue the certificate for the clinical testing, it is the KNH (hospital) that give the results in a report and certify that. (19 mins)
17. Quote: At this level, you submit your things at the PPB and pray! (20 mins)
18. For situations for medical devices that need more clinical testing: In Kenya, the PPB are sometimes looking for a lot of data supporting the use. Does that mean you need to test in 1 or several hospitals to gather the data? Depending on how the clinical trial protocol was delivered. For setting up the clinical trial protocol, you will discuss the protocol with people/ research/Ethics board from KNH or which ever hospital. They develop the protocols. We as designer are not involved in the clinical trials, we are not supposed to touch the protocol. (20 mins)
19. If Clinical Testing as Research, you involve NACOSTI. It is unclear when it is Clinical Testing and when Research.
20. The PPB now: you take your KEBS certificate and your clinical test reports which you submit to the PPB to review. Participant does not know how much you pay but you need to pay a fee and then you wait. Quote: It is Kenya, so it takes a while or you know what I mean... (someone else: but you can speed things up). (22.50 mins)
21. When submitting documents at the PPB, they will check it against KEBS standards or certification from country where device was developed. It may require documentation (FDA, EU and CE)
22. Quote: If those people....if manage to speak to them. The rest is now up to you on how you go to market'. (24 mins)
23. If PPB disputes something for example from KEBS, then you will have to go to KEBS. Quote: What matters here is the time they take to approve it. So, depending on who you are and which organisation you are from it can be very fast or it can take for forever (about PPB). Context of developer may matter for the duration of the process at the PPB (25 mins)
24. After approval PPB you can go to market: depends on the Manufacture but in this phase, you will still be checked by
25. KEBS again for Quality Manufacture during manufacturing.
26. KEBS should be doing Post Market Surveillance (picking a sample) but does not always happen
27. Whether manufacturers do any follow-up themselves, in absence of regulators on their heads, depends on the company's culture. The best thing is onset of the project to bring all the parties together so there are no unpleasant surprises.

Round 2: Preparations, Stakeholders and Difficulties (and why)
28. For KEBS: The position of the guy at KEBS, contact person necessary. The technical preparations, documents, the payments. The difficulty here is when doing this for the first time are the standards: agreeing on the standards which was a lot of work. (1 mins).
29. It was a difficult time to figure out which office to go to. It was another person. Manufacturer had a contact person in KEBS which was helpful because it was just a phone call away to notify the manufacturer to bring him something.
30. Having a contact person there is very helpful.
31. The one contact person could also take them through the departments??
32. For Clinical Testing: who was involved was the research committee that calls you. In the protocol, the nurse is the main user and the biomed is the second user concerning the maintenance. But the evaluation is carried out by the research committee. (4 mins)
33. Quote: It took a lot of preparations. We suffered: we had to manufacture the amount of required samples, assemble them (at sub-contractors), see if these samples are working (internal testing) and then take them to the seal(?) and train the users. The user you are training is the Biomed and the Biomed will now train the nurse. Then you have to prepare for the launch date where all the parties involved are there to hand over the medical devices and wait for 3 months.'
34. The manufacturer is not allowed to go because they can influence the process. The biomed should handle and this is also tested. Doctors are also involved. (5 mins)
35. The steps itself are not difficult but the preparation was a lot of work.
36. For PPB: The research committee at the PPB and the principal investigator are involved. The principal investigator is

responsible for the entire project ('our principal investigator') are the ones who do the submissions to the board. The designers are not involved in this step.

37. Preparations for the PPB: ALL the documents required, depending on the medical device you can see on and retrieve from the website which documents are required which you need to submit.
38. The board they already know?? 8 mins 45
39. Quote: Roadblocks you will hit everywhere. KEBS certification is quite difficult [...]. PPB is mostly to do with bureaucracy: you hand in your paperwork and they sit on it and just look at it, depending on what they think they can get from it. Another large issue if you are dealing with medical devices is that PPB is used to approving medicines and small things like syringes and bandages. This is the same issue that we experienced with KEBS and the clinical trials is because what they are used to doing are small things, class I medical devices where minor certification is required for those. (10 – 11 mins)
40. The contact in KEBS was an Engineer whose title was Chief Engineer in charge of testing and standards. One huge issue the manufacturer experienced with them is that he had to tell them what to test and against what because they had not done this before. Quote: Before this, KEBS was used to dealing with soaps and tissue. So the moment we turned up with a medical device, they asked for CE or FDA approval. (Joke). They rely on those because they are standardised all over the world so once a device gets CE certification, they just confirm the CE-certification is there. They are not used to new things. (11-12 mins).
41. Kenya also has their own (standards?) but the issue is they have not done it before. For X it is the same being because all they do is adopt international standards into their own standards. The standards are there for use but they have not it used before.
42. Even PPB have only dealt with medicine etc. And only manufacturers who have done this are for syringes and gloves etc.
43. The largest hurdle we had to go through is because it was the first time anything of this sort has been done. It was a learning experience for both for the manufacturers/designers and KEBS. Hopefully they have learnt something. (13.30 mins)
44. For the ventilators (in times of COVID), it was pushed by demand that local standards were developed. Within a month, we had standards for the ventilators because that happened was that they look at international standards and ask the question 'Is there anything that needs to be changed specific for us?' and the answer to that is most likely 'no'. So the local standards are there. (14 mins).

APPENDIX V: PERSONAS OF KENYAN MANUFACTURERS

KEBS

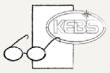
CLASS

n.a.

> *"The PPB and KEBS are involved with one another when it comes to medical devices. The PPB will approach KEBS after a manufacturer has applied for a clinical trial at KEBS.*

A manufacturer approaches the PPB for applying to a clinical trial [O1,5].

KEBS looks into standards applicable to the device. This is done in agreement with the manufacturer [O1,6].



Multiple inspections carried out by KEBS followed by a report about what they observed [lO\,10].

If passed succesfully, KEBS will hand out a permit(s) to the manufacturer. The permit can be recognised in East-Africa [O1,12].

The PPB will check the KEBS approval hand out the permit. The PPB permit needs to be renewed each year [lO\,14].

Timeline

The PPB approaches KEBS to test the device against standards [O1,5].

The manufacturer can prepare itself, purhcase standards from the KEBS wesite, fill in forms and submit documents [O1,8-10].

KEBS also takes a sample and tests the medical device against the standards [O1,11].

Manufacturer recieves a number from KEBS which they can put on a KEBS sticker [O1, 3].

LEARNINGS

When KEBS looks into standards applicable to the medical device, they will first look into: East-African Standards (EA), Kenyan Standards (KS) and then into ISO standards. If there are no standards applicable because the device is novel, KEBS will look into customer specifications. The product will be tested on its function and there will be a strict QMS (ISO 9001:2015) inspection [Ō1,6&7].

The standards can be bought at the KEBS website [Ō1,8].

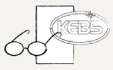
Organisation M

CLASS

B-C

> *"Even when they were doing their review, the questions they were asking were more pharmacy related because they were reviewing like it a drug. I don't think they have ever done a serious technical one (medical device). And the ones they check have often been certified somewhere else so for these devices they are just stamping. But a new one? WOW! For example, they were asking for a placebo and you can not do a placebo with this type of medical device.*

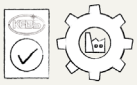
Approached KEBS for certification of the device and the quality check of the production (QMS) [O2,2].



KEBS inspected the production facility.

The organisation approached an Ethical Review Committee for an approval of the clinical trial protocol [O2,10].

Organisation M is awaiting clinical data and will submit this to the PPB [O2,17.



Organisation M wants to find a KEBS certified contract manufacturer for producing the medical device or develop a production facility of their own [O2,19&20]

Timeline

KEBS tested the device to verify its function. This test took the longest [Ō2,5].

After recieving a KEBS permit, Organisation M approached the PPB for a clinical trial application [Ō2,9].

The application was accepted by the second hospital they tried. The hospital insisted they used their own Ethical Review Committee [O2,11].

Organisation M is unsure what will happen next [Ō2,17].

LEARNINGS

Applying for a clinical trial at the PPB took a long time because they had to make the PPB understand the device. The PPB is used to reviewing drugs and pharmaceutical products, not medical devices. During this phase, organisation M had to do a lot of resubmissions [Ō2,6]. At the PPB, there are 3 stages of clinical trials to which you can apply. The organisation was able to argue with the PPB that the first two stages were inapplicable. Application at the PPB took over more than a year, whereas KEBS took 5 months [O2,8].

KEBS publish their own specifications if a manufacturer is developing something novel. The document is not as long as a standard and is often a list of requirements [U2,15]. However, the required documents can refer to an ISO standards which can be bought on their website [U2,16]. KEBS develops these specifications together with the MD manufacturers [O2,15].

Organisation N

CLASS

B-C

> *We did not want to give up any IP and we were looking for a way to hold onto the it while keeping the donors satisfied. One of the donors wanted the IP to be open source and we did not want the IP to be open source. Another donor said that they wanted to take the device and manufacture it because they were attached to a manufacturer.*

The MD was part of a research project to see if it was possible to get an MD from the design phase to the selling phase locally. [O'3,4]

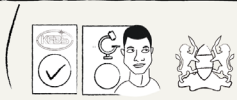
Approached KEBS to test the device against standards [O3,7].

Organisation N succesfully completed the clinical trial and recieved the data [O3,5].

After the PPB, they would have gone back to KEBS for QMS certificate [O'3,8].

Timeline

They checked the Intellectual Property (IP) concerning the novelty of the design. They neglected further IP discussions O'3,2].



After receiving the KEBS report and approval, they approached the PPB for a clinical trial application. |O'3,7].

At the PPB, organisation N was required to show who had ownership. This is where IP discussions arised which ended the process [O3,1].

LEARNINGS

The project was NGO funded and funds had been transferred between various organisations. More stakeholders became involved with partnerships throughout the certification process and eventually, no one agreed on to whom the design/device belonged and what should be done with it. They negelected further IP discussions because it was new terrain to everyone [O'3,3].

The advise now is to make agreements on IP from the very beginning. IP also includes checking the originality of the idea and whether you can borrow something. KIPI is the organisation manufacturers must approach for IP protection [O'3,6].

This organisation knew who to approach during the certification process because the Project Initiator was a medical professional [X,X].

Organisation O

CLASS

B&C

> *Our target market is South Asia and Sub-Saharan Africa. The first requirement will be 'Is your device FDA or CE-marked? Even in the US, the question is: 'Is it FDA approved? If not, does it have a CE mark?' Period. It is just those two. So, you need one of those. Once you have one, you do not actually need the other one. They are both recognised. It is not like KEBS because I can not take a device to Ethiopia and say it is KEBS approved. They will ask who is KEBS?'*

Organisation O recieves design proposals or comes up with designs based on research [. O .].

The organisation obtains an CE (EU) or FDA certificate for their medical devices [O4,4].

The organisation manufactures medical devices in India and one type in Germany. They are looking for manufacturers in Africa |O'4,7].

Timeline

The organisation is doing clinical trials in Kenya and India [O .]

They make sure the IP and the certificates are ready when approaching a contract manufacturer {O4,5].

The organisation is considering a manufacturer in South Africa but it is more expensive than India [O4,2]

LEARNINGS

Organisation O is looking for a contract manufacturer in Kenya but is experiencing difficulty in finding one that is ISO-ceritified. South African manufacturers do have this certification. How this is possible is unclear, but organisation 6 suspects it has something to do with regulations and better financial resources [O'4,3].

All the devices are CE or FDA marked. The reason for this is that the main engineering office is in the US and that Global South countries recognise and even rely on these clearances [O'4,8].

Manufacturing in Kenya would make the process a lot cheaper because there will be no shipping costs, no import costs and fewer government levies. The latter two can end up being 20% of the device costs [O'4,6].

Organisation S

CLASS **A**

> *They (PPB and KEBS) are just like one item. The PPB and KEBS are working closely and are now approving higher class devices.*

> *If dealing with class B devices, you communicate to KEBS and they direct you to the right board.*

Lawyer approaches KEBS for manufacturing ceritficate [O5,5]

Organisation S submits documents to KEBS [O5,7].

The report by KEBS if compared to the documents submitted by organisation M [O5,7].

Recieve order for a medical device [O5,4].

Screens whether the order concerns medical device class A [O5,4].

Timeline

KEBS offers a guide to help manufacturers to make their production process conform [O5,6].

Multiple inspections carried out by KEBS followed by a report about what they observed [O5, 2&7].

Recieve manufacturing certificate by KEBS which needs to be renewed after 1 year [O5,7&10].

Manufacture the medical device

LEARNINGS

Organisation S is sticking to class A medical devices because expanding to higher class medical devices is too complicated. The material they use is inappropriate for these classes [O5,8].

The organisation is unaware of other organisations in Kenya that are certified to medical devices that are class B or higher [O5,9].

A manufacturer can choose to obtain a KEBS certificate that is valid for 3 or 6 months and 1, 2 or 5 years, each with different costs. Choosing 1 year, allows time to improve [O5,10].

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name	Burgers
initials	F. given name
student number	4459113
street & no.	
zipcode & city	
country	
phone	
email	

Your master programme (only select the options that apply to you):

IDE master(s):	( ) IPD ( ) DfI (★) SPD
2nd non-IDE master:	
individual programme:	- - (give date of approval)
honours programme:	( ) Honours Programme Master
specialisation / annotation:	( ) Medisign
	( ) Tech. in Sustainable Design
	( ) Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair	Jan Carel Diehl	dept. / section:	SDE (DfS)
** mentor	Jo van Engelen	dept. / section:	SDE (DfS)
2nd mentor	Roos Marieke Oosting from the Inclusive Global Healthcare Lab TUD		
organisation:	Global Health Initiative Lab,Inclusive Global Healthcare Lab TUD		
city:	Delft	country:	The Netherlands

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

comments (optional): I took two supervisors from the same section but they have different expertise. Jan Carel's expertise lies with the Global South and Jo has expertise in adaptation and acceptation processes.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Jan Carel Diehl date 10 - 02 - 2022 signature jdiehl Digitally signed by jdiehl Date: 2022.02.13 10:22:02 +01'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: _____ EC

Of which, taking the conditional requirements into account, can be part of the exam programme _____ EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name _____ date __ - __ - ____ signature _____

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name _____ date __ - __ - ____ signature _____

Initials & Name F. Burgers Student number 4459113

Title of Project Strategy for a successful adoption of a circular medical device in Kenya

Strategy for a successful adoption of a circular medical device in Kenya

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 10 - 02 - 2022

14 - 07 - 2022 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

In low resource settings, particularly in the Sub-Saharan Africa, many medical devices are inaccessible to the majority of people in need of healthcare. New sustainable/circular initiatives are launched that increase this accessibility (and thus inclusivity) while also reducing environmental impact. One of these initiatives is the CHLOE Syringe Extension Device (SED). CHLOE SED is a reusable, 3D-printable device that extends the locally available 10ml syringes so the needle can reach the cervix to enable injection of analgesia. This allows procedures to take place that are related to pregnancy issues. The project well focus on the process of bringing CHLOE SED to the Kenyan market.

CHLOE SED is reusable; while being economically more attractive, it also reduces environmental impact and so the cleaning process plays a significant role (as well as the use cycles)

The main stakeholders within this context:
- KarlHeinz Samenjo: the creator of CHLOE SED and he will act as my client.
- Inclusive Global Healthcare Lab TU Delft: scientists who use expertise to increase access to healthcare for the Global South.
- Local government: Currently, abortion is not permitted in Kenya, unless there is need for emergency treatment but expectations are this will change soon (JMP project).
- Kenyan patients with pregnancy related issues: Their interest is to receive safe treatment during and after the corresponding gynecological procedures
- Kenyan hospitals and healthcare services: Currently different hospitals have different resources for sterilizating medical devices. They feel the duty to treat their patients however, there are social and economical factors (surrounding the policy of abortion) that complicate or obstruct the necessary gyneological procedures.

Opportunities
- Allowing certain gynecological procedures to be pain free; giving women an actual choice and saving lives.
- CHLOE SED and corresponding procedures are economically more attractive than the procedures currently taking place
- Scale up possibilities to other countries in eastern Africa

Main Limitations
- Limitations caused by certification process, local and international healthcare policy
- Low resource setting: difficult to afford proper tools, acquire necessary knowledge (e.g. trained staff)
- Cultural climate within hospitals
- Public awareness and cultural view on abortion related procedures

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introduction (continued): space for images

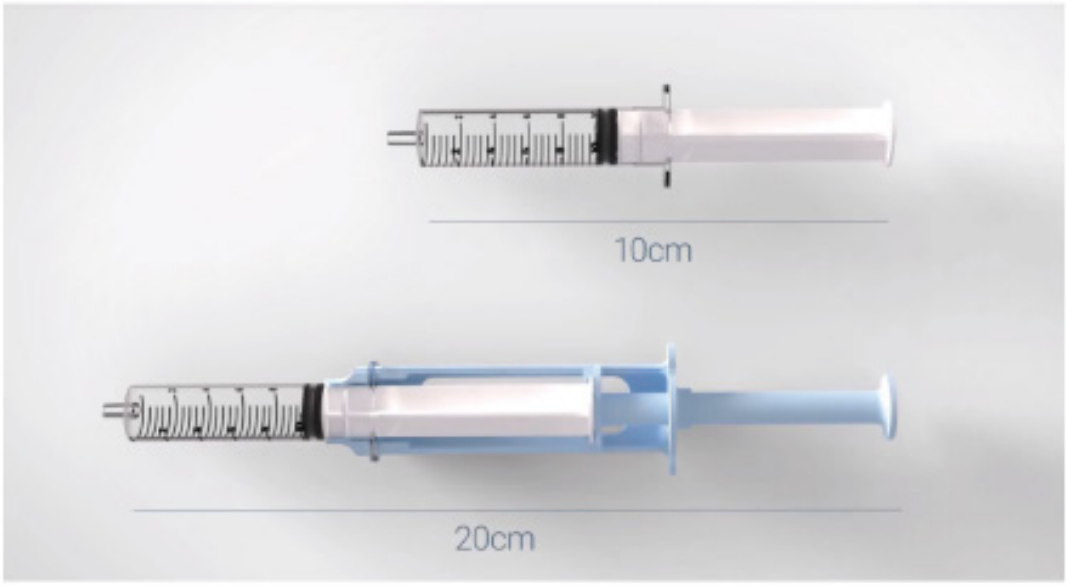

image / figure 1: CHLOE SED depicted in blue. It shows how the device extends the locally available 10 ml syringes.

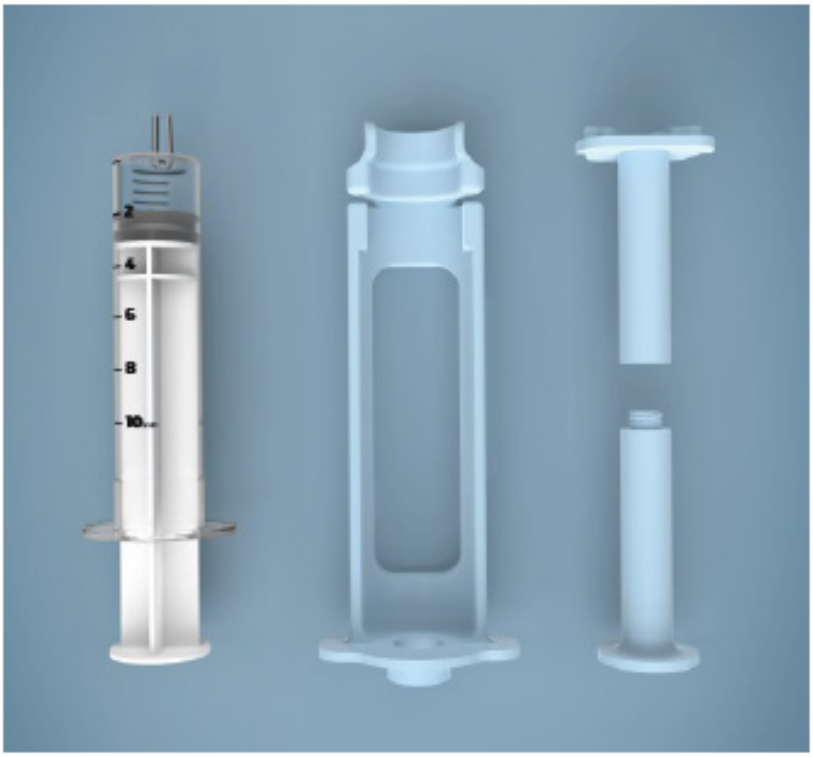

image / figure 2: CHLOE SED taken apart.

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The embodiment design and material of CHLOE SED is investigated by another research group (JMP project). They have worked towards the final design and suggested PEEK as a material. Since the embodiment design is (almost) ready, the question now is: How do we ensure successful adoption of CHLOE SED in Kenya? It is unclear yet how CHLOE SED should pave the way to the Kenyan market.

To bring the device legally a step closer to the market, it must become clear what the a certification proces looks like a what effect this might have CHLOE SED's embodiment design.

In order to bring CHLOE SED another step closer to the market, it is necessary to look into which stakeholders accept the device and are willing to bring it to the market. Two adoption routes will be compared and with the feedback from these two routes, recommendations can be made about possible modifications of CHLOE SED's embodiment design and advise on CHLOE SED's business plan.

The reason for comparing two routes is to ensure the project is doable in 20 weeks.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

I will map and visualize the certification process for CHLOE SED and I will do research into two possible adoption routes. I will research how these processes influence CHLOE SED's embodiment design and value proposition. On the basis of this, I will make recommendations for the embodiment design and business plan of the device.

I expect to bring CHLOE SED one step closer to a successful adoption in Kenya by generating an implementation strategy that consists of recommendations for CHLOE SED's admissibility and accessibility to the market.

Firstly, I will make a map of the certification steps necessary for CHLOE SED and research how this effects the embodiment design of CHLOE SED.
Secondly, I will do research into two adoption routes and feedback from these routes will form the basis for recommending (possible) modifications of CHLOE SED's embodiment design and suggestions for its' market plan.

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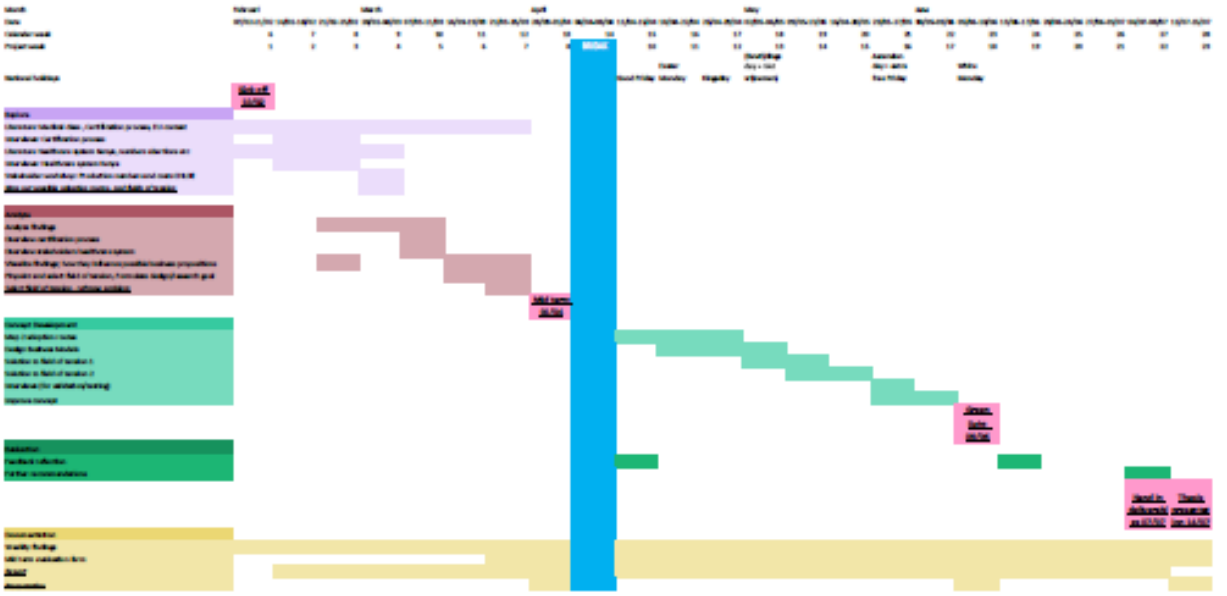
PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 10 - 2 - 2022 14 - 7 - 2022 end date



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MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I chose this project because there are two things that lie at heart of my motivation for designing. One is, I would like to bring positive impact to the planet by making processes more sustainable and two is, I want to make the world a better and more comfortable place to live in for people who live in poverty. This is the first time I will be able to combine both aspects!
Also, I like this project because of the challenge to design with a total new frame of reference and its international character.
Moreover, I immensely enjoyed the second part of the course Design Strategy Project (DSP) for the Red Cross, where we we mapped and visualised how we could protect people against heatwaves. I love bringing complex processes or wicked problems into a big (but comprehensive) visual picture. I enjoyed this same process in the elective course Sustainable Product Service Systems (and Business Models) SPSS.
Lastly, as a woman, I relate to those who are in less fortunate situations regarding the reproductive rights and care currently unable to receive pain-free treatment, simply because it is not prioritised or there are no resources for it. I believe in the potential of CHLOE SED and how it can give women an actual choice for treatment.

Competences, I would like to prove: Visualisation skills, Mapping skills. Also I would like to show (and improve) my facilitation skills because during my internship at a consultant, I was able to participate in and facilitate a few workshops and co-creation sessions. I would like to apply this experience to my project.

Competences I would like to learn or keep improving: Analytical skills (processing a lot of information), Critical reading/thinking and being accuracy, Speaking: being able to formulate your thoughts clearly even when you do not know everything,

Personal learning ambitions:
- Learn more about implementing a product
- Learn more about how certification processes influence business propositions
- Being able to pave the way within a new reference frame
- Working for a different culture: new aspects you need to take into consideration
- Doing this all on my own while having fun and not to let insecurity stand too much in the way. My bachelor thesis, was not the most successful period and it took away some of my confidence in doing things on my own.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.