Incentives for Manufacturers in Certifying Medical Equipment for Low- and Middle-Income Countries

Unveiling the Potential of Appropriate Medical Equipment Label

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Acknowledgement

This thesis research investigates the feasibility of implementing a new product label, namely the Appropriate Medical Equipment (AME) label, in the context of low- and middle-income countries (LMICs), from the perspective of medical equipment manufacturers. With great pleasure, I present you the final report of this thesis, marking the end of my Master in Management of Technology at Delft University of Technology. The last six months have been an enriching experience; collaborating with passionate individuals had made a profound impact on my personal and professional outlook.

During my courses, I had the opportunity to work on several healthcare-related projects, particularly focused on the impact of technology in enhancing the physical and mental well-being of individuals. Gradually, I developed an interest in the intersection of technology and healthcare, which motivated me to utilize my knowledge for a research topic in the healthcare domain. This aspiration was turned into a reality with the invaluable support and guidance of a few people along the way. I take this moment to extend my sincere gratitude to all of them. To begin with, I would like to express my heartfelt gratitude to Dr. Saba Hinrichs-Krapels, my first supervisor, for the valuable guidance and great supervision of the project. Her scientific vision, approach, enthusiasm, and positivity have been a constant source of inspiration, which helped me stay focused and pushed my boundaries in the right direction. Furthermore, all our discussions were really intriguing, without which this research would not have taken its current shape. I would like to thank Prof. dr. Cees van Beers, my chairperson and second supervisor, for your valuable insights and for asking thought-provoking questions during our meetings. These contributions were fruitful and helped me enhance and refine my thesis. I am very grateful to Anna Worm, my external advisor, who believed in my capacity to undertake this topic and supported me in successfully completing the research. Your enthusiasm and dedication to making the AME label a reality have been truly inspiring and persuaded me to give my best at every stage of the research work. Through the AME team meetings, I developed a sense of working towards a greater goal beyond a master thesis research. Lastly, my sincere gratitude to all the industry and academic experts for generously dedicating their time and energy, and whose inputs were instrumental in enriching this research.

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Akshay Rajagopal
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Executive Summary

Medical equipment supplied to low- and middle-income countries (LMICs) are often substandard and inappropriate to the contextual needs. The majority of equipment entering these countries are donated or financed by external agencies. Procurement of equipment also happens through public tendering. However, the assessment and management of the equipment entering these countries are found to be inappropriate and ineffective. This has resulted in equipment that remains unused, malfunctions, or fails to meet its expected lifespan. This ultimately causes harmful consequences to the patient groups in LMIC. It is high time that this situation needs to be addressed and implement measures to provide quality, safe, affordable, accessible, and appropriate health technologies to people in these low-resource settings. One approach to create transparency around the notion of appropriate health technologies for LMICs is by creating a set of measurable criteria, tested in the form of a label. A global team of BioMedical engineers undertook an initiative to implement such a label, namely, 'Appropriate Medical Equipment' or 'AME Label'. This research aims to examine the feasibility and constraints associated with implementing such an initiative from the perspective of medical equipment manufacturers.

The study investigated four main topics to answer the research question: *'How can a new product label support medical equipment manufacturers to sustainably enter the healthcare market of low- and middle-income countries?'*. These are the value of product labels in the market, regulatory challenges faced by manufacturers in the MedTech industry, challenges for manufacturers in entering LMICs, and perception of manufacturers on the concept of AME label. A combination of desk research and qualitative interview was used to deduce the conclusion. Initially, a case study was conducted involving a medical equipment manufacturer based in the Netherlands, whose operations primarily targeted LMICs. The data was collected through one-to-one online semi-structured interviews with managers within this organization. The preliminary findings formed were later validated through survey and interviews conducted with a globally diverse sample size including industry and academic experts.

The results of the study indicated that the adoption of AME label has the potential to benefit manufacturers with enhanced brand value, increased visibility, improved credibility, and greater product transparency in their target markets. These factors can in turn build confidence and trust among LMIC stakeholders on AME-labeled products, opening doors for sustained business opportunities for manufacturers in these countries. By optimizing the product design towards the contextual requirements and including competitive product features, manufacturers could use the AME label as a differentiating factor in their sales. Subsequently, manufacturers could attain higher commercial value for their products and improved operating efficiency in the healthcare market of LMICs. At the same time, it is found that the introduction of the AME label could increase the complexity of the regulatory system. Manufacturers of all sizes face challenges while undergoing any regulatory process, adhering to regulatory norms, or undertaking any product label. This is unavoidable for manufacturers while supplying med-

ical equipment across boundaries. Therefore, the inclination of manufacturers to adopt AME label depends on how effectively it streamlines the supply process, cuts administrative costs, reduces documentation work, and expedites the distribution of equipment to target countries.

Considering the novelty of the label, there are some concerns that could hinder the full-fledged adoption of the AME label by manufacturers. These concerns primarily revolve around the reliability and trustworthiness of the label. To overcome these concerns, the AME team should take into account the following aspects when implementing the label. They should carefully plan and execute steps to ensure that the label is recognized and accepted by authorized bodies like the UN, WHO, etc. It is equally important that measures need to be taken in the direction where the label is validated by all relevant stakeholders in LMICs. It is also essential to establish a clear positioning of the AME label within the regulatory system by highlighting the unique testing methods and distinctive tangible advantages it offers to the manufacturers compared to existing labels. By addressing these concerns, the widespread adoption of the AME label by medical equipment manufacturers could be achieved, leading to the availability of appropriate equipment in LMIC hospitals, and ultimately benefiting the patient groups within.

Contents

Nomenclature

AME	Appropriate Medical Equipment
$ARTG$	Australian Register of Therapeutic Goods
CE	Conformité Européenne
CSR	Corporate Social Responsibility
EU	European Union
FDA	Food and Drug Administration
$GHTF$	Global Harmonization Task Force
HIC	High-Income Country
$HREC$	Human Resource and Ethics Committee
HTA	Health Technology Assessment
$INAHTA$	International Network of Agencies of Health Technology Assessment
$LMIC$	Low- and Middle-Income Country
MDD	Medical Device Directive
MDR	Medical Device Regulation
$MHRA$	Medicines and Healthcare products Regulatory Agency
MOT	Management of Technology
NB	Notified Body
PMA	Pre-Market Approval
SME	Small and Medium-sized Enterprises
SQ	Sub-Question
UN	United Nations
$UNICEF$	United Nations International Children's Emergency Fund
$USAID$	United States Agency for International Development
WHO	World Health Organization

List of Figures

List of Tables

1 Introduction

The aim of this chapter is to give a better understanding of the problem domain and the research objective of this study. This chapter explores the characteristics of the problem, the reasons why it requires attention, and the approach by which it can be tackled. Section 1.1 will outline the purpose of this research. A thorough examination of the research problem will be explained in section 1.2. The research objective is discussed in section 1.2.1, and the main research question and sub-questions are given in section 1.2.2. Finally, the relevance of this research in terms of its link to the program of study this MSc thesis is written for is given in section 1.3, and the reading guide for navigating the subsequent chapters is presented in section 1.4.

1.1 Research Background

All people everywhere have the right to access the best possible level of healthcare. To develop universal health care, deal with health emergencies and promote healthier communities, access to high-quality, affordable, and appropriate health products is essential. Medical equipment are part of healthcare technologies that are indispensable for an effective and efficient healthcare system. These are tools used to diagnose, treat and rehabilitate diseased people or those with illness (WHO, 2016). According to WHO (2023), "Medical equipment are defined as medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. It excludes implantable, disposable, or single-use medical devices.". There are currently about 7000 generic medical device groups and an estimated 2 million different types of medical equipment available on the global market (WHO, 2023). A framework proposed by WHO in 2007 considers factors like access to essential medicines, medical equipment, and appropriate service delivery with quality, safety, and coverage as core components to strengthen the health system and achieve the goal of improved health status (Lazarus, 2014). Medical equipment are regarded as a fundamental part of health systems; the advantages they can offer keep growing since they are necessary for the safe and effective prevention, diagnosis, treatment, and rehabilitation of illnesses and diseases. Manufacturing, regulation, planning, assessment, acquisition, and management processes related to medical equipment are intricate. But they are necessary to ensure high quality, safety, and compatibility of the products with the environments in which they are employed. (PAHO, 2023). Although the discussions in this report have focused on medical equipment, the terms 'medical devices' and 'medical equipment' have been used interchangeably due to their generalized use in various literature.

The demand for medical equipment in low- and middle-income countries (LMICs) is increasing rapidly. The analysis of the economic and social conditions in these countries reveals a need for both affordable and advanced medical equipment. However, many manufacturers struggle to cater to the specific needs and preferences of hospitals in LMICs and tend to ne-

glect the demands of this growing market (Fleßa, 2022). There are several unique challenges in designing and operating medical equipment in low-resource settings when compared to developed countries. Limited resources such as infrastructure, spare parts, equipment support systems, and a lack of trained personnel cause the improper working of medical equipment in these countries (Vasan & Friend, 2020). Inappropriate or mismatch in technology design and demand, indiscriminate procurement methods, high deployment and maintenance costs, and lack of human resource training also contribute to this situation (Diaconu et al., 2017). It is important to understand that hospitals in LMICs rely on equipment acquired through donations or imported from high-income countries (HICs). However, the appropriateness of such equipment are barely reviewed. According to estimates by WHO, 95% of medical equipment in LMICs are imported and 80% of it is funded by international donors or the HICs government (Marks, Thomas, Bakhet, & Fitzgerald, 2019). In the case of sub-Saharan Africa, the majority, around 70% of their medical equipment is acquired through donations (Marks et al., 2019). However, only a fraction, ranging from 10% to 30%, actually becomes functional and operational (Marks et al., 2019). Although the donations to these countries are made with the genuine intent of improving the healthcare system, the technical infrastructure and capability of receiving hospitals are not considered. A guideline for the successful donation of medical equipment to developing countries is proposed by WHO, which is shown in the *Figure 1*. Medical equipment are also imported from HICs through procurement process such as public tendering. An overview of the standard procurement procedure for medical equipment which is proposed by WHO, is shown in *Figure 2*. Most of the modern medical equipment are designed to operate in stable conditions and with sophisticated amenities, such as those in HICs. The operation and maintenance of such equipment happen to be challenging in low-resource settings. This mismatch leaves an inoperative piece of equipment and causes disposal problems. Ultimately, the absence of well-functioning, safe, and effective medical equipment weakens the health service provision in these countries (Diaconu et al., 2017).

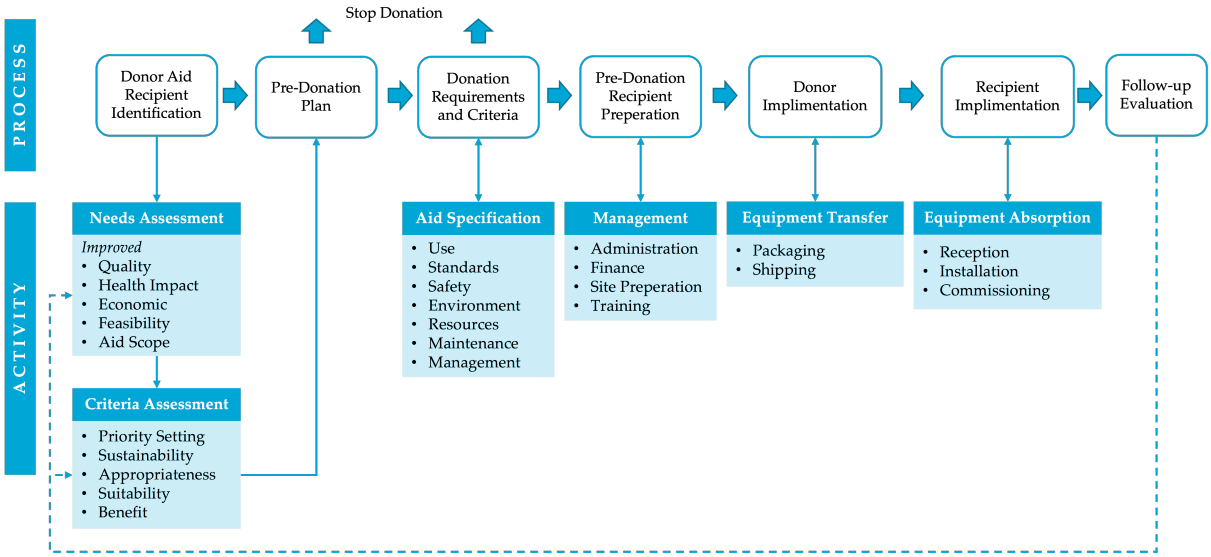

Figure 1: *Medical equipment donation process flow chart and checklist (WHO, 2000)*

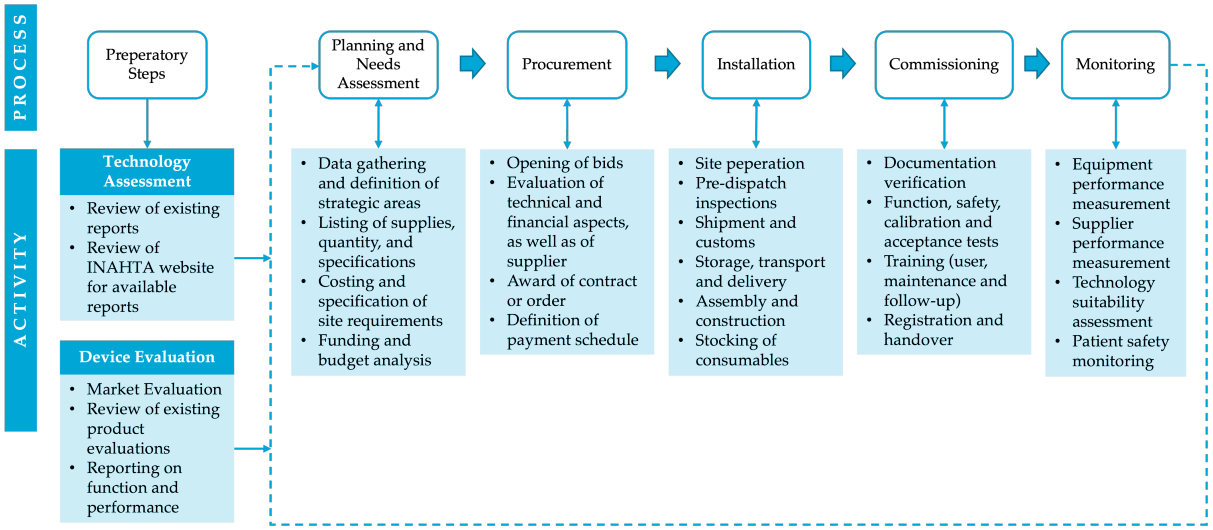

Figure 2: *Medical equipment procurement process flow chart and checklist (WHO, 2011)*

Despite the limited infrastructure, resource deficiency, and misalignment in technology design and demand, there are other usability factors affecting the successful deployment of medical equipment in LMICs. Contextual conditions like high temperatures, fluctuating electricity, and lack of clean water supply prevent the efficient use of some equipment. Products deployed in such conditions do not reach full life expectancy. Also, there is no clear indication of the device specifications conforming to the LMICs environment and setting (e.g. durability, humidity, or temperature resistance). The lack of regulatory authorities or biomedical engineers to advise on the deployment setting of medical equipment in these countries lead to the premature disuse of equipment. The absence of sufficient training programs, installation services, preventive and corrective maintenance services in these countries leads to unsafe use of equipment with possibly harmful consequences for patients (Diaconu et al., 2017). It is found that authorities rarely follow the regular preventive maintenance schedules which causes the early breakdown and subsequent escalation of problems. Furthermore, the lack of a disposal system for outdated or irreparable equipment adds to the burden of non-functional equipment in hospitals (Perry & Malkin, 2011).

The literature and other sources of data used in this research have mostly focused on the health technology management challenges in public hospitals within sub-Saharan African countries. Public hospitals often depend on medical equipment donations to provide basic healthcare to the people. The accessibility, and affordability of quality healthcare are limited to relatively affluent cities in LMICs. In rural areas, people frequently face challenges in accessing hospitals and lack resources to afford basic healthcare services. (Gnanaraj & Rhodes, 2015). Therefore, the contextual conditions and requirements of LMICs or low-resource settings that are referred to throughout this report specifically pertain to public hospitals in rural regions of sub-Saharan African countries.

1.2 Problem Definition

There are many instances where LMIC hospitals become recipients of inappropriate donations, have limited training programs for technicians and engineers, and subsequently have high breakdown rates of equipment. This lead to the situation where the equipment are dumped unused and ends up in 'medical equipment graveyards' (Marks et al., 2019). These low-resource countries often adopt equipment designed for home use or for developed countries, which somehow becomes unsuccessful in operation due to infrastructural and environmental differences. However, the status of inappropriate medical equipment and insufficient human capacity in such hospitals can be improved. Medical equipment manufacturers can play a crucial role in improving this status by tailoring their design approach to the contextual requirements of these countries. A shift from top-down and sophisticated engineering design to simple and user-enabled design further subjected to field tests can improve the accessibility and usability of medical equipment in low-resource settings (Coulentianos, Rodriguez-Calero, Daly, & Sienko, 2020). This research investigates methods for sustained adoption of robust medical equipment in the LMICs by ensuring that manufacturers meet certain design requirements in their products that should be contextually standardized while supplying to LMICs. The visual representation of the problem underlying this research is shown in *Figure 3*.

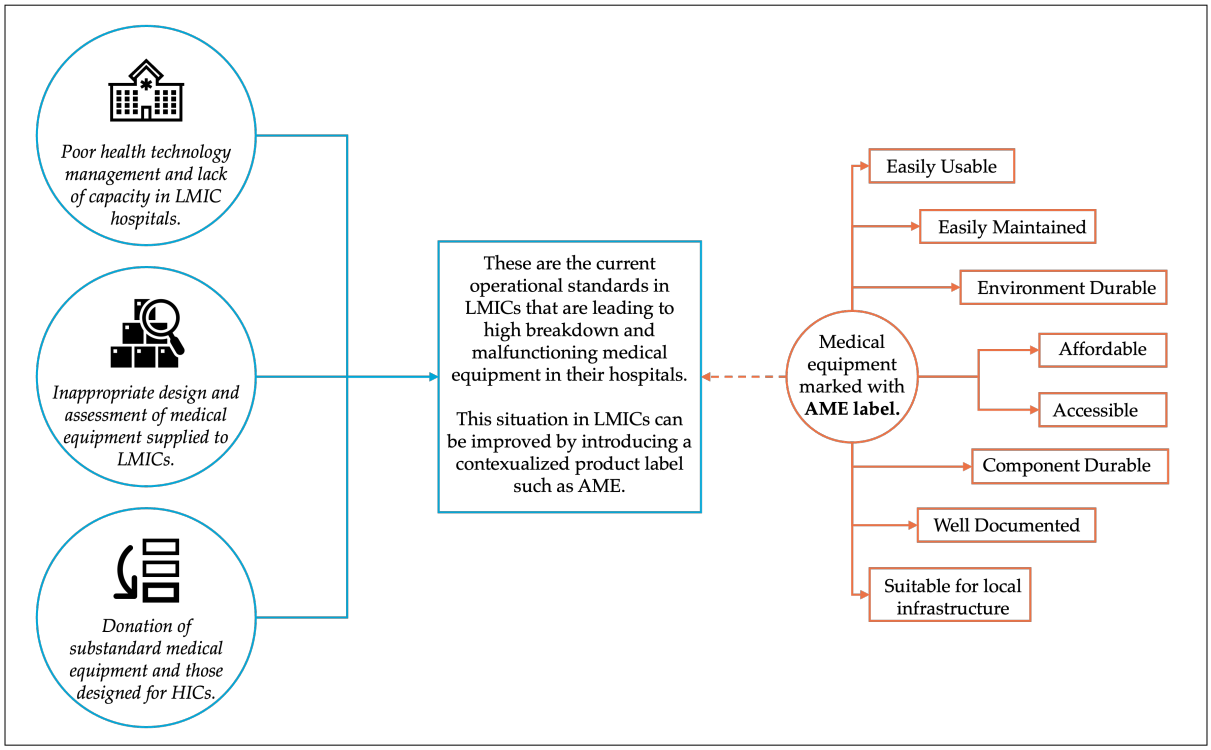

Figure 3: *Visual representation of the problem underlying this research*

A possible solution to improve this situation can be the introduction of a new product label, namely Appropriate Medical Equipment (AME) which offers a way to filter medical equipment before it reaches the LMIC hospitals. The concept of AME was introduced by a team of 12 global BioMedical Engineers with over 150 years of experience in LMICs all over the world.

The vision of AME is to improve the situation of malfunctioning medical equipment in the daily working environment of low-resource countries. Medical equipment marked with the AME label is defined as clinically safe, adapted to local needs, and acceptable to those who use them, and that can be maintained and utilized with resources available and affordable to the community or country. Currently, the AME label exists in a theoretical phase, and once implemented, it is voluntary for manufacturers to adopt it. It is aimed to create visibility of appropriate equipment and ensure the equipment is the right fit for the low-resource setting. The equipment will be independently tested against criteria like maintainability, usability, durability, accessibility, and affordability. Generally, product labels are used to demonstrate that an entity has met specific requirements, which are normally based on certain standards. A labeled product or service increases the trust between stakeholders or cooperation partners in the market (Harjuoja, 2016). Labeling plays a crucial role in gaining consumers' confidence and trust in the product, process, or service. With the increasing option for products and services, consumers prefer manufacturers that showcase certain values like safety, quality, environment, and conformance at the forefront. This creates the market more competitive and motivates manufacturers to adopt product, process, and/or service certifications to maintain their competitive edge. Also, having a product label can be a differentiating and attractive factor for manufacturers during their marketing phase (Stepka, 2022).

Over the past decade, firms are laying emphasis on social responsibilities and environmental performance in addition to profit maximization. They express these values through labels and certifications. Labels are focused on specific attributes of the product and aimed to convey targeted information to the consumers. A standard-setting body usually controls the use of labels. On the other hand, certification includes an extensive assessment of the product to verify it meets certain standards. A third-party verification is done to validate the compliance of the product with broader established standards (Matus, 2010). An example of this is the emergence of B Corporations, certified by B Labs, a non-profit organization founded in 2006. B Corporations are profit-making companies that voluntarily meet the heightened standards of social and environmental sustainability. It is aimed to characterize purpose-driven enterprises fulfilling actions of Corporate Social Responsibility (CSR) (Harjoto, Laksmana, & Yang, 2019). While the B Corp certificate is a holistic evaluation of a company's social and environmental performance, there are labels such as eco-labeling which is more product-specific. The eco-labels are intended to provide specific information to customers about the environmental characteristics of a product. Similarly, there are many more labels in the market aimed to convey different objectives. A detailed explanation of different labels are given in section 4.1. In this study, the AME label can be viewed as a product-level label applied to medical equipment.

As shown in *Figure 3*, manufacturers achieving the AME label for their medical equipment fulfill the criteria for appropriate and context-sensitive design and servicing requirements that are adequate for LMICs [1]. Also, the AME label ensures that purchasers in LMICs have an independent, trusted standard for procuring medical equipment suitable for operating in their context. AME label tends to close the gap between manufacturers and users of medical equipment with

[1] source: Appropriate Medical Equipment (AME) Label information flyer

the ultimate goal to let users benefit from equipment fit for their purpose and setting.

1.2.1 Research Objective

This research analyses the situation mentioned in the previous section from the perspective of a medical equipment manufacturer. The healthcare industry and medical equipment market are highly regulated by various national and international bodies. All manufacturers ranging from small-sized enterprises to large-sized enterprises face tremendous challenges in one way or the other in adhering to these regulatory norms and selling their equipment across boundaries. Although most of the widely used labels in the global regulatory system are sufficient for manufacturers in entering the healthcare market of LMICs, the appropriateness of the products supplied is still questionable. It is difficult for manufacturers to align their product features with contextual requirements, which leads to the supply of inappropriate equipment. Hence, the concept of a contextual label such as AME was introduced to minimize this mismatch of medical equipment with the contextual requirements of LMICs. Therefore, it is important to understand the perspective of medical equipment manufacturers toward new labels such as AME and understand their constraints in undertaking this label. This research will help to reshape and develop the AME label on a wider scale, with due consideration of the added benefits a manufacturer can recoup by investing in it. It is important to understand this market perspective which will help the AME team to effectively position it in the regulatory system. This leads to the main objective of this research, which is:

"To investigate whether and how companies who sell medical equipment specifically to low- and middle-income countries would be incentivized to adhere to a product labels such as AME"

1.2.2 Research Questions and Scope

The main research question is formulated as follows:

How could a new product label support medical equipment manufacturers to sustainably enter the healthcare market of low- and middle-income countries?

Several sub-questions need to be answered first to conclude and answer the main research question. The sub-questions are as follows, and the flow of these sub-questions and the research methodologies used to answer these questions are later presented in Chapter 3.

SQ1: How does product labels in different industries help manufacturers with sustainable marketing?

SQ2: What are the challenges faced by medical equipment manufacturers in adhering to product labels and certifications?

SQ3: What are the challenges faced by medical equipment manufacturers in entering the LMIC market?

SQ4: What are the perceptions of medical equipment manufacturers in adhering to a product label such as AME?

1.3 Relevance to MOT Study Program

This thesis concludes with a Master degree in Management of Technology (MOT). Some of the core themes of the MOT program are Technology, Organization, Commercialization, and Social Responsibility. The program addresses technology-based products, their services, stakeholder interaction, risks, and most importantly corporate social responsibilities. The root cause of this research is the poor management of healthcare technologies, especially in geographical regions having low resources and infrastructure. This situation is analyzed and the possible action plans are proposed from the perspective of organizations (medical equipment manufacturers) in this industry. The relevance of organization, technology-based products, and society in this research creates ground for human and technology interaction, fitting it as an MOT thesis.

1.4 Reading Guide

This chapter introduces the research background, the problem scope, the research objective, and the questions that need to be answered. This depicts the boundaries of the study. A literature review in Chapter 2 will help in providing a deeper understanding of the current state of healthcare technology management and assessment system in LMICs. It concludes with the knowledge gap that will be addressed through this study. Chapter 3 will dive deep into the methodology, providing a detailed description of the research methods used to answer each sub-question. Chapter 4 is aimed to answer the first sub-question, by exploring the significance of product labeling in the consumer market and its role in enabling sustainable marketing practices for the manufacturers. Chapter 5 explain the challenges confronted by medical equipment manufacturers in the process of complying with various existing certification and regulations, which concludes by answering the second sub-question. Chapter 6 will explore the challenges faced by manufacturers when supplying products to LMICs, including different stages like design, distribution, and maintenance of medical equipment. Chapter 7 will present the perspective of manufacturers towards the AME label - a general impression of the label, expected roadblocks in adhering to it, and a few concerns in its implementation phase. Chapter 6 and 7 are concluded with some prepositions which are later validated in Chapter 8. By consolidating and validating all the findings, Chapter 8 will conclude by answering sub-questions 3 and 4. Chapter 9 discusses and compares the findings from different research methods used in this study, along with indicating the limitation of this research and recommendations for the AME team to develop the label to a larger scale. Finally, Chapter 10 concludes the report by answering the main research question.

2 Identification of Knowledge Gap

While Chapter 1 provided an overview of the problem domain and study context, the focus of this chapter is to identify the knowledge gap underlying this research. This is identified by examining current literature having a focus on aspects such as the assessment and management of healthcare technologies in LMICs.

Section 2.1 explains the search description and selection criteria for the literature that are used to investigate the research problem in detail and identify the knowledge gap. Section 2.2 discusses the existing literature or articles that are reviewed. This is followed by the literature findings and finally concluded by explaining the knowledge gap, which is explained in section 2.2.3.

2.1 Search Description and Selection Criteria

The aim of this section is to identify relevant literature that will help to deepen the understanding of the problem domain and identify the knowledge gap. The search keywords for the literature review are categorized into three concepts -'medical equipment and/or health technology, 'low- middle-income countries and/or developing countries', 'regulations and/or certification'. The categorization of keywords is shown in the *Table 1*.

Concepts: Combine with AND			
Synonyms and/or related terms: Combine with OR	Concept 1	Concept 2	Concept 3
	Medical Devices	Regulations	Low-and Middle-Income Countries
	Medical Technology	Labeling	Developing Countries
	Health Technology	Certifications	Low-resource settings

Table 1: *Main Keywords used in the Literature Search*

Health Technology Assessment, HTA, Product Labeling, Appropriate, LMIC, Healthcare, Sustainable Marketing, Contextual Design, Barriers, Challenges, Incentives, Health Technology Management, MedTech Industry

Table 2: *Alternate Keywords used in the Literature Search*

Since the study focused on the healthcare domain, Scopus and Pubmed were used initially for the literature search. Since most of the relevant literature was overlapping in both databases, Scopus was used as the primary search platform for the later stage of research. Apart from these databases, Google Scholar was used to find related articles, conference papers, books, and other grey literature related to the topic. In order to include all aspects of the research question in the search results, some alternate keywords and synonyms were also included which helped in gathering useful documents. These are listed in the *Table 2*.

The concepts were combined using **'AND'** and **'OR'** commands. The **'AND'** command was used to narrow the search and the **'OR'** command was used to find related searches. After many iterations and using alternate keywords, the final search resulted in 89 documents. The final search string used was the following:

TITLE-ABS-KEY((“medical device*” OR “medical equipment” OR “health technolog*”) AND (regulation* OR label* OR certification) AND (lmic* OR “low and middle-income countr*” OR “developing countr*” OR “low resource setting”))

The results were further screened for title, abstract and full text to find the eligibility for final selection. The detailed selection process is shown in *Figure 4*.

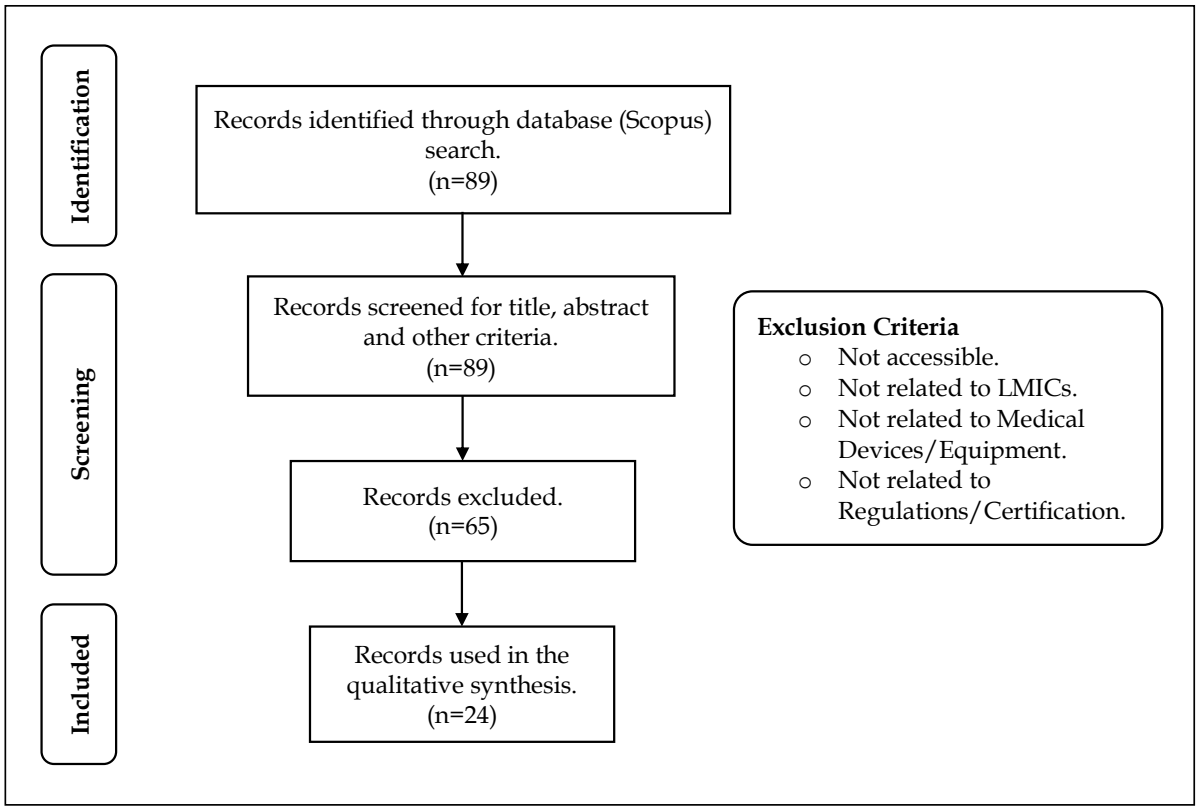

Figure 4: *PRISMA flow-chart of the literature search (Moher et al., 2009)*

After screening the records and applying the exclusion criteria, 24 articles were finally found relevant to this study. The overview of the articles used for the qualitative synthesis is given in Table 3.

Sl.No	Article	Purpose
1	(Banta, 1984)	Addresses the poor assessment of medical technology in Latin American countries.
2	(Barlow & Stuckler, 2021)	Analysis of all the trade challenges to national health regulations based on the dataset developed by WTO health.

3	(Freeman, 2004)	Highlights the current progress and future plans of the GHTF in developing guidance documents for developing countries.
4	(Cordero, 2014)	Evaluating the life-cycle challenges of medical devices designed for developing countries.
5	(Dacombe et al., 2019)	Analysis of the emerging regulatory landscape and perceptions of key stakeholders in three LMICs.
6	(Dang & Sharma, 2019)	Presents the economics of the medical device industry in a developing country.
7	(Di Pietro et al., 2020)	Presents and validates a framework for assessing healthcare facilities in low-resource settings.
8	(Eze, Ijomah, & Wong, 2019)	Provides and validates a definition for medical equipment remanufacturing that could be used to increase access to functional medical equipment in developing countries.
9	(Gauthier, Cruz, Medina, & Duke, 2013)	Determining the design factors for medical devices designed specifically for developing countries.
10	(Hanafy, Yu, & Jin, 2009)	Presents the analysis of the mode of entry for cardiac rhythm management devices in a developing market.
11	(Heimann, 1994)	Explains the role of HTRG in supporting health technology management in Sub-Saharan African countries.
12	(Houngbo et al., 2008)	Investigates the factors causing the mismanagement of healthcare technology in a Sub-Saharan African country.
13	(Hubner et al., 2021)	Summarizes of the state of medical device regulation in the 14 member countries of the COSECSA and South Africa.
14	(J.-H. S. Chen, Kou, & Lee, 2006)	Presents the safety issues of medical devices in developing countries.
15	(Maccaro et al., 2022)	Focuses on MDR and its applicability in LMICs, specifically presenting the case of a Sub-Saharan African country.
16	(McDonald, Fabbri, Parker, Williams, & Bero, 2019)	Assessment of compliance of medical device donations with WHO guidelines in LMICs.
17	(McNerney, 2015)	Presents the poor infrastructure and the development challenges in healthcare systems at LMICs.
18	(Morin, Bazarova, Jacon, & Vella, 2018)	Presents the perspective of manufacturers on WHO prequalification of IVDs.

19	(Mori, Ravinetto, & Jacobs, 2011)	Investigates the quality of medical devices and in vitro diagnostics in resource-limited settings.
20	(Newton et al., 2010)	Evaluating the issues with healthcare technology management in developing countries.
21	(Piaggio et al., 2021)	Presents the design and technical validation of a mobile app aimed to perform smartphone-based pupillometry, suitable for use in LMICs.
22	(Reddy, Gosavi, & Kale, 2013)	Evaluating the quality standards of medical devices and the need to develop it from the perspective of a developing country.
23	(Thangavelu, Pillay, Yunus, & Ifeachor, 2008)	Explains the development and implementation of international standards in the medical devices regulations in Malaysia.
24	(Wiysonge, Abdullahi, Ndze, & Hussey, 2016)	Assessing the effects of public sector regulation, training, or co-ordination of the private for-profit health sector in LMICs.

Table 3: *Overview of articles used to identify the knowledge gap*

2.2 Knowledge Gap

The literature review provided an overview of health technology management and medical equipment procurement practices followed in developing countries. The above articles can be categorized into two subtopics; [1] The development, utilization, and management of medical equipment designed for LMICs, [2] Current regulatory systems, guidelines, quality and safety assessment related to the medical devices supplied to LMICs. Hence, these two topics are elaborated in the following sections. The above articles have laid focus on the poor health technology management and assessment of equipment entering LMICs. A few of them have proposed implementing contextualized design to the medical equipment as a solution to mitigate the inappropriateness of products supplied to LMICs. However, none of the literature has analyzed this problem and possible solutions from a manufacturer's perspective. This leads to the knowledge gap which is to identify the incentives for medical equipment manufacturers to comply with contextualized design requirements (such as standards defined by AME label) for their products supplied to LMICs. Section 2.2.3 that concludes this chapter will elaborate on the knowledge gap thereby found from the literature review.

2.2.1 State of Medical Equipment in LMICs

Medical equipment are an integral part of many life-saving situations and is essential to provide quality healthcare services. However, they pose several challenges in developing coun-

tries that have scarce health assessment practices and poor regulatory control over the importation and use of substandard medical equipment (Thangavelu et al., 2008). Currently, the accessibility of medical equipment to patients and healthcare providers in LMICs is a pressing issue. The situation arose mainly due to economic challenges such as lack of funds and high importation cost of medical equipment. If this was the primary and sole issue, donations from HICs could have served as a viable solution. But, there are other technical challenges that emerged subsequently (Di Pietro et al., 2020). WHO estimated that LMICs have 80% of their medical equipment donated from HICs and only 10-30% of those were operating (Di Pietro et al., 2020). Lack of specialized personnel, maintainability issues, poor health technology management system, and inappropriate design for the harsh environmental conditions hinder the safe and efficient operation of medical equipment in these countries (Di Pietro et al., 2020; Piaggio et al., 2021). Manufacturers, entrepreneurs and social enterprises are keen on designing innovative medical equipment that are presented as a solution to meet the unmet needs of the healthcare system. However, many of these initiatives fall short of addressing crucial concerns like local regulations, cultural acceptance, distribution, and post-sale assistance, rendering them useless for users in the low-resource settings (Cordero, 2014).

Management of medical equipment in LMICs hospitals encounters regular challenges. This includes lack of spare parts and consumables, unreliable main power supplies, instruction manuals in foreign languages, differences in temperature or application conditions that are significantly different from the time of its development, and technical staff with inadequate training on medical equipment (Maccaro et al., 2022). As mentioned above, donated medical equipment to LMICs poses several technical challenges, mainly because of the fact that they are manufactured and designed in HICs. The equipment has undergone good manufacturing practices, designed for international standards and minimum operational requirements, optimized for well-structured facilities, and designed for a clean, sterile, climate-controlled environment with consistent electricity, and expert healthcare staff (Di Pietro et al., 2020). These equipment when imported to low-resource settings are exposed to extremely different conditions (high temperature, humidity, dust, poor infrastructure, and lack of trained equipment operators). Consequentially, it becomes inappropriate for such settings and causes constant failure, demanding maintenance requirements that are unmet and finally exacerbating the usability or operational issues of equipment (Di Pietro et al., 2020). Donors of medical equipment may not always prioritize providing sufficient training to healthcare workers. This results in equipment remaining unused, ultimately causing storage challenges and equipment graveyards in hospitals (McDonald et al., 2019). An overview of the challenges for the healthcare technology management cycle in the LMICs hospital is shown in the *Table 4*.

Categories	Factors
Policy, Planning and Budgeting	• Lack of awareness of healthcare technology management issues • Lack of effective and efficient maintenance planning • Lack of sufficient annual maintenance budget allocation
Technology Assessment	• Lack of equipment assessment • Lack of implementation of asset management tools (e.g., software)
Procurement	• Insufficient involvement of equipment end users into the device acquisition process • High medical equipment acquisition cost through public procurement • Ineffective planning and inappropriate device procurement
Distribution	• Unequal and inappropriate distribution of devices within the healthcare facilities • Inappropriate technology for site, size, capacity of healthcare facilities
Use	• Lack of continued training and misuse of equipment • Lack of equipment use manual
Maintenance and Repair	• Lack of availability of equipment spare parts • Lack of equipment service manual • Lack of preventive maintenance of the equipment • Lack of resources (financial, material and human) for implementation of maintenance activities

Table 4: *Factors affecting the healthcare technology management cycle in LMICs hospitals (Houngbo et al., 2008)*

2.2.2 Regulations for Medical Equipment in LMICs

There is a significant economic and technical challenge to manage imported medical equipment in LMICs, especially in sub-Saharan African countries. Unlike developed countries, these countries lack a regulatory system to monitor the equipment donated by HICs. EU, USA and Japan have clear standards, homogenous technical knowledge, harmonized regulations and trade agreements to ensure the safety, quality and efficacy of medical equipment circulating among their hospitals/countries. As a result, the challenges in LMICs are often neglected by equipment designers and regulators who consider the contextual condition of HICs as standard for design and manufacturing medical equipment (Maccaro et al., 2022). Stringent regulatory authorities (like US Food and Drug Administration [FDA] and Conformité Européenne [CE]) are established in developed countries to regulate medical equipment entering their healthcare market. Unfortunately, there are no regulatory authorities in LMICs to enforce rigorous standards for medical equipment reaching the patient group and healthcare

providers. The lack of stringent regulatory control has made it challenging for the healthcare sector in low-resource settings to access quality-assured and appropriate medical equipment (Morin et al., 2018). Regulations in medical equipment are essential to ensure access to quality, safe, efficient and effective equipment and improve the public health outcome (Maccaro et al., 2022). Certification and standardized procurement practices are common and mostly followed by industrialized countries with existing regulatory frameworks (Newton et al., 2010). The *Figure 5* shows the distribution of countries with regulatory control for medical devices.

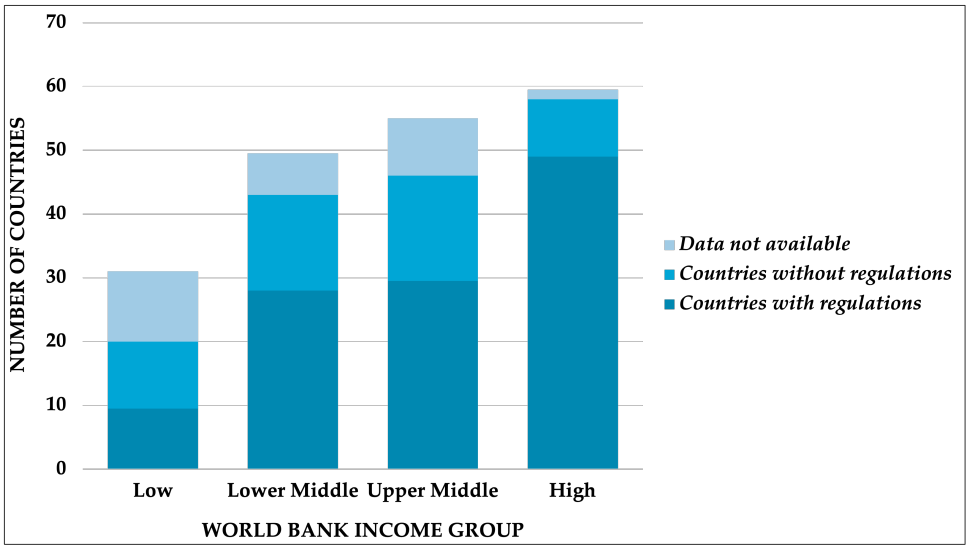

Figure 5: *Number of countries with legal framework for Medical Devices by income group (Maccaro et al., 2022)*

The lack of an appropriate regulatory control system in most resource-limited countries exposes them to the risk of low-quality medical products (Mori et al., 2011). Many countries are realizing this gap and taking measures to establish a quality control system that can reduce the chance of nonconforming products entering their market, and ensure safety, efficacy and consistency in the quality of products throughout their lifespan. Regulatory standards and certification are principal elements to confirm the safety and performance of medical equipment - conformity to product, process and management standards. Such regulatory measures can also prevent the dumping of substandard and defective equipment in hospitals of LMICs (Thangavelu et al., 2008). Medical equipment imported through donations can be made more effective by developing a checklist for both recipients and donors to evaluate compliance against WHO guidelines, ensure local availability of spares and consumables, and appropriate resources to train the healthcare operators to use and maintain the donated equipment (McDonald et al., 2019).

2.2.3 Conclusion

The literature review helped to identify the knowledge gap which is to find the incentives for medical equipment manufacturers in adhering to contextualized design requirements (through standards such as AME). Findings from the literature indicated the need for strict regulatory

oversight of medical equipment entering LMICs, especially sub-Saharan African countries. Labels based on contextualized standards can improve the quality of healthcare technology being supplied to these countries. Therefore, a more comprehensive regulatory control system like a contextual-specific product label (such as AME) can ensure medical equipment meet the design and usability requirements of LMIC standards. This label can tend to close the gap between manufacturers and users of medical equipment with the ultimate goal to let users benefit from equipment fit for their purpose and setting. The quality, safety and effectiveness of medical equipment in these countries are depended on its availability, affordability, accessibility, adequacy, and appropriateness (Maccaro et al., 2022). However, medical equipment manufacturers are the ones who are obligated to comply with these regulations, which inevitably incur them costs in terms of time, finances, resources, and other related factors. The benefits for manufacturers investing in LMIC-specific standards or labels for their medical equipment have not been the subject of any studies hence no scientific literature is available. Therefore, the challenge of this research is to identify the incentives that will encourage medical device manufacturers to adopt new certifications or product labels that have standards adhering to the condition and requirements of developing countries or LMICs.

3 Methodology

While Chapter 1 provided an overview of the research objectives and questions, the purpose of this chapter is to provide a thorough explanation of the research methodology and justifies the design choice. Additionally, acknowledging the importance of a comprehensive real-world evaluation, this study will incorporate a case study conducted in collaboration with an organization targeting the LMICs market. The details of this case study interviews and the subsequent validation methods used in different stages of research will be discussed in this chapter. The ultimate aim of this chapter is to provide insight into the interconnectedness between the research approaches, the different methods employed, and the sub-questions answered in this study.

Section 3.1 presents a schematic representation of the research methods, activities, and their link to each sub-questions. It helps to give an overview of the research flow and structure of this report. Section 3.2 provides a detailed description of the different methods used to answer each sub-question. This section also provides a detailed examination of the triangulation method employed, encompassing the data collection methods and protocols followed at different stages of the research.

3.1 Research Flow and Structure

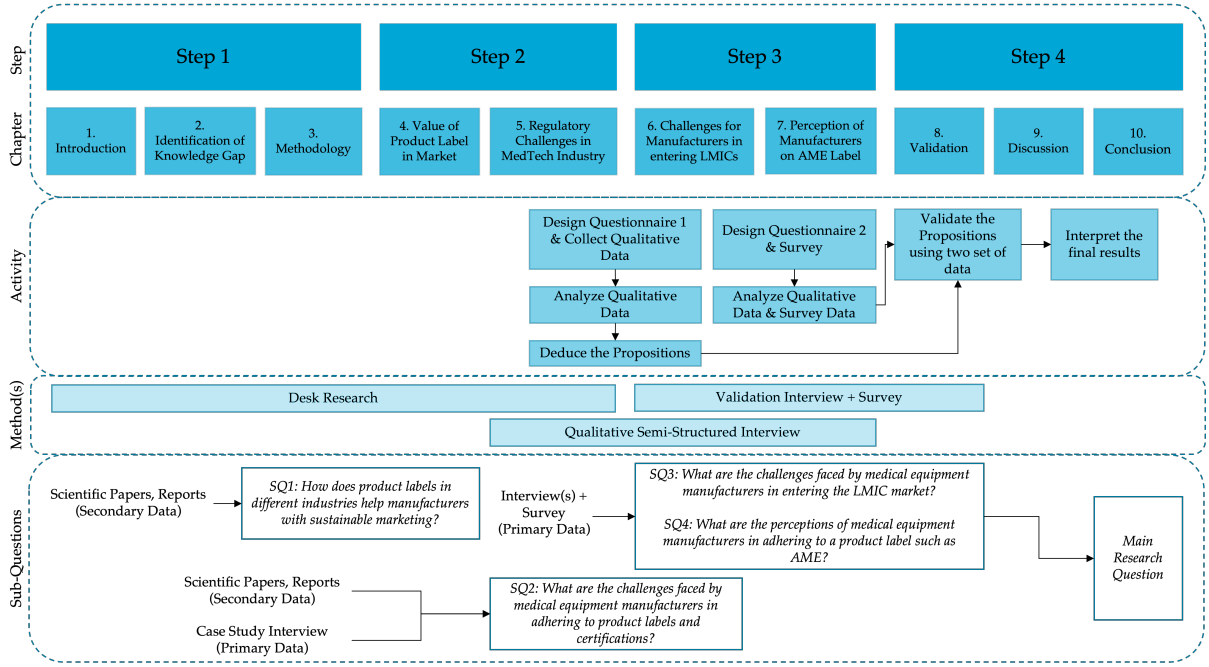

Figure 6: *Research Flow Diagram*

This study will follow an *exploratory research* approach. An overview of the different steps in the research, the activities of the research approach, and the methods used to answer the

sub-questions are shown in the research flow diagram in *Figure 6*.

3.2 Methods in Sub-Questions

Throughout this study, multiple research methods have been used at different stages to provide a comprehensive analysis. This section will elaborate on the different methods used in the research along with their aim and how they helped to answer each sub-questions. The four main research methods used are summarized in *Figure 7*.

Figure 7: *Research Methods*

3.2.1 Method Triangulation

Qualitative approaches to data gathering are often used in *exploratory research*. This can be from focus groups, interviews, case studies, or informal discussions with employees, managers etc (Sekaran & Bougie, 2016). Data obtained in the form of words are called *qualitative data*. They are generated from the broad answers to questions in interviews, or from responses to open-ended questions in a questionnaire, or through observation, or from already available information gathered from various sources such as the Internet. The aim of analyzing qualitative data is to make inferences from often a large amount of collected data (Sekaran & Bougie, 2016). To generate a comprehensive understanding of the phenomenon, the technique of *Triangulation* is used in this qualitative research where multiple methods or data sources are used. Triangulation is considered a qualitative research strategy to test validity by bringing together data from different sources (Carter, 2014). There are four types of triangulation and *Method Triangulation* is used in this research, which generally involves data collection and analysis from methods such as interviews, observation, and field notes. However, data collected in this research are mainly from desk research and interviews which were converged to find useful information related to the topic of interest. The desk research has used a literature study which is discussed in detail in section 3.2.2. The interview was conducted in two stages - the former for preliminary findings and the latter for validation. The details of the interviews are explained in section 3.2.3.

3.2.2 Desk Research

Desk research is used to answer sub-questions 1 and 2 partly. This section explains the appropriateness of desk research and the scientific approach followed to answer sub-questions 1 and 2.

The first sub-question (SQ1) is focused on understanding the role of product labels in different industries. The goal is to understand the strategic use of product labels by manufacturers in connecting to consumers. It also aims to find the perceived use of product labels by consumer groups in influencing their purchasing behavior. Hence *desk research* is chosen as the research method to answer this sub-question. Scientific papers, research articles, and grey literature are used to gather the secondary data. Online platforms used are *Scopus* and *Google Scholar*. For the scope of answering this sub-question, three industries are selected from a pool of industries where product label is relevant to both manufacturers and consumers. A detailed explanation of the *Search Description and Selection Criteria* is given in the subsection below. Correlating the findings of this sub-question to the AME label gives an initial idea of how the label will be valued in the market as well as its use as a strategic marketing tool by manufacturers.

- ***Search Description and Selection Criteria***

  The keywords related to the first sub-question are product, labeling, certification, product label, social, environment, sustainability, industry, and manufacturer. Therefore, the following search string was applied in Scopus.

TITLE-ABS-KEY (product AND (label* OR certification) AND (sustainab*) AND (industry OR manufacturer))

  This search resulted in 283 documents with open access. The exclusion process began with screening based on the year of publication. It was noted that there were not any significant publications related to product labeling in any industry before 2002, hence the search was limited to 21 years. Further screening of documents based on title and abstract was done excluding documents not related to product labeling, manufacturer or industry-specific and sustainability. The final search resulted in 94 documents. A general overview of the search result indicated that product labeling has been existing and has been widely applied in practice by consumers and manufacturers in industries such as the food and beverages industry, aquaculture industry, building and construction industry, clothing and textile industry, cosmetics and fashion industry, and wood industry.

  To analyze the application of product labels by manufacturers, the study was limited and focused on three industries among the above. They were the food and beverage industry, the clothing and textile industry, and the cosmetics and personal care industry. All three industries involve the production and sale of consumer goods where quality and safety are of prime importance. Also, the competitiveness of each industry is highly dependent on the brand value of the products and marketing techniques deployed by manufacturers, hence these industries were found relevant for the study. The detailed selection process is shown in *Figure 8*.

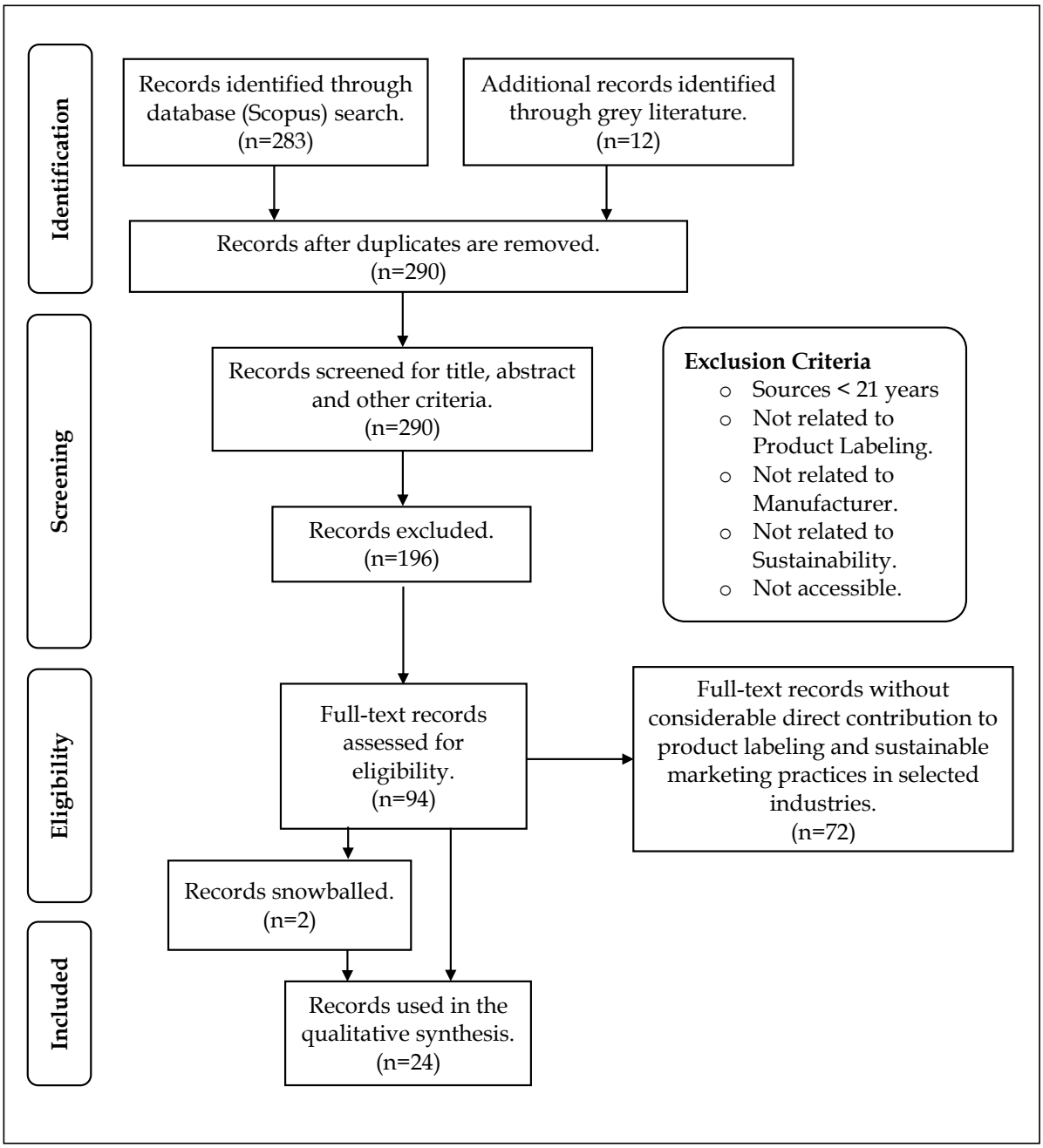

Figure 8: *PRISMA flow-chart of the literature search (Moher et al., 2009).*

The second sub-question (SQ2) aimed to understand the general challenges faced by medical equipment manufacturers in the process of undertaking any certifications or labels related to medical equipment. The sales and manufacturing of healthcare technologies are bound to different regulatory norms. Hence manufacturers of all sizes face several roadblocks in getting their products approved by respective authorities. A combination of desk research and expert interviews was used as the research method to answer this sub-question. Scientific papers, research articles, and grey literature (e.g., WHO reports) are used to gather the secondary data. *Scopus* and *Google Scholar* were the primary sources used for data collection. To gain more insights and weigh the practical relevance of different challenges found in the literature, the research relied on expert interviews at a later stage. It is expected that manufacturers may

face some of these challenges while adhering to the AME label as well.

3.2.3 Qualitative Semi-Structured Interview

This section explains the appropriateness of interviews as a research method in answering sub-question 3 and 4. A detailed explanation of the case study selection and the protocols of the interview are also given in the subsections.

The third (SQ3) and fourth (SQ4) sub-questions are focused on getting an overview of the challenges faced by medical equipment manufacturers in entering LMICs and their perspective on the concept of AME label respectively. The goal of these two questions is two-fold. The first is to find the challenges (in design, regulatory, sales, and after-sales support) for manufacturers in designing and supplying their equipment to LMICs. The second is to understand the perception of manufacturers on the AME label, its mission, value propositions, and the expected challenges in adhering to or adopting it. The research method used here was a qualitative semi-structured online interview with medical equipment manufacturers whose business focus is on LMICs. Semi-structured interviews are done to collect exploratory data from key informants who have professional experiences and perceptions related to the topic. The findings from the semi-structured interviews can be triangulated with other data sources, thereby validating to get meaningful results (DeJonckheere & Vaughn, 2019). This mode of interview provides the opportunity to include open-ended and spontaneous questions. It allows participants to openly express their opinion on the subject of discussion (Adams, 2015). They can be guided in certain directions by asking sub-questions. Hence, semi-structured interviews provide the flexibility to ask questions that are not pre-defined. This is particularly useful when participants have different expertise (Adams, 2015).

Qualitative research is one in which the analysis is based on the information that is expressed through language and behavior in a natural environment. Examples of qualitative data collected are interview notes, transcripts of focus groups, transcriptions of video recordings, answers to open-ended questions, etc (Sekaran & Bougie, 2016). This study has used a *Case Study Interview* to answer the sub-questions. In research, case studies are used to collect information about a real-life situation or problem from an organization or particular business unit. It provides the advantage of getting multiple perspectives of the situation and helps in obtaining a better picture of the problem of interest (Sekaran & Bougie, 2016). The findings from the case study are formulated into propositions. These propositions are later validated through interviews and survey. A detailed explanation of the case study interview and the procedure and protocols followed for expert interviews are given below.

- ***Case Study Interviews***

  Delft Imaging was the company selected to conduct a case study for this research. They are a medical equipment manufacturer based out of the Netherlands and have business targeted to LMICs. They are specialized in tuberculosis (TB) screening and provide medical equipment ranging from portable to mobile X-ray systems in over 40 LMICs. They

also provide innovative diagnostic solutions like artificial intelligence (AI) software to detect tuberculosis, cardiomegaly, etc. The selection of this company for the case study was due to three main reasons. Firstly, the organization has rich experience in doing business in more than 60 LMICs. This ensures their knowledge of designing, manufacturing, regulatory assessments, procurement, sales, and service processes (and all associated challenges) that come with the supply of medical equipment to LMICs. Secondly, they are certified by recognized bodies for their high-standard practices in business, social and environmental aspects (DelftImaging, 2023). This is an indicator of their willingness to consider investing in a label that is designed with the ultimate aim of improving the well-being of the inhabitants of LMICs. Lastly, the organization has a successful track record of collaborating with TU Delft on different academic projects. Therefore, considering the relevance of the organization in the context of this study, their experience with successful projects in the LMIC context, the right ethical and social outlook, and their willingness to cooperate and access to relevant stakeholders justify the selection of Delft Imaging for the case study.

- ***Expert Interviews***

  For the purpose of better understanding the challenges for manufacturers in entering LMICs and their general perception of the AME label, semi-structured interviews were conducted with medical equipment manufacturers. All the interviews were conducted in an online mode. An online interview gives the advantage of scheduling interviews and completing them in a relatively short period of time. This mode of the interview eliminates any feeling of discomfort for the respondents in facing the interview (Sekaran & Bougie, 2016).

  Two stages of expert interviews were conducted throughout the research; case study and validation. As discussed above, a case study interview was conducted with four manager-level employees from Delft Imaging. They have different roles and responsibilities in their business related to LMICs. This allows an in-depth understanding of the challenges in various stages of the product life cycle, i.e., quality control/regulatory challenges, product development/design phase challenges, project implementation challenges, training and capacity building, and the business and marketing aspects. Throughout the research, all participants were approached via one employee who served as the central point of contact with the organization. The questionnaire was developed with the support of findings from the literature study and the inputs from the AME team. Questionnaire 1 along with the prompts used in this interview is given in Appendix A. Since this is qualitative research, it is of utmost importance to validate the findings and convince the readers about its accuracy (Creswell, 2014). A validation interview was conducted in the later stage with five manager-level employees and one academic expert, all from different parts of the world. The complete list of participants interviewed in this research along with their role in the organization is given in the *Table 5*. Questionnaire 2 for this validation interview was developed based on the findings deduced from the case-study interview. The questionnaire along with the prompts used in this validation

interview is given in Appendix B.

Interviewee No. / Code	Study Phase	Company / (Country)	Function
P1	Case Study	1 / (NL)	Business Unit Director
P2	Case Study	1 / (NL)	Quality Assurance Manager
P3	Case Study	1 / (NL)	Operations Manager
P4	Case Study	1 / (NL)	Project Manager
E1	Expert Validation	2 / (VNM)	Business Director
E2	Expert Validation	3 / (USA)	Director of Market Strategy
E3	Expert Validation	4 / (USA)	Vice President, Global Health
E4	Expert Validation	5 / (UK)	Training and Innovation Head
E5	Expert Validation	6 / (NZ)	Global Partner Manager - Africa
E6	Expert Validation	TU Delft / (NL)	Associate Professor at Faculty of Industrial Design and Engineering

Table 5: *Full list of persons interviewed throughout this research*

- ***Ethical Considerations & Interview Protocols***

  This section discusses how the interview was conducted and what protocols were followed prior to the interviews. Since this research involved human participation as a source of data collection, it was important to ensure that the research is conducted without causing any undue harm or disproportionate risk to the human research subjects. Hence a risk assessment and mitigation plan was developed by consulting the Data Steward at TU Delft. As part of this, both the consent form and data management plan were developed before the interviews. All the interviews and their transcripts were recorded for future reference during the research period. Hence a consent form was required to inform the participants about the anonymization and usage of data in the research. On the other hand, the data management plan was developed to ensure the confidentiality of the data collected, i.e., the ownership, intellectual property rights, sharing, and storage of data. These documents were submitted to Human Resource and Ethics Committee (HREC) for approval. Once approved, the informed consent form along with the interview questionnaire was sent to the participant two days before the interview. The interviews were conducted after receiving the signed informed consent form from the participant.

- ***Data Analysis***

  According to Sekaran and Bougie (2016), analysis of qualitative data is done through three main steps: (1) Data reduction, (2) Data display, and (3) Drawing conclusions. Among the three, the most important step in the analysis is data reduction. This is done

through coding and categorization of the collected data. Coding is the analytical process that involves reducing, reorganizing, and integrating qualitative data to generate theory. The purpose of coding is to help derive meaningful conclusions from the data. Codes serve as labels assigned to units of text, which are subsequently grouped and classified (Sekaran & Bougie, 2016). Categorization is the process of organizing, arranging, and classifying coding units (Sekaran & Bougie, 2016). The software ATLAS.ti was used to analyze qualitative data for qualitative research. This tool helps to conduct a *thematic analysis* of the qualitative data collected by generating codes and categorizing it. Codes and categories can be developed both inductively and deductively. However, this study has used a mix of inductive and deductive coding. All the themes related to the challenges and opportunities for manufacturers in entering LMICs and the perception of manufacturers towards AME label were reduced through inductive coding. All the themes related to the challenges and procedures in the regulatory approval process were reduced through deductive coding since some of the codes for this category were already formed based on the literature study. These codes are grouped into categories which are manually analyzed to draw conclusions that helped to answer sub-questions 3 and 4.

3.2.4 Survey

As discussed above, the findings from the case study interview (framed as propositions) are validated through interviews and survey. A survey is a commonly used system in exploratory research to collect data from people to describe, explain or compare their knowledge, behavior, and attitude (Sekaran & Bougie, 2016). Here, a quantitative survey is used, which is commonly used to collect quantitative data such as demographic data, satisfaction rating, sales/production figures, etc (Sekaran & Bougie, 2016). The survey used in this study was designed for participants from organizations of different sizes/academic institutes, globally distributed and having a business presence/research interest in LMICs. The targeted sample population had manager-level experts with professional expertise in Sales, Marketing, Business Development, etc, and academic experts from the university having research experience in the topic of this study. Due to the requirement of subject-specific respondents, the survey was distributed to the participants through e-mails, and not openly circulated through any online platforms. The sample of non-academic participants for both interview and survey was provided by the AME team with the help of their professional relations in the industry. In the survey, participants were asked to express their agreement with the propositions and their perception of the AME label using a 5-pointer likert scale. The survey form used in this study is given in Appendix C.

4 Value of Product Labels in Market

This chapter aims to provide a comprehensive understanding of the role and significance of product labeling in consumer markets. The discussion centers around three industries where quality and safety of goods are of utmost importance. The research method used in this chapter is previously explained in section 3.2.2 and presented in *Figure 6*. The findings derived from the literature review provide valuable insights into the role of product labels across various industries and their significance for manufacturers in adopting sustainable marketing practices. This chapter is concluded by addressing sub-question 1.

The findings from the desk research are discussed in section 4.1. This section explains how product labels are used by manufacturers as a strategic tool to communicate and express their business values to consumers in order to create brand value and capture the market with examples. Later, section 4.2, gives an understanding of sustainable marketing and its importance for manufacturers in maintaining a balance between their business objective and the future development of their operating ecosystem. Finally, this chapter concludes by answering sub-question 1, which is given in section 4.3.

4.1 Product Labeling

Consumers worldwide are increasingly laying emphasis on concepts like safety, health, and environmental protection. As consumer groups are focusing on issues of "greenism" and sustainable development, certification labels have become an important and reliable tool in deciding their purchasing behavior (Chang & Chen, 2022). Labels are generally defined as any text that appears on packaging, documents, notices, boards, or collars and that refers to or describes a product (Koszewska, 2015). This includes words, details, trademarks, brand names, pictures, and symbols (Koszewska, 2015). The labels are displayed in a way that is easy to process, thereby increasing the odds of consumers utilizing a piece of information (Bui, D. Kaltcheva, Patino, & C. Leventhal, 2013). Businesses use social and environmental labels as a tool to share information related to social and environmental aspects involved in their procurement, manufacturing, and supply chain stages. Applying product labels is an approach to inform consumers about the making of products and assist them in making choices matching their standards of environmental and social responsibility (Koszewska, 2015). Product labeling gives information about specific characteristics of products that are generally inaccessible and unobserved by consumers. Labels can act as a reliable and credible source of information given their systematic and structured implementation (Catrina, 2020). The significant role of labels as a source or outlet of product information has been supported by many researchers (McEachern & Warnaby, 2008). One of the recent developments in industries regarding labeling communication is the implementation of value-based labels, which are also commonly known as 'eco-label', 'quality-assurance label', and generic 'green' labels. These labels are intended to convey value-laden information about the product process and quality, thereby evidently expressing

product superiority. Ultimately, consumers' knowledge of value-based products is a vital component for success in today's competitive market (McEachern & Warnaby, 2008). Hence, labels awarded from recognizable certification bodies will help manufacturers to communicate their brand value and express the integrity, ethics, and sustainability of their product. The following section looks into the existing product labels across different industries. The industries selected for this purpose are the food and beverage industry, the clothing and textile industry, and the cosmetics and personal care industry. The detailed selection procedure and the underlying reasoning are explained in section 3.2.2. Among the final articles selected, Chang and Chen (2022), Koszewska (2015), and Bozza, Campi, Garelli, Ugazio, and Battaglia (2022) provided a detailed discussion of different labels in food and beverage, clothing and textile, and cosmetics and personal care industries respectively. Hence, these references will be frequently cited under the respective sections in the following discussion.

4.1.1 Food and Beverage Industry

Ensuring food safety has become a growing challenge for businesses in this globalized economy. Sourcing of technology and ingredients from business partners across boundaries has increased the complexity and chances for errors, which has led to potential harm in the food industry (Yeung & Robert, 2018). There has been a continuous increase in food safety issues for the last five years. This situation has limited the public to purchasing natural and organic food instead of delicate and delicious food (Chang & Chen, 2022). Food contamination accidents such as those related to BSE and POPs are widespread in Europe in recent decades. The adoption of controversial food technologies such as GMOs, the use of artificial ingredients, additives, and colorants such as E133 have raised consumer concerns about the adverse health effects of the food system. Such concerns have motivated consumers to purchase food products that are more respectful of human health and the environment (Chang & Chen, 2022). As the demand and business opportunities for healthy food increase, businesses often adopt the phenomenon of mislabeling in the market which is further worsening the situation by affecting the health and right of consumers. This has made consumers skeptical about different claims made by businesses, creating the necessity for clear and reliable product information (Chang & Chen, 2022).

Therefore product labeling in the food and beverage industry is considered as a tool to share food- and health-related information in a transparent manner. Apart from providing relevant information, manufacturers use labels as a strategic communication tool to awaken consumer emotions and motivate their purchasing behavior. Labels have become important for generating sustained consumer loyalty and an instrument for charging a premium price by businesses (Dressler & Paunovic, 2021). Some of the commonly used labels in the food and beverage industry are:

- ***Clean Label***: A 'Clean Label' product is one that is positioned as "organic", "natural" (i.e., following a natural production process), and/or "free of" artificial ingredients or additives (Chang & Chen, 2022). Nevertheless, 'clean label' food products are attributed to

the presence or absence of particular ingredients in food such as additives and preservatives. It has been found that the presence of a 'clean label' on food products has increased the consumer's willingness to pay, implying a growing market for the 'clean label' food products (Chang & Chen, 2022).

- ***Allergen Label***: Food allergy is a common health issue in many industrialized countries and it is essential for the food industry to manage them. An 'Allergen Label' on food products is an indication of the allergens present in the food products so that consumers can take informed decisions about the level of risk they can take without having to give up their food preferences (Yeung & Robert, 2018). This is an important label, especially for consumers having a food allergy who rely on accurate allergen labels on packaged food they intake. The label can keep consumers safe by informing them to avoid potentially allergenic food products (Yeung & Robert, 2018).
- ***Eco-Labeling***: With the increased consumer awareness, the industry is shifting its focus towards more sustainable products and practices. This transition has enabled the introduction of eco-labeling. The label has been used to sell greener products by informing consumers of certain product attributes. Eco-label for food products primarily targets the agricultural sector of the food supply chain with a focus on promoting organic farming (Miranda-Ackerman & Azzaro-Pantel, 2017). Product eco-labels tell the consumer about steps made by the manufacturers in reducing the environmental impact of the product, thereby providing greener products that consumers value differently than traditional ones (Miranda-Ackerman & Azzaro-Pantel, 2017).

Businesses approach product labels as a marketing tool to communicate the health, safety, and environmental friendliness of their product. Along with satisfying the needs of the general public, manufacturers who implement these labels in a systematic and transparent way can influence consumers' purchasing intentions and win their confidence in the product (Chang & Chen, 2022). A consumers' purchasing intention is directly connected to their product knowledge. Educating consumers on the importance of labels is a way to strengthen their marketing strategy. Spreading the concept of label, not only help the consumer choose the right products but also eliminate the uncertainty of new products. The outcome can boost the market for food businesses and raise consumers' buying intention (Chang & Chen, 2022). Businesses can introduce a series of labeled products to gain an advantage of the consumer's trust in the brand and increase publicity (Chang & Chen, 2022). Also, brand managers can utilize these labels as a powerful brand communication tool by aligning the food product portfolio for higher recognizability and reducing information overload for consumers (Dressler & Paunovic, 2021).

4.1.2 Clothing and Textile Industry

The clothing and textile industry is one of the longest, complicated, dispersed, and worldwide supply chains. When compared to other industries like food, the manufacturing processes of the clothing and textile industry are less transparent (Koszewska, 2015). All this has created an

ambiguity and problematic state in understanding and defining the sustainability of textile and clothing products (Koszewska, 2015). Consumer interest in environmentally friendly, or more broadly, sustainable products, has increased recently. Textile and clothing products play a significant role in this trend (also known as eco-consumption, green consumption, or sustainable consumption) (Koszewska, 2015). Although sustainability is widely connected to the environment, it is important to address its social and economic inclinations. Accounting for the social component, sustainable clothing and textile product are those manufactured in good working condition, free of child labor, and in accordance with fair trade standards. Currently, there is an asymmetry in the information between producers and consumers (Koszewska, 2015). This is evident from the fact that consumers lack knowledge and awareness regarding the level of sustainability in the product or the environmental performance of the business. A solution to minimize this asymmetry of information is to systematically introduce third-party-certified labels which can express the credible environmental and social characteristics of the product and manufacturer (Koszewska, 2015). Clothing industry can cause a great deal of environmental damage, mainly due to high chemical usage throughout its manufacturing process, hazardous solid waste generated and discharged, and greenhouse gas emissions. In the modern economy, sustainable production and consumption are some of the key attributes influencing the buying behavior of consumers. Therefore textile ecolabeling plays an important role in providing consumers the opportunity for informed decision-making while purchasing clothing products (Ranasinghe & Jayasooriya, 2021). Some of the commonly used labels in the clothing and textile industry are:

- ***Oeko Tex Standard 100***: STANDARD 100 label (certified by OEKO-TEX) on any textile product ensures that every component of the product including every thread, button, and other accessories, are tested for harmful substance and guaranteed harmless for human health (OEKO-TEX, 2023a). Transparency is the key to sustainable products. This label gives confidence to the consumers regarding the health and environmental friendliness of the product. The label also provides insights about the manufacturing details of the products such as how and where it was made (OEKO-TEX, 2023b).
- ***Fair Trade***: Fair Trade label in the fashion industry was introduced to address and prevent the exploitation and underpaid situation of people who work in the industry. Fairtrade clothing is clothing that was made with the best interests of the workers, under strict guidelines and ethical standards (Moorhouse, 2022). The fair trade movement in the fashion industry set guidelines for the manufacturers that ensure ethical working conditions and fair pay for factory workers. Manufacturers following such practices are granted the Fair Trade Label (Moorhouse, 2022).
- ***Eco-Label***: Eco-labeling is a tool that proves the environmental friendliness of a clothing product and helps consumers to make informed decisions on their purchase (Ranasinghe & Jayasooriya, 2021). The process of eco-labeling ensures that the manufacturers will meet all requirements of the label before certifying their product as "green". Some concepts associated with the eco-label are eco-friendliness, environmental safety,

biodegradability, recyclability, ozone-friendliness, and low energy consumption (Ranasinghe & Jayasooriya, 2021).

For manufacturers in the clothing and textile industry, labeling is a way to increase the environmental standards of their products and services in the market. Labels can help reduce the environmental and social impacts of textile and clothing companies, such as reducing water usage, reducing waste and emission volume, replacing toxic chemical processes with earth and human-friendly processes, controlling disposal and adopting recycling manufacturing processes, and providing good working conditions respecting the fair trade rules (Koszewska, 2015). Manufacturers can use these labels to provide consumers with desirable information and thereby increase their market efficiency. Apart from being an information policy instrument, product labeling is a way to encourage more sustainable consumption patterns in the market (Koszewska, 2015).

4.1.3 Cosmetics and Personal Care Industry

The approval of the Pollution Prevention Act by the American Chemistry Society in 1990 led to the rise of Green Chemistry, which aimed at molecular-level modification in chemical products and processes in order to prevent pollution and reduce or eliminate the use of hazardous substances (Bozza et al., 2022). Green chemistry promotes the use of recycled materials, less raw materials, natural resources, as well as reusable products and packaging (made of glass, aluminum, and paper), regenerated/recycled products, and fewer hazardous substances being released into the environment (Bozza et al., 2022). As consumers' awareness of environmental issues has increased, the cosmetics sector has been forced to develop "greener" products. Although there are legal instruments like the European and USFDA (United States Food and Drug Administration) Directives to regulate the production and marketing of greener products, they do not have standardized definitions to categorize cosmetics products into green products (such as vegetarian/vegan, organic/natural and ecological products). The influence of the cosmetic supply chain on sustainability along with growing consumer demand for greener products has pushed manufacturers to consider all steps of the cosmetic's product life cycle (design, sourcing, manufacturing, packaging, distribution, use, and post-consumer use) (Bozza et al., 2022). This has helped to ensure a balance between environmental, economic and social aspects of sustainable development (Bozza et al., 2022). Therefore many brands have used product labels and certification as a marketing strategy to guarantee consumers certain characteristics of the product and fulfill their sustainability concerns. Some of the commonly used labels in the cosmetics and personal care industry are:

- ***Cosmos and Natrue***: COSMetic Organic Standard or COSMOS is an internationally accepted standard for organic and natural cosmetic products (Bozza et al., 2022). Natural cosmetic products are those containing natural materials and are derived from raw materials rather than synthetic ones. Whereas organic cosmetic products are those whose ingredients are derived from organic farming and not genetically modified. A COS-

MOS label is a safety indicator for natural and organic cosmetic products (Bozza et al., 2022). They carry a strong message to environmentally-conscious consumers and influence their buying behavior. On the other hand, a NATRUE label is a standard for Green Chemistry in the cosmetic industry, which evaluates the production processes and packaging of cosmetic products in addition to the nature of ingredients (Bozza et al., 2022).

- ***EU Eco-Label***: This label aims to identify and assess the environmental performance and impact of cosmetic products. Ecological cosmetic products are characterized by minimum environmental impact in the areas like composition, production, and packaging. The product having this label is established to have limited substances and mixtures like boric acid, EDTA, BHT, nitrogen musks etc., and regulates certain materials in packaging (Bozza et al., 2022).

It is essential that companies pay close attention to durable and recycled materials while manufacturing products. Besides the environmental responsibility, manufacturers can utilize these labels to tap the enormously growing green market and capture market share. Consumers favor and trust companies that uphold environmental values. There are numerous conventional products in the beauty supplies retail outlet outnumbering green and organic products, therefore these product labels can be used to convey the message of a modern image and attract eco-friendly consumers (Cosper, 2018). Even consumers who don't thoroughly examine organic products can connect the natural or organic label with green values. Consumers perceive these labeled products as high-quality products in comparison to their conventional counterparts. This influences consumers' willingness to pay more for innovative products having specific labels (Cosper, 2018). Labeled products approved by standards have the advantage of increased brand reliability, recognition, and product differentiation in the market, and they are found to acquire greater commercial value (Bozza et al., 2022).

4.2 Sustainable Marketing

As the importance of 'sustainability' and 'sustainable development' is deepening, countries worldwide are concerned about applying these concepts in all forms of marketing in order to boost the collaboration between the ecological environment, social life, and economic market (Sun, 2020). Sustainable marketing is defined as "a social and management process being compatible with sustainable development, by creating, selling, and exchanging sustainable products and values to meet the needs of contemporary people while maintaining the coordination of economy, society, environment, and resources without compromising future generations" (Sun, 2020).

The idea of sustainable marketing is relatively new, but manufacturing and service businesses are seen to increasingly implement it as a way to make their organization sustainable. Good businesses are always connected with natural and cultural environments (Sun, 2020). The feature which differentiates sustainable marketing from traditional marketing is the social and environmental focus of the businesses apart from the sole focus on market success (Trojanowski,

2022). From the perspective of a manufacturer, sustainable marketing is a way to keep a balance between their own business objective or survival and the future development of the operating ecosystem. This can help to ensure stability for the business in the longer run (Sun, 2020).

Recent studies have found that investors perceive the sustainable marketing practices of a firm as a major source of competitive advantage. Modern consumers value improved health and community well-being apart from the direct utility of products and services. Shifting to sustainable marketing practices is a way for businesses to engage multiple stakeholders while meeting consumer expectations (Trivedi, Trivedi, & Goswami, 2018). Sustainable marketing is the way forward for manufacturers to create a difference in a highly competitive market. Sustainability improves efficiency and lowers costs in the production process, packaging, distribution and promotion, ultimately providing the firm with a better market position against its competitors. Sustainable marketing is also found to increase customer retention and brand loyalty. It strengthens the consumers' awareness of society and motivates their willingness to pay a premium for sustainable products and services (Trivedi et al., 2018).

4.3 Conclusion

This section concludes the above findings and answers the SQ1 - ***'How does product labels in different industries help manufacturers with sustainable marketing?'***. The answer to the subquestion is supported by a comprehensive summary of the values of product labels, which is shown in the *Table 6*.

The consumer groups are shifting their focus to issues of greenism, sustainable development, safety, health and environmental protection. It is found that consumers favor and trust companies that uphold environmental values. This demand has been met by manufacturers across industries through various product labels. Product labels are used by manufacturers to effectively communicate the businesses' commitment to sustainability and share information related to social and environmental related practices adopted in the manufacturing stages of the product. Product labels are found to help manufacturers with sustainable marketing by informing consumers of the social and environmental benefits of the product, being transparent about the environmental impact of the product, highlighting the recognizable certification bodies awarding labels and encouraging more sustainable consumption patterns in the market. Consumers value this information which increases their reliability and trust in the product. This ultimately influences their purchasing intentions and wins their confidence in the product. Manufacturers also use labels as a tool to educate consumers about the value propositions of a product and thereby express the product's superiority. Such product details have helped to awaken the consumers' emotions, motivate their purchasing behavior and generate sustained consumer loyalty. Once implemented transparently and systematically, labeled products can offer manufacturers the benefits of enhanced brand reliability, recognition, and product differentiation in the market. Thereby, manufacturers can increase their market efficiency and finally acquire greater commercial value.

The literature highlighted the significance of product labels in recent times where consumer preferences are shifting towards safer, higher quality, and sustainable products. Manufacturers have embraced labels as a means to support this change in consumer behavior. Most of the literature are from recent years, which indicates the growing importance of value-driven product labels. While there are only limited literature that examined labels from both the manufacturer and consumer perspectives, all of them have consistently discussed the advantages of product labels for manufacturers in attracting consumers, which is summarized in *Table 6*.

Label	Purpose of Label	Benefits to Manufacturer
CLEAN LABEL	**Clean label** position food products as organic, natural and free from artificial ingredients or additives.	Attracts health-conscious consumers, and build consumer trust in the product.
OEKO TEX® STANDARD 100	**OEKO-TEX STANDARD 100** is certified to products that are tested free of harmful substancesand protect the consumer health.	Demonstrate product safety, and provides a competitive advantage in the market.
FAIRTRADE	Products certified with **Fair Trade** labels are made with best interest of workers, under strict guidelinesand ethical standards – fairly produced and fairly traded products.	Demonstrates commitment to fair trade practices, and accessto new markets which demands fair trade label.
bluesign®	**Bluesign** is an eco-label for textile products tested for harmful substances in the world.	Demonstrates commitment to sustainability, and reduce therisk and increase efficiency insupply chain management.
WWW.NATRUE.ORG	**NATRUE** label is a standard for Green Chemistry in the cosmetic industry, which evaluates the production processes and packaging of cosmetic products in addition to the nature of ingredients.	Demonstrates product quality, enhance brand reputation, and build trust with consumers who are looking for safe and healthy cosmetics.
ORGANIC AND NATURAL COSMETICS COSMOS STANDARD	**COSMOS** certified products guarantee consumers with organic and natural cosmetics products produced to the highest feasible sustainability practices.	Demonstrate commitment to sustainability and environmental responsibility, and communicate consumers about the product quality.
EU Ecolabel www.ecolabel.eu	**EU Ecolabel** aims to promote products with reduced environmental impacts during their entire lifecycle.	Demonstrates commitment to sustainability, enhance brand reputation, and access to new markets seeking sustainable products.

Table 6: *Product Labeling and Sustainable Marketing*

5 Regulatory Challenges in MedTech Industry

Chapter 5 examines the challenges faced by medical equipment manufacturers when complying with various certifications, product labels, and regulatory standards such as CE (Conformité Européenne) marking, FDA (Food and Drug Administration) regulations, and similar global requirements. The objective of this chapter is to gain a comprehensive understanding of these challenges. The activities and research methods used towards the end of Stage 2 in the Research Flow Diagram (*Figure 6*) are used in this chapter. This chapter concludes by addressing sub-question 2, consolidating the key findings and insights gathered throughout the desk research and case study interviews.

The chapter begins by introducing the importance of regulations in the medical equipment industry and explaining the different regulatory control systems present worldwide. This is discussed in section 5.1. Moving forward, section 5.2 provides a detailed explanation of different challenges faced by medical equipment manufacturers while going through the whole regulatory process. There, the findings from the literature are tied with the findings from case study interviews to produce in-depth insights. This helps in developing a deeper reflection and performing a comparative analysis of each factor. Finally, a conclusion is given in section 5.3 to answer sub-question 2.

5.1 Regulations in Health Technology

The market for medical equipment includes a wide range of products with various applications. Over the past twenty years, there has been an increase in the number, diversity, and complexity of medical equipment. The global medical equipment market has observed a growth trend of CAGR of 5.7% in the last five years. The main factors causing this growth are the global issue of aging and the increased spreading of chronic diseases (Y.-J. Chen et al., 2018). Since the safety and effectiveness of medical equipment are crucial to human health, strict regulations and standard procurement indicators should be key to managing these products. Labels, marking, and certification of medical equipment is a tool to ensure the regulatory compliance of these products. It is an informed way of communicating the risks and benefits of medical equipment to the patient and the environment in which they will be deployed. These indicators are means to provide sufficient information about the use of medical equipment, its maintenance and potential problem, the category of people who can use it, and the compatible situations for its use (Songara, Sharma, Gupta, & Gupta, 2010). As discussed in Chapter 4, product labels such as *Clean Label* help in positioning the food products to meet consumer demands, while certifications such as *OEKO-TEX STANDARD 100* confirm the quality and safety standards followed in the manufacturing of textile products. Similarly, there are different labels, markings, and certifications in the regulatory system of healthcare technology to ensure the quality, safety, and standards of medical equipment designed and supplied globally. Regulatory controls on medical equipment are generally applied in three stages of its life

span. The three common stages of regulations are pre-market, placing on-market and post-market surveillance (WHO, 2003). This is shown in *Figure 9*. Pre-market control is placed on equipment to ensure that products that are ready to enter the market comply with regulatory requirements. Labeling and advertising are done appropriately for correct product representation. Placing on-market control ensures device listing, establishment registration and after-sale obligations. Post-market surveillance ensures the safety and performance of equipment while it is used.

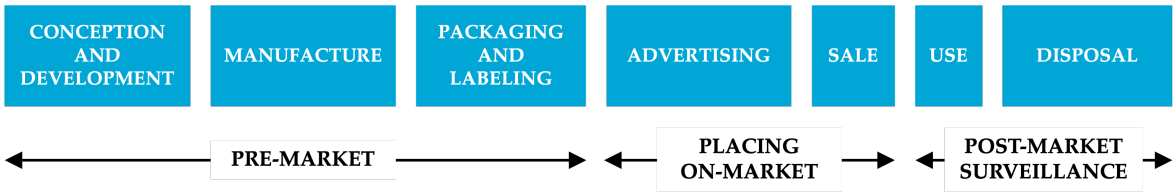

Figure 9: *Life Span diagram, indicating the three common stages of regulations for medical equipment (WHO, 2003)*

Globally, different authorities have different regulatory tools for product control and give product clearance for market entry. ARTG (Australian Register of Therapeutic Goods) is issued by the Therapeutic Goods Administration in Australia. A Device License is issued by Therapeutic Products Directorate in Canada. In European Union, the manufacturer places a CE marking (compliance label) on the product, after receiving approval (EC Certificate) from a Notified Body. The Pharmaceutical and Medical Safety Bureau of the Ministry of Health, Labour and Welfare in Japan issues a Shounin as approval for medical equipment. In the United States, FDA (Food and Drug Administration) issues a Pre-Market Approval (PMA) or Marketing Clearance (510k) for the medical device manufacturer (WHO, 2003). In some of these countries, the products are subjected to additional in-depth regulatory scrutiny depending on the risk profile of the medical equipment. An overview of the different regulatory tools existing globally is given in *Table 7*.

Previously, medical equipment regulations were often lacking in many countries, and there were limited controls to prevent the use of low-quality devices (Gupta, 2016). According to Lamph (2012), 30% of countries have an established regulatory framework for medical equipment, approximately 30% of countries have a partial regulatory framework and the rest of the countries are either developing or do not have any regulation for medical equipment. This has caused the infiltration in the healthcare sector in many countries with low-quality medical equipment (Gupta, 2016). Hence, competent authorities are compelled to draft strict regulatory policies and renew existing regulatory systems to ensure the quality, safety, and efficacy of medical equipment (Y.-J. Chen et al., 2018).

The existing regulatory frameworks are nowadays challenged by the variety and innovativeness of medical equipment (Gupta, 2016). Innovations in medical equipment are rapidly increasing and are crossing national boundaries. Small and medium enterprises (SMEs) and start-ups are observed to be the frontrunners in producing such innovations (Baines et al., 2023). With the advancement in innovations, there has been a simultaneous increase in the

number of medical equipment and significant improvements in its critical functionality. However, the situation is also followed by a number of challenges, risks and safety scandals. The rapid growth of innovation, especially the digital innovation of medical equipment has outpaced the regulatory system (Baines et al., 2023). Such concerns have been recognized by regulatory authorities worldwide like European Union's Medical Device Regulation (EU MDR, Regulation 217/745), Food and Drug Administration (FDA, USA), The Medicines and Healthcare products Regulatory Agency (MHRA, UK) and Therapeutic Goods Administration (TGA, Australia), and measures are taken to a fundamentally revise the current regulatory system and/or policies to establish a transparent, predictable, robust and sustained regulatory framework in order to ensure the co-existence of health, safety, and innovation (Baines et al., 2023).

Country/Region	**Product Control Tools for acknowledging product cleared for the market**	**Medical Equipment establishment controls**	**Advertising Control**
Australia	ARTG number	Enterprise Identification (ENTID)	Generally, prohibition of advertisement before an equipment is cleared to enter the market. Prohibition of any misleading or fraudulent advertisement
Canada	Device license	Establishment license	
European Union	Compliance Label (CE mark)	Responsible person registration	
Japan	Shounin (approval) or Todokede (notification)	Seizo-Gyo (Manufacturer License), Yunyu Hanbai-Gyo (Import License), Hanbai Todoke (Sales Notification)	
United States of America	Pre-Market Approval (PMA) or Marketing Clearance (510k)	Establishment registration	

Table 7: *Varying regulatory tools and requirements in different countries. (WHO, 2003)*

5.2 Challenges for Manufacturers in Adhering to Certification

The following sections explain the different challenges faced by medical equipment manufacturers in adhering to regulatory norms and certifications while supplying product globally.

5.2.1 Lead Time and Cost in the Assessment Process

The cost of clinical evaluation in the certification process varies depending on the risk profile of the medical equipment. In Europe, 95% of medical device manufacturers are SMEs and they have a high share in higher safety class (*Class IIb*, in particular) equipment (Maresova, Rezny, Peter, Hajek, & Lefley, 2021; Pelayo, Marcilly, & Bellandi, 2021). This puts a burden of considerable certification costs on these manufacturers. Having relatively small total revenues,

complying with CE mark regulations is a real challenge for SMEs and affects their competitiveness in the market (Maresova et al., 2021). Similarly, as the complexity of medical equipment increases, the approval in the design and testing phases for equipment becomes expensive for manufacturers in terms of time and cost (Marcus & Biersach, 2003). Therefore, medical equipment manufacturers should understand and deal with the certification requirements in their early design phase to help them control costs, faster certification turnaround, and increased product safety (Marcus & Biersach, 2003).

In addition to these literature findings, interviews also provided some valuable insights. All experts in the interview unanimously stressed this one big challenge any manufacturer would face in the regulatory process/while adhering to certification. The complexity, type, and class of the equipment are directly proportional to the assessment time and cost, as P1 [Business Unit Director] states: *"It depends also on the type and complexity of the product. But I know that it can be incredibly, incredibly, incredibly costly, like almost not able for a small enterprise to do that"*. A ballpark figure of the time and cost involved was provided by P2 [Quality Assurance Manager] with an example: *"Let's say to get a product through the entire regulatory process, it would take about one year and it would cost about €60.000,00 to €70.000,00. Usually, it depends on the class, complexity, and type of the product you are dealing with, say hardware or software"*. Looking specifically at the time delay component, the unavailability of NBs plays a major role in this delay, as P1 [Business Unit Director] states: *"So if you want to start your CE process right now, maybe a year from now if you are lucky, you can get an audit in place"*. The time delay in this process is connected to the activities of Notified Bodies, which is explained separately in section 5.2.2.

5.2.2 Incompetency and Unavailability of Assessment Bodies

The conformity assessment of medical equipment in the certification process has been criticized by several manufacturers. In the EU, Notified Bodies (NB) are private companies responsible for assessing medical equipment. Products approved by NBs are given CE marking which allows the manufacturer to market their product and conform to the relevant regulatory requirements (Jarman, Rozenblum, & Huang, 2021). Since these are private bodies operating in a competitive market, they compete with one another and often adopt market behaviors. Such competition among Notified Bodies may not always be ideal when considering their role in public health (Huusko, Kinnunen, & Saranto, 2023). The introduction of MDR is really challenging the competency of NBs. There is a notable shortage in the skills and knowledge of NBs to handle new regulatory policies, including the inefficiency of handling an immense amount of certification documents in the assessment process. This creates a delay for manufacturers producing innovative products (Pelayo et al., 2021). Over the past 5 years, a number of NBs have closed in the EU. Currently, there are only 20 NBs designated in EU's regulation 2017/745 on Medical Devices (Pelayo et al., 2021).

The challenges caused by NBs were highly emphasized by experts in the interviews. Getting regulatory approval from NBs is challenging for any medical device manufacturer. The current status of NBs is that they are incredibly packed in their schedules and not available for

performing assessments of equipment, as P4 [Project Manager] states: *"The Notified Bodies are so full in capacity, that if we need to certify a new product we are supposed to wait at least a year and a half from today. They are already booked till that time, and this is a big bottleneck we see in the process of getting certified"*. P2 [Quality Assurance Manager] provides an example of the unavailability of the NBs: *"For one product we have that required Notified Bodies, we went all over Europe - Sweden, Finland and maybe now we have a Notified Body available now in Germany. Also, the three Notified Bodies in the Netherlands just said 'No, we don't have capacity'"*.

Furthermore, SMEs and startups face disadvantages in getting their product approved by NBs as these are private bodies that have their private business motives, as P2 [Quality Assurance Manager] states: *"If I'm a big company and I go to the Notified Bodies with a product, they see us as an established customer and see potential business in the future. They basically gonna move me up in their preference list"*. Similarly, P4 [Project Manager] states: *"If you want to certify a new product, and you are not already a customer of that particular Notified Body, they tend to keep you aside saying 'we don't see that kind of returns coming from you even if we put in the efforts with you now'. All SMEs and startups have that disadvantage"*. Hence the private interest of NBs challenges small-size firms to introduce innovative products in the market in terms of delay, cost, and administrative burden.

5.2.3 Lack of Harmony in Regulations

Currently, the regulations for medical equipment are considerably different across the world. For example, manufacturers should comply with EC Medical Device Directive 93/42/EEC to sell their equipment in European Community (through CE marking), and comply with US FDA to sell their equipment in the USA (Martin, Norris, Murphy, & Crowe, 2008). Although the essential requirements for product certification or labeling are mainly the same in most countries, there are some differences that manufacturers should account for while developing products for different countries (Brolin, 2008). The regulatory control systems followed by different countries are shown in the *Table 7*.

However, there are certain common quality requirements established by the International Conference of Harmonization (ICH) such as Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP) and Good Vigilance Practice (GVP). Apart from these requirements, most countries have adopted their own variations of the guidelines. However, the degree of regulatory scrutiny is different in different countries, which is summarised in the *Table 8*. It varies according to the potential risk caused by the medical equipment (WHO, 2003).

Therefore, the non-harmonized regulatory systems constitute a challenge for manufacturers who target to expand their business globally. They have to adjust to the country-specific regulations while selling their products in multiple countries (Brolin, 2008). To reduce the regulatory differences worldwide, eliminate country-specific requirements and establish a transparent and consistent international regulatory system, Global Harmonization Task Force (GHTF) was established by a group of representatives from national regulatory authorities (Y.-J. Chen et al., 2018; Songara et al., 2010).

Country/Region	Degree of Regulatory Scrutiny	Exemptions
Australia	All *"registrable"* devices require rigorous pre-market evaluation, while *"listable"* devices may undergo safety evaluation based on regulatory concerns	Devices made for an individual or within a healthcare facility are exempt from registration or listing requirements
Canada	In-depth regulatory scrutiny for *Class III and IV* devices, while *Class II* devices require only manufacturer's declaration of device safety and effectiveness before sale	*Class I* devices are exempted from pre-market submission, but they must still satisfy the safety, effectiveness and labelling requirements
European Union	Manufacturers of *Class II and III* devices, and *Class I* devices with measuring or sterility functions must follow conformity assessment process. Notified body-issued EC-Certificates for higher risk class devices must be submitted along with design/type examination	*Class I* medical devices are exempt from pre-market submissions but must adhere to essential safety and performance principles
Japan	Regional authorities grant Todokede to *Class I* devices. Some *low-risk Class II* devices can also obtain Todokede if their safety and effectiveness are established. All devices above *Class II* require a central government license for market entry	NA
United States of America	*Most Class III* and new devices that are not substantially equivalent to a legally marketed product require clearance through the PMA process. *Most Class II* and *some Class I* devices require pre-market entry notification (termed 510k)	*Most Class I* and *some class II (low-risk)* devices are exempt from 510k submission before sale, but are still subject to general control requirements

Table 8: *Difference in the level of regulatory scrutiny among countries (WHO, 2003)*

5.2.4 Managing Regulatory Changes (MDD to MDR)

The evolving regulations for medical equipment focusing more on safety and risk reduction are causing stricter processes and stringent quality assurance measures for manufacturers in the authorization of their products in the market (Maresova et al., 2021). Medical Device Regulation (MDR 2017/745) is the regulatory framework introduced in 2017 and came into practice in 2021 with the aim of ensuring well-functioning medical devices in the EU. MDR replaced Medical Device Directive (MDD 93/42/EEC) which was in practice in the medical device industry in the EU (Huusko et al., 2023). The regulatory framework of MDD had certain weaknesses which led to a few scandals such as PIP breast implant scandal in France (Huusko et al., 2023). Hence, MDD was framed to ensure high-level protection of human health and safety, ensure a functional internal market, and a sustainable regulatory framework supporting all innovation and competitiveness of the MedTech industry in the EU (Huusko et al., 2023). Despite the mandatory requirement for all manufacturers to comply with MDR, they widely accept it due to recognizing the enhanced product traceability and improved patient safety it offers.

However, manufacturers of different sizes face certain challenges due to the change in regulation from MDD to MDR. They are:

- The categorization of medical devices according to the risk class of products has changed under the new regulatory framework of MDR. The standards of clinical trials have also been revised. There are four risk classes under MDR - *Class I, IIa, IIb, and III* and subclasses for *Class I*. This led to the shift of certain medical devices to high-risk categories, which is challenging manufacturers to undergo a much more stringent regulatory process (Huusko et al., 2023). However, this challenge is subjective to the size of the organization. Practically, only a few manufacturers have products in high-risk classes and subclasses, and it is widely found that only larger manufacturers have more medical devices in their portfolio (Huusko et al., 2023).

  Practically, it is difficult for manufacturers to undergo this shift in the class of medical devices. This was verified by the expert interview, as P2 [Quality Assurance Manager] states: *"The easiest way to think about it is, for instance, you can just assume a product should be good and they would accept that under MDD. And now, let's say, a product in Class I under MDD suddenly or slipping into Class II or Class IIb or into Class III under MDR. So I think it is making the entire workload to demonstrate this a lot more for companies"*.

- The new requirement introduced by MDR demands the necessary expertise in an organization, that can be entrusted to manage all matters related to regulatory policies. Larger organizations are well equipped with regulatory departments to adapt to changing regulations. While it can be challenging for SMEs in many European countries, especially those operating with limited resources to meet this requirement (Maresova et al., 2021). SMEs consider undertaking this new regulation as an additional administrative burden apart from the significant rise in external-cost such as high implementation costs and certification or verification costs. The situation hinders their capacity to develop new

products and restrains innovation of medical equipment (Maresova et al., 2021). Strict regulations with rapidly changing expectations on usability, application, and development of medical equipment are increasing the pressure on manufacturers. In the course of applying a faster production cycle, stricter quality assessment processes, and remaining compliant with industry regulations, manufacturers are pressurized with time and budget constraints. Therefore it is natural that the evolving stricter regulations for medical equipment are a cause of concern to manufacturers of different sizes (Maresova, Hajek, Krejcar, Storek, & Kuca, 2020).

Generally, shifting the existing portfolio of medical equipment from MDD to MDR along with high validation standards is a challenge for manufacturers of all sizes - the lengthy process and associated administrative burden, and required expert resources. When asked about the challenges caused due to the introduction of new regulatory requirements, P2 [Quality Assurance Manager] replied: *"The biggest thing for MDD is that it was quite easy compared to MDR. So the biggest challenge now is for companies that have products under MDD to convert those to MDR. They might have to go back and do a lot more stuff or redo a lot of stuff that they didn't need to do for MDD because essentially it was assumed to be good"*.

- Despite the presence of significant information sources like the EU website and medical device consultants, some organizations face challenges in accessing and understanding the information related to MDR. This was based on the findings from Huusko et al. (2023), who used an online questionnaire to understand the perception of managers and regulatory professionals in health technology organizations in Finland towards MDR. They found it challenging to refer to multiple information sources as the information related to MDR was fragmented. Hence it was difficult, especially for the small and medium enterprises that have limited resources at their disposal, to take decisions on the basis of such fragmented or poor-quality information (Huusko et al., 2023).

  Since this was a finding obtained from a specific case, it required to be tested by experts through interview. When asked about the relevance of this finding, P2 [Quality Assurance Manager] explained: *"There's a lot of information on it, and I think they have a lot of clarifications. There's a lot of guidance from the European Union through sources like Blue Guide, and they're updating them regularly"*. But, P1 [Business Unit Director] commented on it as: *"I think there are still some unclarities about the process. I think that makes sense also, because a lot of the things are still fairly new"*. Therefore, it is difficult to conclude from the available sources whether the factor - 'fragmented/poor-quality information regarding MDR' - is a regulatory challenge for medical equipment manufacturers or not.

5.2.5 Language Barrier

Manufacturers who market and sell their medical equipment in different countries face many practical and legal difficulties. Many countries worldwide insist their local manufacturers on using their national language, especially in product labeling. This is aimed to provide accurate and comprehensive labeling to medical equipment, help the user understand the warnings

and instructions related to the product, and avoid any potential legal consequences due to insufficient or unclear labeling. Therefore manufacturers supplying medical equipment to other countries find it difficult to accurately translate product labels in multiple languages. They must ensure that translations are not just technically accurate, but also sensible and comply with local regulatory requirements (Songara et al., 2010). In general, adhering to English which is the language of medical professionals and international conferences makes sense to resolve this issue.

There was limited literature discussing the significance of language barriers for manufacturers in adhering to certification and selling equipment across national boundaries. Therefore, to understand the magnitude of this challenge, data was collected from experts in the interviews. It was found that English as a language is widely used in the documentation, user manuals, etc., and this situation of translating documents is rarely encountered by manufacturers, as P2 [Quality Assurance Manager] states: *"So we need to translate the user manuals. We sometimes need to translate other documentation, but labeling generally is fine. But that doesn't mean it will not happen. Some countries say you must put labels and all the warnings in the local languages. We just haven't encountered that yet"*. Hence, this is one of the less significant challenges that manufacturers face in adhering to certification and selling equipment in different countries.

5.3 Conclusion

This section concludes the above findings and answers the SQ2 - ***'What are the challenges faced by medical equipment manufacturers in adhering to product labels and certifications?'***.

Globally, medical equipment manufacturers face a number of challenges in the process of adhering to product labels and certifications. This is mainly due to the increasing complexity of the regulatory landscapes and the increasing demand for the safety, efficiency, and quality of health technologies across the world. The nature and relevance of challenges can be different depending on the size of the organization. A comprehensive representation of the different challenges faced by manufacturers in the MedTech industry along with its degree of relevance is shown in the *Figure 10*.

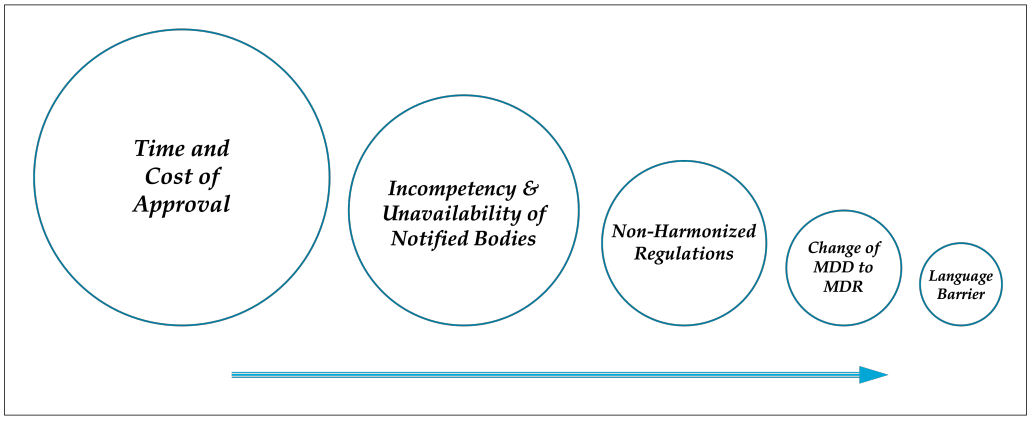

Figure 10: *Significant regulatory challenges for manufacturers according to their degree of relevance. (The Degree of Relevance directly proportional to the Size of Circle)*

The most important challenge faced by manufacturers is the excessive time in the whole regulatory process and the significant cost involved in getting approval for the product. This challenge exists for all organization irrespective of their size. The second most important challenge faced by manufacturers is the incompetency and unavailability of assessment bodies. The conformity assessment bodies varies from country to country. A NB is an assessment body specifically designed to assess the conformity of products before it is placed in the EU market. Since most of the literature discussed only NBs and as the expert interviews were taken from an EU manufacturer, the challenges related to the conformity assessment bodies here are limited to the context of NBs. It was found that NBs and other auditing bodies are overloaded or incredibly packed in their schedule. Currently, the NBs are also equipped with the migration of MDD to MDR. Therefore, it is difficult to get an appointment of NB. The unavailability of these bodies creates bottlenecks for manufacturers in terms of delay in the assessment, certification process, and ultimately sale of innovative products. Also, NBs being private organizations have their own business interests which creates unfair disadvantages for SMEs and startups in getting their products approved.

A notable challenge, though not stressed in practice is the lack of harmony in regulations across the world. Different countries or regions have different regulatory tools for assessing product clearance for their market. This causes challenges for manufacturers who supply their products globally. However, in most countries, CE and FDA are recognized as primary requirements for purchasing products. Also, there is GHTF working to reduce the regulatory differences worldwide and establish a transparent and consistent international regulatory system. Next, the change in the regulatory framework from MDD to MDR in 2017 has caused some challenges for manufacturers. MDR has introduced new categories of risk classes for equipment. The products in the portfolio have shifted from a low-risk class (earlier) to a high-risk class (now) or vice versa. This along with the stringent assessment process and validation standards has excessively increased the workload for manufacturers in revisiting and demonstrating the quality and safety of their products. Lastly, the situation where manufacturers have to face a language barrier in the labeling process and sales of equipment globally is also noted as a challenge, although less frequently encountered by manufacturers. The translation to the local language is not meant simply for product labels but includes a translation of the user manuals, description of the concept of label/logo, description of warnings, etc. It is sometimes challenging but important for manufacturers to make sensible and accurate translations of these documents while supplying equipment to other countries.

Although explained on a global scale, the regulatory challenges discussed are equally applicable to medical equipment manufacturers targeting LMICs. However, regulatory challenges are just one pillar of the challenges they face while they enter the healthcare market of LMICs. There are other challenges thant manufacturers face in different phases of the equipment life cycle (pre-market, placing-on-market, and post-market phases). The next chapter will provide a detailed explanation of other challenges, providing a holistic view of the roadblocks faced by manufacturers in supplying products to LMICs.

6 Challenges for Manufacturers in Entering LMICs

Chapter 6 examines the challenges encountered by medical equipment manufacturers when supplying products to LMICs. The observations are exclusively derived from the data collected through case study interviews. Relevant quotations from participants are included to substantiate the observations. This chapter ultimately aims to address sub-question 3, which will be answered after validating the propositions derived from the observations.

To facilitate the analysis, challenges are categorized into three phases aligned with the equipment's life cycle. Consequently, the chapter is structured as follows: Section 6.1 explores challenges in the design and manufacturing phase. Section 6.2 addresses challenges in regulatory approval and distribution, drawing on regulatory issues previously discussed. Lastly, Section 6.3 delves into challenges related to the installation and maintenance of medical equipment in LMIC hospitals. Each section concludes with comprehensive propositions, which will later be validated through expert interviews and survey.

6.1 Design and Manufacturing

The design and manufacturing of medical equipment include those stages in the equipment life cycle before it is placed on the market, also called the 'pre-market' phase. The pre-market phase is indicated in the *Figure 9*. This mainly includes conceptualization, engineering, and development of medical equipment. Observations from the interview show the challenges in this phase are mainly due to the unique contextual conditions of LMICs. In this study, the contextual conditions are referred to as the harsh environmental factors and limited/poor infrastructural capacity of LMIC hospitals.

When developing products for low-resource settings, manufacturers must prioritize and ensure the effectiveness, safety, robustness, and reliability of their equipment. This is required to prevent the premature failure of the products when it is used in extreme conditions. This may not be a roadblock for manufacturers while designing equipment for HICs, as all the operating conditions are favorable and standard to the equipment. On the other hand, a product designed for LMICs should be able to withstand high levels of humidity, high temperature, excessive dust, fluctuating electricity, etc. Moreover, these conditions tend to vary from region to region. As P1 confirms:

"So you're working in, high levels of humidity, high temperatures, a lot of dust occasionally, so the system needs to be able to withstand that". [P1 - Business Unit Director]

"I think one of the design challenges that you really have, is to understand what that environment looks like, and of course, that environment is different per country, also different per region in a country". [P1 - Business Unit Director]

Hence, a thorough understanding of contextual conditions is essential to ensure the efficient

operation of equipment in low-resource settings. But the difficulty arises when manufacturers are not aware of these contextual conditions, as P4 states:

"The major challenge is designing for the environment. When we initially designed and assembled one of our products, something that we didn't think of was the extreme temperatures where they would be used, which kind of hampered the efficiency of the system. Although the system functioned and progressed, its efficiency fell short of our expectations. This lack of understanding of the exact conditions in which the system would be used, I think is a big challenge in terms of designing and manufacturing these equipment". [P4 - Project Manager]

A similar comment was mentioned by P3:

"Some people here (HICs) are actually not aware of the LMIC condition. Most of the difficult thing is how to create products that suit these markets". [P3 - Operations Manager]

Hence, insufficient knowledge or understanding of the LMIC environment is a challenge for manufacturers in the early phases of product development.

Furthermore, the contextual condition also refers to the poor infrastructure capacity in LMIC hospitals. Understanding the limitations in infrastructural capacity is important to design products that align with customer requirements. However, manufacturers face a gap in understanding the requirement of customer and their capacity to operate the equipment. This is mainly due to lack of honest assessment by LMIC stakeholders regarding their capacity to effectively operate equipment, as P1 states:

"I think on the implementation side, one of the challenges we sometimes see is that countries tend to overestimate their capacity to install certain systems. So they might have in their mind that they can handle a certain level of system, where in practice, maybe electricity is not available". [P1 - Business Unit Director]

Also, the distribution of resources and support systems to operate the equipment are not always the same in all hospitals at LMICs. This depends on the type of geographical areas where hospitals are located, as P1 explains this with an example:

"A capital might have more means than a remote area does in a lot of cases. You might not know for which area you're developing and designing the system. For example, a place like South Africa might have different means than a remote area of Uganda might have. So you really need to keep in mind the setting and understand the setting and its limitations of what you're developing the equipment for". [P1 - Business Unit Director]

The aforementioned observations primarily stem from the business operations of Delft Imaging, the organization chosen for the case study. From these observations, the following propositions can be summarized regarding the design and manufacturing challenges faced by manufacturers who target the LMICs market.

Proposition 1: The limited knowledge of contextual conditions (environment factors and infrastructure capacity) in which the equipment will be used makes it difficult for manufacturers to design appropriate medical equipment for LMICs.

Proposition 2: Because LMICs stakeholders overestimate their infrastructural and human capacity to install and operate medical equipment, this makes it difficult for manufacturers to effectively implement projects in those countries.

These propositions are later validated with a larger population before they can be concluded as the final findings.

6.2 Regulatory Approval and Distribution

This section will explain the challenges faced by manufacturers in the 'placing-on-market' phase of medical equipment in its supply to low-resource settings. The placing-on-market phase is indicated in the *Figure 9*. This phase of the equipment life cycle includes stages such as regulatory control, marketing, and sale (overseas sales to LMICs) of products.

The supply of medical equipment to LMICs occurs mainly through the public tendering process and international procurement agencies (e.g., PFSCM - Partnership for Supply Chain Management) assigned by bodies like the UN, USAID, The Global Fund, WHO, etc. Most of these countries (represented by procurement agents/channels) demand CE or FDA labels as a regulatory tool to assess the quality of equipment entering their healthcare system, as P3 states:

"In kind of all the tenders they mention CE or FDA. I think these countries really trust these certificates and whenever we sell a product, all the safety tests, and the quality and assurance procedures followed are added along with the product". [P3 - Operations Manager]

Therefore, a manufacturer needs to undergo all the regulatory procedures and overcome the associated challenges to certify their medical equipment. All these regulatory challenges are previously explained in section 5.2. Among those, some of the challenges relevant to the LMICs context are explicitly mentioned by participants. This includes cost and time involved in the approval process, the unavailability of notified bodies, and the change of MDD to MDR.

Apart from these regulatory assessment procedures, the recipient countries have different trade compliances and requisites for local registration of medical equipment. These laws vary from country to country, and the clearance of which causes administrative burdens and shipment delays to the manufacturers. The challenge in trade compliance is explained by P4 using an example, and those of local registration of products is explained by P2:

"Well, that's another tricky thing because even though let's say if Mozambique and Ghana, they're within the African continent, they have different import-export regulations. So, if I want to send something to Mozambique through Ghana, then I have to pay the import duties for sending it to Ghana and then the export duties for sending it from Ghana to Mozambique". [P4 - Project Manager]

"For most countries where you import into, you also need to do country registration. So you need to register with the ministry of the particular country you're shipping a medical product. You cannot ship it in until it becomes registered in that medical jurisdiction. So then there's another process to go through as well to register the medical products, which can take three months, six months, or nine months". [P2 - Quality Assurance Manager]

A detailed investigation of the procurement processes indicated that it creates challenges for manufacturers in supplying the appropriate equipment. It was observed that procurement agents simply focus on the technical specifications of the equipment without considering the LMICs' capacity to operate it. Manufacturers find it beneficial to have more open discussions with these agents to share their experiences and recommendations regarding the suitability of equipment. This opens the space to include the right technical specifications, which could ultimately enhance the effectiveness of the equipment. But, this rarely happens, P1 discusses:

"The issue that I see with the procurement agents is that people can get quite hung up on technical specifications and focus too little on experience and actually implementing. I think especially there should be a big emphasis on experience and expertise also in this, not just technical specifications". [P1 - Business Unit Director]

A similar opinion was raised by P4, emphasizing the inappropriate product requirements mentioned in the tenders. P4 explains:

"These kinds of tender requirements are so 'out of the world' kind of a scenario, where they are expecting the highest possible system. I think it's more of an image thing. That's like somebody writes something for them (procurement agencies) and then it becomes generalized. And then when it reaches these tender points, then it becomes too generalized that at some point it's just open to interpretation what a manufacturer wants to provide to the customer". [P4 - Project Manager]

Finally, most of the participants mentioned that companies of small sizes may face an additional challenge in supplying equipment to LMICs. For established companies, having a well-established track record of working with the UN and other international procurement agencies brings significant validation and importance. The UN places great value on successful contracts and implementations. However, for new entrants or small-size companies trying to enter the market without such a track record, it could be challenging to prove their capabilities. P1 explains:

"I think the UN puts a lot of importance on business track records like successful contracts and successful implementation. I guess that if you're very new to the market and coming into this as a startup and you don't have that track record yet, then that might be more difficult to prove because you need a high level of evidence and performance statements basically". [P1 - Business Unit Director]

These observations related to the challenges in the regulatory process and distribution phase were from the experience of Delft Imaging in supplying their products to a few LMICs. These observations can be condensed into the following propositions:

Proposition 3: Periodic changes in national regulation and different import-export regulations within LMICs create complexity, delay, and cost for manufacturers in supplying medical equipment.

Proposition 4: The requirement of country-specific registration and regulatory approval for medical equipment causes delays in supplying equipment to LMICs.

Proposition 5: Procurement agencies who highly emphasize the technical parameters of medical equipment and ignore the operating conditions and implementation capacity of LMICs make it difficult for manufacturers to supply appropriate equipment.

Proposition 6: SMEs and startups that lack proven track records and performance statements for their medical equipment face relatively more challenges than established organizations in selling equipment to LMICs.

However, these propositions are later validated with a larger population to make the final conclusions.

6.3 Installation and Maintenance

This section explains the challenges faced by medical equipment manufacturers after the equipment is supplied to LMIC hospitals, mainly in rural public hospitals. This includes the installation, utilization, and maintenance stages of the equipment life cycle, also called the 'post-market' phase. The post-market phase is shown in the *Figure 9*. Findings from interviews indicated that, in this phase, manufacturers face challenges due to lack of human capacity in hospitals to efficiently operate the equipment, difficulty to access remote installation locations, and unavailability of high-quality spare parts. However, these challenges can be tackled to an extent by manufacturers taking control measures.

It is frequently observed that there is insufficient knowledge for technicians and other healthcare personnel in some low-resource setting hospitals to use the equipment. The human capacity in such hospitals is not trained enough, or they lack basic IT skills and basic engineering skills to handle certain systems. However, due to their experience, manufacturers acknowledge this gap in product implementation and address it by offering comprehensive installation and training to the equipment users, P4 mentions:

"I think another thing which I feel is very relevant is how the people are using it. In terms of, the capacity of the people who will be using these systems. Even if the systems work well and are passed all kinds of certifications and requirements, one wrong step by the user sometimes can create a lot of issues". [P4 - Project Manager]

"I think we have really intense training, installation and training modules that we provide along with the products. But there have been instances where even after doing this, the required amount of knowl-

edge is still within them after the training, and that's something we flag to the respective authorities or the customer saying, 'probably you need to put in some more effort in terms of building capacity, because although our systems are quite intuitive and usable if you have the basic radiographic knowledge'. So that's a big challenge for us". [P4 - Project Manager]

Adding to this aspect of capacity building in LMICs, P1 explains the unavailability of health-care personnel with an example:

"You see in most LMICs the human capacity like, for example, radiologists, they're not available to the extent that we might have them here in Europe or in other places". [P1 - Business Unit Director]

The second significant challenge for manufacturers during this phase is the accessibility to hospitals in rural areas of LMICs. It is important for manufacturers to actively engage with users during and after the implementation of projects. This helps them to receive feedback from the end users which serves as a valuable source of information to shape their product development strategy. Therefore, manufacturers have to undertake an extra effort to physically reach such working sites and ensure the product is in operating condition. P4 explains this with an example:

"We put in that extra effort to ensure that the systems work in these kinds of harsh resource, resource minimal locations. Many of our installations are in really, really rural areas where you need to travel for at least 2 1/2 days in a car in really bad road conditions to get there. I think it's quite important for us to ensure that these systems are working from the time they reach that site and it's been set up. And that's where we do that extra effort to get the system to work basically. We put in an extra effort to send them replacements which are sometimes quite cheap. But then, the efforts that we put in sitting here and to our actual site are much more in terms of effort, time, and actual money". [P4 - Project Manager]

P3 agrees to this difficulty of accessing working sites, and states that:

"Another challenge that we have is with countries that you cannot really easily travel to for example, like Ethiopia, it's not easily accessible and dangerous". [P3 - Operations Manager]

Finally, there are a few challenges for manufacturers in addressing the maintainability and availability of spare parts in LMIC hospitals. A general practice followed by hospitals is to purchase spare parts from the local market. But, it is difficult to find high-quality spare parts for medical equipment like X-rays and systems that use artificial intelligence software. Therefore manufacturers are required to analyze the viability of projects and develop a support system. This is normally done either through opening stock with local partners or establishing a centralized distribution center that can cater to different regions within LMICs. Having such warehouses and a local support system reduces the turnaround time in supplying the spare parts. But all manufacturers cannot afford this business model, especially SMEs and start-ups who work with limited resources. P3 mentions the importance of local partners in providing service support:

"We try to divide regions. So for example we have here let's say, Ghana and Nigeria that are close to each other. And then if you have one centralized stock that can cover two or three extra countries, so you don't have to worry about that anymore. So sending spare parts from the Netherlands to Nigeria takes

5 days, then from Ghana to Nigeria, it's one day and 1/2 or two. So we see where we have big projects so we can open stock immediately and where we should be centrally located". [P3 - Operations Manager]

Similar to other observations, the insights regarding the installation and maintenance of medical equipment in LMICs are also derived solely from Delft Imaging's business operations experience. These observations are condensed into the following propositions:

Proposition 7: The lack of human capacity in LMIC hospitals to handle medical equipment creates challenges for manufacturers to successfully implement projects in these countries.

Proposition 8: Regular post-market surveillance helps manufacturers to iterate and improve the design of medical equipment supplied to LMICs.

Proposition 9: The presence of local partners and centralized distribution centers can improve the service and maintenance of medical equipment supplied to LMICs.

Similarly to the previous propositions, these observations are also validated (Chapter 8) with a broader sample of professionals with relevant experience in LMICs to establish the final conclusions.

7 Perception of Manufacturers on AME Label

This chapter revolves around the concept of the Appropriate Medical Equipment (AME) Label by examining how manufacturers perceive and adhere to such labels. The AME information flyer was distributed to both interview participants and survey respondents. The findings presented in this chapter are based on participants' comprehensive understanding of the AME label from the information provided, their past experiences in supplying equipment to LMICs, and their insights into the working of regulatory systems and certification processes within the MedTech industry. This chapter marks the end of step 3 in the research flow diagram provided in section 3.1. This chapter concludes with some propositions which will be later validated to answer sub-question 4.

The structure of this chapter is divided into two sections. Section 7.1 discusses the agreement of manufacturers on the overall concept of AME and different value propositions guaranteed through the AME label. The results from the case study interview and survey are consolidated to create a bar diagram that provides a concise summary of manufacturers' agreement levels. The expected roadblocks or constraints of manufacturers in adhering to adopting the AME label are discussed in section 7.2. Relevant quotations from different manufacturers are included in each section to substantiate the findings.

7.1 Concept and Value Proposition of AME Label

Manufacturers' perception of the concept and value proposition of AME label is explained in this section. It was generally observed that all the participants had a positive impression of the concept of the AME label. All the participants acknowledge the presence of inappropriate medical equipment in low-resource countries and believed that such a context-specific label could improve the situation. Some manufacturers agree that the adoption of AME label will presumably help companies enter new markets with appropriate and competitive product features, as P1 states:

"I think as a company, if you see the value and something like AME and you think that it would help you to get into certain markets to put in very good businesses, then people can consider whether that's worth the investment or not". [P1 - Business Unit Director]

This was validated by E5, emphasizing the value addition AME would potentially give to small and medium size companies. E5 states:

"For many startups, their primary focus is on a specific market. By complying with country-specific regulations and obtaining the necessary approvals, startups can expand their market reach and gain visibility for their products. This broader market exposure can be particularly beneficial for startups seeking growth opportunities and increased visibility in the industry". [E5 - Global Partner Manager]

E6 acknowledges that manufacturers from HICs often ignore the unique operating conditions

in LMICs while supplying medical equipment. Therefore introducing such a label can act as a control measure for the products entering LMIC hospitals, as E6 mentions:

"I think it is very relevant because we are still stuck that nobody's really making contextualized kinds of products, and a lot of people might label it as localized but not localized. It will be definitely important to have something like AME which is providing some security on that". [E6 - Researcher]

The mission of AME states that the label will help manufacturers by creating transparency, visibility, and credibility for medical equipment supplied to LMICs [2]. The agreement of manufacturers on these factors along with a few others were tested through interviews and survey, whose results are given in the *Figure 11*.

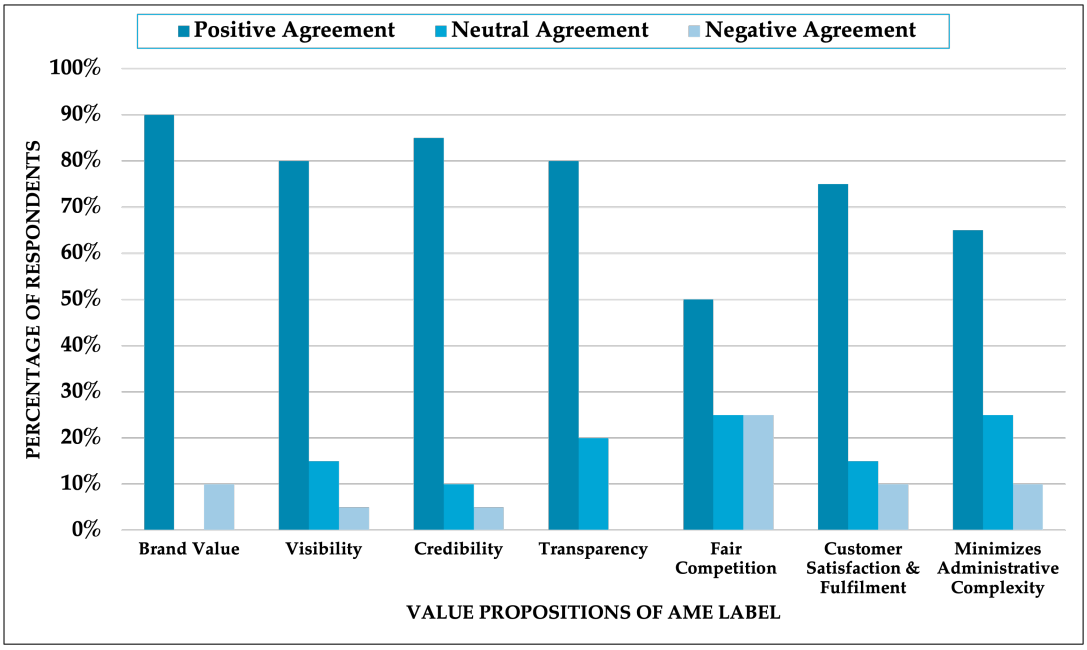

Figure 11: *Perception of Manufacturers towards different value propositions of AME Label (n=20)*

The results showed that the majority of manufacturers (from the sample size) consider AME label as a value addition to their business in LMICs. The choice of neutral agreements by some participants can be attributed to their uncertainty regarding the implementation of the AME label on a large scale and its ability to effectively deliver the stated value proposition to manufacturers. This conclusion was derived from the validation interviews, where a few participants expressed practical uncertainties regarding the execution of the AME label.

These key values are defined as follows:

- ***Brand Value***: Refers to the overall significance of the brand in the marketplace. A strong brand value impacts the bottom line of the company, differentiates them from competitors, and creates worth in the market or among customers.
- ***Visibility***: The degree to which medical equipment is easily seen, noticed, and recognized by potential customers. Higher visibility attracts customers and generates sales

[2] source: Appropriate Medical Equipment (AME) Label information flyer

for manufacturers.

- ***Credibility***: Refers to the level of trustworthiness and reliability of medical equipment. Establishing credibility for medical equipment is important to ensure product safety, and develop trust among healthcare professionals in the safety, efficacy, and quality of the product.
- ***Transparency***: The degree to which accurate, reliable, and comprehensive information related to medical equipment is available and accessible to customers. The information includes process, safety, efficacy, and potential risk associated with the product, which can help stakeholders make informed decisions to purchase the product.
- ***Fair Competition***: Refers to a level market where manufacturers can compete fairly on the basis of product quality, customer service, pricing, and marketing strategy. Fair competition prevents monopolistic, corruptive, and unfair practices in the procurement process for LMICs.
- ***Customer Satisfaction & Fulfilment***: The extent to which medical equipment meets and fulfills the specific requirements and demands of LMICs stakeholders. It ensures the alignment of product features with the contextual requirement of the customer., leading to overall satisfaction and a positive perception of the manufacturer.
- ***Minimizes Administrative Complexity***: Refers to simplifying the administrative tasks and eliminates unnecessary time-consuming processes for a manufacturer while supplying medical equipment to LMICs.

Although the participants expressed their willingness to undertake AME label for their medical equipment, the majority of them had some concerns about its execution in the regulatory platform. P1 and P4 mention this as:

"Right now what's been written about AME is a purely very high-level theoretical framework. So the question whether how I would score it depends on how it would be executed". [P1 - Business Unit Director]

"Personally, I think I would go for it. But again yeah, it depends on the amount of how, what the whole process is set up in. But I think that's something the company would definitely go for, especially if you are focused on the LMICs market". [P4 - Project Manager]

All the concerns of manufacturers regarding the AME label and the potential constraints in the adoption process are elaborated in the section 7.2.

7.2 Key Constraints in adhering to AME Label

7.2.1 Recognition of AME Label

The primary concern for manufacturers was regarding the global recognition of the AME label. The recognition and acceptance of label by authoritative bodies such as WHO, Global Fund,

UN, etc., will play a crucial role in motivating manufacturers to comply with the AME label. Given the significant difficulties that manufacturers already encounter in complying with current regulations and obtaining certifications, it would be challenging for them to embark on an equally costly and time-consuming process for implementing the AME label without a clear mandate and assured benefits. P4 explains this:

"Yeah, AME label would something we would be very much interested in. But I think the biggest motivation for us would be about for the acceptance of the AME label. If funders like the Global Fund, UN, WHO these kind of organizations ask us 'If you don't have a CE do you have an AME label?' That's kind of a motivation for us to learn that this is something they would be happy to have instead of the CE. Then you should probably think in that direction and go for it". [P4 - Project Manager]

A similar opinion was given by P1, which was also connected to the novelty of the label and its scope of marketing, which states:

"Let's say that AME label is right and it's internationally recognized. Everybody knows what it is. Everybody knows what it stands for. Everybody knows what it entails. Then it's a different story than you know, it's a small certification. People don't know what it is yet, we don't know how it works. I think the promise is very interesting. But the execution of that and recognition of it really matters". [P1 - Business Unit Director]

On the other hand, the discussion regarding recognition of AME label does not limit to the acceptance by authorized bodies. The manufacturers emphasized the need for the label to be recognized by healthcare stakeholders in concerned LMICs. Such a validation is equally important to motivate the manufacturers in adopting the label and enhance the market value and trustworthiness of the label. P1 states:

"I think the strength of any certification depends on how well it is recognized. Theoretically, if the whole world of LMICs and all the stakeholders would know what it is, and it's a high level of validation then it can do a lot. If people don't find it important, if people don't trust it, if people don't understand it, then it's not gonna, add that much value. I think that's on both sides, right? That's not just for the manufacturer, but also for the client side". [P1 - Business Unit Director]

Also, P3 supports this finding by stating:

"Its intention is to benefit everybody overall, but unless it was accepted by all the stakeholders as being that, then it's no value". [P3 - Operations Manager]

7.2.2 Positioning of AME Label in the Regulatory System

The second concern discussed by manufacturers is the differentiation of the AME label from the existing certifications, labels, and regulatory tools in the market. Although there is a clear distinction from a branding point of view, the difference in the testing process from the existing labels like CE or FDA is still unclear. This distinction is important for manufacturers and influences their motivation in adhering to the AME label. For instance, the labeling process becomes easier for manufacturers if they can utilize the same documentation, testing methods,

or results previously employed for other product labeling processes to obtain the AME label. P1 explains this with an example:

"I think the distinction of AME from a branding point of view is clear because it's an orientation to LMIC. But in terms of the process of how to get it and the validation, I think we have to see how different is it really. So, for example, now the WHO has their own certification process which is called the WHO-PQ, it's like pre-qualifying. It looks depending on the product exactly like the CE. So you can reuse a lot of the documentation that you might have for your CE in the WHO-PQ application". [P1 - Business Unit Director]

"I think you have to look at how this is gonna be different than other certifications. Like, if you wanna do durability testing, that's also part of the CE. So I think you wanna kind of like do this in like a lean and mean kind of way that you don't have to redo a whole CE kind of process. But can you maybe work with data that are already available with the manufacturer with their own durability testing for example". [P1 - Business Unit Director]

This implicitly refers to the positioning of the label in the regulatory system. During the implementation phase or execution of the AME label, it is important to determine whether it should be positioned as a competitive alternative to CE, MDR, or other regulatory frameworks.

7.2.3 Cost and Time delay in the Labeling Process

Surpassing any regulatory process is a major challenge for any manufacturer. Therefore, in the process of adhering to the AME label, manufacturers might presumably face some of the regulatory challenges discussed in section 5.2. The most relevant among them can be the time delay and cost involved in the labeling process, and the administrative workload associated with the introduction of a new product label. Currently, these factors are uncertain and remain a concern for manufacturers in adhering to AME label. P3 explains the perspective of small-size manufacturers toward this uncertain cost element:

"Particularly for small startups, they don't know what's going to happen with their product. It's a lot of money upfront to be to get compliant with regulations before you can actually ship the product that you don't know how many will actually sell. So, you're burning money very quickly with regulations". [P3 - Operations Manager]

Currently, there is a lack of clarity on the cost associated with the assessment of medical equipment against AME standards. For example, ensuring robustness may require adding layers of protection to prevent external access to components, which could increase the overall cost compared to current devices. Also, more regulations in the market mean, more expenses for manufacturers. Manufacturers also argue that new and changing regulations are delaying their product release. Manufacturers would be greatly inclined to adopt the AME label if it offers streamlined processes, minimal paperwork, clear concepts, and eliminates the requirement of sending products to notified bodies. The ability for manufacturers to self-declare various aspects and help minimize the overhead administration cost could further enhance their willingness to adhere to such a label.

All the above observations are derived from the case study interview. These can be summarized into the following propositions:

Proposition 10: Recognition and acceptance of AME label by authorized bodies (Global Fund, UN, WHO, etc) boosts the motivation for manufacturers in adhering to it.

Proposition 11: Recognition and validation of AME label by whole world of LMICs and their stakeholders strengthens its value in the regulatory system.

Proposition 12: Differentiation of AME label from existing regulatory tools and its unique positioning in the regulatory system is key to its successful implementation and adoption by manufacturers.

Proposition 13: Manufacturers show a higher preference for regulations that require a minimum amount of documentation, administration cost, and approval time.

Proposition 14: Organizations of different sizes and market presence have different acceptance behavior towards AME label.

These propositions related to the manufacturers' perception of AME label are validated (Chapter 8) with a larger population before providing the final conclusions.

8 Validation

Chapters 6 and 7 identified the challenges faced by manufacturers in entering LMICs and their perception of the AME Label. A total of 14 propositions were formed based on data collected from the case study. The goal of this chapter is to validate these propositions. The validation was done using an interview and a survey. This is step 4 of the research flow diagram shown in section 3.1. This chapter concludes by answering sub-questions 3 and 4 by consolidating the validated propositions.

Section 8.1 presents the survey results, illustrating the average of the scores assigned by participants to each of the propositions. This is represented in a table under this section. The validation results from the expert interviews are discussed in section 8.2. A summary of the participants' responses is presented in a tabular format, highlighting any exceptions or non-agreements along with their corresponding reasoning. Relevant quotations from different manufacturers are included in this section to validate different reasoning. Finally, section 8.3 will conclude the chapter by answering sub-questions 3 and 4.

8.1 Validation of Propositions through Survey

The case study provided insights into two main topics: the challenges faced by manufacturers when entering LMICs, and the perceptions of manufacturers on the AME label. These observations directly align with the primary objectives of sub-questions 3 and 4 respectively. A total of 14 propositions were derived from the case study, which was validated by the subject experts (*Table 5*) and a subsequent survey. In the survey (n=16), the respondents were asked to mark their agreement with these propositions on a scale of 1 to 5; 5 being *Strongly Agree* and 1 being *Strongly Disagree*. The weighted average of the scores of individual propositions is shown in the *Table 9*.

The findings indicated that the majority of propositions have a weighted average score of above 3,5 and 11 out of 14 propositions were scored above 4. While the survey did not inquire about the participants' motivations for scoring each finding, these results have been qualitatively validated through 'validation interviews' with medical equipment manufacturers located globally (*Table 5*). Consequently, the rationale behind varying scores for different propositions is substantiated by the validation interview outcomes, which are discussed in section 8.2.

	No	Proposition	Weighted Average Score
Challenges for Manufacturers in Entering LMICs			
Design & Manufacturing	1	The limited knowledge of contextual conditions (environment factors and infrastructure capacity) in which the equipment will be used makes it difficult for manufacturers to design appropriate medical equipment for LMICs.	4,1
	2	Because LMICs stakeholders overestimate their infrastructural and human capacity to install and operate medical equipment, this makes it difficult for manufacturers to effectively implement projects in those countries.	3,4
Regulatory Approval & Distribution	3	Periodic changes in national regulation and different import-export regulations within LMICs create complexity, delay, and cost for manufacturers in supplying medical equipment.	4,5
	4	The requirement of country-specific registration and regulatory approval for medical equipment causes delays in supplying equipment to LMICs.	4,2
	5	Procurement agencies who highly emphasize the technical parameters of medical equipment and ignore the operating conditions and implementation capacity of LMICs make it difficult for manufacturers to supply appropriate equipment.	3,8
	6	SMEs and startups that lack proven track records and performance statements for their medical equipment face relatively more challenges than established organizations in selling equipment to LMICs.	4,3
Installation & Maintenance	7	The lack of human capacity in LMIC hospitals to handle medical equipment creates challenges for manufacturers to successfully implement projects in these countries.	3,4
	8	Regular post-market surveillance helps manufacturers to iterate and improve the design of medical equipment supplied to LMICs.	4,4
	9	The presence of local partners and centralized distribution centers can improve the service and maintenance of medical equipment supplied to LMICs.	4,4
Perception of Manufacturers on AME Label			
Key Constraints in adhering to AME Label	10	Recognition and acceptance of AME label by authorized bodies (Global Fund, UN, WHO, etc) boosts the motivation for manufacturers in adhering to it.	4,7
	11	Recognition and validation of AME label by whole world of LMICs and their stakeholders strengthens its value in the regulatory system.	4,6
	12	Differentiation of AME label from existing regulatory tools and its unique positioning in the regulatory system is key to its successful implementation and adoption by manufacturers.	4,3
	13	Manufacturers show a higher preference for regulations that require a minimum amount of documentation, administration cost, and approval time.	4,6
	14	Organizations of different sizes and market presence have different acceptance behavior towards AME label.	4,1

Table 9: *Significance of propositions on a scale of 1 to 5 (n=16)*

8.2 Validation of Propositions through Expert Interviews

The validation through expert interviews, yielded similar outcomes as that of the survey. The overview of agreement among the experts regarding propositions is presented in *Table 10*, *Table 11*, *Table 12*, and *Table 13*. In the tables, the symbol 'x' indicates that experts have agreed to the respective finding, while the symbol 'o' indicates that experts have a disagreement or have not emphasized the respective finding. An overview of the tables indicates that, for certain propositions 50% or more experts have shown a disagreement. This implies a lack of validity

for those propositions. These disagreements (marked by 'o') can be attributed to the distinct business practices of individual companies. Therefore a description is given under each table to explain the experts' reasoning behind their difference of opinion for those particular propositions. It is to be noted that E6, having a research and academic background, could only give a general opinion of the propositions, especially those related to the unique contextual challenges, regulatory challenges, and those in the procurement process. Hence, only the most relevant opinion of E6 is quoted in the following description.

	E1	E2	E3	E4	E5	E6
Proposition 1	x	x	o	x	o	o
Proposition 2	x	x	o	o	x	x

Table 10: *Validation of challenges in the design and manufacturing phase of products supplied to LMICs*

Table 10 summarizes the responses of experts in validating the challenges faced by manufacturers in the design and manufacturing phase of medical equipment supplied to LMICs. The responses indicate a lack of validity for Proposition 1. This implies certain manufacturers are able to understand the exact contextual conditions (environmental factors and infrastructural capacity) where their equipment operates. They do it in practice and believe that it can be achieved by either physically visiting the region or collaborating with partners who have experience working in that specific area. E3 mentions: *"I don't think that's as big of an issue. I think that information is possible to get either by going to a region or to work with partners who worked in that region. So when we built the RAD-G device, we partnered with the Gates Foundation and we did human factors research in a number of different settings. We've worked in four countries to do it"*. But, E3 representing a large organization has enough resources and network to perform such research, which may not be the case for small-size organizations. Hence this can be considered as an exception for large-size organizations, and cannot be generalized to all manufacturers.

	E1	E2	E3	E4	E5	E6
Proposition 3	o	o	x	x	x	o
Proposition 4	x	o	x	o	x	o
Proposition 5	x	o	x	o	x	x
Proposition 6	o	o	o	o	x	o

Table 11: *Validation of challenges in regulatory approval and distribution phase of products supplied to LMICs*

Table 11 summarizes the responses of participants towards the challenges in regulatory approval and distribution of medical equipment to LMICs. It can be seen that there is no clear majority of agreement on these propositions. From the analysis, it can be deduced that this variation in responses can be attributed to the different operational methods of organizations.

Considering Propositions 3 and 4, some manufacturers find it less challenging to deal with the regulations and adhering to trade compliance while supplying equipment to LMICs. When asked about the challenges in foreign trade and regulatory approvals of medical equipment, E2 states: *"It does to an extent we've had, and we have to figure out how to work with our customers when it comes to these regulations. We often will say we deliver to port of entry that's our terms and then our local either in countries where we have distributors, our distributor then clears and provides equipment"*. Also, some organizations have their business operation methods that eliminate many challenges, as E2 adds: *"We of course, try to be both proactive and reactive to opportunities, but we really only work in countries where we think we could support the customer"*.

During the discussion on the tendency of procurement agencies to overlook the operating conditions and implementation capacity of LMICs (as stated in Proposition 5), it was noted that while the majority of experts agreed with this finding, a few experts mentioned that the situation has been gradually changing over the years. These experts observed a shift in focus among procurement agencies, with an emphasis on considering operational aspects as well. E2 state: *"Tenders have started to include more requirements on training and service. It used to be like an optional warranty. It means that the agencies are seeing the need to have for suppliers and manufacturers to provide more support to the customer. So we think it's a really good thing that we've seen those changes over the last maybe three years of more and more tenders really focused on the non-technical aspects as well. There's still more room for improvement"*. A similar opinion was shared by E1: *"Increasingly more often they do consider the contextual conditions. It was totally ignored for a long time, but now they look at certain issues now"*.

Regarding Proposition 6, the experts did not specifically address or validate the advantage that established manufacturers have over SMEs and start-ups based on their proven track record. As explained by E2, *"Although our company has achieved listings in prestigious catalogs such as the UN catalog, UNICEF catalog, and WHO catalog, we have found that being included in these catalogs did not lead to substantial sales for our company. This outcome came as a surprise, as we had expected greater benefits from being included in these catalogs"*.

	E1	E2	E3	E4	E5	E6
Proposition 7	o	x	x	x	x	o
Proposition 8	x	x	x	x	x	x
Proposition 9	x	x	x	x	x	x

Table 12: *Validation of challenges in the installation and maintenance of products supplied to LMICs*

While validating the challenges faced by manufacturers in the post-market phase, the majority of experts agreed to the challenges due to insufficient human capacity. They also emphasized the importance of post-market surveillance, local support and centralized distribution hubs while doing business in these countries. This can be observed from responses marked in *Table 12*.

	E1	E2	E3	E4	E5	E6
Proposition 10	x	o	x	x	x	o
Proposition 11	x	o	x	x	x	o
Proposition 12	o	x	x	x	o	o
Proposition 13	o	x	x	x	o	x
Proposition 14	o	x	x	x	x	x

Table 13: *Validation of key constraints for manufacturers in adhering to the AME label*

The latter part of the validation interview aimed to corroborate the propositions regarding manufacturers' perceptions of the AME label. The focus was on identifying the challenges they anticipate when it comes to adhering to the standards of the AME label. As shown in the *Table 13*, the majority of the experts agreed on all the propositions related to key constraints and proved to have similar perceptions of the AME label as those from the case study findings. The majority of them agreed that the recognition and trustworthiness of label in the market are important factors that can motivate them to adhere to it.

8.3 Conclusion

Chapter 6 elaborated on the specific challenges faced by manufacturers in supplying appropriate medical equipment to low-resource settings. It explained the challenges in regulatory systems, those due to the unique contextual conditions of these countries and their healthcare facilities. These challenges are further substantiated and validated in this chapter. The most pertinent challenges will be summarized here to answer the SQ3 - ***'What are the challenges faced by medical equipment manufacturers in entering the LMIC market?'***. The major challenges are given below in the order of relevance:

1. ***Regulatory Approval and Trade Compliance***: Medical equipment manufacturers find it challenging to deal with the periodic changes in national regulations, local registration of medical equipment, and different import-export regulations within LMICs. They have to undergo administrative complexities, which are associated with cost and further time delays in supplying products.

2. ***Poor Business Track Record for Emerging Organizations***: Small and medium size manufacturers who lack proven track records and performance statements for their medical equipment have challenges at different stages in supplying equipment to LMICs. Some major bottlenecks include time delays and cost in getting regulatory clearance for their products, and disadvantages due to poor local networks in the recipient countries. SMEs and startups lack the experience and resources in navigating these challenges encountered in the business landscape.

3. ***Limited Knowledge of Operating Conditions***: Manufacturers often lack sufficient knowledge and understanding of the environmental factors and infrastructural capacity of LMIC hospitals where the equipment will be deployed. It is also observed that LMIC stakeholders sometimes overestimate their capacity to install and operate the equipment. This creates challenges for them to design and manufacture appropriate medical equipment which can function effectively in these low-resource settings.

4. ***Inappropriate Product Specifications by the Procurement Agencies***: Manufacturers till recent times have to undergo challenging situations where procurement agencies disregard the product requirements suitable for LMICs. Instead, these agencies prioritize technical specifications without considering the operating conditions and infrastructure capabilities of hospitals in these countries. However, established manufacturers with local support systems are better equipped to address these challenges by obtaining comprehensive information about where and under what conditions the equipment will be operated.

5. ***Insufficient Human Capacity in LMICs Hospitals***: LMIC hospitals often lack healthcare personnel and technicians with sufficient knowledge to operate and maintain the medical equipment they receive. They lack training or sometimes the trained personnel are not available to the patient groups. This creates challenges for manufacturers to successfully implement projects and ensure complete utilization and effectiveness of the medical equipment supplied.

Furthermore, the perception of medical equipment manufacturers on the concept of the AME label, their confirmation of the value propositions, and key constraints expected in adhering to this new label were explained in Chapter 7. This chapter has validated those findings, which are consolidated to answer the SQ4 - ***'What are the perceptions of medical equipment manufacturers in adhering to a product label such as AME?'***.

Medical equipment manufacturers focusing on LMICs recognize several advantages in adhering to the AME label. These benefits are considered valuable and relevant for their business operations in LMICs. They are:

1. ***Brand Value***: AME label could help manufacturers gain an overall significance of their brand in the healthcare market of LMICs.

2. ***Visibility***: Adhering to the AME label could increase the degree to which medical equipment are easily seen, noticed, and recognized by potential customers in LMICs.

3. ***Credibility***: AME label can help increase the level of trustworthiness and reliability of medical equipment utilized in LMIC hospitals.

4. ***Transparency***: The AME label could facilitate the provision of accurate, reliable, comprehensive information regarding medical equipment by manufacturers, which can also be made readily available and easily accessible to stakeholders in the MedTech industry within LMICs.

5. ***Customer Satisfaction & Fulfilment***: By adhering to the AME label and standards, manufacturers could guarantee that their medical equipment satisfies the unique demands and requirements of stakeholders in the MedTech industry within LMICs.

6. ***Minimizes Administrative Complexity***: Adhering to AME label could help manufacturers simplify administrative tasks and eliminate unnecessary time-consuming processes while supplying medical equipment to LMICs.

While manufacturers recognize the benefits of adhering to the AME label, they also consider various factors that can influence their decision in adhering to or adopting this label. These factors are mostly related to the implementation of the AME label. Therefore the answer to SQ4 is complete only by mentioning these constraints for manufacturers in adhering to the AME label, which are:

1. ***Recognition of AME Label***: The adoption of the AME label by manufacturers depends on its recognition by two groups of stakeholders. Firstly, authorized bodies such as the Global Fund, UN, WHO, etc., should recognize and accept the label. Secondly, the recognition and validation of the AME label by LMICs and their stakeholders are essential. Recognition at both levels is crucial to incentivize manufacturers to adhere to the AME label and enhance its value in the regulatory system.

2. ***Cost and Time delay in the Labeling Process***: Manufacturers encounter significant challenges in terms of high costs and time delays when undertaking certification and adhering to regulatory processes. The decision to adhere to the AME label becomes difficult without the awareness of associated costs and time commitments. The adherence or acceptance behavior towards the AME label could be different for companies of different sizes. On the one hand, there are SMEs and startups who are unsure about their business outcomes. While, on the other hand, there are established manufacturers who would face the additional burden of transitioning their entire product portfolio to meet AME standards, further impacting time and financial resources.

3. ***Positioning of AME Label in the Regulatory System***: The AME label, in its current theoretical stage, needs further clarification regarding its position in the regulatory system. Manufacturers who have already aligned their product portfolio with labels such as CE, FDA, or others express concerns about the distinguishing features of the AME label compared to existing labels. These concerns primarily revolve around the differences in testing methods and the possibility of reusing test results and regulatory documents from their existing labels. The implementation of the AME label alongside widely accepted labels like CE and FDA in LMICs puts manufacturers in a dilemma to adhere to the AME label.

9 Discussion

Several aspects reported in this research are relevant to manufacturers targeting the healthcare market in LMIC. The concept of a contextualized label (such as AME) has grabbed the interest of many stakeholders. In this chapter, the findings from the literature and interview are analyzed and the feasibility of the AME label for better assessment and management of health technology in LMICs are discussed.

A reflection on the research findings (segregated as answers to sub-questions), correlating to the concept of the AME label is given in section 9.1. The limitations of this research and recommendations for the AME team related to the future development and execution of the label are given in section 9.2 and 9.3 respectively. Finally, the relevance of this research on the MOT study program is explained in section 9.4.

9.1 Reflection on the Research Findings

- **Reflection on the answer to sub-question 1**

The objective of this research was to assess the feasibility of implementing a contextualized product label, known as the Appropriate Medical Equipment (AME) label, which could be a potential solution to address the intricacies surrounding health technology assessment and management in LMICs. Given the novelty of the AME label, limited direct evidence exists regarding its benefits for both medical equipment manufacturers and end users. Therefore, this study was structured into different stages to systematically examine the value of this product label to the manufacturers and its potential to address the challenges of supplying appropriate medical equipment to LMICs. The desk research and interviews used in this study contributed equally to reaching the final conclusion. Initially, it was essential to understand the general functioning of product labels across various industries, including how manufacturers utilize them and how consumers perceive them while purchasing products. It was found that product labels serve as a dependable and trustworthy source of information, and play a crucial role in unveiling hidden product characteristics and providing valuable insights to the consumers (Catrina, 2020; Koszewska, 2015). Informing consumers about the product's benefits, value propositions, superior qualities, and the design and manufacturing process will evoke emotional responses in consumers and significantly impact their purchasing behavior. These findings can be transferred to the case of AME label. In the context of LMICs, the input of user groups (patients, healthcare personnel, and technicians) regarding the quality and specifications of medical equipment is often limited. They are only informed when the products reach their premises. This lack of involvement can be associated with factors such as their procurement system and governance practices, which is a whole different discussion area. However, educating these user groups about the benefits of AME-labeled medical equipment, its suitability and appropriateness to the LMICs context can help to cultivate trust and reliability on

the label and labeled equipment. In the long run, this recognition can foster greater acceptance of AME-labeled medical equipment and its utilization in these countries. From the perspective of a medical equipment manufacturer who targets LMICs for their business, can gain an added advantage while pitching products with unique user needs. As mentioned by Bozza et al. (2022), labeled products approved by standards have the advantage of increased brand reliability, recognition, and product differentiation in the market. This is found to be true in the case of the AME label, which is presented in *Figure 11*. Hence, it can be inferred that products featuring value-based labels, backed by approval from standardized third-party bodies, have the potential to instill trust and confidence in consumers, thereby enhancing their market value. Similar to any innovative label, the growing recognition and acceptance of the AME label could ultimately enable manufacturers to attain higher commercial value and improved efficiency in the LMIC market.

- **Reflection on the answer to sub-question 2**

Globally, the complexity of regulatory landscapes in the MedTech industry is increasing. There are many quality assurance labels and regulatory norms which vary from country to country. The introduction of the AME label will also contribute to this complexity. Although this complexity exists, only mandatory enforcement of stringent regulatory norms for medical equipment can improve the quality of healthcare technologies delivered in LMICs (Mori et al., 2011). Hence innovative labels such as AME with stringent regulatory standards could help remove infiltration of equipment supplied and provide access to quality and appropriate equipment. Similar to other labels in the MedTech industry, manufacturers seeking the AME label are also required to subject their products to specific testing criteria. These are criteria such as usability, durability, maintainability, affordability, and accessibility of the equipment. As the AME label is currently in its theoretical stage, it is crucial for the AME team to consider factors that can readily attract manufacturers. It is found that generally manufacturers face a lot of challenges in the process to adhere to or adopt any labels or regulations for their equipment. The AME team needs to consider these challenges and take measures to minimize the same for manufacturers who are willing to adhere to the label. One of the most important challenges faced by manufacturers is the time and cost involved in the approval process (Maresova et al., 2020). This challenge was emphasized by industry experts and shared a ballpark figure of the time and cost involved, which were enormously huge from a business perspective. SMEs and start-ups play a key role in developing innovative medical equipment (Baines et al., 2023), and having them face excessive costs and time in the approval process will challenge them to supply quality innovative products. For LMICs, innovative medical equipment could help meet the contextual needs which sometimes is not met by the traditional high-end technical equipment. Contextual needs generally mean accessibility, affordability, and usability of equipment reaching hospitals in low-resource settings. The second most relevant challenge is the lack of harmony in the regulations (Brolin, 2008). This normally happens when manufacturers try to expand business globally and have to adjust to country-specific regulatory standards. The AME label is specifically formulated to cater to the contextual needs of LMICs. In order to have a wider acceptance of the label among manufacturers, there should be elements in the testing

criteria that can resonate with those of CE or FDA which is currently accepted in many LMICs and widely used by manufacturers. In this case, manufacturers would find it less cumbersome to transition their products to AME standards and adopt the label. A significant challenge, which was less explored in the literature but highly emphasized in the interviews was the incompetency of Notified Bodies. This is especially applicable to manufacturers in the EU, as these bodies operate within EU boundaries. Due to the private nature of these bodies, they sometimes act according to their business interest. This leads to unfair disadvantages for SMEs and start-ups in getting their products approved. In the current development stage of AME, the extent of involvement of such conformity assessment bodies in the product approval process is uncertain. However, this will remain a less controllable factor for the AME team while developing the conformity process for AME-labelled medical equipment.

- **Reflection on the answer to sub-question 3**

As previously mentioned, the introduction of the AME label aims to fulfill the unmet requirements of LMIC hospitals and patient groups in terms of ensuring that appropriate medical equipment reaches their premises. LMICs rely on equipment manufacturers in HICs for acquiring healthcare technologies. However, only a fraction of the procured equipment becomes operational after reaching their hospitals (Marks et al., 2019). The manufacturers in HICs cannot be solely held responsible for this issue. They face many challenges in developing medical equipment matching the contextual requirements of LMICs and supplying it to those countries. The majority of these challenges are beyond their control and the degree of challenge varies depending on the resources and market presence of the manufacturer. The introduction of AME could potentially help mitigate many of those challenges. To begin with, most manufacturers seldom have direct contact with hospitals and end-users in LMICs, which limits their awareness of the capacity, operation conditions, and product requirements suitable for the effective operation of equipment. The distribution of equipment mostly happens through procurement agencies, which are global bodies not aware of the ground realities in LMICs. Given this lack of awareness, these agencies disregard the unique product requirements that these countries require for the effective operation of medical equipment. They simply prioritize the technical specifications of the product without considering the operating conditions and infrastructure capabilities of their hospitals. Manufacturers find this information gap challenging while designing equipment. The procurement of equipment through public tendering also has similar limitations that challenge manufacturers in supplying appropriate products. Manufacturers who have prior experience doing business in these countries, find the product specifications in the tender unrealistic and generalized. The tender specifications tend to demand the highest possible systems instead of the systems that meet the end-users (patient) needs. Manufacturers face other challenges in the supply stage too. They have to do a local registration of their equipment supplied to these countries. This is a time-consuming process and cumbersome to execute from the country of origin or the shipping country. These are all practical challenges and are not widely explained in the literature. However, very few manufacturers have their own business model and resources which helps them to overcome some of these challenges. A prominent one observed through the research was the presence of local

partners, distribution centers, sister companies, etc. Having a local presence supports manufacturers or donors by providing sufficient information on the operating conditions, accurate technical requirements, and operational capacity in hospitals. This is valuable for them in designing medical equipment that can meet the contextual requirements of LMICs. This information is also helpful for manufacturers to have effective communication regarding product specifications in the pre-bid meetings held in the case of public tendering. Furthermore, the presence of local support can help manufacturers streamline the supply process in terms of understanding the local regulation and registration protocols, minimizing a tremendous administrative overload for them. Only a few manufacturers who completely focus on LMICs have taken proactive measures, allocated extra resources, or exercised precautions to adapt their business operations specifically for these countries, which helped them to mitigate these challenges to an extent. At the same time, it is challenging for small-sized manufacturers (SMEs and startups) to invest in such resource-intensive business models to pursue business opportunities that are uncertain and less assured. The introduction of AME label could possibly assist such manufacturers in overcoming these challenges. Through the guidelines of the AME label, they become informed about the contextual design requirements of LMICs which could guide them to design appropriate equipment. The conventional procurement process could also be modified by including technical specifications meeting AME standards. From a manufacturer's perspective, AME label could raise awareness about the specific contextual conditions of LMICs and could simplify the tendering process, which ultimately leads to the supply of equipment that is tailored to meet the needs of end-users in low-resource settings.

- **Reflection on the answer to sub-question 4**

From the research findings, it can be concluded that the AME label has the potential to effectively address issues related to the inadequate assessment and procurement of health technologies in LMICs. As previously mentioned, the introduction of this new label adds complexities to the regulatory landscape. Hence, it was imperative to explore manufacturers' perspectives on this label, including their willingness to adopt it, the perceived value they associate with it, and the factors that motivate or hinder them from undertaking it. Based on the available information about the AME label and its vision, the majority of manufacturers who participated in the research expressed agreement with the vision and different value propositions offered by the label. This is summarized in section 7.1. By increasing the visibility and credibility of AME-labelled medical equipment, manufacturers could generate brand value in the MedTech market of LMICs. AME label could create transparency for the medical equipment entering LMICs. This fosters trust and confidence among stakeholders regarding the suitability and appropriateness of the equipment for their specific needs. Given that the study began by investigating the role of product labels in various industries and examining how manufacturers and consumers engage with them, the findings concerning the perception of manufacturers towards the AME label in the later stage of research were anticipated and in line with expectations. However, from the perspective of business viability, manufacturers raised some concerns regarding the implementation of the label. These concerns included the recognition of the AME label in the market, the cost and time delay involved in the labeling process, and

the positioning of the label within the regulatory system (for instance, the compatibility issues with other accepted labels). These concerns can be better consolidated as recommendations for the AME team, which are discussed in section **??**. In addition to this, widespread adoption of the AME label is difficult to achieve in the near future, particularly considering manufacturers' familiarity with the existing system. Therefore, a more practical approach may involve a gradual transition or modification of the existing regulations, facilitating a smoother and more feasible way forward for implementation. An alternate way could be to implement the label like introducing any innovation in the market. Similar to any innovation, the AME team could search for a potential manufacturer who can be considered an early adopter and willing to experiment by aligning their product portfolio with AME standards. The success of this early adoption could serve as a compelling example and confidence booster, attracting more manufacturers and stakeholders from LMICs to consider, adhere to, and adopt the AME label.

9.2 Limitations of the Research

The study encountered a few limitations. The first one is notably the inability to compare opinions among the participants in case study interviews. The four participants represented different roles within the company and offered insights into their respective domains. The availability of one or more participants in similar roles could have helped with direct comparisons and potential reinforcement of opinions. For example, having two Operations Manager in the case study could have either provided different perspectives or strengthened the opinions expressed. This could have opened the space for a better conclusion and supported framing the propositions. Also, having more experts from the quality assurance division could have provided better insights into the regulatory challenges and further reinforced the respective findings from the literature study. Another limitation concerns the poor availability of subject-specific experts. This includes academic researchers in this domain and industry professionals having business targeting LMICs. Despite the survey being shared with a wide population, there were only limited responses. In addition to the database of manufacturers provided by the AME team, another set of academic experts and relevant manufacturers in the Netherlands were also reached out to participate and complete the survey form. The survey was shared with 40 participants, and only 20 responses were received. More responses could have strengthened the survey results better. Also, due to the requirement of subject-specific experts, the survey form used in this study was not circulated to the general public through common digital platforms like LinkedIn, Whatsapp, etc. The availability of more respondents would have enhanced the robustness of the survey-based validation process.

9.3 Recommendations to the AME Team

In light of the research, a few recommendations can be given to the AME team regarding the future development of the label. As discussed in Chapter 5, medical equipment manufacturers encounter various challenges when seeking approval for their products, whether it is for domestic or international sales. Labels such as CE or FDA are currently facilitating manufacturers

with a sufficient business opening to any market. Hence, there should be an added advantage that the AME label offers. In the further expansion phases of the label, the team should specifically look into the possibilities of providing any tangible incentives to the medical equipment manufacturers. A few recommendations for this can be - adopting the AME label could help fast-forward the tendering process for manufacturers, they should be free of unreasonable expenses while adhering to the AME label. In order to reduce testing costs, the AME team could explore the possibility of reusing test results for similar factors, such as durability and reliability (if the standards match those of AME) that manufacturers have already conducted for their products according to existing regulatory standards. It is found that manufacturers may worry about potential overlaps or conflicts between the AME label and well-established regulatory labels such as CE or FDA. This could lead to confusion in the market or additional compliance burdens for the manufacturers. Therefore, it is crucial for the AME team to address these compatibility issues. This could involve harmonizing the testing criteria (as mentioned above) or aligning the requirements of the AME label with those of CE or FDA labels to a possible extent so that manufacturers can adopt the label seamlessly. By doing so, the AME label could be perceived as a valuable addition to the existing regulatory systems, gaining the recognition and acceptance necessary to promote its adoption in LMICs and address the challenges faced in health technology assessment and management. Finally, the global adoption of the AME label could only be realized if it is mandated by the relevant stakeholders in LMICs. Therefore, it is important to generate demand by educating these stakeholders on the significant role AME plays in the betterment of equipment suitability entering LMICs.

9.4 Reflection on the link to MOT Study Program

The research findings of this study have made a valuable contribution to addressing a real-world situation that requires an analysis of organizational and stakeholder roles and behaviors. This reflects the relevance of the research to the MOT study program. The research background and problem definition explained in Chapter 1 are analyzed from an organizational, commercial, and societal perspective. These are the key elements that any Management of Technology problem deals with.

As discussed in Chapter 6, the research primarily contributes to finding the challenges faced by medical equipment manufacturers in entering LMICs, and the limitations they face in executing projects effectively in these countries. The case study provided profound insights into the organizational challenges, shedding light on how companies structure their business practices and employ diverse strategies to overcome the challenges in their pursuit to do business in LMICs. The expert interviews helped in identifying the correlation between the business strategies employed by various organizations and their level of success in achieving their business objectives. The findings reveal that organization size, market presence, external relations, and inherent capacity are major differentiating factors in establishing and extending business in the healthcare market of LMICs. This aligns with the organizational aspect of the study program which recognizes different management practices and their alignment with business strategies to promote technologically driven products in the market.

Another key element of the MOT study program is the reflection on the commercial viability of a product. This research is centered around the concept of the AME label, a new concept aimed to overcome the healthcare technology challenges in LMICs. Chapter 7 deep-dived into understanding the commercial viability of this label, by understanding the perception of the market and weighing the cost and benefits for manufacturers in adopting it. These findings helped in concluding some of the strategies that AME team could consider in further development of the label. Subsequently, this research provided some valuable recommendations to the AME team on strategic measures for positioning the AME label and guiding them to address potential challenges during the implementation phase of the label.

Finally, the societal relevance of this study is evident from the problem definition and research background in Chapter 1. The research aimed to address an issue that directly deals with people, risks, and corporate social responsibility. The status of equipment graveyards, inappropriate donations, and lack of capacity building in LMICs have been a discussion that is limited to literature. The concept of the AME label is an initiative in the right direction to improve these situations in the low-resource setting. Although the label is in the theoretical stage, many industry experts have shared their agreement on the label's objectives. Adopting this label could be a way for manufacturers to strengthen their corporate social responsibility, by addressing the requisite needs of patient groups in LMICs. The outcomes of this research could be beneficial for industry experts before aligning their product portfolio with the AME standards, by understanding the values associated with the new label along with providing safe, appropriate, and quality healthcare technologies to LMICs.

10 Conclusion

Aiming to understand the incentives of medical equipment manufacturers in adhering to the new product label, this chapter will ultimately answer the main research question from the incentives offered by AME label.

Consolidating the findings from different sources used in this research, the main research question, which is - ***'How could a new product label support medical equipment manufacturers to sustainably enter the healthcare market of low- and middle-income countries?'*** is answered.

The AME label holds the potential to provide different tangible and intangible incentives to medical equipment manufacturers who aim to expand their business in LMICs. Given the prevalent issue of inappropriate donations and supply of medical equipment to LMICs, the AME label could create transparency for the medical equipment entering LMICs. By adopting AME label or adhering to AME standards, manufacturers could guarantee that their medical equipment satisfies the unique demands and requirements of stakeholders in the MedTech industry within LMICs. AME-labeled equipment could build trust and confidence among stakeholders regarding the suitability and appropriateness of their equipment for specific end-user needs. Apart from ensuring the suitability of the equipment, AME label also advises manufacturers to contribute to the capacity building in LMICs, by developing and implementing training materials and programs for equipment users. Given the effective and strategic implementation of the AME label, an increasing number of manufacturers are expected to adopt the label. This will increase the visibility and credibility of AME-labeled equipment. As a result, the brand value of the manufacturer and the market value of the equipment will be enhanced, enabling manufacturers to attain higher commercial value for their products and improved operating efficiency in the healthcare market of LMICs. Furthermore, by optimizing the product design towards the contextual requirements and including competitive product features, manufacturers could use this new value-laden label as a differentiating factor in their marketing phase. This will help medical equipment manufacturers to gain an overall competitive advantage in the healthcare market of these countries. All the above-mentioned intangible incentives apply to manufacturers of all sizes, ranging from small-sized enterprises to large enterprises. However, their willingness to accept it remains uncertain at this stage, mainly because the label is still in its theoretical state and most of the tangible incentives are not defined. There are some tangible incentives to manufacturers which could be shaped along the way as the AME label develops. The recognition and acceptance of AME label in the market could support manufacturers with streamlined processes, minimize overhead administration costs, reduce documentation work and time while supplying equipment to LMICs. By obtaining an AME label, manufacturers could accelerate the tendering process, which typically lasts for a year or more. With AME-labeled products, manufacturers could bypass lengthy procurement procedures, resulting in cost and time savings compared to the current process. Hence, the adoption of AME label is found beneficial for manufacturers targeting the healthcare market of LMICs.

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Appendix A

Questionnaire for Case Study Interview

Introduction of Participannt

1. What type of equipment does your company manufacture for LMICs context?
2. What is your involvement/role in your company with respect to LMIC business?
3. How long have you been working in this role?

Challenges for Manufacturers

A. Design and Manufacture

1. What do you think are the design and manufacturing requirements for medical equipment supplied to LMICs?
    - With respect to local requirements like, affordability, ease of use, energy efficiency, robustness.
2. What are the challenges in adhering to these design and manufacturing requirements?
    - With respect to technical challenges or challenges in designing unique product characteristics.
3. How do you ensure that your medical equipment are compatible with LMICs context?
    - With respect to contextual conditions like harsh environments, low-power sources and poor infrastructure.
    - With respect to tackling conditions of inadequate education or lack of trained personnel to operate the equipment.

B. Regulatory Approval

1. Which regulations and standards apply to your medical equipment supplied to LMICs?
    - Can you brief me about the pathway for getting these regulatory approvals?
    - How often does your product need clinical approval?
2. What are the regulatory challenges you normally face while seeking approval for your medical equipment supplied to LMICs?
    - With respect to roadblocks in the conformity assessment procedure.
    - With respect to extra paperwork or documentation required.

- Any estimate of time and cost involved in the certification process?

C. Marketing and Sales

1. What are the challenges in the selling process of medical equipment to LMICs?
   - With respect to your approach to the tendering process.
2. How do you ensure the availability of spare parts and consumables in LMICs hospitals that are required for fully functioning medical equipment?

Perception of the AME label

1. To what extent do you think AME label will add value for medical device manufacturers in targeting the LMICs market? (Rate on a scale of 1 [strongly disagree] to 5 [strongly agree]).
   - Creates a Brand Value for Manufacturers.
   - Creates visibility for medical equipment in the market.
   - Helps in developing credibility for medical equipment.
   - Creates transparency in the equipment supplied.
   - Helps in improving recognition for the products and services.
   - Helps in enforcing fair competition in the market.
   - Helps in meeting customer requirements and stakeholder demands.
   - Useful in minimizing complexity in different stages of the equipment life cycle – design, documentation, approvals, supply chain.
2. What are the expected roadblocks for a manufacturer in adhering to/adopting a new label such as AME?
   - With respect to redefining the policies related to quality, environment, and safety.
   - With respect to the extra cost of labeling and consultation fees.
   - With respect to reliability and trust issues on the label.
3. Would you be willing to undertake the AME label for your medical equipment in the near future?

Appendix B

Questionnaire for Validation Interview

Introduction of Participants

1. What type of equipment does your company manufacture for LMICs context?
2. Does your company target only a specific region of LMICs or all LMICs or also HICs?
3. What is your role in your company with respect to LMIC business?
4. How long have you been working in this role?

Challenges for Manufacturers

A. Design and Manufacture

1. How do the contextual conditions of LMICs affect manufacturers while designing and developing appropriate medical equipment?
    - Challenges due to limited knowledge of operating location infrastructural capacity.
    - Designing equipment for the lowest resource setting vs success rate of project implementation.
    - LMICs overestimate their infrastructural and human capacity vs effective project implementation.
2. What is the role of post-market surveillance in the product development strategy for the equipment supplied to LMICs?

B. Regulations, Sales and Maintenance

1. How does the local support system influence regular maintenance for equipment supplied to LMICs? How important is that for you?
2. Do you have any unique challenges in supplying equipment to LMICs?
    - Time delay from Notified Bodies or conformity authorities in approving products.
    - Lack of track records and performance statements.
    - Lack of resources to handle the administrative overload.
3. In your experience, do procurement agencies in LMICs consider the contextual parameters (harsh environment, poor infrastructure and human capacity, remote operating conditions) of LMICs apart from simply focusing on the technical specifications of the product?

4. How do changing national regulations and import-export regulations within LMICs affect the manufacturer while supplying products to these countries?
    - Periodic changes create complexity, time and cost in supplying equipment.
    - Country-specific registration and regulatory approval vs delay in supplying equipment.

Perception of the AME label

1. What is your general opinion of AME label idea, just from the brief information provided?
2. Imagine you as a manufacturer would adhere to/adopt a label such as AME; what would be the main challenges in doing so?
    - With respect to the extra cost of labeling and consultation fees.
    - With respect to reliability and trust issues on the label.
3. Do you expect any difference in the perception of AME label (in terms of investing in them) from startups, SMEs, and established manufacturers? Why
    - Preference to regulations having minimum documentation, administrative cost and time.
4. Would you be willing to undertake AME label for your medical equipment in the near future?

Appendix C

Survey Form to Validate the Prepositions

Opening Statement

You are invited to participate in a research study titled *'Investigating the Incentives for Manufacturers in Certifying Medical Equipment Designed for Low- and Middle-Income Countries: A Case of Appropriate Medical Equipment Label'*. This study is being done by Akshay Rajagopal from Technical University Delft in collaboration with 12 global biomedical engineers with over 150 years of experience in LMICs.

The purpose of this survey is to understand the challenges faced by medical equipment manufacturers in selling products to LMICs. We are also interested in understanding the willingness of manufacturers in adhering to the AME Label and the expected cost and benefits associated with adopting it. The survey will take you approximately 7 minutes to complete. The data from this survey will be used for research purpose, as part of a Master thesis. We will be asking for your agreement on some statements related to:

- Challenges for manufacturers in the different stages of equipment supplied to LMICs
- Perception of AME label for manufacturers targeting LMICs

As with any online activity, the risk of a breach is always possible. To the best of our ability, your answers in this study will remain confidential. We will minimize any risk by ensuring security measures to store the data collected and keeping the results anonymous without disclosing any personal data. Only aggregated survey answers will be published at the end of the study, which means your answers will not be traced back to you.

Your participation in this study is entirely voluntary and you can withdraw at any time. It will not be possible to remove answers to questions once the survey form has been completed and sent.

You can reach the researcher through the following contact information:

Akshay Rajagopal (a.rajagopal@student.tudelft.nl)

By clicking through to this online survey and completing all its mandatory questions, you are agreeing to this Opening Statement and providing your informed consent to participate in this study.

The following statements suggest the potential challenges and opportunities faced by medical equipment manufacturers in entering the low-and middle-income countries (LMICs) market. Please indicate how much you agree with the following statement.

(1-Strongly Disagree, 2-Disagree, 3-Neither Agree nor Disagree, 4-Agree, 5-Strongly Agree)

1. The limited knowledge of the location in which the equipment will be used makes it difficult for manufacturers to design appropriate medical equipment for LMICs.
2. The limited knowledge of contextual conditions (harsh environment and poor infrastructure) in which the equipment will be used makes it difficult to design appropriate medical equipment for LMICs.
3. Designing medical equipment for the lowest possible resource settings (both infrastructural and human capacity in LMICs) guarantees the reliability and durability of the equipment supplied.
4. Because LMICs stakeholders overestimate their infrastructural and human capacity to install and operate medical equipment, this makes it difficult for manufacturers to effectively implement projects in those countries.
5. Regular post-market surveillance helps manufacturers to iterate and improve the design of medical equipment supplied to LMICs.
6. The presence of local partners and centralized distribution centers can improve the service and maintenance of medical equipment supplied to LMICs.
7. SMEs and startups that lack proven track records and performance statements for their medical equipment face relatively more challenges than established organizations in selling equipment to LMICs.
8. Procurement agencies highly emphasize the technical parameters of medical equipment and ignore the operating condition and implementation capacity of LMICs.
9. Procurement agencies that highly emphasize the technical parameters of medical equipment and ignore the operating conditions and implementation capacity of LMICs make it difficult for manufacturers to supply appropriate equipment.
10. Periodic changes in national regulations and different import-export regulations within LMICs create complexity, delay, and cost for manufacturers in supplying equipment.
11. The requirement of local registration and regulatory approval for medical equipment causes delays in supplying equipment to LMICs.

The following statements suggest the potential advantages and difficulties for medical equipment manufacturers in adhering to/adopting AME (Appropriate Medical Equipment) Label. Please indicate how much you agree with the following statements.

(1-Strongly Disagree, 2-Disagree, 3-Neither Agree nor Disagree, 4-Agree, 5-Strongly Agree)

1. To what extent do you think AME Label will add value for manufacturers targeting LMICs market? The label:
    - Creates a brand value for manufacturers.

- Creates visibility for medical equipment in LMICs market.
- Helps in developing credibility for medical equipment.
- Creates transparency in the equipment supplied.
- Creates fair competition in the market.
- Helps in meeting end-user requirements and stakeholder demands.
- Minimizes administrative complexity in different stages of equipment sales.

2. Recognition and acceptance of AME Label by authorized bodies like UN, WHO, Global Fund encourage manufacturers to undertake the label.
3. Manufacturers value the AME Label more, when it is recognized and validated by all LMICs stakeholders.
4. Differentiation (e.g., testing factors, validation process) of AME Label from those of existing regulatory tools is key to its implementation success and having manufacturers adopt the label.
5. Organizations of different sizes and market presence have different acceptance behavior towards AME Label.
6. Manufacturers prefer regulations that require a minimum amount of documentation, administrative cost, and approval time.