Potential Benefits and Implications of Applying MDR in Food-Based Products

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The definition of a medical device has expanded during the recent years, and today also food-based products can under certain conditions qualify as CE marked medical devices. The purpose of this thesis is to clarify these circumstances and the benefits of a CE marking, and thus, to explore whether a section of food-based products should utilise the route of medical devices more often. To succeed in this, documents, directives, and regulations of European Union and Finnish Authorities are examined, some companies from the industry interviewed, and a questionnaire on pharmacists' opinions on the topic conducted. The findings of the thesis show that food supplements with health claims and medical devices have overlapping sections. The mechanisms of actions of the two concepts, however, are different according to the strict definitions. As an example of a food-based product, xylitol pastilles may have a chance in qualifying as a medical device due to the properties, which are similar to a CE marked case example examined, Lingora®. The results of the questionnaire show that the CE marking is highly trusted by pharmacists and customers of pharmacies. This topic must be further studied to obtain more clarity and to utilise its full potential.

Keywords: food-based medical device, CE marking, MDR, medical device, health claim, food supplement, food-based product, xylitol

Contents

1 Introduction

The core of this thesis is to discuss the new industry of food-based products that are classified as medical devices. Medical devices are usually seen as physical objects that promote health. Today, however, the term can include also food-based products under certain conditions. As traditional medical devices, food-based medical devices must fulfil the same requirements. One of them is a physical mechanism of action that means that the product does not achieve its primary function by interacting with the human physiology, which refers to, for instance, the biochemical processes of the human body. Furthermore, the primary mechanism of action should not utilise enzymes or receptors present in the human body, which is common for pharmaceuticals. [1], [2] Previously there have been two main categories for health-inducing food-based products: food supplements and pharmaceuticals. Medical devices create a third category for such products. In brief, the basic idea and requirements behind traditional and food-based medical devices are the same. This perspective is new, and thus, not many have utilised this route of medical devices to access the market as a health-inducing food-based product.

The definition of a medical device has expanded during the recent years, and today the term can include software and food-based products, in addition to the traditional medical devices such as blood pressure apparatus. Likewise, a medical device may refer to a reagent for in vitro use and implants. Related to medical devices, the meaning of the CE marking (Conformité Européene) is important to

acknowledge. The letter combination is presented on products which meet the European Union's (EU) requirements of high quality related to safety, health, and environment. Thus, the marking of the product conveys to customers the message of the safety. Therefore, the advantage of a CE marking for companies is the confidence gained by customers, and the permission to trade the product in Europe. [1] This thesis will examine the matter of medical devices with focus on food-based products in Europe, more specifically in Finland.

"Medical Device Regulation" (MDR) is responsible for assuring the high quality of regulation of CE marked medical devices. The legislation controls that the products do not cause any harm to human health, and that the products have a medical benefit. [1] Similarly, the European Food Safety Authority (EFSA) and European Commission control that food supplements on European markets are not dangerous and safe to use. Health claims are used to prove the health benefit of a product. [3] Therefore, from one perspective, the purpose of the CE marking in medical devices is to some extent similar to health claims' intention in food supplements. There are some fundamental differences in the nature of the terms. This thesis focuses on declaring how food-based products and products closely related to food supplements could apply for and receive the status of a medical device, and what the benefits and disadvantages of that are.

In order to cover the topic successfully, the following research questions (RQ) are discussed in the thesis:

RQ1 : How do food-based medical devices and food supplements with authorised health claims overlap?

RQ2 : Could a xylitol-based product apply for and receive a CE marking as a medical device, and if so, under what conditions?

RQ3 : What are the benefits and disadvantages of a CE marking in a food-based product?

The contribution of RQ1 is to introduce the terms medical device, health claim and food supplement, and to study their qualification processes. In addition, the range of different food-based products classified as medical devices is examined. RQ2 will focus on the application possibilities of MDR in food-based products, especially in xylitol. In addition, the commercial perspective of pharmacies will be covered by RQ3. The main focus of the thesis is to discuss RQ2, and to clarify the possibilities of food-based products, such as xylitol pastilles, becoming qualified as medical devices. Hence, RQ1 will prepare the base for answering RQ2, and the contribution of RQ3 is to further examine the potential of food-based medical devices from a more practical perspective. In addition, xylitol will be used as an example of a food-based product in order to guide the discussion around the topic.

Furthermore, this topic is important to research for a couple of reasons. Firstly, this kind of research focuses on ensuring the steady and controlled way of developing and using medical devices. Secondly, when this topic is critically examined, the safety of CE marked products on the markets is preserved. Moreover, this research aims to assure that products that should contain a CE marking actually contain it, and therefore, also fulfil the requirements regarding their quality and safety. Hence, the safety of people, and the trust related to CE marked products are conserved. However, the topic of food-based medical devices is fairly new, and thus, the thesis also aims to clarify whether products under this category should utilise this route more often. In addition, the industry is growing fast, which only increases the importance of the research. In 2020 most patent applications received by European Patent Office (EPO) were related to medical technology [4]. As the industry grows, new outlooks are formed, and hence, the definition and the size of the industry expands.

This topic has not been studied before, which further highlights the importance of the research. However, it also means that the results of this thesis cannot be compared to prior studies. Therefore, the research is conducted by examining and interpreting official documents of EU and Finnish authorities related to medical devices, the CE marking, food supplements, and health claims, in addition to studying case examples. The case examples are CE marked medical devices that are not traditional medical devices but rather examples of the expansion of the definition from the perspective of food-based products. To deepen the understanding of the topic, professionals of this field are interviewed, and this data is examined. Additionally, through a brief questionnaire on food-based medical devices pharmacists are requested to clarify the commercial potential of CE marked food-based products in pharmacies. The information found will be combined, and the research questions answered.

To give insight into the research method used, the search words and platforms are introduced. The literature information was obtained through authorities' web pages and National Library of Medicine, using Google as a search tool. The search words used were "medical device", "MDR", "CE marking", "food supplement", "Finnish Food Authority", "Finnish Medicines Agency", "European Food Safety Authority", "European Commission", "food-based product", "Lingora®" and "Esolief®". The information, however, appeared to be difficult to find, and thus, the main focus of the literature research was on the official articles and documents of EU, Finnish Food Authority, and MDR. Information regarding the case examples was obtained through the companies' web pages, and interviews were conducted in the companies. The mentioned search words were used also on Web of Science, but no useful articles for this research were found from that database. Similarly, the results on PubMed were weak although some utilisable articles were found. To conclude, the origins and the number of sources used are shown in Table 1.1.

Table 1.1: Number of sources used from each origin.

Origin	**Number**
National Library of Medicine (PubMed and PubChem)	8
EU Regulations and Directives	7
Companies' Websites (Lingora®, Esolief®, Fazer, Eurodev)	4
Databases (Food and Feed Portal, EUDAMED)	3
Finnish Food Authority	3
Personal Interviews	3
Finnish Legislation	2
Finnish Medicines Agency	1
MedTech Europe	1
Webinar (MedFiles)	1
In Total	33

As can be concluded through Table 1.1, a large part of the sources are from authorities and directly from EU legislation. This is due to the high importance of authorities on the topic; the core of this topic is to study the application possibilities of MDR on food-based products, and thus, to apply the legislation to an industry, which is novel to this topic. In addition to sources related to legislation, websites of Lingora® and Esolief® and interviews with people close to the companies were utilised in this thesis. The reasons for choosing Lingora® as one of the examples handled in the thesis were the following: the product was previously a food supplement but nowadays a medical device, and the product has similarities to xylitol. Esolief® was chosen as an example since the product had the alternative to access the market as a pharmaceutical but chose the CE marking instead. Therefore, these two products show from two different perspectives reasons for choosing the CE marking over the category of pharmaceuticals and food supplements. Lastly, xylitol provides an interesting perspective on the issue since a form of the ingredient has received a health claim, and the ingredient has similarities to the CE marked medical device, Lingora®.

Furthermore, the aim of the interviews was to learn the products' backgrounds and the types of research conducted on them, in addition to clarifying the conditions

in which the CE marking has been applied for. However, the greatest benefit of the interviews was the deeper understanding gained of the field, which helped in finding useful information online. Due to the lack of information on the benefits or disadvantages of a CE marking, a questionnaire on pharmacies' personnel was conducted; the method of the questionnaire is described in detail in Chapter 4.1.

To conclude, this thesis will clarify the boundaries of the classification of medical devices by comparing them to food supplements with qualified health claims. Furthermore, it will be discussed whether MDR can be applied to cover a section of food-based products, and what the repercussions and potentials of that would be. To add, xylitol is used as an example to better illustrate the implications of the topic.

In Chapter 2, the central concepts and their common factors are introduced. Thereafter, the potential of xylitol-based products in qualifying as medical devices is examined in Chapter 3. To clarify the effect of receiving a CE marking on food-based products sold in pharmacies, the results of the questionnaire on pharmacies' personnel are presented in Chapter 4. Subsequently, the topic is discussed in Chapter 5, and finally, in Chapter 6, the topic is concluded and summarised.

2 Medical Devices and Food Supplements with Health Claims

As earlier mentioned, today also food-based products can under certain conditions apply for and receive the status of a medical device, and thus, the CE marking. To begin, the pivotal terms, food supplement, health claim, and medical device, are defined, and features of their application processes are introduced. Hence, a discussion of the field on xylitol and other food-based products is enabled.

Health-inducing food-based products can be categorised into different categories. Food supplements and medical devices are examples of these different categories. The proof of the benefit on health for these categories are provided by health claims and the CE marking, respectively. To add, there are other categories for this section of products such as medicines. These two categories are illustrated in Figure 2.1.

2.1 Food Supplements

According to the Finnish food supplement regulation (78/2010), food supplements are considered as food products, but their energy content does not have significance in a diet. Moreover, the amount of a food supplement used should be small. In addition, the marketing of food supplements should not be misleading. [3], [5] Many food supplements have utilised health claims since food supplements cannot state any health benefits related to the product unless the product has a qualified health

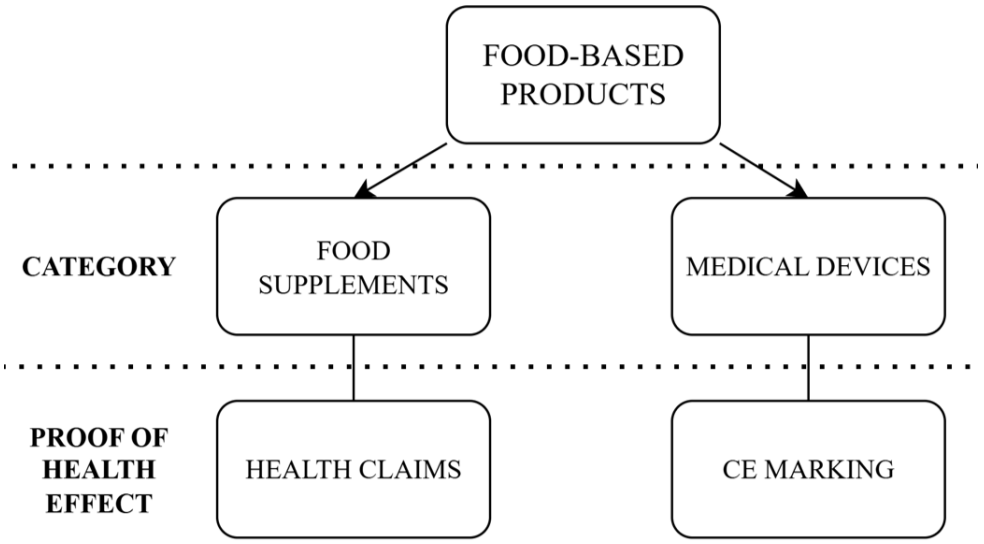


Figure 2.1: Two categories of food-based products with health-promoting effects illustrated.

claim, which are discussed in Chapter 2.2. Furthermore, since food supplements are considered as food products, the regulation of them is on a fundamentally different level compared to medical devices or health claims. The responsibility of assuring the safety is on the manufacturer of the product.

In some cases, products similar to food supplements can be classified as medicinal products if the product contains a very high dosage of a vitamin or a mineral [6]. On the other hand, for a food supplement to be marketed and sold as a source of a specific vitamin or mineral, the dosage must contain at least 15% of the daily intake of the vitamin or the mineral [7]. Furthermore, food supplements have a nutritional or a physiological effect [8]. For example, vitamins are food supplements due to their physiological mechanism of action, which is based on absorption [9]. However, there are products categorised as food supplements that have a physical mechanism of action, such as some fibre-based products, which shows the complexity of the topic [7], [10].

The regulation of food supplements is conducted in a couple of steps; the food supplement notification and the self-regulated plan [11]. The self-regulated plan is

often based on HACCP (Hazard Analysis and Critical Control Points) system [12]. The food supplement notification requests information about the product's package labelling including its brand and the name of the food ingredient. In addition, also the origin country, the category of the food supplement (such as vitamins or amino acids), the target group, a list of its ingredients, the recommended daily dosage and the content amount that refers to for example the number of tablets, capsules, or other dosage unit, and the net weight of the product must be mentioned. [7] In contrast with a health claim and a medical device application, however, the process of introducing a new food supplement to the market does not require as carefully documented clinical trials. This is due to the classification of food supplements. As mentioned, they are basic food products, which have a more flexible regulation compared to medical devices and health claims.

The self-regulated plan of the process is conducted by the manufacturer of the product, and it requires monitoring of the product's composition including the control of the ingredients' amount and microbiology. To add, the manufacturer's responsibility included in the self-regulated planning, is to assure that the food supplement does not include any medicines or unaccepted ingredients. The responsibility of the manufacturer also includes that the ingredients of the product must be traceable, and the responsibility to update the food supplement notification whenever changes are made. [7]

Additionally, the regulation of food supplements does include an external part. In Finland, municipal food safety authorities supervise and monitor the rules and manufacturers of food supplements; the inspectors are region-specific. [7] Moreover, there are challenges related to the process of food supplements' marketing regulation in Finland. The inspection and checking of the food supplements' marketing are examined by individual health inspectors, which easily leads to the guidelines being interpreted differently in different areas. This could lead the marketers and

consumers being handled and informed differently depending on their living area. [13]

2.2 Health Claims in Food Supplements

A health claim is considered as an official qualification of the product's health benefits, which means that it partially fulfils a similar role as the CE marking that is discussed in Chapter 2.3. Moreover, health claims are statements, based on scientific evidence, of the relation between health and a food ingredient, and they are provided by European Commission and evaluated by EFSA [3]. For example, many food supplements use health claims, which allow the producer to state claims about the product's health benefits in the marketing. Today, for example xylitol, several vitamins, magnesium, calcium, and many other minerals have received health claims. [14]

Similarly to medical devices, health claims are categorised into three main types. The categories of health claims, however, are not classified by the risk associated with the ingredient as medical devices, but rather by the effect of the ingredient on health. All health claims are included either under Article 13 or Article 14 of EU regulation No 1924/2006, which are responsible for listing the authorised health claims. "Function Health Claims"-category includes ingredients contributing to the growth and the development of the body as well as to the behavioural functions. The second type, "Risk Reduction Claims", state for example the disease's development reducing effect of an ingredient. Lastly, "Claims referring to children's development" prove the importance of an ingredient for a normal development of a child. [3], [7] In contrast to the CE marking, a health claim is voluntary to present in the product and in the marketing [1], [7].

When a health claim is applied for, the application will be evaluated based on three parts, which are the ingredient, the claimed effect, and the scientific data. In

order to obtain a health claim, the ingredient must be defined, the effect on health must be physiologically beneficial, and the effect needs to be measurable in humans. In addition, the scientific data provided must show that there is a causal relationship between the stated effect and the consumption of the ingredient. Furthermore, in the accepted health claim applications' clinical trials, the clinical study has a low risk of bias, the results are statistically significant, the outcome variables for the effect are appropriate, the control group of the study is randomised, and the trials are conducted under the conditions proposed for the health claim. [15]

2.3 CE Marked Medical Devices

A medical device is a product that has a medical purpose, for instance reduction of a disease. Additionally, they are classified by the risk associated with the device in its intended use. As mentioned, in Europe MDR is responsible for clarifying the conditions and possibilities for receiving the status of a medical device. When discussing the possibilities of food-based products in the field of medical devices, it is essential to note that MDR excludes food covered in EU Regulation No 178/2002. [1] In addition to processed and unprocessed food, for example chewing gum is included in Regulation No 178/2002 [16]. Consequently, traditional chewing gum cannot be a medical device.

Similarly, medicines, also referred to as pharmaceuticals, differ from medical devices in their nature of effect; pharmaceuticals can interact with the metabolic or the immune system, whereas medical devices do not cause the interactions mentioned [1], [2]. Therefore, medical devices have primarily a physical mechanism of action, which must be acknowledged when food-based products are discussed in this field. Furthermore, pharmaceuticals are often discussed together with the field of personalised medicine; it aims to study the genetics of the patient in order to choose the pharmaceutical with the best effect on the symptoms of the patient as an individual

[17]. This field is pivotal for pharmaceuticals but can be often excluded in medical devices due to their physical mechanism of action.

The status of a medical device, such as a CE marking, is determined on a case-by-case basis, and thus, the status cannot be obtained without specifically applying for it. [1] In addition to medical devices, also other product categories, including safety components and lifting accessories, must apply for the marking before setting the product to the markets [18]. Moreover, the CE marking is a way for the manufacturer to indicate that the product obeys the requirements and regulations set by the EU [19].

The requirements for the results of clinical trials involved in the CE marking applications can be divided into different sections. The results need to show that the product design and package is appropriate for its intended use. In addition, the trials must prove that the clinical benefits are correct and valid. The requirements demand to verify that the device is safe under the intended conditions of use, and that the potential risks associated with the device are justified. Furthermore, there are specific guidelines for the design and conduction of the trials; the trials should for example follow the national law regarding ethics. [1]

Although it still today is rare, there are some food-based products that have received the CE marking and are labelled as medical devices. The first example discussed is Esolief®. It is a grape tasting solution that is intended for treating symptoms of oesophageal reflux. The product consists of hyaluronic acid and chondroitin sulphate, which protect and repair oesophagus, in addition to poloxamer 407 and polyvinylpyrrolidone, which help the first mentioned compounds to extend their duration of effect. [20] Chondroitin sulphate has an animal origin that means that the product is a class 3 medical device [1], [21]. Esolief® works by creating a protective layer on oesophagus [20]. Another example is Lingora®; a natural oral rinse of lingonberry juice. In Lingora®, the lingonberry juice is fermented, and

it has shown to reduce dental plaque and to balance the oral microbiota [22]. To conclude, the common factors in Esolief® and Lingora® are that they are both administered orally, and they both are CE marked medical devices.

Additionally, one reason for the medical device application can be that the only other option would be to classify the product as a pharmaceutical. This is the reason for the CE marking of Esolief®; although Esolief® is a class 3 medical device, which is the most regulated class of medical devices, the process of accessing the markets via CE marking is often faster than through the category of pharmaceuticals. In addition, for Esolief®, the category of food supplements would have been clearly less useful, since the product does not have official health claims. [13] Furthermore, the route of CE marking is often also less expensive than the route of pharmaceuticals [23], [24].

2.4 Borderline of Medical Devices and Food Supplements

To reach the goal of this chapter and answer RQ1: "How do food supplements with authorised health claims and food-based medical devices overlap?", the main points presented in the question are compiled in Table 2.1.

As suggested in Table 2.1, the energy content of a medical device has not been specified in MDR. By contrast, that is restricted for food supplements. Both certificates, a CE marking and a health claim, indicate that the product is safe to use. However, there is a difference in the strict definitions of the terms. Medical devices require a physical mechanism of action, whereas food supplements and health claims have a physiological mechanism of action. This issue, however, is not simple since a product with a physiological mechanism of action on the bacteria in the mouth, Lingora®, has received a CE marking, which will be further examined in Chapter

3. The consumption of the product should have a positive effect on health and cause no danger, regardless of the product type of the two analysed.

Table 2.1: The overlap between medical devices and food supplements with health claims illustrated.

Statement	**Medical Device**	**Food Supplement with Health Claim**
Energy content negligible	-	x
Physical mechanism of action	x	-
Consumption affects health	x	x
No danger for health	x	x
Suitable design for use	x	-
Certificate must be presented	x	-
For a complete product	x	-
Reusable statements for other products	-	x

Key: x = yes; - = no or not specified.

In the collection of scientific data for the application process of medical devices, the clinical studies need to show that the product design is safe to an adequate degree in the intended use, which is not required for a health claim application. Nevertheless, it is required to show that the ingredient suits the intended use, in a health claim application. This difference, however, is mostly due to the different approaches of the terms; the majority of health claims concern specific ingredients whereas a CE marking is typically granted by entire products. To this, xylitol sweetened chewing gum is an exception. It has received a health claim that covers the product form instead of the ingredient of the product.

Another difference between the terms is related to the process of making statements of the products' health benefits; food supplements that contain an ingredient that has a qualified health claim, can for free use the specific health claims in the marketing of the product. However, to state anything related to the health in the context of medical devices, an official qualification must be received for the specific product, which in most cases requires extensive preparation.

Additionally, a fundamental difference between the CE marking and the food supplement notification is that if the product requires CE marking of a medical device, it must be received and marked on the product before entering the market, which is not as strictly defined with the food supplement notification [1], [7]. In addition, products with health claims are not required to present the health claim in the package [3]. To add, there is no clear set deadline for when the food supplement notification should be made although the recommended time is before bringing the products to the market. [7]

Although there are differences in the application processes, and thus, in the clinical trials, it is in theory possible to design the clinical trials of a food product with a health claim and a food-based medical device so that they contain the pivotal parts of both. However, if the trials for health claims in food products are designed to suit the requirements of MDR, also the key aspects of the intended food-based medical device should be known already in the design phase, and the planning of the trials must be done thoroughly. This means that the extent of the unified trials would be greater than what is required for one type of application, e.g. to obtain a health claim qualification, as other applications, e.g. to obtain MDR approval, may require other aspects. To conclude, in the case that the trials aim at several types of applications, the trials should include all aspects required by all planned types of future applications.

3 Possibilities of Food-Based Products as Medical Devices

Now, after the pivotal terms of the research are discussed, the concepts can be connected to one another. Xylitol is used as an example to competently illustrate under which conditions the status of a medical device could possibly be used from the industry of food-based products' point of view. Xylitol-based products have characteristics that provide interesting insights to their possibilities as theoretical medical devices and products with health claims.

3.1 Scope and Limits of Health Claim and CE Marking on Xylitol

Xylitol ($C_5H_{12}O_5$) is a natural sugar found in plants, which is widely used in chewing gums as a sweetener [25]. Xylitol has received a health claim that can be used in this product form. According to the EFSA qualified health claim, chewing gum that has been 100% sweetened with xylitol, reduces dental plaque levels that decreases the risk of developing caries in children. [26] However, the possibilities of xylitol sweetened chewing gum in obtaining a CE marking are negligible since chewing gum has been excluded from MDR, as mentioned. Therefore, if a xylitol-based

product requires a CE marking, the product form must be something else than a chewing gum.

Even if xylitol sweetened chewing gum was not excluded from the legislation, its benefits in obtaining CE marking are low due to its health claim. Usually a CE marking is applied for if there is no other possibility or if it is the quickest and cheapest route to successfully access the market. Since health claims provide strong scientific evidence of the product's health benefits, manufactures would not always need the CE marking although that in some cases could in theory be obtained as well. Furthermore, this point may possess a role on why there are not many products that have obtained both qualifications. To add, the power of a health claim compared to a CE marking is discussed in Chapter 4.

Although xylitol sweetened chewing gum and xylitol as a replacement of sugar have health claims in these applications, it is clear that xylitol as a pure ingredient does not hold the health claim status in all product applications [14]. Thus, for example xylitol pastilles cannot officially market or even mention their health benefits to customers. Therefore, xylitol pastilles could from one point of view be compared to Lingora®; neither of them has authorised health claims that could be used in the marketing of the products, and both of the products are related to oral health [14], [22], [25]. The mechanism of action of Lingora® affects the microbiome in the mouth; it has an inhibiting effect on bacteria in the mouth [27]. Similarly, the effect of xylitol is caused by the inhibition of the growth of Streptococcus mutans, which leads to the death of the bacteria [28]. In the light of this information, the mechanisms of actions are fairly similar in both products.

Moreover, the main reason for applying a CE marking in the case of Lingora® was the lack of qualified claims on the health benefits of the product, which could be used in the marketing of the product. Although there were many clinical studies conducted on the product, the criteria for applying for a health claim was not fulfilled

since international trials are highly valued in health claim applications. However, the amount of research and clinical trials was enough to apply for and receive the status of a medical device. The CE marking in Lingora® is valid for the final product after the fermentation process. [29]

To conclude, in the case of xylitol sweetened chewing gum, when there already is a qualified health claim, the potential of the CE marking would not be as great as for a product without any health claims. Since chewing gum cannot be a medical device, another form of xylitol, pastilles, are considered.

3.2 Possibilities of Receiving CE Marking for Xylitol Pastilles

Xylitol as an ingredient has similarities to Lingora®'s mechanism of action. Moreover, both affect the bacteria in the mouth. Thus, from this point of view, the possibilities of obtaining a CE marking for xylitol pastilles could be plausible. However, the mechanism of action of inhibiting the growth of bacteria is physiological, which is not included in MDR. The reason why this mechanism in some cases is accepted as a medical device might be because the effect does not primarily affect the human physiology, but rather the physiology of the independent bacteria. In addition, it is important to remember that each case is examined independently when the medical device application is sent. Since this topic of food-based medical devices is new, the number of similar cases is low, and thus, it is difficult to predict how this topic is received by the authorities.

Due to the topic being new, there is not a lot of data on how the EU authorities view the situation when a product, that is already on the market without the CE marking, applies for the status of a medical device. This is a new way of approaching the topic, and a relevant point to consider since xylitol pastilles have accessed the

market successfully. As an example, Lingora® was on the market already before receiving the medical device status when it was classified as a food supplement. Thus, it can be possible to obtain a CE marking even if the product would have been on the market before, and therefore, also the category of the product can change. In the case of Lingora®, the legislation that the product must follow changed as a result of the change in the product category. Today, Lingora® must only follow MDR, and guidelines related to food supplements do not need to be followed anymore. [30] To conclude, it can be accepted and possible to obtain a CE marking even if the food-based product would not require that to access the market, although this is a novel perspective to medical devices.

Furthermore, the status of a medical device is often applied for when it is the only possibility to access the market or when it is the fastest and the cheapest way of succeeding in that. As in the case of Lingora®, the status can be applied for also if it is pivotal for the marketing of the product [30]. Moreover, the list of health claims is growing slowly; the register of health claims shows that a large part of the applications has been rejected. One example of a non-authorised health claim is pure xylitol as an ingredient. [14] Therefore, the CE marking may provide a faster way of presenting claims of a product's health benefits more legally. Today, it is not rare that products such as xylitol pastilles use health claims, which are authorised for xylitol sweetened chewing gum, in the marketing of the product [31]. If the guidelines regarding health claims and food products are strictly interpreted, this might not be accepted. However, since this does occur, the topic is complex and ambiguous.

There is, a fundamental difference between xylitol pastilles and Lingora®, which is related to the use of the products. Lingora® is used as an oral rinse, meaning that the intention is not to ingest the product, whereas xylitol pastilles are swallowed in the end. Thus, xylitol pastilles would theoretically be invasive medical devices.

Due to this difference, the theoretical CE marking of xylitol pastilles would be class 2 instead of class 1 in which Lingora® is categorised [32]. As stated in MDR, products that are invasive and for short-term use, will be categorised as class 2a. If the product was within the body for maximum of one hour, it could be categorised as class 1. In this case, however, due to ingestion, the product will remain in the body for a longer period of time, and thus, the theoretical class would be 2a. In addition, according to MDR, the primary effect should not be achieved by pharmacological or metabolic mechanisms. [1] This criterion is fulfilled due to xylitol pastilles' local effect on bacteria in the mouth that occurs before ingestion. [28]

In conclusion, if xylitol pastilles' product category changed to a medical device, caries could be prevented more effectively since in the marketing of the product, more powerful statements about the health benefits of the product could be made. Therefore, the product would reach more customers, and thus, oral health of the population could increase.

4 Possibilities of CE Marked Food-Based Products in Pharmacy Channel

Due to the lack of research on the benefits of a CE marking from a commercial point of view, a brief questionnaire was conducted on pharmacies' personnel. The aim of the questionnaire was to investigate how pharmacies' personnel view the topic. Furthermore, this can indirectly indicate the market of food-based medical devices in pharmacies since customers in pharmacies tend to consult pharmacists on their purchase decisions. Thus, the results of the questionnaire provide information on to which extent it is beneficial to apply for a CE marking.

In addition, there has been discussion about the marketing of products in pharmacies by pharmacists in Finland. Moreover, the critique has pointed out the significance of whether the product recommended by a pharmacist is a medicine or not. Furthermore, the core of the discussion is that customers should have knowledge of the product in case they are not consciously intending to purchase or being recommended to purchase a non-pharmaceutical, as the primary function of a pharmacy is to deliver medicines. [33] Therefore, if a product is a medical device, the possibilities to recommend it in pharmacies are larger due to the qualified CE marking, which

allows official claims regarding its health benefits to be presented. Thus, products, especially in pharmacies, are largely dependent on a certificate of their health effects.

The questionnaire consists of four questions, which all aimed to survey the trustworthiness of medical devices compared to health claims and medicines from pharmacists' and customers' perspectives. Moreover, the questionnaire received 50 responses from the personnel of pharmacies in Finland. The questions of the questionnaire were the following:

1. Do you perceive the health effect demonstrated by a medical device as more reliable than the health effect indicated by a health claim? (Yes/No/Other)

2. Would you be more likely to recommend a food-based product that is classified as a medical device rather than a similar product that does not have the status of a medical device and is not a medicine? (Yes/No/Other)

3. Would you be equally likely to recommend a food-based medical device as you would a medicine, assuming both products provide comparable symptom relief? (Yes/No/Other)

4. Do you perceive that customers trust medical devices? (Yes/No/Other)

4.1 Questionnaire Methodology

As mentioned, 50 pharmacists were surveyed during April and May in 2025. Most of the respondents work either in Turku or in the capital region close to Helsinki and Espoo. 29 respondents hold a Bachelor of Pharmacy degree, 10 hold a Master of Pharmacy degree, and three are pharmacy owners. In addition, five of the respondents are pharmacy technicians, and two are pharmacy students. One respondent did not want to share their title.

Every respondent decided freely if they opted to answer all or only some of the questions. In addition to the four questions, space for a free-formulated reasoning was provided. The questionnaire was filled electronically and independently. Approximately 80% of the responses were obtained by first contacting pharmacies and then distributing the questionnaire to the personnel electronically. The remainder, approximately 20% of the respondents, were contacted in-person in pharmacies, and a few respondents who were known to be pharmacists were contacted outside their work. The respondents contacted in-person were given a tablet that had the questionnaire open to fill. All respondents working in a pharmacy were allowed to participate.

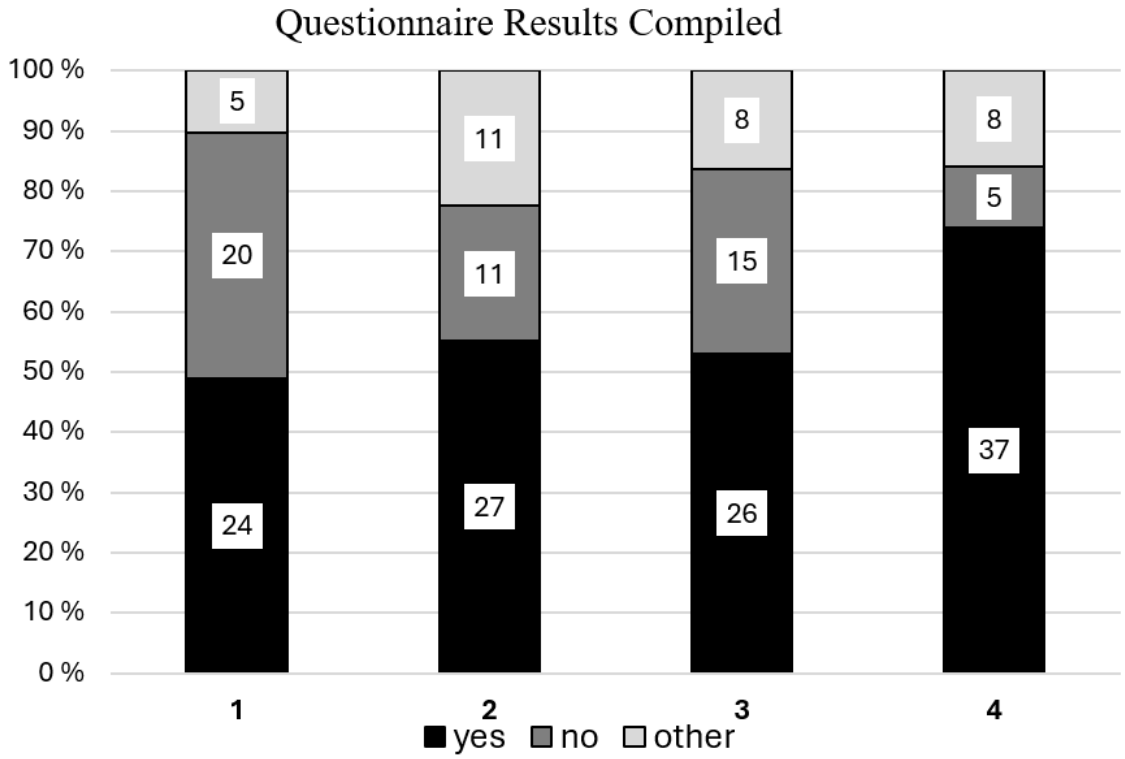
The reliability of the questionnaire was ensured by contacting the respondents through their workplace in pharmacies, or by contacting respondents who were known to work in a pharmacy. In addition, an electronic form was used to allow each respondent to express their opinions anonymously. The significance of this, from the point of view of the reliability of the results, is that this way it was ensured that the target group of pharmacies' personnel was reached, and that the respondents could privately share their thoughts on the topic.

4.2 Results of the Questionnaire

The results of the questionnaire are shown compiled in Figure 4.1. The figure consists of four bars that represent the four questions of the questionnaire.

To the first question 49% responded positively, 40.8% negatively, and the remainder responded "other". Furthermore, most respondents find CE marked products more reliable than products with health claims. However, some of the respondents imply that the class of the medical device is crucial to know in order to answer the question. One open comment mentioned that the level of regulation and clinical studies required for a CE marking depends on the product. In addition, some of

the respondents find both qualifications equally reliable. Since health claims are directed more commonly than medical devices to food-based products, one respondent trusts health claims more when it comes to food-based products. The majority of the open comments implies that the requirements for a CE marking are greater than for health claims, and thus, pharmacists find them more trustworthy.



1: Do you perceive the health effect demonstrated by a medical device as more reliable than the health effect indicated by a health claim?

2: Would you be more likely to recommend a food-based product that is classified as a medical device rather than a similar product that does not have the status of a medical device and is not a medicine?

3: Would you be equally likely to recommend a food-based medical device as you would a medicine, assuming both products provide comparable symptom relief?

4: Do you perceive that customers trust medical devices?

Figure 4.1: Results of the questionnaire compiled.

According to the results on the second question, 55.1% of the respondents would be more likely to recommend a product that is a certified medical device than a similar product that does not have the status of a medical device. In the opposite

way thinks 22.4% of the respondents. The remainder answered that their opinion would depend on the product, manufacturer, and the need of the patient. To add, one respondent mentioned that also the representative of the product affects the likelihood of recommending the product for customers. Some respondents mentioned that their decision of recommending a product is, nonetheless, never based on the CE marking alone. To conclude, the majority is more likely to recommend a product with a CE marking than a product that does not have the certificate since the CE marking assures that the product is safe to use.

The third question aimed to investigate the competitiveness of medical devices relative to medicines. 53% of the respondents responded that they could recommend a medical device as likely as a medicine under the conditions in which both products provide a similar help to the customer's symptoms. However, 30.6% responded that they would not recommend a medical device as likely as a medicine, and the remainder responded that their answer would depend on the type of the product. Some of the respondents invoked to the greater level of regulation of medicines compared to medical devices, and thus, would rather recommend a medicine to a customer.

On the other hand, some respondents commented that the product categories of pain relieving gels, products against oesophageal reflux, and cough mixtures include both pharmaceuticals and medical devices, and in these cases the CE marked products may sometimes provide a more effective result on the symptoms. In addition, the price of the product affects the recommendation of pharmacists. Some respondents mentioned that if the two products relieve the symptoms to the same extent, they would recommend the product with the greater profit. On the other hand, one respondent said that the cheaper product would be recommended for the customer. However, some respondents would always recommend a medicine since often there is more information about the medicines' pharmacokinetics and interactions with

other substances, in comparison to medical devices. In conclusion, medical devices are competing alternatives to medicines in pharmacies.

The purpose of the final question was to find out how customers find medical devices. The results show that customers do trust medical devices; 74% of the respondents responded that customers view medical devices with trust. 10%, however, responded that customers do not trust medical devices, and the remainder that the level of trust depends on the person and the product, or that they do not know how customers view medical devices. In addition, the open comments revealed that the trust customers have on pharmacies is high, and therefore, they may not pay attention to or know about the different product categories or their differences. Thus, in general, customers of pharmacies trust all products sold in pharmacies.

In the section of open comments, some of the respondents expressed their scepticism regarding the concept of food-based medical devices. For some pharmacists it is suspicious to categorise food-based products as medical devices since there already are two large categories for similar products: food supplements and medicines.

In conclusion, the results of the questionnaire show that the majority of pharmacists and customers trusts medical devices. Additionally, medical devices have the potential to compete with medicines, and at the same time, medical devices are trusted over health claims. The CE marking is a strong proof of the product's safety.

5 Discussion

In overall, the topic is new, and thus, rather complex. Due to the small amount of example cases on this field, no generalisations can be made. Each medical device application is in any case considered on a case-by-case basis. As mentioned, the topic shows to have different ways of interpreting for example the mechanisms of actions of different product categories. Therefore, more research and case examples on this issue should be obtained in the future.

Since food supplements with health claims have overlapping similarities with CE marked medical devices, the CE-marking can under certain conditions be utilised to allow more powerful statements of the products' health benefits. Therefore, this could be a way to make marketing of a food-based product easier. In addition, in some cases accessing the market could occur faster if the food-based product was categorised as a medical device, especially if compared to pharmaceuticals. Hence, the sales could be increased since the product would be available longer for customers due to the time saved in its regulation.

Changing the product category from a food product to a medical device, however, brings even more responsibility to the company. Many xylitol pastilles are produced by confectionery companies, and thus, the producers follow food products' legislation and guidelines. One disadvantage of the medical device status can potentially be the high regulation required by medical devices. Therefore, the company would have to use more resources for regulation if the category of a product was changed

from a food product to a medical device. Thus, although the CE marking allows more possibilities in the marketing compared to a traditional food product, it also demands fundamental changes in the working of the company. Hence, when considering applying for the status of a medical device, each company should evaluate if the positive outweigh the possible downsides of the liabilities in their case.

In addition, conducting the needed clinical trials for the application of a medical device can be expensive if compared to launching a regular food product. However, if the food-based product has benefits to health, but none of the ingredients have an EFSA qualified health claim, the marketing of the product may be impossible if the health benefits are desired to be expressed. In this case, the possibilities would be applying for a health claim or a CE marking. Furthermore, if the product is aimed to be sold in pharmacies, the status of a medical device might be more useful since pharmacists showed to trust CE marked medical devices more than health claims. This increased trust would reach more customers. Therefore, the significance of this research is high also from the commercial perspective.

The regulation of food supplements has possible weaknesses. As mentioned, the guidelines regarding food products are examined by individual health inspectors, which might lead to different interpretations of the guidelines. Thus, regional differences in the regulation and marketing of food supplements in Finland are possible since the individual inspectors work independently within certain areas. This difficulty, however, is not similarly present in medical devices since their supervision is conducted by larger institutes. Therefore, the CE marking can, in addition to other benefits, avoid the difficulty described and provides clear rules for all operators.

On the other hand, if the category of a product is considered between a medical device and a medicine, the CE marking could allow a faster and a cheaper enter to the market, assuming that the primary mechanism of action of the product is physical. Furthermore, in this kind of cases the route of CE marking would be

beneficial to consider since, as the results of the questionnaire show, the product might not lose anything in terms of its reliability even if it was a medical device rather than a medicine. In other words, the benefit of upgrading a medical device to a medicine might be negligible in case the product remains unchanged, and it is sold in pharmacies. Hence, resources could be saved by registering a product as a medical device rather than as a pharmaceutical.

As previously mentioned, the field of personalised medicine has become topical during the past years. The field targets to individualise treatment of each patient to maximise the positive effect of the treatment. Due to the physical primary mechanism of action in the human body of medical devices, the field of personalised medicine does not concern medical devices. The mechanism of action of food-based medical devices does not create additional drug interactions. Therefore, this aspect, which is highly important to acknowledge in relation to pharmaceuticals, can be ignored in medical devices. Thus, food-based medical devices can provide a convenient route to avoid the need of applying personal medicine in patients' treatments, which easily would create additional costs to the treatment. Overall, food-based medical devices are for these reasons more straightforward to apply on treatment plans.

To add, the expansion of the field of medical devices does not affect the level of trust regarding the CE marking, due to the high standards of MDR. Therefore, the expansion of the field will most likely have a positive effect overall. If the concept of a medical device became more familiar in the field of food-based products, it would have a positive impact on customers as well. In comparison to health claims, which usually are subjected to specific ingredients used in the product, the CE marking tells the customer immediately that the product as a whole is safe to use, and it produces the announced health benefits.

In addition, the risk of misuse of qualifications is clearly smaller for medical devices since the status is obtained by the product as a whole. In theory, ingredients that contain health claims, such as vitamins, can be added to food-based products only to allow the certain health claims to be used in the marketing of the product. However, the allowed health claims concern only the specific ingredient in the product. Hence, the main purpose of the product may be different to what is implied by the health claims used in its marketing. This issue is not present in medical devices since, as mentioned, the CE marking is granted by the product as a whole instead of only one ingredient used in the product.

To sum up the discussion, the main effects of obtaining a CE marking on a food-based products are compiled in Table 5.1. The effects are divided to arguments and their outcomes.

Table 5.1: The main effects of the CE marking on food-based products.

Key Effects of CE Marking in Food-Based Products		
	Argument	**Outcome**
compared to food supplements with health claims	• more powerful health statements	→ easier to market
	• higher level of trust	→ more customers reached
	• less space for different interpretations of guidelines	→ clear rules for everyone
	• for the entire product	→ safe product as a whole
	• more responsibility for company	→ more resources for regulation required
compared to medicines	• faster access to markets	→ increased sales
	• negligible difference in level of trust	→ resources saved
	• less drug interactions	→ more straightforward to apply

However, some of the respondents of the questionnaire showed doubt in their responses. As said, the topic is not simple, and therefore, there is variation in opinions regarding the topic. Thus, the majority's trust on medical devices can not directly be generalised. On the other hand, it is promising that already at this phase, when the topic is novel, it has gained the majority's trust of the surveyed pharmacists.

Hence, it can be assumed that when food-based medical devices become more familiar, the trust among pharmacists and customers increases, which further increases the commercial potential of the topic.

Although medical devices are highly trusted, one effective approach to increase their sales in pharmacies might be to further educate pharmacists on the topic. As the results of the questionnaire show, generally customers do not pay attention to or even know about the different product categories, and trust the recommendations by pharmacists. Although the majority trusts and has a wide understanding on the topic of food-based medical devices, it causes confusion in some pharmacists. Confusion around the topic is probable to decrease their likelihood of recommending food-based medical devices to customers. Therefore, if more information and knowledge was obtained by pharmacists in general, the amount of food-based medical devices recommended could increase, and thus, sales could grow. In brief, convincing pharmacists on the topic can affect the customers' purchase decisions.

6 Conclusions and Summary

This thesis focused on examining the conditions and possibilities that food-based products could have in applying for the CE marking of a medical device, using xylitol as an example. To succeed in this, the central terms, medical device, food supplement, and health claim, were clarified. In addition, two case examples, Lingora® and Esolief®, were discussed. To examine the commercial significance and effect of obtaining the CE marking, a questionnaire for pharmacies' personnel was conducted.

There are clear sections of overlap between food supplements with authorised health claims and food-based medical devices. Both of the terms aim to clarify the effects of products on health. Moreover, the consumption of products of the both categories impact health positively, and cause no danger for health. However, the largest difference in the strict definitions is that medical devices require a physical mechanism of action, whereas most food supplements have a physiological mechanism of action. On the other hand, the topic is not this simple since there is an introduced example of an official CE marked medical device, which shows that the requirements for a CE marking are always considered on a case-by-case basis. Moreover, according to the strict definitions, food supplements would not have possibilities to obtain a CE marking due to most of them having a physiological mechanism of action. Nevertheless, there is an example of a product that has a physiological mechanism of action on bacteria, and has succeeded in this, regardless.

Furthermore, a xylitol product could in theory qualify as a medical device in the form of pastilles due to the similarities it has with Lingora®. In this case, the class of medical devices would be 2a since the product would be categorised as an invasive medical device due to it being ingested in the end. However, the medical device applications are always considered individually, and thus, no certainty can be reached before sending an application and receiving the results.

As the results of the questionnaire show, benefits of the CE marking include the high trust of pharmacies' personnel and customers. At the same time, the CE marking is valued over health claims, and there is not a significant difference in the trustworthiness between medical devices and medicines for pharmacies' personnel. Therefore, the route of medical devices may be very interesting for a certain category of food-based products. In addition, the CE marking increases the chances that pharmacists recommend the product to customers if compared to a product that does not have the status of a medical device. On the other hand, in the case of a food-based product, the fundamental change within the company can be large if the category of a product changes from a food product to a medical device. Thus, the resources needed for regulation would increase. In conclusion, the benefits of a CE marking are high from the commercial point of view of pharmacies.

To conclude the findings of the thesis, very concise results to the research questions, defined in the introduction, are given:

RQ1: Food-based medical devices and food supplements with health claims overlap by both having a beneficial effect on health,

RQ2: The pastille form of xylitol could potentially receive a CE marking as a class 2a medical device.

RQ3: CE marking allows to state the health benefits of the product in the marketing, and its benefit-effort ratio is high compared to medicines or food supplements in pharmacies.

A consolidated point that has arisen from all sections of the research is that the concept of food-based medical devices is new, and thus, unfamiliar to some. This is seen in some of the results of the questionnaire, and in the analysis of the possibilities of xylitol as a medical device; no clear and certain answers are given to questions around this topic.

In the future, this topic should be researched more to bring clarity to the field of food-based medical devices. It would be interesting to apply for a CE marking for a pastille product containing xylitol to explore and compare the results of this thesis with the opinions of authorities. Additionally, more information on the authorities' opinions on the boundaries of medical devices must be obtained to further clarify the topic. In addition, there should be more open information about the possibilities of food-based products in qualifying as medical devices. Authorities and other responsible for informing about medical devices revealed to lack expertise on food-based medical devices.

In conclusion, the topic of food-based medical devices has the potential to change the field of health-promoting food-based products.

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