Studying the implications of regulation:

Regulatory concepts of the therapeutic products law

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Abstract

Pharmaceuticals and medical devices are not ordinary consumer goods. Both are therapeutic products and are regulated by the Therapeutic Products Act. However, they follow different regulatory principles along their value chains. The market approval of medical devices differs from the governmental approval process as it is the case for pharmaceuticals. Medical devices are approved by accredited, non-governmental conformity assessment bodies. These are referred to as "notified bodies" in EU law. It remains to be clarified whether the pharmaceutical and medical device sectors can be compared in the nature of their regulatory regimes. Because of this, this paper will first look at the two different sectors in order to examine these regulatory concepts behind them. The aim is thus to describe the differences and similarities between the two sectors. And any impacts of the new EU regulation in the medical device industry will be determined.

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List of abbreviations

AIMD	Active Implantable Medical Devices
AMBV	Arzneimittel-Bewilligungsverordnung
AMZV	Arzneimittel-Zulassungsverordnung
BSE	Bovine spongiforme Enzephalopathie
BV	Bundesverfassung
EEA	European Economic Area
EEC	European community of values
EU	European Union
EUDAMED	European medical device database
HMG	Heilmittelgesetz
IVDR	In-vitro Diagnostics Regulation
MDD	Medical Device Directive
MDR	Medical Devices Regulation
MepV	Medizinprodukteverordnung
nMepV	neue Medizinprodukteverordnung
MRA	Mutual recognition agreement
PrSG	Produktesicherheitsgesetz
SME	Small and medium-sized enterprises
UDI	Unique Device Identification
VAM	Arzneimittelverordnung

1 Introduction

In today's modern healthcare system, therapeutic products are indispensable. However, they can also pose considerable risks, which is why government regulation is essential (Brugger, 2021, p. 1). Regulation is needed where a minimum level of quality must be guaranteed for consumers, and where market failure would have catastrophic effects on the population. Access to medicine and medical devices is just such a sector. The highly technological nature of this field harbors other factors, such as information asymmetries, externalities, economies of scale, or uneven compliance with protective regulations, which work against the efficient functioning of the market (Tarricone et al., 2020, p. 117).

Over the past century, there have been numerous incidents in the pharmaceutical industry that have harmed the health of populations around the world. These incidents, such as the thalidomide scandal, the Haiti glycerol case, and the TeGenero scandal, have increased the effectiveness, and efficacy of pharmaceuticals. More recently, the PIP scandal occurred in the medical device field, which influenced the revision of Directive 93/42/EEC and the enactment of the new Medical Device Regulation (MDR) in the European Union. As Carpenter & Sin (2007) noted, it is a common assertion among regulatory scholars that new regulatory rules follow from tragedies or crises. Because of the incidents, the public outcry spurs elected officials to enact government regulations. But it remains to be determined whether the regulatory regimes for the pharmaceutical and medical device sectors can be compared. Because of this, this paper will first look at the two different sectors in order to examine regulatory concepts in them. The overall aim is to describe the differences and similarities between the two sectors.

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How has regulation in the pharmaceutical and medical device industry evolved and what has been the impact of tighter regulation?

To answer this question, the following paper first introduces the field of pharmaceutical and medical device regulation in order to compare the developments of the regulatory framework of pharmaceuticals and medical devices in the context of the EU and

Switzerland. Further, the similarities and differences between the two areas will be discussed. In a further step, the implementation problems in practice will be discussed. In a final step, the impact of the new EU regulation in the medical device industry will be determined.

2 Theory

The widely known policy cycle model assumes that a public policy changes in the course of its creation and implementation (Sager et al., 2017, p. 89 ff.). The policy cycle model describes the ideal-typical linear sequences of the policy process in various stages. In the last place in this process is the termination. However, according to Sager et al. (2017, p. 167), this model has limited value, as public policies are not completely abolished in the majority of cases, but are transformed and reformulated within reforms. Examining specific policy areas requires uncovering more specific theoretical assumptions about the preconditions for policy change. An important distinction is the division of change into two categories. *Minor policy changes* refer to relatively frequent changes in public policy, such as the introduction of new policy instruments. On the other hand, a *major policy change* is understood to be a large policy change in the sense of a paradigm shift. Major policy changes are rather rare and manifest themselves, for example, in the form of new regulations in a previously unregulated area, or in fundamental changes in institutional structures due to far-reaching reforms (Sager et al., 2017, p. 167).

In addition to the dominant behaviorist theories of the 1960s and 1970s, which placed the behavior of political actors at the center of policy change research, various analytical approaches have developed independently. These are grouped under the term *neoinstitutionalism.* In contrast to the two well-known approaches of the advocacy coalition framework (Sager et al., 2017, p. 178) and the multiple stream approach (Sager et. Al., 2017, p. 168), neoinstitutionalism approaches are increasingly devoted to the role played by institutional structures (Sager et al., 2017, p. 188). In general, according to Sager et al. (2017, p. 188), social institutions can be understood as forms of solidified action. Besides, Hall (1986, p. 19) defines political institutions as "formal rules, compliance procedures, and standard operating practices that structure the relationship between individuals in various units in the polity and economy." By involving individuals in negotiation and decision-making processes, the agency of actors in institutions can be influenced and their scope limited (Sager et al., 2017, p.188). Due to this, institutions represent a fundamental factor for the study of political change (Hall, 1986).

In their paper, Hall and Taylor deal with neoinstitutionalist approaches and identify three schools of thought that try to explain the phenomenon of institutions in different ways (Sager et al., 2017 p. 188).

Rational choice institutionalism recognizes institutions as voluntary arrangements that result from repeated interactions of several individuals in order to guarantee certainty of expectations in collective actions. Since this approach assumes that institutions are created by individuals, it is argued that institutions are deliberately formed to serve the interests of members (Sager et al., 2017, p. 189).

Sociological institutionalism, unlike rational choice institutionalism, assumes bounded rationality on the part of individuals. It argues that social norms, cultural values, symbols, and habits limit individuals' capacities to act and thus define their role. This approach is characterized by the fact that the concept of an *institution* is not defined as narrowly as rational choice institutionalism does. It also refers to moral values that are used to explain the behavior of individuals. Thus, sociological institutionalism helps to explain social actions, attitudes, and roles through intuitions, since institutions in this approach are viewed as culturally specific practices in the respective context (Sager et al., p. 190).

Historical institutionalism defines institutions as formal and informal processes, social routines or legal norms that structure a political system and define access to decisions. In this school of thought, institutions emerge from already existing institutions and primarily have a stabilizing function (Sager et al., 2017, p. 191). Based on this theory the concept of path dependence and positive feedback effects was developed. In this concept, path dependence represents policy decisions that depend on institutional rule systems that have emerged in the past. The historical path of an institution cannot simply be abandoned by political actors in order to introduce new rule systems, since new developments, according to the understanding of historical institutionalism, are always dependent on already existing conditions. According to Pierson, the so-called positive feedbacks are the cause of such path-dependent developments. This is because far-reaching changes or the abolition of existing institutions are associated with very high costs. These consist not only of the accumulation of knowledge, but also for the new creation of an institution. All this occurs at the same time that there is an established complex institution in which a lot of resources have already been invested, and which offers a certain degree of certainty in terms of expectations vis-à-vis the actors (Sager et al., 2017, p. 191).

Historical institutionalism is a suitable theory for the comparative analysis of different regulatory regimes. The article by Krapohl (2007, p. 25 ff.) can be used as an example. In his article "Thalidomide, BSE and the single market: An historical-institutional

approach to regulatory regimes in the European Union", Krapohl (2007, p. 25 ff.) uses a historical-institutional approach to find an explanation for the similarities and differences between the regulatory concepts of the pharmaceutical and the food sector in the European Union. In my paper, however, the focus is on the comparability of the pharmaceutical and medical device sectors. It will examine which challenges have arisen so far during the implementation of reforms in the respective sectors. Also, the EU's newly enacted medical device regulation (MDR) represents a policy change. The new MDR has consequences for the medical device industry. They will be derived and assessed on the basis of the overall experience of reforms already implemented in the pharmaceutical industry.

3 Method

The present work is qualitative, and it deals with the existing literature on the topic of the research question, which is why a systematic literature research method was chosen. A systematic literature search is characterized by the fact that a selection of search terms is chosen as a result of the research question. With those terms, various sources of information are searched for in suitable databases. The search results obtained are then sorted by their abstracts and summaries, and the suitable sources are collected and processed in a first literature list. Likewise, the reference lists of the various information sources are considered and, if usable, are included and processed in the literature list. The methodical procedure in my work is oriented to a systematic literature search, but represents only an approximation of it, since otherwise too many sources would have had to be included in this work, would have been infeasible.

At the beginning of the work phase, a brief overview of the topic was obtained before further articles were searched for in a literature search. The examination of the introductory literature led to narrowing down the topic and selecting various keywords. By formulating these key words, a research question could be defined. Based on the research question, the search terms "regulation", "impact", “medical device" and "pharmaceuticals" were selected. Then, the databases selected include PubMed, IBSS, Google Scholar, as well as the swissbib database This selection was made based on thematic proximity and availability (free access) of the information. The aforementioned databases were searched by using a keyword search with the search terms defined above. Combinations of the different keywords were also used, such as "regulation" AND “pharmaceutical". The targeted search for results with the combination of "regulation" AND "pharmaceutical" yielded few hits. So, to broaden the search for results, the catalog of search terms was expanded to include the keyword "framework".

Based on the summaries and abstracts of the results, they were presorted, and a literature list was created. The literature list thus created was worked through, and the various references of the articles and books were checked. References that were considered important were added to the literature list if they were not already there, and then edited. Occasionally it happened that obviously important articles cited often were not publicly accessible, or accessible via the University of Bern network. These sources could not be consulted and included in the bibliography, as they would have exceeded the financial

budget for this project. The research work was conducted as an iterative process in order to identify and consider all important sources of information. The state of the literature of the present work includes articles and other sources of information published until March 2021, since the literature search and processing took place in October 2020 and March 2021.

4 Results

This part of the paper is devoted to the results of the preceding literature review. Swiss legislation on therapeutic products distinguishes between medicinal products and medical devices. The regulation of these two categories is based on fundamentally different concepts. In this paper, their principles are first presented and then compared.

4.1 Regulatory principles

Protecting citizens from dangers is one of the most important tasks of the state. Its duty to provide for risks already arises directly from a constitutive-institutional understanding of fundamental rights (Brugger, 2021, p. 3). In Article 10 paragraph 2, the Swiss Federal Constitution guarantees every Swiss citizen the right to physical integrity. According to the case law of the Federal Supreme Court (BGE 139 IV 121, p. 125 f. E. 4.6 f.), this right includes the physical integrity of consumers with regard to goods that are harmful to health, which is why appropriate state protection measures are required. The protection of the general public from products and production methods that are harmful to health is achieved by means of preventive regulation of the potential risk generators (Brugger, 2021, p. 4).

Regulation is the control of society and the economy by means of law (Rütsche, 2013, p. 1). The constitutional basis for regulation in the area of product safety can be found in Article 118 paragraph 1 of the Swiss Federal Constitution (BV). This article states that the federal government shall take measures to protect public health within the scope of its powers. According to Article 118 paragraph 2 BV, the Confederation shall issue regulations on the handling of dangerous objects, such as therapeutic products, for this purpose. According to the literature, the concept of handling is to be understood broadly. It includes every conceivable activity along the value chain from the production to the consumption of the products mentioned (Brugger, 221, p. 6).

Good regulation is a central factor for freedom, security and prosperity. Good regulation can be measured by so-called *legalistic principles*. These principles include effectiveness, subsidiarity, necessity, practicability, transparency and coherence (Rütsche, 2013, p. 1; Mader, 2004, p. 137; Brugger, 2021, p. 6).

The principle of *effectiveness* states that laws serve a specific goal and that these goals can be achieved effectively. Symbolic laws that have no effect in practice and are not implemented are bad laws. Pharmaceutical and medical device laws primarily serve to protect public health and, relatedly, to protect against deception. The scandals about health-damaging breast implants or hip joints in the medical device sector in recent years raised the question about regulatory weaknesses in the area of market approval and surveillance of medical devices (Rütsche, 2013, p. 2).

The market approval of medical devices differs from the governmental approval process as it is the case for pharmaceuticals. Medical devices are approved by accredited, non-governmental conformity assessment bodies. These are referred to as "notified bodies" in EU law. Before medical devices are placed on the market, the "notified bodies" test them for conformity with technical product standards, which are drawn up by private standards organizations and harmonized throughout Europe. This regulatory concept is referred to as the "new global approach". After successful conformity assessment, the notified bodies award the CE marking to the products, after which they may be placed on the market (Rütsche, 2013, p. 2).

Switzerland is part of the EU market due to the Agreement of 21 June 1999 between the Swiss Confederation and the European Community on Mutual Recognition of Conformity Assessments (Mutual Recognition Agreement, SR 0.946.526.81), in short MRA. Therefore, the necessary conformity assessments for placing on the Swiss market can also be carried out by notified bodies in EU member states.

This system of private self-regulation serves the overriding objective of the free European movement of goods. The tension between the concerns of the free movement of goods and public health protection can lead to conflicting goals, as there is a risk of varying density and quality of product testing (Rütsche, 2013, p. 3).

Good regulation is further characterized by the principle of *subsidiarity*, according to which not all social problems should be solved by the state. The principle requires that the state should only take action when society and the economy are unable to solve a problem satisfactorily (Rütsche, 2013, p. 3). European and Swiss medical device law serves as a prime example of the subsidiarity principle. This is because in the two central areas of placing on the market and product monitoring, there is state-regulated self-

regulation by private organizations and market participants. These control themselves, while the state limits itself to controlling the controllers. In this way, the extensive and rapid changes in the medical device industry are taken into account. The existing expertise from the industry can thus be incorporated directly into the technical standards without having to go through lengthy detailed government standardization processes (Rütsche, 2013, p. 4).

In the case of placing medical devices on the market, private self-regulation in accordance with the principles of the "new and global approach" even takes place in two respects. On the one hand, at the level of concrete product testing, controls are carried out by private conformity assessment bodies. And on the other hand, at the abstract level, the product regulations for precisely these concrete tests are issued by private standards organizations. A look overseas confirms that this understanding of the system is not self-evident. In addition to drug approval, US law also has a state approval system for medical devices (Rütsche, 2013, p. 4).

Product monitoring after market launch is primarily the responsibility of the manufacturer. The first distributor of a medical device in Switzerland or in a contracting state is obliged to take the necessary measures to identify the dangers of defective medical devices in good time and to be able to trace them. For this reason, it is incumbent on manufacturers to set up a product monitoring system that meets the legal requirements (Rütsche, 2013, p. 4). As soon as serious incidents, so-called health hazards, occur in connection with a product, the manufacturer must immediately take the necessary safety measures. Necessary safety measures include, for example, recall, replacement, modification or destruction of the defective product. Furthermore, the manufacturer must notify the competent authorities (Rütsche, 2013, p.5). The monitoring and reporting system described above is also known as the "medical device vigilance system".

Necessity as a further legal principle describes that regulations which are not necessary cannot be good regulations. And this is independent of whether it is a matter of state or private regulation (Rütsche, 213, p. 5). Or as Montesquieu once put it, "If it is not necessary to make a law, it is necessary not to make a law." For even overregulation of one area can prove problematic. An increasingly dense web of national and international standards can lead to application difficulties in practice.

Legal reality is reflected in the principle of *practicability*. This is because regulations can only have their desired effect in practice if they are implemented quickly and effectively by the bodies entrusted with implementation and are actually followed by the obligated addressees (Rütsche, 2013, p. 6).

In terms of practicability, the current European regulation of medical devices has made progress for manufacturers with the introduction of CE marking. Mutual recognition of conformity assessment bodies also allows manufacturers to limit themselves to one conformity assessment procedure in order to gain access to the European market (Rütsche, 2013, p. 6). Globally, however, very different approval procedures and criteria still stand in the way of a simple global market launch for medical devices. However, various authors agree that harmonization of market approval conditions beyond Europe with the most important countries, such as the USA, does not appear to be realistic in the foreseeable future (Rütsche, 2013, p. 6; Sprecher, 2017, p. 120).

Transparency is another legal principle. Only transparent law can be controlled and criticized by the public. The behavior of private individuals can only be effectively controlled by means of regulations if the regulations are known to the private individuals and are comprehensible to them (Rütsche, 2013, p. 6).

In his article, Rütsche (2013, p. 6) speaks of a considerable transparency problem in the area of medical device regulation with regard to technical standards and the decision-making practice of conformity assessment bodies. This is because, in accordance with Article 4(3) of the Medical Devices Ordinance (MepV), the technical standards are published in the Federal Gazette only with their title and reference. The texts of the relevant standards have to be obtained at great expense from the standards organizations, and the decision-making practice of the conformity assessment bodies is completely obscure. Rütsche (2013, p. 7) also criticizes the fact that there are hardly any published appeal decisions by state courts that deal with the control activities of the conformity assessment bodies from the perspective of the rule of law. Furthermore, Rütsche (2013, p. 7) emphasizes that the formal law in the field of medical devices is only rudimentarily standardized and that essential material and procedural regulations are to be found at the ordinance level in the Medical Devices Ordinance and, by means of references, in the European Regulation.

The final principle of good regulation is *coherence*. This means that there are no contradictions between the legal norms, but also between the values on which they are based (Rütsche, 2013, p. 7). A coherent legal system is considered to be more stable, more predictable and meets with greater acceptance among the addressees of the law (Mader, 2004, p. 145).

In a comparison between the regulation of medical devices and pharmaceuticals, inconsistencies can be identified. According to Rütsche (2013, p. 7), the problems that are the same in both areas should also be regulated in the same way. In principle, it should be noted that regulation in the area of medicinal products tends to be stricter and more intervention-intensive than in the area of medical devices. According to Rütsche (2013, p. 8), this is based on the premise that medicinal products are generally more dangerous than medical devices. However, this generalization is not tenable, since, for example, complementary medicines are less dangerous than pacemakers. A consistent continuation of this idea would lead to a regulatory system based on the hazard potential of the product instead of the current dichotomy of regulating medicinal products and medical devices. However, according to Rütsche (2013, p. 8), there is no foreseeable move away from the regulatory dichotomy of medicinal products and medical devices toward hazard-based regulation.

4.2 Horizontal and vertical regulation

Swiss legislation ensures the safety and health of people in connection with products through a two-tier system. By means of horizontal decrees, such as the Product Safety Act (PrSG), minimum standards are set for all product categories. In addition, over a hundred vertical decrees regulate according to the hazard potential and their particular characteristics in the specific sectors (Brugger, 2021, p.7). In the case of therapeutic products, the Therapeutic Products Act (HMG) corresponds to a vertical decree. The PrSG thus serves as a subsidiary catch-all law if the minimum requirements for the level of protection of the sectoral area would not be met. With this structure, real regulatory gaps can be prevented (Brugger, 2021, p. 7).

4.3 European compatibility

The free cross-border movement of goods is impeded when a state imposes internationally incompatible regulations to protect consumers and public health. Such technical barriers to trade make cross-border competition more difficult, to the detriment of consumers, and place a burden on economic sectors that rely on imports or exports (Brugger, 2021, p. 7). Switzerland has a considerable economic interest in access to the EU internal market and thus in the removal of technical barriers to trade, as trade in goods with the EU accounts for 60% of Switzerland's trade volume (Brugger, 2021, p. 8). However, since Switzerland is not a member of the EEA, access to the EU internal market is realized with the harmonization of product regulations by means of autonomous enforcement as well as through the mutual recognition of conformity assessments by treaty (Brugger, 2021, p. 8).

4.4 Pharmaceuticals and medical devices

Pharmaceuticals and medical devices are not ordinary consumer goods. Both are therapeutic products and are regulated by the Therapeutic Products Act. However, they follow different regulatory principles along their value chains (Brugger, 2021, p. 9).

According to Article 1 paragraph 1 HMG, the primary purpose of the Therapeutic Products Act is to ensure that only high-quality, safe and effective therapeutic products are placed on the market to protect human health. Also, the Therapeutic Products Act regulates the handling of therapeutic products according to Article 2 paragraph 1 HMG in a comprehensive manner, whereby according to Article 118 paragraph 2 lit. a BV the term handling is to be interpreted broadly. Thus, it includes all processes from development to application (Brugger, 2021, p. 9).

Based on their different modes of action, remedies are divided into two product categories. Medicinal products, as defined in Article 4 paragraph 1 lit. a HMG, are products of chemical or biological origin that are intended or advertised to have a medicinal effect on the human or animal organism. In particular, they are used for the detection, prevention or treatment of diseases, injuries and disabilities. They also include blood and blood products. Thus, medicinal products interact pharmacologically, immunologically or metabolically with the body (Brugger, 2021, p. 9). Medical devices are described in Article 4 paragraph 1 lit. b HMG as products, including instruments, apparatus, in vitro diagnostics, software, and other articles or substances intended or advertised for medical use, whose principal effect is not achieved by a medicinal product. Thus, the effect of medical devices is usually physical or mechanical (Brugger, 2021, p. 9). If a product has properties of both medicinal products and medical devices, it must be assigned to one of the two categories according to its main effect if it cannot be readily separated (Brugger, 2021, p. 10).

4.5 Regulatory concepts of the Therapeutic Products Act

The distinction and specific allocation of products to the categories of medicinal products or medical devices is crucial, as they follow different regulatory concepts. According to Article 5 of the HMG, the handling of medicinal products in principle requires prior state authorization. In the case of medical devices, on the other hand, the focus is on entrepreneurial self-responsibility in the sense of the "new and global approach". Both systems provide for specific post-marketing obligations for economic operators and market surveillance by the authorities (Brugger, 2021, p. 10).

The different regulation of the two categories of therapeutic products is mainly due to safety and practicability considerations. This is because, while medicinal products in principle pose an increased health risk, which justifies the principle of requiring a license, medical devices are considered to be less dangerous. However, this statement must be questioned. Certain medical devices, such as pacemakers, pose a considerably higher risk than relatively harmless medicines, such as herbal tea. Accordingly, the regulation of therapeutic products takes this into account by distinguishing between various risk-based category-internal gradations (Brugger, 2021, p. 11). Furthermore, Brugger (2021, p. 11) argues that comprehensive preventive monitoring of the handling of medical devices by the authorities, as is the case in the area of medicinal products, would hardly be feasible, if only because of the quantity and variety of medical devices. This can be countered by the fact that in other legal systems, such as US law, a state approval system is also common in the case of medical devices. The "new and global approach" is seen by Brugger (2012, p. 11) as a considerable relief for the state through the inclusion of private economic actors. The dichotomous structure of the regulation of therapeutic products is also known in union sectoral law. This structural similarity promotes and simplifies the mutual state recognition process. This is also the reason why the harmonization of Swiss therapeutic products law with the corresponding European regulations is largely harmonized (Brugger, 2021, p. 11). The delegation of the enactment of most of the detailed regulations to the issuer of the ordinance or to the administrative authorities or private parties enables faster adaptation to new technological developments. However, this is not always unproblematic from the point of view of the rule of law.

4.5.1 Manufacturing

Article 4 paragraph 1 lit. c HMG defines manufacture as all the operations involved in the production of therapeutic products, from the procurement of the starting materials through processing to packaging, storage and delivery of the end product, as well as quality controls and the releases of the therapeutic products. To ensure the safety of therapeutic products, their production is subject to certain regulations.

4.5.1.1 Authorization requirement for pharmaceuticals

According to Article 5 paragraph 1 letter a HMG, the manufacture of medicinal products requires a license from the Institute. The Swiss Agency for Therapeutic Products, Swissmedic, acts as the institute. The authorization is an operating license that does not relate to the manufacture of specific medicinal products, but to the manufacturing company (Brugger, 2021, p. 11). According to Article 6 paragraph 1 HMG, the license is granted if the necessary technical and operational requirements are met and a suitable quality assurance system is in place. Article 3 of the Ordinance on Licensing in the Medicinal Products Sector of November 14, 2018 (AMBV) specifies what these requirements are. Thus, a functional system for ensuring the pharmaceutical quality of medicinal products must be operated and the management and staff of the individual areas concerned must actively participate in it (Article 3 paragraph 1 lit. a AMBV). It must be demonstrated that in each area as many competent persons trained for the respective tasks are available so that the objectives of quality assurance are achieved (Article 3 Paragraph 1 lit. b AMBV). In particular, there must be a person with technical responsibility within the meaning of Articles 5 and 6 AMBV (Article 3 Paragraph 1 lit. c AMBV), who exercises direct technical supervision and bears responsibility (Article 5 AMBV). Furthermore, the operational organization must be appropriately designed (Article 3 paragraph 1 lit. d AMBV). The facility for the manufacture of medicinal products must be arranged, designed, retrofitted and maintained in such a way that safe manufacture is guaranteed. Premises and equipment that can influence the quality of the medicinal products must be qualified for this purpose (Article 3 paragraph 1 lit. e AMBV). In addition, a documentation system must be in place that includes work instructions, process descriptions and protocols on the relevant processes within the scope of manufacture (Article 3 Paragraph 1 lit. f AMBV). After the granting of the manufacturing authorization, Swissmedic or the competent cantonal authorities, as the case may be, check by means of periodic

inspections in accordance with Article 58 paragraph 1 in conjunction with Article 60 HMG whether the prerequisites for this continue to be fulfilled.

4.5.1.2 No authorization requirement for medical devices

In contrast to the manufacture of medicinal products, the manufacture of medical devices is not explicitly regulated in the Therapeutic Products Act. The Federal Product Safety Act (PrSG), which is of subsidiary application, also contains no regulations in this regard (Brugger, 2021, p. 12). Although state control is waived in the case of the manufacture of medical devices, it must be carried out in such a way that medical devices comply with the basic requirements for placing on the market set out in Article 45(2) HMG. For example, a medical device must not endanger the health of users, consumers, patients or third parties when used as intended. The advertised performance or efficacy of the product must be verifiable (Article 45 paragraph 1 HMG). According to Article 45 paragraph 3, the Federal Council defines the requirements for medical devices. The Medical Devices Ordinance of October 17, 2001 (MepV) issued by the Swiss Federal Council regulates further principles for the handling of medical devices at ordinance level. Depending on the risk potential, certification of the production process and the quality assurance system is required for conformity assessment (Brugger, 2021, p. 12). The totally revised Medical Devices Ordinance, which will come into force on May 26, 2021, will further impose obligations on manufacturers that today affect the initial distributor. These include the appointment of a person with the necessary expertise analogous to pharmaceutical law and the requirements for the quality management system (Article 46 nMepV).

4.5.1.3 Interim summary

The state authorization requirement for the manufacture of medicinal products starts earlier than actual market access regulations, which contributes to a high level of safety. According to the "new and global approach," no state authorization is required for the manufacture of medical devices. The risks associated with the manufacture of medical devices are addressed indirectly and, in the future, also directly through market conduct rules (Brugger, 2021, p. 12).

4.5.2 First placing on the market

The core of the Swiss Therapeutic Products Act is the regulation on first-time marketing. These market access regulations ensure that only safe and effective medicinal products are placed on the market. Article 4, paragraph 1, letter d of the Therapeutic Products Act defines the placing on the market as the distribution and dispensing of therapeutic products. The regulation of the marketing of medicinal products and medical devices is one of the most significant differences between the two categories (Brugger, 2021, p. 13).

4.5.2.1 Official approval for pharmaceuticals

Article 9 paragraph 1 HMG states that ready-to-use medicinal products may only be placed on the market if they have been authorized by the Swiss Agency for Therapeutic Products Swissmedic. International agreements on the recognition of marketing authorizations are reserved. In accordance with the principle of proportionality, the Therapeutic Products Act provides for a graduated system of different authorization procedures depending on the risk potential (Brugger, 2021, p.13).

The *ordinary marketing authorization procedure* is a standard procedure for a large part of the medicinal products, which mainly includes new active substances. According to Article 10 paragraph 1 lit. a HMG and Article 2 of the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorization of Medicinal Products of November 9, 2001 (AMZV), the applicant must prove the quality, safety and efficacy of the medicinal product to be authorized by means of comprehensive documentation. Safety and efficacy of the medicinal product to be authorized. According to Article 11 paragraph 1 HMG, the marketing authorization application must contain all information and documents essential for the assessment. In particular, Article 11 paragraph 1 lit. a-c HMG requires information on the name of the medicinal product, the manufacturer and the distribution company and the manufacturing method, composition, quality and shelf life. Article 11 paragraph 2 HMG requires additional information on the application for marketing authorization for medicinal products with indication. From a qualitative point of view, the medicinal product must have the specified chemical, physical, galenic and biological properties, whereby the regulations of the Swiss and European Pharmacopoeia must be observed. A decisive criterion for approval is proof of a positive benefit-risk ratio. This means that the efficacy of a drug must justify the potential undesirable side effects (Brugger, 2021, p. 13). The marketing authorization establishes the right of

the marketing authorization holder to place a drug on the market in accordance with the terms of the marketing authorization.

Swissmedic may provide for a *simplified authorisation procedure* for certain categories if this is compatible with the requirements for quality, safety and efficacy in accordance with Article 14 paragraph 1 HMG and if neither Swiss interests nor international obligations conflict with this. The simplification of the authorization procedure consists in particular in the fact that certain proofs are not required in the application for authorization or they can be provided in another way. Article 14a HMG mentions, for example, a compilation of equivalent evidence or proof of approval of a foreign comparator as alternative information and documents for the submission of an application for marketing authorization in the simplified procedure. The authorization of a medicinal product with already known active ingredients is also called a second application (Brugger, 2021, p. 14). Article 12 paragraph 1 HMG speaks of the authorization of essentially identical medicinal products. In this context, the applicant may rely on the results of the pharmacological, toxicological and clinical trial documents of an already authorized original preparation if, according to Article 12 paragraph 1 lit.a HMG, the consent of the marketing authorization holder has been obtained or, according to Article 12 paragraph 1 lit. b HMG, the deadline for document protection has expired. According to Brugger (2021, p. 14), this is a compromise between the economic interests of the first applicant, who had to bear considerable costs for the preparation of the marketing authorization dossier, and the reduction of the marketing authorization costs and thus indirectly also of the drug prices for patients. The so-called parallel import under the simplified marketing authorization procedure according to Article 14 paragraph 2 HMG is also provided for the import of medicinal products by someone other than the marketing authorization holder, if they are authorized in Switzerland and in the exporting country with an equivalent authorization system. In this way, Swiss consumers benefit from cheaper yet safer foreign medicines (Brugger, 2021, p. 14).

According to Article 15 HMG, a marketing authorization based on a notification to the Institute is possible for certain medicinal products for which the implementation of the simplified procedure would prove disproportionate.

According to Article 9 paragraph 2 HMG, certain medicinal products are also completely exempt from the authorization requirement. This is done for reasons of practicability, for

example in the case of magistral formula. These are medicinal products that are manufactured in a public pharmacy or in a hospital pharmacy in execution of a medical prescription for a specific person or a specific group of persons (Article 9 paragraph 2 lit. a HMG). In these cases, the safety of medicinal products is ensured by the requirement of the manufacturing authorization stipulated in Article 5 paragraph 1 HMG and, in some cases, by an authorization requirement for the manufacturing process pursuant to Article 33 of the Ordinance on Medicinal Products of 21 September 2018 (VAM).

The Swiss Therapeutic Products Act does not provide for unilateral recognition of foreign drug approvals. However, according to Article 13 HMG, the approval results from other countries with comparable drug controls are taken into account. In addition, the approval requirements are largely harmonized with those of the European Union (Botschaft HMG, BBl 1999 III 3453, p. 3469). Brugger (2021, p. 15) points out that, due to Switzerland's orientation towards the safety level of the EU, participation in the procedures for coordinating national marketing authorizations within the EU would be possible without any relevant loss of safety and should be discussed in favor of greater economic integration into the EU internal market.

4.5.2.2 Conformity assessment for medical devices

Unlike medicinal products, medical devices can be placed on the market without government approval. In accordance with the principle of self-responsibility in the "new and global approach", the marketer must be able to prove that his medical device meets the essential requirements for safety and efficacy in accordance with Article 45 paragraph 2 HMG and Article 9 paragraph 2 MepV. For the detailed provisions of the essential requirements for the various categories of medical devices, the Federal Council merely refers to the relevant European law in Articles 4 and 7 MepV. This sets out general and technical requirements for the product as well as for its information and labeling. Further specification is provided by the harmonized technical standards of private standards societies, which are designated by Swissmedic in accordance with Article 45 paragraph 4 HMG. According to Article 4 paragraph 2 MepV, compliance with the essential requirements is presumed if these technical standards or the regulations of the Pharmacopoeia are complied with.

According to Article 46 paragraph 1 HMG and Article 8 paragraph 1 in conjunction with Annex 1 and 2 of the Medical Devices Ordinance, compliance with the essential requirements must be confirmed as part of a conformity assessment before a medical device can be provided with the mark of conformity (MD or CE) and placed on the market. The difference between the MD and the CE marking is that the indication of the MD conformity mark is only valid for the placing on the market of a medical device in Switzerland (Article 8 paragraph 1 MepV). According to Article 10 Paragraph 1 in conjunction with Annex 3 of the Medical Devices Ordinance, a conformity assessment must always be carried out by a state-accredited and designated conformity assessment body. Exceptions exist only for products with a minor hazard potential. These can be carried out by the distributor himself. According to the wording of Article 9 paragraph 1 of the HMG, distributors of medical devices must be able to provide the authorities responsible for market surveillance with the declaration of conformity upon request. In addition, Article 6 of the HMG stipulates a notification obligation for the placing on the market of certain medical devices.

The regulations for placing medical devices on the market are practically fully harmonized with those of the European Union. In some cases, there are even direct references, as for example in the case of the categorization of medical devices in Article 5 paragraph 1 HMG. There it is stated that classical medical devices are to be classified by the person placing them on the market for the first time in classes I, IIa, IIb and III on the basis of the possible risks they present with regard to their intended use. For the classification, reference is made to Annex IX of Directive 93/42/EEC of the Council of the European Union of 14 June 1993 concerning medical devices. This harmonization allows the mutual recognition of conformity assessments based on Article 1 paragraph 2 MRA. This partial linkage of Switzerland to the EEA serves not only the ex-port-oriented Swiss medical device sector, but also security of supply (Schroeder de Castro Lopes, 2018, p.197).

4.5.2.3 Interim summary

The Therapeutic Products Act ensures that only safe and effective therapeutic products are placed on the market. It does this in accordance with the distinction between medicinal products and medical devices by means of two different, self-contained systems of market access rules. According to Brugger (2021, p. 16), these are justified from an economic perspective, as there are information asymmetries between manufacturers of therapeutic

products and consumers. Furthermore, according to Brugger (2012, p. 16), the healthcare professionals who prescribe, dispense or use medicines often lack the knowledge and resources to assess the effects and risks of a medicine.

The common feature of the two systems is the gradation of the authorization requirements according to the risk associated with the products in the sense of a proportionate and efficient economic regulation. These gradations are achieved through the creation of subclasses and a multitude of exemption provisions. In all cases, the marketing of a therapeutic product requires a positive risk-benefit ratio. According to Brugger (2021, p. 16), the decisive difference lies in the fact that a state approval procedure is provided for the marketing of medicinal products. Whereas for medical devices, compliance with the essential requirements must be demonstrated in a conformity assessment procedure. In the latter case, the role of the state is limited primarily to the designation of technical standards and the accreditation of assessment bodies. Thus, a controlled framework is established for private regulatory activities. In the opinion of Sprecher (2015, p. 120) and Brugger (2021, p. 17), however, doubts remain as to whether a state licensing requirement would not be more suitable for risk prevention.

4.5.3 Post-market phase

The further marketing of medicinal products is also subject to certain regulations. Article 4 paragraph 1 letter e TPA defines the distribution of therapeutic products as the transfer or making available of a therapeutic product, including the activities of brokers as well as agents, for or against payment, with the exception of dispensing. This is because even a safe therapeutic product carries the risk of misuse or incorrect application (Botschaft zur Änderung des Heilmittelgesetzes vom 7. November 2012, BBl 2013 I, p. 73).

4.5.3.1 Authorization requirement for pharmaceuticals

Wholesale trade in medicinal products is subject to a licensing requirement pursuant to Article 28 paragraph 1 HMG. According to Article 28 paragraph 2 HMG, this authorization is only granted if a medical prescription is available for the medicinal product in question, there are no safety requirements to the contrary, appropriate advice is ensured and sufficient medical monitoring of the effect is guaranteed. For the distribution of medicinal products, it is crucial that the correct storage and transport conditions as well as the traceability of the products are ensured (Giger et al., 213, p. 67). A license is also required for professional importation according to Article 18 paragraph 1 lit. a HMG. According to Articles 19 paragraph 1 and 28 paragraph 2 HMG in conjunction with Article 11 AMBV, both licenses are linked to the fulfillment of professional and operational requirements and the establishment of a quality assurance system.

Article 30 HMG stipulates a cantonal authorization for the supply of medicinal products. According to Article 30 paragraph 2 HMG, the authorization is granted if the necessary professional requirements are met and a suitable quality assurance system adapted to the type and size of the business is in place. The rules of Good Distribution Practice must also be complied with (Article 29 paragraph 1 HMG). Medicinal products are divided by Swissmedic into four categories based on their risk potential. According to Article 23 paragraph 2 HMG in conjunction with Article 40 VAM, the requirements for the prescription obligation and professional competence of the person authorized to dispense vary depending on the category. Thus, prescription drugs of categories A and B can be dispensed by pharmacists and medical personnel (so-called self-dispensing). Non-prescription drugs in category D can also be sold by druggists, among others. Over-the-counter medicinal products in category E may be dispensed by anyone. For the latter, the provisions on distribution and dispensing apply only to a limited extent according to Article

23 paragraph 2 HMG. The subsequent control of the legality of distribution is carried out by Swissmedic, that of dispensing and use according to Article 57 VAM by the cantons.

4.5.3.2 No authorization requirement for medical devices

The Therapeutic Products Act does not impose any regulations on the distribution of medical products. According to Brugger (2021, p. 18), the Federal Council has not made use of the powers granted to the Federal Council regarding restrictions on the introduction of certain medical devices in Article 50 paragraph 1 HMG. Accordingly, a medical device that has been permissibly placed on the market may be freely distributed (Balsiger, 2019, p. 211). However, the requirements of Article 45 paragraph 1 HMG and the duty of care in Article 3 paragraph 1 HMG must be observed. Brugger (2021, p. 18) argues that the licensing regulations for medicinal products, namely the technical and operational requirements and those relating to the quality management system, should be consulted for their interpretation. In future, Article 53 of the new Medical Devices Ordinance will contain specific obligations for importers and distributors.

With regard to the dispensing and use of medical devices, the Federal Council may stipulate in accordance with Article 48 paragraph 1 HMG that they may only be dispensed on a doctor's prescription. It may also stipulate professional and operational requirements for the dispensing and use of medical devices or a reporting obligation. It is also incumbent upon the Federal Council to link the dispensing of medical devices with the requirement that the products in question can be tracked and traced from their manufacture to their use. These provisions are further specified at the ordinance level. Thus, according to Article 17 paragraph 2 MepV, the dispensing center must guarantee professional advice. According to Article 16 paragraph 1 MepV, a medical prescription is exceptionally required if the medical device contains prescription-only medicinal products. In addition, Article 18 MepV regulates the use of a small number of medical devices intended for use by healthcare professionals, which may endanger human health if not used properly. According to Article 19 MepV, professionals are also responsible for the reprocessing and maintenance of medical devices that can be used several times. In this way, it can be ensured that the essential requirements are met even after the device has been placed on the market for the first time (Brugger, 2021, p. 19). As is already the case with medicinal products, the duties of care under Article 48 paragraph 2 in conjunction with Article 26 of the HMG must also be observed when prescribing, dispensing and using medical

devices. According to Article 24 paragraph 2 MepV, the subsequent control of the dispensing and use of medical devices is the responsibility of the cantons.

4.5.3.3 Interim summary

According to Brugger (2021, p. 19), the regulation of therapeutic products may justifiably not end after the product has been placed on the market for the first time. Brugger (2021, p. 19) emphasizes that the safety of consumers can only be guaranteed if a product reaches them unimpaired and they are informed about its correct use.

From a regulatory perspective, market access is already regulated for medicinal products by means of the personal authorization requirement. Whereas for medical devices, the principle of self-responsibility of the economic actors applies according to the principle of the "new and global approach" (Brugger, 2021, p. 19).

4.5.4 Marktüberwachung und Produktebeobachtung

The Therapeutic Products Act provides for a system of retrospective control of products already on the market, since certain risks only become apparent after the products have been placed on the market (Brugger, 2021, p. 19).

4.5.4.1 Market surveillance and reporting requirements

Primarily, the ex post control is based on the official market surveillance by Swissmedic, which is regulated in the chapter on the common provisions for therapeutic products. Article 58 paragraph 2 HMG states that authorized medicinal products are periodically checked for their compliance with the authorization. In particular, the composition, the specification, the quality requirements, the product information and the packaging material are checked for compliance with the marketing authorization. According to Article 58 paragraph 3, Swissmedic has the right to request the necessary documents on the occasion of the quality checks. In order to ensure the safety of therapeutic products, Swissmedic is authorized to take the necessary measures, such as warnings, sales stops, recalls or even the revocation of a marketing authorization in accordance with Article 58 paragraph 3 HMG.

According to Brugger (2021, p. 20), effective market surveillance by the authorities would hardly be possible without the involvement of the various economic actors. For this reason, the manufacturer or the distributor of medicinal products must operate an institutionalized reporting system in accordance with Article 59 paragraph 1 and 2 HMG, as well as report adverse effects, incidents and quality defects to Swissmedic. These reports support the monitoring activities of Swissmedic, so that possible risks can be responded to quickly with appropriate measures (Brugger, 2021, p. 20).

4.5.4.2 Product monitoring for medical devices

In addition to the notification system, the first person to place medical devices on the market must set up a product monitoring system in accordance with Article 47 paragraph 1 HMG. This serves the purpose of self-responsible self-monitoring in accordance with the heading of Article 14 MepV. Article 14 paragraph 1 MepV requires that the person who places a product on the market for the first time in Switzerland or in a contracting state must take appropriate measures to be able to recognize the hazards that may emanate from the product during the specified period of use. It should also be possible to avert any

hazards and the product must be traceable. According to Article 14 paragraph 2 MepV, the product monitoring system records product-specific complaints, relevant experience of use and efficacy, reports from the trade press, the company's own test results and corrective measures. Similar obligations to set up a product monitoring and reporting system are already contained in part in the regulations on conformity assessment and are thus already a prerequisite for placing medical devices on the market for the first time (Brugger, 2021, p. 21). According to Brugger (2021, p. 21), this highlights the importance of private conformity assessment as a central instrument in medical device regulation.

4.5.4.3 Pharmacovigilance plan for drugs

The product monitoring obligation under medical device law corresponds to the obligation under pharmaceutical law to draw up a pharmacovigilance plan, which under Article 11 paragraph 2 lit. a point 5 HMG must already be submitted to Swissmedic as part of the marketing authorization. In pharmaceutical law, however, according to Article 4 paragraph VAM, this obligation only extends to medicinal products that contain a new active ingredient. Article 4 paragraph 3 VAM requires that the pharmacovigilance plan systematically records and clarifies the risks associated with the use of the medicinal products. Furthermore, it must be clarified which preventive measures are planned. Based on this plan, the marketing authorization holder must track its products throughout their life cycle and evaluate the data collected with a view to improving drug safety (Balsiger, 2019, p. 208).

Furthermore, it is envisaged that the marketing authorization holder must periodically submit to Swissmedic an updated report on safety and the risk-benefit balance in accordance with Article 60 VAM as a preventive measure for four years after marketing authorization.

4.5.4.4 Interim summary

The Therapeutic Products Act provides for both regulatory market surveillance and private aftermarket obligations for the aftermarket phase. According to Brugger (2021, p. 22), the aim of supplementing the market access rules is to ensure that no danger arises from the therapeutic products already on the market. In other words, any danger that does arise should be detected early enough and averted by taking appropriate measures. Thus, the safety measures that apply when a medicinal product is placed on the market continue to apply throughout its life cycle.

State market surveillance thus encompasses the transition from prevention under risk law to repression under classical police law. According to Brugger (2021, p. 22), the more concrete risk of a health hazard compared with the first placing on the market legitimizes the sovereign supervision of therapeutic products. This is particularly important in the case of medical devices, since the "new and global approach" dispenses with the need for state approval. However, the state reserves the right to check the result of the private conformity assessment for compliance with the legal requirements in individual cases. According to Brugger (2021, p. 22), this is evidence of a certain justified mistrust of private self-regulation.

Due to the diversity of medical devices, the authorities are dependent on the cooperation of the industry. To this end, two different types of market conduct rules are established. The obligations to proactively identify and avert hazards within the framework of the product monitoring system and the pharmacovigilance plan thus go further than the reporting obligations of government monitoring. According to Brugger (2021, p. 22), these are suitable supplements to government monitoring. In this way, the principle of self-responsibility of the economic actors is given deeper validity even after the first placing on the market and the state is relieved by the efficient use of private infrastructure and expertise from the industry (Brugger, 2021, p. 22).

4.5.5 Summary and appraisal

The risks posed by therapeutic products require preventive government regulation to ensure the protection of public health. To this end, the Therapeutic Products Act establishes sectoral regulations to ensure the quality, safety and efficacy of therapeutic products throughout their life cycle and at all stages of the value chain. However, the respective regulatory concepts for medicinal products and medical devices differ visibly (Brugger, 2021, p. 23).

The regulation of medicinal products is primarily based on a state licensing requirement, whereas the regulation of medical devices does without such a requirement. In accordance with the "new and global approach", the regulation of medical devices is based on the self-responsibility of the economic actors, which is reflected, among other things, in the conformity assessment procedure. However, both categories of therapeutic products are subject to market surveillance by the authorities, the aim of which is to identify and avert specific dangers at an early stage (Brugger, 2021, p. 23).

The choice of the respective regulatory instrument is primarily based on the hazard potential. Based on this hazard potential, direct state economic supervision by means of market entry barriers and official market monitoring measures is justified. At the same time, it is considered necessary and sensible for economic actors to be involved in regulation (Brugger, 2021, p. 23).

However, the literature questions whether it is appropriate to regulate medicinal products and medical devices so differently in the same law. According to Sprecher (2015, p. 120) and Brugger (2021, p. 23), a uniform, risk-based system for both categories of therapeutic products would certainly be considered expedient, at least conceptually. However, this conceptual proposal would require a fundamental reformation of the regulation of therapeutic products and would be associated with considerable practical challenges and difficult delimitation issues.

In addition, it is considered difficult to make such a design of the therapeutic products law compatible with Europe, which is why it should be rejected according to Brugger (2021, p. 24). It is precisely the connection to European regulation that exists today that proves to be advantageous. Harmonization with Union law helps to reduce technical barriers to trade and to ensure increased safety in the area of medical devices (Brugger, 2021,

p. 24). Finally, Brugger (2021, p. 24) states that the current Therapeutic Products Act represents a largely balanced, internationally compatible system through the combination of various regulatory instruments. It is capable of minimizing the risks of medicinal products and medical devices and ensuring a high risk-benefit ratio.

5 Discussion

Medical device regulation in Europe dates back to 1990. Prior to that, there were only state-specific regulations for medical devices. These were harmonized step by step. The European Community at that time chose the legal form of directives, which were not automatically adopted in the various national legal systems. The member states had to integrate the objectives formulated therein into national law (Quinto, 2020, p. 279). In May 2017, the European Union Commission enacted two new regulations: the Medical Devices Regulation (MDR) and the In-vitro Diagnostics Regulation (IVDR) (Quinto, 2020, p. 279). However, the outbreak or response to the corona pandemic brought the postponement of the full entry into force of the MDR by one year to May 26, 2021, and the corresponding follow-up in the revised Medical Devices Regulation (Reudt-Demont, 2020, p. 231).

The new regulation is considered a milestone for compliance with product safety and product quality of medical devices (Wagner & Schanze, 2018, p. 653). The aim of the new EU regulations and the equivalent national law is to further improve patient safety. Accordingly, the main changes of the MDR are: higher requirements for the qualification of the personnel of the testing laboratories, complete traceability of individual medical devices by means of clear labeling, higher requirements for the proof of clinical efficacy of devices, and the registration of all devices in the central European Database for Medical Devices (EUDAMED). In addition, the requirements for market surveillance have been tightened and cooperation between the nationally responsible surveillance authorities has been institutionalized (Quinto, 2020, p. 279).

These changes in the regulation of medical devices have manifold effects on the medical device industry, the medical profession and ultimately on patients. In the following part of this thesis, the various effects of the new medical device regulation will be discussed.

5.1 Small and medium-sized enterprises

The MDR replaces the previous Medical Device Directive (MDD) 93/42 / EEC and the Active Implantable Medical Devices (AIMD) 90/385 / EEC. The new regulations contain 123 articles, so they are much more complex and effective compared to the old laws. Some of the articles in MDR are the same as those in the previous directives, but have become much more detailed. In addition, new articles have been introduced that never existed before. These new regulations are a major concern for medical device manufacturers, but especially for small and medium-sized enterprises (SMEs). Because of the change, manufacturers must make significant efforts (Wagner & Schanze, 2018, p. 654). Manufacturers must explicitly consider whether a new product classification or conformity assessment is required for their product. The UDI also provides an exceptional effect. In the absence of a UDI, manufacturers must implement a full UDI system. In addition, post-market surveillance is relevant, as it must be verified whether a surveillance system is in place or whether a new one must be developed. Due to the new technical documentation requirements, there is also a significant effort here. SMEs have to make great efforts, relatively speaking, to meet the organizational and financial requirements of the new EU regulations (Wagner & Schanze, 2018, p. 655).

To meet these requirements, many companies will need to increase their quality management staff. It will take a lot of time to review all specifications of all products to verify their compliance. Often, the ability of SMEs to overcome these regulatory hurdles is misjudged by authorities (Wagner & Schanze, 2018, p, 655).

Another problem for manufacturers of Class IIa, IIb and III devices is that it is not yet clear when the first notified body will be accredited under MDR. The notified body will have to put in much more effort, as under the new MDR it will have to work with a panel and apply quality so that it can certify companies. Thus, this situation is another hurdle for small and medium-sized companies, as only the large companies will be certified first. If a medical device company does not have a suitable notified body, it does not have many options. Either the company is closed, sold, or the company is forced to specialize in other things (Wagner & Schanze, 2018, p. 655).

Developing a new medical device or a new use for an existing one takes a long time; safety and efficacy must be demonstrated before it can be brought to market. This process

is enormously expensive because of laboratory costs and often high costs are required for trials for regulatory approval (Contardi, 2019, p. 168).

Further, the process is uncertain in terms of time and cost for compliance procedures under MDR. This will encourage smaller and medium-sized companies, and especially new or smaller companies, to select a product market outside the European single market where procedures are well established (Vasiljeva, 2020, p.128).

5.2 Conformity Assessmnt Bodies

According to Quinto (2020, p. 279), timely implementation of the MDR is unrealistic, as it can be assumed that there will be delays in authorizing the conformity assessment bodies. They will also have to undergo a comprehensive qualification process. According to a publication of the EU Commission, the introduction of the EUDAMED platform will be further delayed. This will significantly weaken the traceability of medical devices. Furthermore, expert panels, reference laboratories and guidance documents are lacking (Quinto, 2020, p. 279). Sprecher (2015, pp. 118, 119) also raised the question of whether it makes sense to make the time intervals for the follow-up inspections dependent on the number of customers of the conformity assessment bodies in accordance with Art. 13a and Annex 3c MepV. The regulation stipulates that, for the purpose of follow-up inspections, Swissmedic must carry out an on-site assessment every 12 months for conformity assessment bodies with more than 100 customers and only every 18 months for those with fewer than 100 customers. It is questionable what relevance the number of customers has on the functioning of a conformity assessment body and whether the risk of improper management is really lower with a smaller number of customers. Medical device manufacturers should also think about appointing an authorized representative in the EU or Switzerland (Reudt-Demont, 2020, p. 237).

5.3 Supply shortage

According to Quinto (2020, p. 280), the unrealistic transitional provisions jeopardize the idea of safe and effective regulation and seamless care with higher quality standards. The MDR's goal of improving patient safety is in danger of being overturned.

In an open letter to the Federal Council, physicians, hospitals, patient advocates and industry representatives also draw attention to the fact that the adequate supply of patients with quality-tested medical devices is at risk (communication Swiss MedTech, 2021).

Contardi (2019, p. 168) emphasizes that the current European regulatory system makes innovative medical device technology available to people the fastest while ensuring the highest safety standards. On average, consumers in the European regulatory system are 36.6 months earlier to gain access to innovations in the medical device industry than consumers in the United States (Contardi, 2019, p. 168). Based on this, it is speculated that the lack of new technologies in the medical device space may dramatically impact patient safety itself by not approving potentially safer materials and methods in the EU internal market or delaying their approval due to the manufacturer's focus on existing devices (Vasiljeva, 2020, p. 129).

According to Quinto (2020, p. 280), the foreseeable shortage of medical devices will also have an impact on the economic environment. Higher prices are to be expected due to a mismatch between supply and demand. The associated unstable sales markets could lead to purchasing tourism. This, in turn, is associated with a security risk.

5.4 Product range

A change in the product range is also to be expected. According to Quinto (2020, p. 280), manufacturers will adjust their product range in response to the new situation in order not to jeopardize their economic position and to remain competitive. This may mean that the manufacture of certain products is discontinued. Quinto (2020, p. 280) considers niche products and products with low added value to be particularly at risk.

Vasiljeva (2020, p. 128) also assumes that the introduction of the MDR will drastically reduce the publication of new products in the European single market. First, for medical device manufacturers, re-certification of existing products in compliance with the MDR will be a priority. This will result in a significant amount of research and development activity within manufacturing organizations being dedicated to re-evaluating documentation for existing products.

5.5 Innovation

According to Maresova et al. (2019, p. 2), the greatest challenge in implementing the Medical Devices Regulation lies in the area of innovation. Most of the innovative research in the field of medical devices is not carried out by large companies, but by small to medium-sized enterprises. These rely on collaboration between healthcare professionals and small local companies or university laboratories. Of the 25,000 MedTech companies in Europe, up to 95 percent can be described as SMEs (Contardi, 2019, p. 167). It is the small to medium rather than large companies that are most vulnerable to forced market exit due to the high administrative costs of development (Maresova et al., 2019, p. 2). Yet these companies are critical to the development of new medical technologies and often focus on narrowly therapeutic areas (Kesavan, 2020, p. 255).

6 Conclusion

In principle, the improvements in the safety of medical devices to be expected as a result of the developments in the EU and Switzerland described above are to be welcomed. Nevertheless, doubts remain as to whether the existing regulatory concept for medical devices offers sufficient safety for patients.

The revised Medical Devices Regulation continues to operate with many references to EU law. As a result of the one-year extension of the deadline for full applicability of the MDR in the member states, entry into force of the revised Medical Devices Regulation on the same date (i.e., from May 26, 2021) should now also be realistic, although there is still a lot to do for the individual companies. In particular, the continuing lack of mutual recognition of medical device regulations between Switzerland and the EU continues to pose major challenges for manufacturers (Reudt-Demont, 2020, p. 237).

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8 Declaration of independence

Ich erkläre hiermit, dass ich diese Arbeit selbstständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe. Alle Stellen, die wörtlich oder sinngemäss aus Quellen entnommen wurden, habe ich als solche kenntlich gemacht. Mir ist bekannt, dass andernfalls der Senat gemäss dem Gesetz über die Universität zum Entzug des auf Grund dieser Arbeit verliehenen Titels berechtigt ist.

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