Medical Devices Ordinance

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ONLINE COMMENTARY
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COMMENTARY ON

Art. 68 MedDO

A commentary by Philippe Fuchs / Ann-Kathrin Brackwehr

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Chapter 8 Conduct in relation to Devices

Art. 68 Supply

Devices are supplied in accordance with their intended purpose and the information provided by the manufacturer.

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I. GENERAL

In contrast to medicinal products, the dispensing of medical devices is only regulated very superficially in the legislation on therapeutic products. Art. 48 para. 1 let. b and c TPA allows the Federal Council to define, for the protection of health, (a) professional and operational requirements or a reporting requirement for the dispensing of certain medical devices, and (b) to link the dispensing to the requirement that the products in question can be traced from their manufacture to their use and back. In addition, Art. 48 para. 2 TPA states that Art. 26 TPA, which regulates the principles for the prescription, dispensing and use of medicinal products, applies mutatis mutandis to the dispensing of medical devices. 1

The Federal Council has been very cautious in exercising its authority under Art. 48 para. 1 TPA, because only Art. 68 MedDO contains a regulation at the ordinance level for dispensing. According to Art. 68 MedDO, medical devices may be dispensed in accordance with their intended purpose and the manufacturer's instructions. Before the revision of the Medical Devices Ordinance in 2021, the dispensing of medical devices was regulated in detail in Art. 17 para. 1 aMepV. In contrast to the current regulation, under the aMepV, in particular, professional advice had to be provided by the point of care for devices for self-administration (see Art. 17 para. 2 aMepV). This requirement was dropped during the revision, as this provision proved to be unsuitable in practice and was almost impossible for the competent authorities to verify. 2

Paragraphs 2, 3 and 4 of Art. 17 aMepV, which concerned in vitro diagnostics, initially remained in force in accordance with the transitional provision of Art. 105 MedDO. However, Art. 105 MedDO was subsequently repealed by Annex 5 of the Ordinance on In Vitro Diagnostics (IvDO) of May 4, 2022, with effect from May 26, 2022. Since then, the provisions on in vitro diagnostic medical devices previously found in Art. 17 para. 2 and 3 aMepV can be found in Art. 61 IvDV. Now, the dispensing of medical devices is based only on the intended purpose of the device and the information provided by the manufacturer, whereby the medical devices must, of course, fulfill all other legal requirements for placing them on the market in order to be dispensed in accordance with Art. 68 MedDO. 3

II. THE CONCEPT OF "SUPPLY"

4 As already mentioned, the supply of medical devices in accordance with Art. 68 MedDO is based on the intended purpose and the manufacturer's information. The definition of the term "*supply of goods*" is therefore crucial for this provision. Art. 4 para. 1 MedDO does not contain a separate definition of the term "*supply*", nor does Art. 4 para. 2 refer to the corresponding definition ("making available on the market") in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("EU MDR"). However, a definition of this term can be found in Art. 4 para. 1 let. f TPA. According to this, dispensing is to be understood as the transfer or provision, whether in return for payment or free of charge, of a ready-for-use therapeutic product for use by the purchaser or for application to third parties or to animals. If we compare this with the definitions in Art. 4 para. 1 MedDO, it is noticeable that this definition corresponds to the term "*putting into service*" in Art. 4 para. 1 let. c MedDO. In fact, the term "putting into service" also refers to the point in time at which a ready-to-use medical device is made available to the end user for the first time on the Swiss market for use in accordance with its intended purpose. In summary, "*dispensing with intent to sell*" refers to the act of handing over a medical device to the end user, i.e. a medical professional or a patient.

5 The term "*supply of a medical device*" does not include the prescription of a medical device, i.e. the issuing of a prescription by an authorized medical professional. The supply of a medical device is only deemed to have taken place once a medical prescription has been filled. With the revision of the medical device legislation, Art. 16 of the MedDO, which regulated the prescription requirement for medical devices, was deleted without replacement and the corresponding ordinance repealed (Art. 99 no. 2 MedDO). According to the Federal Office of Public Health, the reason for this was that the medical devices listed in the Ordinance on the List of Prescription-Only Medical Devices of June 22, 2006 (VLvM) (intrauterine devices for contraception and saturation compressors) are no longer as risky today, which is why a prescription is no longer required. Therefore, there are no longer any medical devices that require a prescription by law. However, a prescription requirement may arise from the intended purpose or the manufacturer's information, which must be taken into account in the context of Art. 68 MedDO. Unlike the situation with medicinal products, it is not the Swiss Agency for Therapeutic Products that

assigns medical devices to a dispensing category when they are officially authorized, and thus determines whether they are prescription-only or not, but rather the manufacturers themselves who can determine whether their products are prescription-only or not, provided this makes sense, for example, for safety reasons.

The application of medical devices must also be distinguished from their dispensing, although neither the TPA nor the MedDO contain a definition of the term "*application of a*". In particular, the application is characterized by the independent decision to administer the device and the assumption of responsibility for this decision. The application is therefore to be equated with the use that occurs after the device has been dispensed and which means the specific use of the medical device for the intended medical purpose. 6

Possible actions that may fall under the dispensing of medical devices include, in particular, selling, distributing, delivering or making them available to patients. These actions can be carried out by doctors, healthcare institutions, pharmacies, drugstores, supermarkets, mail-order companies, web shops or self-service vending machines, among others. Making medical devices available to medical personnel or professional users also falls under the term "dispensing" if this medical device is intended for use by the medical personnel on patients. The execution of a medical prescription by an authorized person ultimately leads to the dispensing of the medical device. The case in which manufacturers provide their medical devices directly to patients is also to be evaluated as a dispensing in the sense of therapeutic products legislation. 7

In addition, the general regulations – such as their respective risk class – are also to be observed when dispensing medical devices. Consequently, only medical devices that are intended for use by the public, i.e. lay users, in accordance with the manufacturer's specifications, i.e. persons who cannot be assumed to have medical or technical expertise, may be supplied directly to end users (see also Art. 70 para. 2 and 3 and Annex 6 MedDO). 8

In principle, the distribution of medical devices does not require official authorization. However, if the costs for the distribution are to be covered by health insurance, a cantonal authorization is sometimes required. 9

III. PURPOSE AND MANUFACTURER'S INFORMATION

10 The distribution of medical devices is based on the **intended purpose** and the **manufacturer's instructions**. A uniform definition of the term "*intended purpose*" cannot be found in either the MedDO or the TPA. With regard to Art. 2 no. 12 EU MDR, the definition of which also applies to Switzerland in accordance with Art. 4 para. 2 MedDO, the intended purpose refers to "*the use for which a device is intended, as specified by the manufacturer on the label, in the instructions for use or in promotional or sales material, or in promotional or sales information and in the clinical evaluation*". The labeling refers to written, printed or graphically displayed information affixed either to the device itself or to the packaging of each unit or to the packaging of multiple products (Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 13 EU MDR). The instructions for use refer to information provided by the manufacturer in which the user is informed about the intended purpose and correct use of a product, as well as any precautions to be taken (Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 14 EU MDR). Consequently, it is primarily the manufacturer who determines the purpose of his product, and he thus has a great deal of discretion. This is surprising in that the dispensing of medicinal products is strictly regulated by law. In any case, the limits of this discretion are set by Art. 70 para. 2 and 3 in conjunction with Annex 6 MedDO, which indirectly affect the dispensing of such products only to professionals – and thus not directly to patients. These are so-called long-term injectable products that are intended to remain in the human body for more than 30 days (no. 1 of Annex 6 MedDO).

11 According to Art. 4 para. 1 let. f MedDO, a **manufacturer** is any natural or legal person who manufactures a device or reprocesses a device, or who has a device designed, manufactured or reprocessed, and markets that device under his name or trademark. According to Art. 4 para. 1 let. f MedDO, the clarifications and exceptions listed in Article 16 para. 1 and 2 of the EU MDR – which particularly affect distributors and importers and the cases in which they do or do not have the obligations of a manufacturer – must also be taken into account.

12 Since the revision of the medical devices legislation in 2021, the MedDO applies both to medical devices and their accessories in accordance with Art. 3 para. 3 MedDO and to products without an intended medical purpose in accordance with Annex 1 MedDO (see Art. 1 para. 1 MedDO). Products without

an intended medical purpose include, for example, contact lenses or hair removal products. Consequently, Art. 68 MedDO applies to both medical devices and products without an intended medical purpose (Art. 1 para. 2 MedDO).

IV. APPLICATION BY ANALOGY OF ART. 26 TPA

According to Art. 48 para. 2 TPA, Art. 26 TPA applies by analogy to medical devices. Art. 26 TPA regulates the principles for the prescription, dispensing and use of medicinal products. These rules also apply by analogy to medical devices by virtue of the reference in Art. 48 para. 2 TPA. Since there are currently no legally prescribed prescription-only medical devices, the reference is (currently) without legal consequence with regard to prescription, unless a manufacturer voluntarily subjects its product to a prescription requirement. However, this reference and thus Art. 26 TPA must be observed in any case for dispensing and use, even if the Federal Council has not exercised its authority under para. 1 of Art. 48 TPA. Para. 2 of Art. 48 TPA is an independent provision, and thus separate from para. 1, which must be observed in any case. The analogous application for medical devices therefore means in particular that the recognized rules of medical and pharmaceutical science must be observed when dispensing and using medical devices (Art. 48 para. 2 in conjunction with Art. 26 para. 1 TPA). 13

Observing the recognized rules of medical and pharmaceutical science when dispensing means, in particular, a concretization of the duty of care arising from Art. 3 TPA. What exactly the term “recognized rules of medical and pharmaceutical science” means is not defined in more detail in the TPA. According to the Federal Supreme Court, a breach of due diligence on the part of the medical profession is deemed to have occurred if a doctor's actions no longer appear justifiable according to the general state of professional knowledge and do not correspond to the current state of scientific knowledge. The applicable standard of care is primarily based on special standards that prescribe a certain course of action. According to the Federal Court, this also applies to generally recognized rules of conduct issued by a private or semi-public association that do not constitute legal norms. These rules of conduct include, for example, the rules of good dispensing practice for therapeutic products of the Swiss Association of Cantonal Pharmacists and the FMH drug policy, which are covered by Art. 26 para. 1 TPA. These rules of conduct merely 14

form the framework on the basis of which a breach of due diligence can be determined. Specific cases of breaches of due diligence must be examined on a case-by-case basis by means of medical reports. When dispensing medical devices, the rules of good dispensing practice for therapeutic products must be observed in particular, which define the basic due diligence to be observed when dispensing and using therapeutic products. However, it should be noted that the rules of Good Dispensing Practice for therapeutic products generally only apply to prescription-only medical devices. For non-prescription medical devices, which make up the majority of medical devices, the principles of the rules of Good Dispensing Practice for therapeutic products should therefore be consulted for reference only.

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Art. 72 Reprocessing

[1] Any person using in a professional capacity a device intended for repeated use must ensure on each occasion and prior to use that its functionality has been tested and that it has been reprocessed in accordance with current scientific and technological standards and taking account of the instructions of the manufacturer and the requirements of hygiene.

[2] Reprocessing must employ suitable procedures that have been validated in accordance with current scientific and technological standards and whose efficacy has been demonstrated and can be reliably traced and reproduced within a quality management system.

[3] Any natural or legal person who reprocesses devices for third parties must:

a. declare that the reprocessed device:

has been reprocessed in accordance with the manufacturer's instructions, or
has been reprocessed using a procedure specific to the processor that is equally safe and effective as the procedure specified by the manufacturer and has been demonstrated to be equally safe and effective by means of a risk analysis and validation process;

b. operate a quality management system that is both suitable and certified to nationally or internationally recognised standards;

c. provide proof that reprocessing takes place in suitable premises, in accordance with the recognised rules of science and technology and in compliance with hygiene requirements.

d. document that the device has been reprocessed in accordance with letter a.

[4] The declaration required under paragraph 3 letter a must identify the device and state the name and address of the establishment that reprocessed it.

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I. GENERAL

1 Art. 72 MedDO deals with the reprocessing of medical devices that are intended for multiple use. Such reusable medical devices must be distinguished from single-use devices, which are regulated by Art. 73 MedDO. Not least for reasons of sustainability and cost, medical devices that can be reprocessed are of interest to service providers (in contrast to single-use products). Art. 72 MedDO is based on the statutory maintenance obligation under Art. 49 TPA. According to Art. 49 TPA, anyone who uses a medical device commercially or on third parties must take all measures necessary for maintenance to preserve the performance and safety of this medical device. The TPA does not further define the term "maintenance," but the MedDO contains a definition in Art. 4 para. 1 lit. d: Maintenance includes all measures such as servicing, software updates, inspection, repair, preparation for initial use, and reprocessing for reuse, in order to maintain or restore the functional condition of a medical device. In the MedDO, maintenance is regulated in detail by Art. 71. Reprocessing – which, according to the definition in Art. 4 para. 1 lit. d MedDO, is fundamentally part of maintenance – is regulated separately from maintenance in Art. 72 MedDO due to its relevance in practice.

2 However, Art. 71 and 72 MedDO cannot be completely separated from each other. According to Art. 71 para. 4 MedDO, Swissmedic may issue and publish guidelines on maintenance measures, which are then considered to represent the state of the art in science and technology. Since reprocessing is part of maintenance according to Art. 72 MedDO, Swissmedic's corresponding powers also extend to this area, enabling it to issue guidelines on measures that are then considered to represent the state of the art in science and technology. In the field of medical device reprocessing, the Swiss Good Practice for Medical Device Reprocessing (version 2022), which was developed jointly by the Swiss Society for Sterile Supply (SGSV), the Swiss Society for Hospital Hygiene (SGSH) and Swissmedic, is particularly relevant. Swissmedic bases its inspection activities on these guidelines and requires that any deviations be justified. In practice, healthcare facilities seem to have difficulty complying with the reprocessing regulations – the Swissmedic hospital inspection concerning medical devices in 2024 revealed numerous deficiencies in the area of reprocessing in the reprocessing units for medical devices (AEMP, central sterilization departments). It was found that individual reprocessing processes

were affected by deficiencies, particularly the cleaning and disinfection process (92%), the packaging process (100%), the sterilization process (75%), and the storage of sterile instruments (67%). In addition, the AEMP's quality management system was affected by deviations in 75% of the inspections, with the main issues being missing or inadequate work instructions and interface agreements, as well as the lack of risk management.

But what exactly does the term "**reprocessing**" mean from a legal perspective? Art. 4 para. 1 lit. e MedDO contains a definition of this term: Reprocessing is defined as a process to which a used product is subjected so that it can be safely reused; this process includes cleaning, disinfection, sterilization, and similar procedures, in particular packaging, transport, and storage, as well as testing and restoring the technical and functional safety of the used product. This definition corresponds to that in Art. 2 para. 39 of Regulation (EU) 2017/745 ("EU MDR"), although in Art. 4 para. 1(e) MedDO, unlike the European definition, the "similar processes" are specified in a list of examples. The aim of reprocessing medical devices is to eliminate all risks of infection that may arise from these products, and the reprocessing procedure must ensure that these products are sterile or disinfected. 3

The reuse of medical devices in everyday medical practice is commonplace. For example, surgical instruments such as clamps and forceps, ventilators, and endoscopes are used multiple times. The proper reprocessing of reusable medical devices is crucial in practice to prevent infections caused by contaminated medical devices. 4

II. REQUIREMENTS FOR REPROCESSING (PARA. 1)

A. Introduction

Professionals who use medical devices that are intended for repeated use shall ensure that the functionality of the device is checked and that it is reprocessed in accordance with the state of the art and technology, taking into account the manufacturer's instructions and hygiene requirements (Art. 72 para. 1 MedDO). Art. 72 para. 1 MedDO stipulates a duty of care in connection with the repeated use of medical devices, which applies to the specific user of such a product. This duty of care applies to the **professional** who uses such a product in a specific case. Specialists are defined as members of the healthcare professions, such as doctors and dentists, but also nurses and physiother- 5

apists. Although the wording of Art. 72 para. 1 MedDO refers exclusively to specialists, Swissmedic also applies this provision to **healthcare facilities**. On its website, Swissmedic states that "*hospitals must regard the GPA (including corrigendum) as a reference work that provides guidelines for the correct operation of a reprocessing unit. It contains mandatory requirements that must be followed on the basis of the applicable laws and standards, as well as recommendations based on current practice and literature.*" Due to the clear wording of Art. 72 para. 1 MedDO ("specialist"), it is questionable whether this extension to healthcare facilities is permissible by the supervisory authority, as there is no legal basis for such an extension. In substance, however, Swissmedic's view is of course understandable, as the duties of care under Art. 72 para. 1 MedDO should also apply to healthcare facilities, not just to professionals – but from the point of view of legal certainty, a better wording of Art. 72 para. 1 MedDO would have been desirable. It therefore remains to be seen whether Swissmedic's decisions against healthcare facilities for violating Art. 72 MedDO will stand up in court.

6 The reprocessing of medical devices must be carried out in accordance with the state of the art in science and technology, taking into account the manufacturer's instructions and hygiene requirements (Art. 72 para. 1 MedDO). Since reprocessing is part of maintenance, Swissmedic may, on the basis of Art. 71 para. 4 MedDO, issue guidelines in this regard which are considered to represent the state of the art in science and technology. Swissmedic considers the Swiss Good Practice for the Reprocessing of Medical Devices (version 2022) to be such a requirement within the meaning of Art. 74 para. 1 MedDO and designates it as a guideline for the reprocessing of medical devices in healthcare facilities, which must be observed in all areas of the healthcare organization (central sterilization, operating rooms, endoscopy departments, etc.). These guidelines contain both mandatory requirements that must be followed on the basis of applicable laws and standards, as well as recommendations based on current practice and literature.

B. Requirements relating to personnel and premises

7 Swiss Good Practice for the Reprocessing of Medical Devices (Version 2022) contains guidelines on the correct operation of a reprocessing unit, including premises, personnel, equipment, and information management systems. With regard to **personnel** and responsibilities, Swiss Good Practice for the Repro-

cessing of Medical Devices (Version 2022) sets out various requirements. A manager must be appointed for the reprocessing unit, as well as a person responsible for the quality assurance system for the reprocessing of medical devices. Both persons must have appropriate professional experience and training in the reprocessing of medical devices. The person responsible for the quality assurance system must also have appropriate training and experience in quality management. In small healthcare facilities, both functions can be performed by the same person. If this is the case, however, the internal audits must be carried out by a qualified third party, who must also write the corresponding reports. The manager of the reprocessing unit must write an annual activity report and submit it to the management of the healthcare facility. In addition, (i) all personnel involved in the reprocessing of medical devices must be listed in the operational organization chart, (ii) the activities of these personnel must be included in a job description, and (iii) all tasks related to the reprocessing of medical devices may only be performed by selected, competent employees who have received appropriate training. The Swiss Good Practice for the Reprocessing of Medical Devices (version 2022) contains further regulations relating to personnel on pages 32 to 34, which must be observed.

8 The Swiss Good Practice for the Reprocessing of Medical Devices (Version 2022) also contains various requirements relating to **premises** that must be observed by healthcare facilities. In principle, the layout of the premises must allow for the physical separation of the following areas: (i) area designated for receiving and cleaning work (cleaning zone), (ii) area for packaging work (clean zone), and (iii) area available for removing medical devices from sterilizers and for storing sterile goods (sterile zone). The premises and the process flow must be designed in such a way that any risk of confusion between sterile and non-sterile medical devices can be ruled out. The Swiss Good Practice for the Reprocessing of Medical Devices (Version 2022) also contains various other requirements that must be met with regard to the premises, e.g. with regard to lighting (Chapter 5.2.2), noise pollution (Chapter 5.2.3), maintenance (Chapter 5.2.5), ventilation and indoor air quality (Chapter 5.3), medical compressed air (Chapter 5.4), water (Chapter 5.5) and materials (Chapter 5.6). For details regarding these requirements, please refer directly to the relevant chapters of the Swiss Good Practice for the Reprocessing of Medical Devices (Version 2022).

C. Requirements relating to the reprocessing of medical devices

9 Reprocessing must be carried out in accordance with the **manufacturer's instructions** (see Art. 72 para. 1 MedDO). According to Annex I, no. 23.4(n) of the EU MDR, in order to comply with the essential requirements, the manufacturer is obliged to provide the following information in connection with the labeling and instructions for use of reusable medical devices: Information on suitable reprocessing procedures, e.g. for cleaning, disinfection, packaging and, where applicable, the validated procedure for re-sterilization in accordance with the Member State(s) in which the product is placed on the market. It must be made clear how to recognize that the product should no longer be reused, e.g., signs of material wear or the maximum number of permitted reuses. Pursuant to Art. 6 para. 2 MedDO, these provisions of Annex I of the EU MDR also apply to Switzerland.

10 A manufacturer of medical devices must therefore describe in detail how a user must reprocess the product in question and how they can determine whether the product is still suitable for further reprocessing. The manufacturer is obliged to provide objective evidence that the specified reprocessing procedures lead to the desired result. Further specific standards relating to the information to be provided in connection with reprocessing procedures can be found in ISO standard 17664, in particular in the sixth chapter, which deals with the information to be provided by the manufacturer to the user. This manufacturer information must be provided for all reprocessing steps, including, for example, information on the validation parameters (such as temperature, time, water quality) and the process chemicals. In principle, machine reprocessing procedures are preferable to manual procedures due to their standardization and reproducibility.

11 Compliance with the manufacturer's specifications is not mandatory. This already follows from Art. 72 para. 3 lit. a no. 2 MedDO with regard to reprocessing by third parties. The Swiss Good Practice for the Reprocessing of Medical Devices (version 2022) also states that anyone who deviates from the manufacturer's instructions when reprocessing medical devices must analyze and evaluate the new risks that arise as a result and assess the acceptability of the residual risks. This risk assessment must be documented accordingly. However, for liability reasons, it is recommended that the manufacturer's instructions, if available, regarding the reprocessing of medical devices be followed.

D. Testing of functionality

Art. 72 para. 1 MedDO requires the professional using the product to test its functionality before each use. The legislator thus imposes a specific duty of care on the professionals using the product – e.g., the physician who uses a (re)processed medical device during an operation – when handling (re)processed medical devices. It is not possible to say in general terms what this check should entail; rather, it depends on the medical device in question and also on the manufacturer's specifications. Failure to comply with this duty of care may – provided that the other conditions for liability are met – result in liability on the part of the responsible professional. 12

III. QUALITY MANAGEMENT SYSTEM (PARA. 2)

According to Art. 72 para. 2 MedDO, procedures that are suitable and validated according to the state of the art in science and technology must be used for (re)processing. Their proven effectiveness must be guaranteed in a traceable and reproducible manner within the framework of a quality management system ("QMS"). Reprocessing consists of various process steps whose effectiveness cannot be fully confirmed by in-process controls and product testing. Therefore, documented evidence of the consistent and reproducible effectiveness of such a reprocessing process is necessary, which is achieved by validating the critical process steps. Validation is a documented procedure for generating, recording, and interpreting the results required to prove that a process consistently delivers products that meet the specified requirements. A healthcare facility must therefore develop a QMS for the (re)processing of medical devices, document it in writing, implement it, keep it up to date, and ensure its long-term effectiveness. The QMS must cover all processes involved in the reprocessing of medical devices. The following steps may be part of the reprocessing process: sorting, preparation, pre-cleaning, cleaning, disinfection, cleanliness control and functional testing, packaging, sterilization, batch release, transport and storage, and provision. Swiss Good Practice for the Reprocessing of Medical Devices recommends a QMS based on the concepts described in the ISO 9000 series of standards. However, a specialist is free to apply other concepts, in which case the legal requirements must also be met. With regard to the specific requirements and design of a QMS and the validation of the reprocessing procedure, reference is made to Swiss Good Practice for the Reprocessing of Medical Devices (version 2022) and the 13

Swiss Guideline for the Validation and Routine Monitoring of Cleaning and Disinfection Processes for Medical Devices.

IV. REPROCESSING FOR THIRD PARTIES (PARAS. 3 AND 4)

14 Para. 3 of Art. 72 MedDO deals with the reprocessing of medical devices for third parties. Due to staff shortages and cost pressures faced by many healthcare facilities and professionals, they are increasingly outsourcing the reprocessing of medical devices to specialized service providers. Service providers wishing to undertake reprocessing for hospitals must meet the requirements of Art. 72 para. 3 and 4 MedDO. Even if the reprocessing is outsourced to a service provider, the overall responsibility under Art. 72 para. 1 MedDO remains with the professional who uses the product. It is therefore in the interest of the outsourcing healthcare facility and professional to carefully select the service provider and to set out the requirements that the service provider must comply with, as well as information and control rights, in a contract.

15 Anyone who reprocesses a medical device for third parties must declare, in accordance with Art. 72 para. 3 lit. a MedDO, that the product has either (a) been reprocessed in accordance with the manufacturer's instructions, or (b) been reprocessed using their own reprocessing procedure that is equally safe and effective as the procedure specified by the manufacturer, and that this equivalence has been demonstrated by means of a risk analysis and a validation procedure. This declaration must include the identification of the product and the name and address of the service provider (Art. 72 para. 4 MedDO). Furthermore, according to Art. 72 para. 3 lit. b MedDO, the service provider must have a suitable QMS certified according to nationally or internationally recognized standards (usually ISO 13485). In addition, according to Art. 72 para. 3 lit. c MedDO, the service provider must provide evidence that the reprocessing is carried out in suitable premises in accordance with recognized scientific and technical rules and that hygiene requirements are met. Finally, in accordance with Art. 72 para. 3 lit. d MedDO, they must document that the product has been reprocessed in accordance with Art. 72 para. 3 lit. a MedDO.

16 With regard to the individual elements of para. 3, reference is made to the comments on paragraphs 1 and 2. However, it should be noted that, in the context of reprocessing for third parties, additional factors must be taken into account compared to in-house reprocessing, e.g., transport to and from the service provider and, if necessary, external storage. These additional elements

must be taken into account by the healthcare facility with overall responsibility within the framework of Art. 72 para. 2 MedDO.

V. CONSEQUENCES OF NON-COMPLIANCE

From a **civil law perspective**, inadequate reprocessing of medical devices may result in liability on the part of the specialist or healthcare facility towards the injured patient, provided that the other conditions for liability (adequate causal link between the breach of duty and the damage, as well as fault) are met in the specific individual case. The conditions for liability must be proven by the patient concerned (Art. 8 CC), although it may not be easy to prove that the reprocessing was inadequate. For this reason, there is a case for easing the burden of proof if the patient can prove an infection for which a contaminated medical device is a possible cause. In this case, the specialist or healthcare facility must prove that they have fully complied with the duties of care set out in Art. 72 MedDO (reversal of the burden of proof). 17

From an **administrative law perspective**, Swissmedic is the enforcement authority responsible for market surveillance and the enforcement of medical device regulations (Art. 66 para. 1 TPA) . Market surveillance controls include, among other things, checking that economic operators are fulfilling their obligations (Art. 75 para. 1 MedDO) and, consequently, that they are implementing the obligations arising from Art. 72 MedDO. The range of administrative measures available to remedy such deficiencies is not limited in principle, as Art. 66 para. 1 TPA provides that all administrative measures necessary for the enforcement of the TPA may be taken. Art. 66 para. 2 TPA contains a non-exhaustive list of measures that may be ordered by Swissmedic. In any case, the measures ordered must comply with the principle of proportionality. 18

From an **(administrative) criminal law perspective**, it should be noted that, according to Art. 86 para. 1 lit. e TPA, anyone who intentionally violates the maintenance obligation for medical devices is punishable by imprisonment of up to three years or a fine. Negligent acts are punishable by a fine, and in particularly minor cases by a penalty (Art. 86 para. 4 TPA). In this context, the authorities are likely to focus primarily on the person in charge of the reprocessing unit and the person responsible for the quality assurance system, as they bear responsibility for maintenance within their organization. The maintenance obligations are governed by Art. 49 TPA in conjunction with Art. 71 ff. MedDO. Under certain circumstances, however, the healthcare facility 19

itself may also be convicted (cf. Art. 89 TPA). In cases where a breach of duty in connection with the reprocessing of medical devices leads to the death of a patient or to bodily injury, it is also conceivable that the criminal offense of negligent homicide (Art. 117 SCC) or negligent bodily injury (Art. 125 SCC) has been committed.

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COMMENTARY ON

Art. 73 MedDO

A commentary by Philippe Fuchs

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Art. 73 Single-use devices and their reprocessing

[1] Reprocessing and further use of single-use devices is forbidden.

[2] Single-use devices reprocessed in a foreign country under Article 17 paragraph 3 EU-MDR must neither be used nor made available on the market.

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I. GENERAL

Art. 45 para. 7 TPA authorizes the Federal Council to regulate the reprocessing and reuse of single-use devices and to explicitly declare these activities to be permissible. Even if the TPA itself does not contain an explicit prohibition on the reprocessing of used single-use devices, this prohibition arises implicitly from Art. 45 para. 7 TPA. Whether this implicit prohibition of the reprocessing of used single-use devices and the Art. 73 para. 1 MedDO issued on this basis are sufficient from a constitutional point of view – in particular since violation of Art. 73 para. 1 MedDO is punishable by law – may at least be questioned. 1

If the Federal Council declares the reprocessing and reuse of single-use devices permissible on the basis of Art. 45 para. 7 TPA, it must also define the corresponding requirements. Currently, the Federal Council has not made use of its authority under Art. 45 para. 7 TPA, because Art. 73 para. 1 MedDO explicitly stipulates that the reprocessing and reuse of used single-use devices is prohibited. 2

Before the revised Medical Devices Ordinance came into force, the reprocessing of single-use devices was not explicitly regulated by law. In practice, single-use devices were often reprocessed and reused, especially by hospitals, not least for cost reasons. The law at that time basically allowed the reprocessing of single-use devices, provided that the health of patients was not endangered and that the requirements for the initial placing on the market were also met for the reprocessed single-use device. In addition, the placing on the market as single-use devices by the manufacturers was often seen as economically motivated (and not as a result of increased patient protection), which is why the manufacturers' instructions in this regard were often ignored. However, with the introduction of Art. 73 MedDO, the reprocessing and reuse of single-use devices was prohibited by law and made punishable (Art. 86 para. 1 let. d TPA). 3

II. PARA. 1

According to Art. 73 para. 1 MedDO, the reprocessing and reuse of single-use devices is prohibited. Any procedure to which a used medical device is subjected so that it can be reused safely is deemed to be **reprocessing**. These 4

procedures include cleaning, disinfection, sterilization and similar procedures, in particular packaging, transport and storage, as well as testing and restoring the technical and functional safety of the used product (Art. 4 para. 1 let. e MedDO). However, the term "reprocessing" as defined in Art. 73 para. 1 MedDO does not apply to cases in which a new (single-use) device must be cleaned, disinfected, sterilized or subjected to similar procedures prior to its first use. In this case, it is referred to as **preparation for first use**, which is part of maintenance (see Art. 4 para. 1 let. d MedDO). Since preparation for first use is part of maintenance, the provisions of Art. 71 MedDO apply.

5 However, the MedDO does not contain a separate definition of the term "single-use device", which is why the definition in Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices ("EU MDR") applies by virtue of the reference in Art. 4 para. 2 MedDO. A device that is intended for use on a single occasion is therefore designated as a **single-use device** (Art. 2 no. 8 EU MDR). Examples of single-use devices include disposable drill heads, electrophysiology catheters or ultrasonic scissors, but also simple products such as surgical gloves, cannulas, infusion tubes or plasters. Whether a medical device is a single-use device or can be used multiple times is defined by the intended use and the manufacturer. A single-use device is usually marked with the following pictogram:



6 The manufacturer of a medical device must demonstrate compliance with the general safety and performance requirements, taking into account the intended purpose (Art. 6 para. 2 MedDO in conjunction with Annex I EU MDR). In the case of a single-use device, the general safety and performance requirements are checked with regard to the single application or use, based on the intended purpose. This means that the single-use device meets the prescribed safety and performance requirements in accordance with Annex I EU MDR for a single application or use – further uses were not tested as part of the

conformity assessment procedure (see Art. 21 MedDO) and the manufacturer therefore makes no statement regarding safety and performance in the event of multiple uses.

When a used medical device is reprocessed, it is exposed to very high chemical, mechanical and thermal stresses. Since a single-use device is not designed for such treatment, there is a risk that it will be damaged or weakened, so that its proper functioning after reprocessing is no longer guaranteed. In addition to this problem, however, there is also the risk that a single-use product cannot be completely cleaned and sterilized, which can lead to biological residues with a corresponding risk of infection when it is reused. This risk exists in particular with threads or other areas of a single-use product that are difficult to access. If the manufacturer has placed its product on the market as a single-use device, reprocessing and reuse of such a device is not indicated for reasons of health protection and was therefore explicitly prohibited in the revision of the medical device legislation with the introduction of Art. 73 MedDO. 7

III. PARA. 2

Art. 17 para. 1 EU MDR allows the (re)processing of single-use devices provided that (a) the national law of a Member State permits this and (b) the conditions of Art. 17 EU MDR are met. Unlike current Swiss law, EU law therefore explicitly allows the (re)processing and reuse of single-use devices. However, to prevent the prohibition in Switzerland from being circumvented by importing such single-use devices that have been reprocessed in a permissible manner under EU law, Art. 73 para. 2 MedDO explicitly prohibits the making available and use of devices that have been reprocessed in accordance with Art. 17 EU MDR. 8

However, it is unclear why Art. 73 para. 2 MedDO, according to the wording, only covers devices that are reprocessed in accordance with Art. 17 para. 3 EU MDR. Para. 3 of Art. 17 EU MDR only deals with a special situation regarding the reprocessing of single-use devices: the reprocessing and use of single-use devices within a (European) healthcare facility. However, Art. 17 para. 3 EU MDR does not cover the general reprocessing of single-use devices – this is regulated by paras. 1 and 2 of Art. 17 EU MDR. The FOPH's statements in the Explanatory Report on the Total Revision of the MedDO and ClinO-MedDO do not address this at all, but generally state that single-use devices that are 9

reprocessed in accordance with the provisions of Art. 17 EU MDR are not marketable in Switzerland. The following is stated verbatim: "*Thus, no single-use devices reprocessed under the provisions of the EU MDR are tolerated on the market (import) or for use in Switzerland.*" However, these statements by the FOPH do not correspond to the text of the ordinance, which explicitly refers to Art. 17 para. 3 EU MDR and thus basically only covers single-use devices that are reprocessed within a healthcare facility. In view of the objective of Art. 73 para. 2 MedDO – namely to prevent the circumvention of Art. 73 para. 1 MedDO by importing single-use devices that have been reprocessed abroad – a reference should have been made to Art. 17 EU MDR as a whole, without further reference to a specific paragraph of Art. 17 EU MDR. A purely literal interpretation of Art. 73 para. 2 MedDO would therefore lead to the conclusion that single-use devices that have been reprocessed in the European Union in accordance with Art. 17 para. 1 or 2 EU MDR may in principle be used in Switzerland. However, it is to be assumed that the supervisory authorities will not regard this interpretation as decisive, with reference to the spirit and purpose of this provision.

IV. CONSEQUENCES OF NON-COMPLIANCE

10 Non-compliance with Art. 73 MedDO is punishable. Pursuant to Art. 86 para. 1 let. d TPA, anyone who intentionally places on the market, exports or uses medical devices that do not meet the requirements of the TPA shall be punished with a custodial sentence of up to three years or a monetary penalty. In the event of a negligent offense, a monetary penalty is imposed and in minor cases a fine may be imposed (Art. 86 para. 4 TPA). In this context, however, the question arises as to whether the unclear provision in Art. 73 para. 2 MedDO is sufficient as a basis for punishment if single-use devices that have been reprocessed in accordance with Art. 17 para. 1 or 2 EU MDR are used in Switzerland.

11 The legal requirements for medical devices are set out, among other places, in Art. 45 TPA, para. 7 of which is specified in Art. 73 MedDO, which is why the implementing law must also be observed when assessing a violation of the legal requirements.

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COMMENTARY ON

Art. 74 MedDO

A commentary by Philippe Fuchs / Erik Dinkel

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Art. 74 Cyber security

[1] Healthcare institutions must put in place all technical and organisational resources required by the state of the art to ensure that network-compatible devices are protected against electronic attack and unauthorised access.

[2] Hospitals must identify, evaluate and document the measures taken under paragraph 1 in accordance with the principles of a risk management system. This system forms an integral part of the hospitals' quality management system.

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I. GENERAL

In recent years, hospitals and other healthcare facilities have increasingly become the target of cyberattacks. This trend of more and more cyberattacks on hospitals and healthcare facilities can be observed not only in Switzerland but worldwide. The motivation behind this is clear: a failure of a hospital's technical infrastructure (e.g. of life-supporting medical devices or the hospital information system) can have catastrophic consequences, which is why such targets appear particularly lucrative to cybercriminals. On the one hand, such cyberattacks can have devastating financial consequences for the healthcare facilities affected. On the other hand, they can have negative effects on patients, as life-supporting medical devices may be affected or because previously scheduled operations have to be postponed. This problem has been recognized and addressed as part of the revision of the Medical Devices Ordinance in 2020. With the revision of the Medical Devices Ordinance, which came into force on May 21, 2021, a new Art. 74 MedDO was created, which imposes specific cybersecurity due diligence requirements on healthcare facilities and hospitals. 1

Art. 74 MedDO must be distinguished from the corresponding data protection provisions under federal or cantonal law (e.g. Art. 8 FADP), which serve to protect personal data. Art. 74 MedDO, on the other hand, is not primarily intended to protect patient data, but to protect against the failure of the technical infrastructure of the healthcare facility due to electronic attacks on network-compatible medical devices. However, the two areas cannot be completely separated from each other, because a violation of Art. 74 MedDO can also result in a violation of the data protection security provisions (Art. 8 FADP), since numerous network-compatible medical devices (such as computer tomographs or ultrasound devices) also process patient data and some of this data is stored on the medical device. 2

In addition, the obligations under Art. 74 MedDO must be distinguished from the obligation of manufacturers to manufacture and market safe medical devices. According to Art. 6 para. 2 MedDO, medical devices must meet the general safety and performance requirements according to Annex I of Regulation (EU) 2017/745 ("EU MDR"). Annex I of the EU MDR defines in Nos. 17.2 and 17.4 general (safety) requirements in connection with cybersecurity for devices that incorporate electronic programmable systems, as well as software- 3

only devices. In the case of devices that include software components or that are software-based, the software is developed and manufactured according to the state of the art, taking into account the principles of the software life cycle, risk management and information security (No. 17.2 of Annex I of the EU MDR). In doing so, the manufacturers shall specify minimum requirements in terms of hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, required for the intended use of the software (No. 17.4 of Annex I of the EU MDR). These obligations with regard to cybersecurity – as the "first line of defense" against cyber attacks, so to speak – apply to the manufacturer and must be taken into account as early as the development stage of the medical devices. The obligations under Art. 74 MedDO, on the other hand, do not apply to the manufacturer, but to the user – i.e. the healthcare facility – and are in addition to the manufacturer's obligations. This means that the issue of cybersecurity is regulated by law not only at the manufacturer level but also at the user level, providing dual protection against cyberattacks. In practice, however, it has been shown that at the manufacturer level, cybersecurity efforts do not always meet user expectations. One of the reasons for this is that such network-compatible medical devices usually have an extensive software component that is adapted (and certified) to certain operating systems as part of the certification process. However, hospitals cannot carry out updates without the involvement of the manufacturers, and the manufacturers do not have the corresponding updates available in some cases because compatibility after the update would, under certain circumstances, require a re-certification of the medical device, which is not desired by the manufacturers. As a result, hospitals are sometimes forced to run medical devices on older software, which may serve as a gateway for cyber attacks. To counteract this, in such a case the medical device and the software must be isolated from the rest of the system so that access to the rest of the hospital system via this medical device is no longer possible.

II. DUTY OF CARE FOR HEALTH INSTITUTIONS (PARA. 1)

4 Art. 74 para. 1 MedDO requires health institutions to take all technical and organizational measures necessary according to the state of the art to ensure protection against electronic attacks and access in the case of network-compatible medical devices.

This duty of care applies to healthcare institutions in accordance with Art. 74 para. 1 MedDO. According to Art. 4 para. 1 let. k MedDO, a **healthcare institution** is any organization whose main purpose is to provide care or treatment to patients or to promote public health. This corresponds to the definition in Art. 2 no. 36 of the EU MDR and includes in particular hospitals (under private and public law), but also facilities such as laboratories and other (public) health facilities that support the healthcare system but do not directly treat or care for patients. The definition of a health facility also includes doctors' practices and other outpatient medical facilities, which is why they must also comply with the due diligence requirements of Art. 74 para. 1 MedDO if they use network-capable medical devices. However, Art. 74 para. 1 MedDO does not apply to healthcare facilities that primarily promote a healthy lifestyle, such as fitness studios, spas or wellness centers. 5

The due diligence requirement in accordance with para. 1 only applies to **network-compatible medical devices**. Network-capable means that the medical device can be integrated into a network with other devices, so that information can be virtually exchanged between the various network-capable products and accessed from different locations. In other words, the medical device is not only integrated into the internal system of the healthcare facility, but can also be accessed externally – via remote access. In this context, the explanatory report of the FOPH speaks of medical devices being directly and permanently connected to the internet and intranet. In many cases, external access is mandatory so that the manufacturer can provide appropriate (remote) support. There is an increasing merging between operational technology (e.g. medical devices) and (the rest of) the information technology within the healthcare facility. Practice shows that in modern medicine, numerous medical devices are network-compatible – medicine without digital networking is becoming increasingly unthinkable. Examples of such network-compatible medical devices are computer tomographs, mobile X-ray machines, devices for monitoring in intensive care units (e.g. patient monitoring systems), respirators and anesthesia machines, etc. It should also be noted that the term 'medical device' can also include software if it meets the requirements of a medical device in accordance with Art. 3 para. 1 MedDO – this is particularly likely to apply to patient monitoring software. In this respect, the duty of care in accordance with Art. 74 para. 1 MedDO also applies to software. 6

7 According to Art. 74 para. 1 MedDO, all **technical and organizational measures** must be taken that are necessary according to the state of the art to ensure protection against electronic attacks and access. The MedDO itself does not contain a definition of technical and organizational measures. However, the term "technical and organizational measures" is known from other areas of law, in particular from data protection law. For example, Art. 8 para. 1 FADP requires that controllers and processors must ensure data security appropriate to the risk by means of appropriate technical and organizational measures. In this context, technical measures are those measures that are directly related to an information system or data carriers. Organizational measures, on the other hand, are those that affect the system environment, in particular the people who use it, as well as the processes. The National Cybersecurity Center NCSC has issued recommendations for cybersecurity in the healthcare sector. These include both technical and organizational measures and are considered by the NCSC (BACS since January 1, 2024) to be minimum requirements. However, it should be noted that these recommendations do not specifically cover network-enabled medical devices, but rather the overall information security of a healthcare facility.

8 This understanding of technical and organizational measures from other legal areas can be applied to Art. 74 para. 1 MedDO: All measures that are directly related to the medical device, the IT infrastructure of the healthcare facility and the interface between the medical device and the IT infrastructure are considered to be **technical measures**. Examples of technical measures include: encryption, firewalls, backups, password protection, VPN for remote access, network segmentation, automatic desktop lock, etc. This also includes the implementation of periodic or manufacturer-prescribed (software) security updates and the manufacturer-prescribed or regular maintenance of the medical device. In particular, the BACS system refers to the following technical measures: (a) real-time monitoring of endpoints, (b) offline backups and disaster recovery, (c) network segmentation, (d) protection of authentication (e.g. through multi-factor authentication), (e) blocking dangerous e-mail attachments and (f) controlling the execution of files. The technical measures according to (b), (c) and (d) are considered mandatory by the BACS, while those according to (a), (e) and (f) are considered voluntary or "can" regulations. On the other hand, the **organizational measures** according to Art. 74 para. 1 MedDO are those measures that affect the environment of the medical device or the IT infrastructure, in particular the persons who use the network-com-

patible medical device or the associated IT infrastructure, as well as related processes. Examples of organizational measures include training, processes, guidelines, regulations and contracts. The BACS lists the following as organizational measures: (a) patch and lifecycle management and (b) real-time monitoring of the log data of the security perimeter, with the BACS considering these two measures to be mandatory. The importance of organizational measures should not be underestimated, since the best technical measures (such as strong password protection) are of little use if the operating personnel circumvent these measures (e.g. by placing a post-it with the password on the network-compatible medical device). Consequently, organizational measures (such as internal regulations and employee training) must be taken to ensure that the technical measures can be effective. The authors' experience shows that the following organizational measures in particular have been established in medical practice: guidelines, e-learning, training, internal blog on the topic of cybersecurity, etc. However, keeping an inventory of the network-compatible medical devices used and standardized security assessments of new device types, which are carried out before procurement, have also been established in practice as part of the organizational measures. In particular, the authors believe that larger hospitals will not be able to avoid creating clear responsibilities and dedicated functions with sufficient resources within the organization to address the issue of cybersecurity in order to comply with the legal duty of care. Smaller healthcare institutions must at least have external IT support that also includes cybersecurity in its specifications.

9 The technical and organizational measures to be taken must be based on the **state of the art**. This term is also not defined in more detail by the MedDO. However, "state of the art" is a term that is of great importance in the development of medical devices, as the generally recognized state of the art must be taken as a basis with regard to the general safety and performance requirements according to Chapter I of Annex I EU MDR. However, the EU MDR does not contain a general definition that would give this term more contours. The concept of "state of the art" is familiar to other Swiss law: according to Art. 3 para. 2 PrSG, products must correspond to the state of the art in terms of safety. According to Art. 5 para. 1 let. e PrHG, a manufacturer is not liable if it can be proved that the product defect could not be detected according to the state of the art at the time the product was placed on the market. From literature and case law on this concept in other Swiss law, it can be deduced that the state of the art must be determined according to objective criteria

and must be recognized as reputable by the scientific community concerned. In any case, the specific instructions of the manufacturer regarding cybersecurity (as well as any updates to such instructions) – if there are any – must be observed for a particular medical device. In addition, it is advisable to follow the BACS recommendations on cybersecurity in the healthcare sector. These recommendations are considered by the BACS to be "best current practices" and can therefore – at least from the authorities' point of view – be used to substantiate the due diligence requirements of Art. 74 para. 1 MedDO, provided they relate to network-compatible medical devices. It can therefore be assumed that authorities and courts will consult these BACS recommendations in individual cases to assess the technical and organizational measures and compliance with due diligence, even though they are not legally binding. As far as international (self-regulatory) standards are concerned, ISO 27001 has established itself as the standard for information security management systems. In practice, many hospitals follow this standard even if they are not officially ISO-certified.

10 It is recommended that these requirements, which a network-enabled medical device must meet from a technical point of view, be incorporated into the healthcare facility's **procurement process**. When starting to procure network-compatible medical devices, the healthcare facility should be clear from the outset which technical and IT security-related standards the medical device to be procured must meet in order to ensure cybersecurity in each individual case. In May 2024, H+, the Association of Swiss Hospitals, in close cooperation with those responsible for cyber and information security at Swiss hospitals, published a fact sheet entitled "IT-Grundschutzanforderungen an Systeme – Informationssicherheit und Datenschutz" (IT-Grundschutz requirements for systems – information security and data protection), which defines "*the minimum technical and organizational information security ana data protection requirements of the hospital for systems*", in particular for all medical technology systems. This leaflet was issued with due regard to the duties of care arising from Art. 74 para. 1 MedDO, which is why healthcare facilities affected by Art. 74 para. 1 MedDO should refer to this leaflet for assistance, even if they are not hospitals. In general, however, guidelines and fact sheets issued by authorities (such as the BACS) or associations (such as H+) have no legal force and are therefore not legally binding for courts or users.

In contrast to Art. 5 para. 1 let. e PrHG, for example, Art. 74 para. 1 MedDO does not refer to a specific point in time with regard to the state of the art. Consequently, the understanding of the term "state of the art" is subject to **temporal change**. If the state of the art changes with regard to cybersecurity and the appropriate technical and organizational measures that should be implemented to effectively defend against cyberattacks, the healthcare institution must adapt the measures it has taken accordingly. Consequently, the healthcare institution must regularly review its technical and organizational measures to ensure cybersecurity, compare them with the current state of technology and, if necessary, adapt them to the current state of technology. At least for hospitals, this obligation also arises from para. 2 of Art. 74 MedDO, because part of an effective risk management system is also the periodic review of the risk and the appropriateness of the measures implemented against it. From a fundamental point of view, it must be noted that the topic of cybersecurity is an ongoing process and therefore never complete. 11

According to the wording of Art. 74 para. 1 MedDO, the healthcare institution must take **all measures** that are **necessary to ensure the protection against** electronic attacks and access. The wording of Art. 74 para. 1 MedDO differs in particular from that of the related Art. 8 FADP, which requires "*data security appropriate to the risk*" and thus legally establishes the principle of proportionality in the area of security for personal data, which is why, for example, implementation costs may also be taken into account when assessing appropriateness. This raises the question of whether the wording "*all measures necessary to ensure protection*" in Art. 74 para. 1 MedDO even allows for the principle of proportionality, in particular the element of reasonableness. In our opinion, this is the case, because absolute security against cyber attacks does not exist, which is why it can only ever be a matter of appropriate, but not absolute, protection. However, due to the legal interests at stake – the health of patients – the hurdle for assessing appropriateness is to be set higher than in data protection. Consequently, under Art. 74 para. 1 MedDO, the healthcare institution is only required to implement proportionate (i.e. appropriate, necessary and also reasonable) measures that take into account the importance of the legal interests at stake. 12

The technical and organizational measures must ensure protection against **electronic attacks and access**. In other words, the aim is to protect against cyberattacks, i.e. targeted attacks on the IT infrastructure and the (network- 13

compatible) medical devices used by healthcare facilities by unauthorized persons. A distinction must be made between attacks in which the medical device itself is the actual target and attacks in which the medical device is used to gain access to the healthcare facility's wider IT infrastructure. Art. 74 para. 1 MedDO covers both types of attack and the technical and organizational measures must therefore also cover both types of attack. Typical cyber attacks include malware, phishing, zero-day exploits, DDoS attacks or attacks that affect the availability of systems (such as ransomware). According to the authors, ransomware attacks are generally the most dangerous, as they can result in the systems no longer being available, which can have serious consequences for both the hospital and the patients from an operational and medical point of view.

III. RISK MANAGEMENT FOR HOSPITALS (PARA. 2)

14 Unlike the obligations in Art. 74 para. 1 MedDO, which apply to all health institutions that use network-compatible medical devices, the obligations under Art. 74 para. 2 MedDO apply only to hospitals. According to Art. 4 para. 1 lit. l MedDO, hospitals are healthcare facilities in which inpatient treatment of illnesses or inpatient medical rehabilitation or inpatient medical procedures for aesthetic reasons are carried out by medical and nursing staff. The decisive criterion for distinguishing these from doctor's offices or other (outpatient) healthcare facilities is the inpatient treatment of patients. According to Art. 74 Para. 2 MedDO, such facilities must identify, evaluate and document the technical and organizational measures in accordance with the principles of a risk management system. This risk management system must be an integral part of the hospital's quality management system.

15 Practice shows that comprehensive risk management is also standard in hospitals. With regard to the principles of an effective risk management system, please refer to the relevant literature. Art. 74 para. 2 MedDO requires hospitals to identify, evaluate and document the technical and organizational measures taken in accordance with para. 1 with regard to the risk of “cybersecurity” as part of risk and quality management, thus introducing a statutory risk management requirement for hospitals, at least with regard to cybersecurity. In practice, however, this provision is likely to be of little significance, since risk management already played a crucial role for hospitals before Art. 74

para. 2 MedDO came into force and also covered the issue of cybersecurity – as a significant risk.

IV. LEGAL CONSEQUENCES OF A BREACH OF THE DUTY OF CARE

A. Consequences under civil law

In the event of **non-compliance with** the **due diligence requirements** set out in Art. 74 MedDO, the question arises as to the **legal consequences**. In particular, situations need to be considered in which a cyberattack causes life-supporting medical devices to fail, resulting in the death or serious injury of patients. In addition, numerous other constellations are also conceivable, such as the postponement of vital surgeries or the malfunction of medical devices. A fundamental distinction must be made here between private and public healthcare institutions. This classification determines which liability law applies. This distinction will not be discussed further here; instead, the reader is referred to the relevant literature and case law. 16

If a (private-law) contractual relationship exists between the hospital and the patient, the hospital's potential liability is governed by Art. 97 para. 1 CO: If the obligation cannot be fulfilled at all or cannot be properly fulfilled, the debtor must provide compensation for the resulting damage, unless he can prove that he is not at fault. The conditions for liability under Art. 97 para. 1 CO are therefore (a) breach of a contractual obligation, (b) damage arising therefrom, (c) adequate causal link between breach of contract and the damage incurred, and (d) fault (which is presumed under Art. 97 para. 1 CO). In the context of a breach of a contractual obligation, non-performance or improper performance – i.e. positive breach of contract – is of particular interest in the present case. Although the debtor provides a service, it does not have the quality specified in the contract or does not correspond to the care owed under the contract. In principle, a distinction is made between the actual primary and secondary obligations. The secondary obligations include, among other things, duties of conduct that have the purpose of supplementing the main service and ensuring its proper fulfillment or achieving the purpose of the contract, namely protection, care, advice, omission, information and education. Based on the above, the duties of care resulting from Art. 74 MedDO with regard to cybersecurity can be qualified as contractual ancillary duties, 17

because they are behavioral duties intended to ensure the proper performance of the main service. It is therefore a duty of the hospital to protect the patient.

18 When specifically is there a breach of the duty of care resulting from Art. 74 Para. 1 MedDO? As explained above, this concerns appropriate protection against electronic attacks and access. This appropriate protection must be determined on the basis of an objective standard in each individual case. Information sheets and guidelines – such as those of the BACS or H+ – can be consulted for assistance in specifying this objective standard, but non-compliance with the recommendations contained in such guidelines or information sheets does not automatically constitute a breach of due diligence. In practice, however, affected companies are advised to follow the guidelines and fact sheets of expert groups and to design their safety precautions based on these recommendations.

19 A violation of the duty of care as per Art. 74 para. 1 MedDO can therefore – provided that the other liability requirements of Art. 97 CO are met – lead to the healthcare institution being held liable to the affected patient, whereby the affected patient must prove the liability requirements (Art. 8 CC). In practice, it may be difficult to prove a breach of duty of care due to a lack of insight into the IT infrastructure of the healthcare facility. The fact that an attack or access has taken place is not in itself sufficient to prove a breach of duty of care. Rather, it must be proven that the healthcare institution has not taken all (reasonable) technical and organizational measures to prevent such attacks or access. In this respect, it is to be demanded that the healthcare institution concerned, as part of its procedural obligation to cooperate in accordance with Art. 160 Para. 1 CPC, must hand over the necessary IT security documentation. If the healthcare institution unjustifiably refuses to cooperate and hand over the IT security documentation, the court must take this into account when considering the evidence (Art. 164 CPC).

B. Administrative consequences

20 In addition to the civil law consequences, the administrative consequences of a violation of Art. 74 MedDO must also be considered. As the enforcement authority, Swissmedic is responsible for market surveillance and the enforcement of medical device regulation (Art. 66 para. 1 TPA). The control within the framework of market surveillance includes, among other things, the fulfill-

ment of the obligations of the economic operators (Art. 75 para. 1 MedDO), and thus also the implementation of the obligations resulting from Art. 74 MedDO. The Swissmedic hospital inspection in 2023 with regard to medical devices showed that the issue of cybersecurity was affected by deviations in 43% of the inspections. In particular, deficiencies were found in hospitals in the area of the associated processes and interfaces, as well as in risk management. The range of available administrative measures to remedy such deficiencies is not limited in principle, since Art. 66 para. 1 TPA stipulates that all administrative measures necessary for the enforcement of the TPA may be taken. Art. 66 para. 2 TPA contains a non-exhaustive list of certain measures that can be ordered by Swissmedic. In any case, the ordered measures must satisfy the principle of proportionality.

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