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Assisted Suicide with Sarco capsule in Switzerland – do we need to think about safety rules?

Switzerland has a longstanding liberal solution to access «assisted suicide». Swiss associations provide support procedures for «assisted suicide» according to medical ethical standards and in compliance with criminal law. Currently, a new device developed to assist suicide is on the Swiss market, the so-called Sarco capsule and there have been questions raised about its legality. According to the Swiss Therapeutic Products Act, this article discusses a possible qualification and the consequences of the Sarco capsule as a medical device. It shows how there is still room for legal debate.

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Introduction

[1] Laws on assisted dying are developing or are being discussed in Europe. In Switzerland, this is less the case because of its longstanding liberal solution to access assisted suicide. According to art. 10 para. 2 Federal Constitution¹: «Every person has the right to personal liberty and in particular to physical and mental integrity and to freedom of movement.». Consequently, every person capable of freely forming his or her own will and acting accordingly has the right to decide how and when to die.² Currently, swiss associations provide support procedures for assisted suicide according to medical ethical standards and in compliance with art. 115 Swiss Criminal Code.³ This support includes the intervention of physicians prescribing sodium pentobarbital.

[2] Currently, a new device to assist suicide, the so-called Sarco capsule⁴, is on the Swiss market, and there have been questions raised about its legality. The product is not subject to any conformity assessment assuring its performance, and it is possible to use this solution without any medical person assessing the person's capacity for judgement or prescribing the use of such an object. As a result, introducing this product raises questions about the end-of-life regime in Switzerland.

[3] Switzerland has the Product Safety Act⁵, a horizontal law that sets minimum standards for all product categories. Still, we also have vertical laws that regulate specific sectors according to their potential hazards and characteristics, as it is the case with the Swiss Therapeutic Products Act (TPA⁶) for medical devices and medical products. The TPA constitutes a *lex specialis* in relation to the Products Safety Act.⁷

¹ Federal Constitution of the Swiss Confederation of 18 April 1999 (RS 101).

² Judgement of the Federal Supreme Court, ATF 133 I 58/JdT 2008 I 349; European Court of Human Rights (ECtHR), *Haas c. Suisse*, n°31322/07, 20 January 2011.

³ Swiss Criminal Code of 21 December 1937 (RS 311.0).

⁴ The last resort, Fonctionnement, (09 January 2025): <https://www.thelastresort.ch/francais/sarco/operation/>.

⁵ Products safety Act of 12 June 2009 (RS 930.11).

⁶ Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (Therapeutic Products Act, TPA, RS 812.21).

⁷ Art. 1 para. 3 Products Safety Act; Message Products Safety Act, FF 2008 6787.

[4] This article discusses a possible qualification of the Sarco capsule as a medical device according to the TPA and its consequences. We may have had a narrow view of medical purpose so far, at least in the context of assisted dying, and we need to discuss further whether assisting in ending suffering is in a medical scope or not. Still, we question whether the TPA applies. In line with the scope «to protect humans» and «medical purpose» and in coherence with recent federal case law on assisted dying and the TPA, which was not applicable in the case, the reluctance to consider the Sarco capsule as a medical device is understandable. However, this does not mean that there is enough legal coherence or that there shouldn't be any safety rules. Even if the Sarco capsule is recognized as a medical device, this would not necessarily solve the problem of substantive or procedural safeguards to assisted suicide.

1. Recent legal developments in assisted dying

[5] In some countries, the demand for assisted dying has become a legal and social reality (e.g. the Netherlands in 2001, Belgium in 2002, Luxembourg in 2009, and Canada in 2016); in other countries, it is instead a novelty (Spain in 2021 and Portugal in 2023), and again in other countries such as France, Germany⁸ and the United Kingdom the public debate is ongoing and currently still open.⁹ The fact is that national and European rulings and legislation on assisted dying have developed considerably worldwide over the last 25 years.¹⁰

[6] In Switzerland, the legal framework has always been liberal because assisted suicide as one form of assisted dying has not been criminalized, at least not under some conditions (art. 115 Swiss Criminal Code): subjective capacity of judgment and objective capacity to be able to administer the lethal dose to his/herself and an altruistic motive of the assisting person.¹¹ If the person concerned no longer carries out the act themselves, article 115 Swiss Criminal Code no longer applies. Instead, the articles on homicide (art. 111ss Swiss Criminal Code) are applicable. From a purely criminal law perspective, it is irrelevant whether the suicide wish is well-considered or not, whether the suicidal person suffers from an (incurable) illness or not, or whether his or her motives for suicide are generally comprehensible or not (but the person must have their capacity of judgment at the time of suicide). In this respect, whether a young or older person commits suicide is irrelevant to the assessment of the criminal liability of assisted suicide. Assisted suicide is independent of the use of medication and prescription of sodium pentobarbital. Assisted suicide can theoretically be administered with any «device» or «tool», e.g., suffocation with a plastic bag that an assisting person hands over.

⁸ Federal Constitutional Court in Germany (BVerfG) declared § 217 German Criminal Code unconstitutional in February 2020. Since then, organized, commercial or even professional suicide assistance in Germany has again been possible without punishment and with relatively few requirements. The German Bundestag is in the process of legislation.

⁹ See for a short summary ECtHR, *Karsai c. Hongrie*, n°32312/23, 13 June 2024, §58.

¹⁰ SARAH MROZ/SIGRID DIERICKX/LUC DELIENS/JOACHIM COHEN/KENNETH CHAMBAERE, Assisted dying around the world: a status quaestionis, *Annals of Palliative Medicine* 10(3) (2021), pp. 3540.

¹¹ PETRA VENETZ, *Suizidhilfeorganisationen und Strafrecht*, Zürich/Basel/Genf 2008, p. 101; CHRISTIAN SCHWARZENEGGER, *Basler Kommentar Strafgesetzbuch II* (Art. 111–392), 4th ed., Basel 2019 (BSK-StGB), art. 115 N 2.

[7] There have been several federal Supreme Court cases and two European Human Rights Court decisions to protect the liberty of terminating one's life and within institutions.¹²

[8] However, there are, to date, no political or legal actions to discuss and regulate assisted dying coherently and to legalize assisted dying with the legal justification of the person who wishes to die.¹³ There seems to be, furthermore, no intention to clarify the relations and differences between palliative care as a medical act and assisted dying as no such one. And it remains a dogmatic question, why a person has the uncontested right to decide on his/her own body and decide on his/her treatment by human rights and constitutional and civil law, but has no positive right to assisted dying, whether by own act («suicide,» cf. assisted suicide art. 115 Swiss Criminal Code) or by an act of a third person («homicide,» Art. 114 Swiss Criminal Code).¹⁴

[9] Practically, people wishing to end their lives in Switzerland are traditionally accompanied by one of the eight private organizations (one of them has existed for over 40 years) that work with physicians, who ensure that the person meets the conditions required to benefit from assisted suicide under medical and ethical guidelines. The physician concretely prescribes sodium pentobarbital, a drug that causes death, and the physician evaluates the capacity of judgment of his/her patient to commit assisted suicide. Subsequently, an organization supports the person who will perform the final act himself/herself, e.g., to drink the potion containing the pentobarbital.

2. A new organization and a new device on the market: the Sarco capsule

[10] Since summer 2023, a new organization has been active in Switzerland, operating with a new device to assist suicide. They use the so-called Sarco-capsule, a 3D-printed device for suicide. By pressing a button inside, a low-oxygen environment using nitrogen is created in the airtight space. The device can reduce the oxygen level from 21% to 1% in 30 seconds.¹⁵ So, no drugs are supplied, and there is also no need for a physician to prescribe it and/or be present. The fact that no member of the medical profession is involved raises controversial issues besides the product qualification, that also Swissmedic pointed out in an internal memo.¹⁶ Developed by Exit International, the new device is made available in Switzerland through the association «The Last Resort,» which may have further plans, such as an open-source format.¹⁷

¹² Judgement of the Federal Supreme Court, ATF 133 I 58/JdT 2008 I 349; European Court of Human Rights (ECtHR), *Haas c. Suisse*, n°31322/07, 20 January 2011; ECtHR, *Gross c. Suisse*, n°67810/10, 30 Septembre 2014; ECtHR, *Lambert c. France*, n°46043/14, 5 June 2015; ECtHR, *Karsai c. Hongrie*, n°32312/23, 13 June 2024.

¹³ The Swiss Federal Council does not wish for new legislation (NZZ, 29 November 2024).

¹⁴ ECtHR, *Karsai c. Hongrie*, n°32312/23, 13 June 2024, dissenting opinion judge Felici §§3.

¹⁵ The Last Resort, Fonctionnement, (09 January 2025): <https://www.thelastresort.ch/francais/sarco/operation/>.

¹⁶ Swissmedic, Qualifikation der Suizidkapsel «Sarco», 30 July 2024.

¹⁷ Sarco, FAQs (09 January 2025): <https://www.exitinternational.net/sarco/faqs/>.

3. A medical device?

3.1. Introduction

[11] On August 5, 2024, Swissmedic, the Swiss Authority for the approval of medicines and competent authority for the surveillance of medical devices, issued a public position on the qualification of the Sarco-assisted suicide capsule.¹⁸ According to Swissmedic, the capsule does not meet the definition of a therapeutic product. It is, therefore, *not subject* to the Swiss TPA requirements. Medical devices and medicines are included in the «therapeutic products» category.¹⁹ However, the authority clarified that this is an initial statement based solely on publicly available information. Swissmedic's position is succinct and lacks a detailed explanation.

[12] Art. 4 para. 1 let. b TPA defines medical devices as: «products, including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods or substances which are intended or claimed to have a medical use and whose principal effect is not obtained with a medicinal product.» If the Sarco capsule qualifies as a medical device, it must comply with a legal framework that ensures its safety, efficacy and quality.²⁰ The manufacturer (note that who it might be as it's a 3D printing product is not an easy question²¹) must ensure the capsule's performance.²² It must comply with the requirements of the TPA and its ordinances, the Medical Devices Ordinance (hereafter: MedDO²³) or the Ordinance on In Vitro Diagnostic Medical Devices (hereafter: IvDO²⁴) and specific European regulations:²⁵ Medical devices are therefore also subject to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (hereafter: MDR²⁶) with which Switzerland is aligned.

[13] This would require the device to undergo a conformity assessment procedure.²⁷ TPA ensures that only high-quality, safe, and effective therapeutic products are placed on the market (art. 1 para. 1 TPA and from art. 118 para. 2 Federal Constitution).²⁸ Unlike medicine, medical devices do not require marketing authorization from Swissmedic.²⁹ The pre-market system of medical devices is founded on the principle: «Any person placing a medical device on the market must be able to prove that the device satisfies the fundamental requirements.» (art. 45 TPA). Therefore, Swissmedic and the State would only intervene to ensure the product's monitoring and confor-

¹⁸ Swissmedic, Sarco suicide capsule does not fulfil definition of a therapeutic product, 5 August 2024 (09 January 2025): <https://www.swissmedic.ch/swissmedic/fr/home/news/mitteilungen/suizidkapsel-sarco.html>.

¹⁹ Message TPA 1999 3184.

²⁰ Art. 1 para. 1 TPA; Art. 118 para. 2 Cst.

²¹ Swissmedic, Information sheet 3D printers medical devices, 13 August 2024.

²² Art. 6 para. 2 MedDO, Annex 1 MDR.

²³ Medical Devices Ordinance of 1 July 2020, (MedDO; RS 812.213).

²⁴ Ordinance on In Vitro Diagnostic Medical Devices of 4 May 2022, (IvDO; RS 812.219).

²⁵ Art. 4 para. 1 let. f MedDO, art. 16 para. 1 MDR, art. 46 MedDO; Swissmedic, Aide-mémoire obligations opérateurs économiques, p. 7ss.

²⁶ Regulation (EU) 2017/745 of the European Parliament and of the council of 5 april 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR).

²⁷ Art. 45 para. 1 TPA.

²⁸ THOMAS EICHENBERGER, Basler Kommentar Heilmittelgesetz, 2e ed., Bâle 2022 (BSK-HMG), art. 2 N 1.

²⁹ Art. 76 para. 1 MedDO; Art. 5 para. 1 lit. a, art. 9 and art. 45 TPA.

mity after it is put on the market.³⁰ The cantons must monitor the retail trade if the manufacturer chooses a medical device model.³¹

[14] The criteria for qualifying a product as a medical device will now be revisited to illustrate the ambiguity and the room left for legal debate. To determine if a product meets the definition of a medical device, three criteria³² will be analyzed: a) « products, including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods »; b) intended use and indication of the product for «medical purposes», and c) the product's main action must not be obtained by a drug.

3.2. Medical devices are «instruments, apparatus, appliance, softwares, implants, reagents, materials and other articles»

[15] The legislator has neither defined the terms «instruments, apparatus, appliances, softwares, implants, reagents, materials or other articles», nor is the list exhaustive in art. 3 para. 1 MedDO.

[16] Accordingly, the Federal Court points out that «device» is a vague and extremely broad term encompassing many objects. For example, a plastic-coated paper disc with «energetic, frequency, and quantum» effects, marketed by the manufacturer (in the instruction for uses or advertising) with therapeutic indications, must be considered a medical device.³³

[17] Today, medical devices range from simple bandages to complex programmable pacemakers. They also include in vitro diagnostic (IVD) products such as pregnancy tests and blood glucose sensors. Certain electronic products emit radiation and are used for medical purposes, so they are also considered medical devices. Further examples include diagnostic ultrasound products, X-ray equipment and medical lasers. As a result, the Sarco capsule can easily be categorized as a device.

3.3. A device serving a specific medical purpose?

[18] According to the Swiss Federal Supreme Court case law, medical devices include products intended *for medical use and those presented as such, whether in the instructions for use or advertising*.³⁴ The intended medical use and the medical indication³⁵ are the fundamental characteristics of medical devices and are the decisive criteria for distinguishing a device from everyday objects.³⁶ In other words, the qualification of a medical device is, therefore, determined by its purpose, specifically, whether it is intended to serve a medical purpose for the benefit of an individual (art. 3 para. 1 let. c MedDO).³⁷ According to art. 2 para. 12 MDR, the intended purpose

³⁰ Art. 76 para. 1 MedDO; Art. 5 para. 1 lit. a, art. 9 and art. 45 TPA.

³¹ Art. 76 para. 3 MedDO.

³² Art. 3 para. 1 et 2 MedDO.

³³ Judgement of the Federal Supreme Court, 2C_391/2017, of 19 September 2017, consid. 5.2 and 5.6.

³⁴ Judgement of the Federal Supreme Court, 2C_391/2017, of 19 September 2017, consid. 5.2 and 5.6.; art. 3 para. 1 let. a MedDO; Judgement of the Federal Administrative Court, C-669/2016 of 17 September 2018, consid. 4.7.

³⁵ Message TPA 1999 3186; Judgement of the Federal Supreme Court, 2C_391/2017, of 19 September 2017, consid. 5.3; Judgement of the Federal Administrative Court, C-669/2016 of 17 September 2018, consid. 4.9.

³⁶ Message TPA 1999 3186.

³⁷ Message TPA 1999 3489.

«means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.» A product does not necessarily have to act directly on the body to be considered a medical device.³⁸

[19] Under art. 3 para. 1 let. c MedDO, medical devices «serve to fulfill one or more of the following specific medical purposes either alone or in combination:

1. *diagnosis, prevention, monitoring, prediction, prognosis, treatment or **alleviation of disease**,*
2. *diagnosis, monitoring, treatment, **alleviation of, or compensation for, injuries or disabilities**,*
3. *investigation, replacement or **modification of the anatomy or of a physiological or pathological process or state**,*
4. *providing information using in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations.»*

[20] In the case of the Sarco capsule, this is a controversial criterion. The question is whether assisted suicide can or should be recognized as a medical purpose.

[21] In their position of August 2024, Swissmedic explains that the primary objective of the TPA is to protect the health of humans and animals, which is why only high-quality, safe, and effective therapeutic products (medicinal products and medical devices) may be placed on the market (according to art. 1 para. 1 TPA). Safety and performance requirements for such medical devices are intended to ensure high health protection and not endanger patients' clinical condition and safety. A device that is used for suicide contradicts the medical purpose of a therapeutic product fundamentally.³⁹ In an internal Swissmedic document obtained under the Freedom of Information Act⁴⁰, the authority points out that therapeutic products aim to bring about recognition, healing, relief, improvement and support for health protection⁴¹. The authority deduces that the Sarco capsule has no medical purpose under therapeutic products legislation and cannot be classified as a medical device. This is consistent with art. 118 para. 2 Cst.

[22] However, the lines between «medical» and «non-medical» purposes are not always easy to draw; we know that from abortion or aesthetic interventions. Especially in the case of assisted suicide, the purpose might be more challenging to draw because recent case law on assisted suicide is more nuanced than declaring «assisted suicide» as non-medical, whereas (only) palliative care has (today) a medical purpose. So the question is whether the notion of «**treatment or alleviation of disease**» or «**the alleviation of injuries or disabilities**» could include eventually assisted dying, and, in concreto, assisted suicide, when its purpose is the relief from physical or mental suffering?

[23] In a leading case of March 2024, the Federal Supreme Court states that, from the point of view of medical ethics, assisted suicide should be reserved for patients suffering from terminal ill-

³⁸ Message TPA 1999 3186.

³⁹ Swissmedic, Sarco suicide capsule does not fulfil definition of a therapeutic product, 5 August 2024 (09 January 2025): <https://www.swissmedic.ch/swissmedic/fr/home/news/mitteilungen/suizidkapsel-sarco.html>.

⁴⁰ Federal Act on Freedom of Information in the Administration of 17 December 2004, (Freedom of Information Act, FoIA, RS 152.3).

⁴¹ Swissmedic, Qualifikation der Suizidkapsel «Sarco», 30 July 2024.

nesses or conditions that cause unbearable suffering.⁴² For the Swiss Academy of Medical Science (SAMS) and Foederatio Medicorum Helvetia (FMH), assisted suicide is not considered a medical activity.⁴³ The FMH distinguishes «assistance with suicide,» which is independent of a medical condition, from «aid in dying» in a passive sense, such as palliative care, which is recognized as an essential medical task.⁴⁴

[24] The mentioned ruling concerned the status of sodium pentobarbital, a psychotropic drug in the barbiturate family, which is commonly used in Switzerland for assisted suicide. Pentobarbital is regulated under the TPA and the Narcotics Act.⁴⁵ The Federal Supreme Court ruled *that the use of pentobarbital for assisted suicide in the case of a healthy person was not medically indicated, as it did not serve a therapeutic purpose*⁴⁶. According to the Court, it cannot be considered that, in the case of the suicide of a person in good health, the use of this substance can be assimilated to a medicinal product under art. 4 para. 1 let. a TPA, which covers products of chemical or biological origin used to diagnose, prevent or treat illnesses, injuries and handicaps⁴⁷.

[25] The question then arises: does the use of pentobarbital for lethal purposes constitute a therapeutic use? The ruling suggests that in the case of a healthy person, pentobarbital is not used to diagnose, prevent or treat an illness (Art. 4(1)(a) TPA) and thus does not have a medical indication.⁴⁸ *A contrario*, if a person is ill, can there be a therapeutic purpose for the use of a substance or device in the context of assisted suicide?

[26] Interestingly, the «Last Resort» organization explicitly states on its website that the Sarco capsule is intended for use by *individuals with certain pathologies, such as chronic, terminal, or age-related illnesses*. Furthermore, the organization clarifies that it does not assist young people unless they have a serious physical illness.⁴⁹ This could raise the question of whether a device like the Sarco capsule has a medical or therapeutic purpose when used by a seriously ill person.

[27] A further controversial criterion raised by VOEKINGER to the media, in the case of the Sarco capsule, is the *change in the physiological state* of the person using the capsule.⁵⁰ The suffocation process causes a physiological change in the body of the concerned person. However, at the end of the process, the person will be dead, so this process remains to be qualified in combination with the result. The «protection of human and animal health» as the primary objective of the TPA (see Art. 1 para. 1 TPA) indicates that the criterion «the change of the physiological state» is to be understood in the sense of an improvement or even a restoration of the health of the person concerned.

⁴² Judgement of the Federal Supreme Court, ATF 150 IV 255 consid. 3.3.2; in May 2022, the SAMS revised its guidelines, extending the scope of assisted suicide to patients whose illness or tangible functional limitations cause suffering deemed unbearable.

⁴³ SAMW, Medical-ethical guidelines, Management of dying and death, approved in May 2018 and amended in 2021, published in 2022; FMH, *Prise de position, L'assistance au suicide n'est pas l'aide au décès*, janvier 2008.

⁴⁴ FMH, *Prise de position, L'assistance au suicide n'est pas l'aide au décès*, janvier 2008.

⁴⁵ Federal Act on Narcotics and Psychotropic Substances of 3 October 1951 (Narcotics Arc, Narca, RS 812.121).

⁴⁶ Judgement of the Federal Supreme Court, ATF 150 IV 255, consid.3.4.

⁴⁷ Judgement of the Federal Supreme Court, ATF 150 IV 255 consid.3.4.

⁴⁸ Judgement of the Federal Supreme Court, 6B_646/2020 of 9 December 2023, consid. 1.5.2.

⁴⁹ The last resort, About us (09 January 2024): <https://www.thelastresort.ch/about-us/>.

⁵⁰ The last resort, About us (09 January 2025): <https://www.thelastresort.ch/about-us/>.

[28] Swissmedic has also taken an internal position on this point.⁵¹ The authority expresses its concerns and mentions that if a «killing device» were to be classified as a medical device and, accordingly, the criterion of a «change in physiological state» was no longer to be understood in an exclusively curative sense, a large number of other devices or objects that serve to kill reliably and safely would also have to be subsumed under the term «medical device,» which would significantly expand the range of medical devices regulated by therapeutic products legislation. However, control over the deliberate induction of death is not compatible with the objectives of the current therapeutic products legislation and, specifically, the Medical Devices Ordinance. Instead, it would contradict the principle of protection of human health.

3.4. Distinction from medicinal products

[29] Another criterion to determine whether a product qualifies as a medical device is identifying it as not being a medicinal product.⁵² The medical use of medical devices differs from that of medicinal products in that the effect of medical devices is not based on a pharmacological, immunological or metabolic interaction with the body or metabolism but instead occurs through mechanical, physical, or physicochemical means.⁵³

[30] It is important to note that the nitrogen gas used in the Sarco capsule is not classified as a medicinal product. Swissmedic explains: «The element of a medicinal product intended to have a particular pharmacological effect in a patient's body is classified as its active substance. By contrast, according to the function published by the provider, the nitrogen used in the suicide capsule serves only to change the composition of the air in the closed capsule: it displaces the oxygen, resulting in the suffocation of the person wishing to die.»

[31] However, the NZZ reported on October 30, 2024, that the manufacturer plans to include a drug in the capsule, which could alter its classification.⁵⁴

[32] Mixed products or product combinations that appear to combine medical devices and medicinal products will be classified as one or the other. In practice, however, the distinction is not always straightforward in the case of products that appear to combine medical devices and medicines and thus form a single unit. These are integral combination products (e.g., pre-filled syringes or inhalers)⁵⁵.

[33] In the case of product combinations, to determine whether the product is a drug, it is necessary to determine whether the mode of action is primarily or secondarily pharmacological,

⁵¹ Swissmedic, Traktandum Geschäftsleitungssitzung vom 24. Juli 2024, Rechtliche Einschätzung zur Qualifikation der Suizidkapsel «Sarco» obtained under the Freedom of Information Act.

⁵² Art. 2, para. 1, let. a TPA; Judgement of the Federal Administrative Court, C-1355/2008 of 19 April 2011, consid. 3.2; Message TPA 1999. 3186; MDCG 2022-5 rev. 1 – Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices – October 2024.

⁵³ Message TPA 2019 6; Judgement of the Federal Supreme Court, 2C_391/2017 of 19 September 2017, consid. 5.4; Judgement of the Federal Administrative Court, C-1355/2008 of 19 April 2011, consid. 3.2.3; Judgement of the Federal Administrative Court, C-2093/2006 of 12 December 2007, consid. 3.5, N 15.31.

⁵⁴ NZZ, 30 October 2024, p. 9.

⁵⁵ Swissmedic, La bonne combinaison est la clé, Visible 3/2021; Swissmedic, Nouvelles exigences applicables aux produits de combinaison, 26 mai 2021, (09 January 2025): <https://www.swissmedic.ch/swissmedic/fr/home/medicaments-a-usage-humain/autorisations/informations/revidierte-anforderungen-kombinationsprodukte.html>; MDCG 2022-5 rev. 1 – Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices – October 2024.

metabolic or immunological. If the medicinal action is an accessory, the product is a medical device (e.g., bone cement containing antibiotics)⁵⁶. Whereas if the substance's action is essential and not incidental to the devices (e.g., hormonal IUD), it is a drug⁵⁷. In case of uncertainty, Swissmedic has set up a group of experts to analyze specific cases and determine whether a specific product should be classified as a medicinal or medical device.

3.5. Differentiation from other products

[34] Legal qualification is also needed to differentiate medical devices from other products governed by different regulatory regimes. There are also borderline products. These issues are often highly technical and must be analyzed case-by-case by groups of experts.

[35] In practice, manufacturers must also determine whether their products fall within the definition of other product groups governed by Swiss law, such as chemical products⁵⁸. For instance, the Nitrogen used in the Sarco capsule could be regulated under the Federal Act on Protection against Dangerous Substances and Preparations (Chemicals Act).⁵⁹ In this case, an expert group would be tasked with determining whether the principal action of the product arises from the apparatus or from the chemical itself.

3.6. List of non-medical devices which are subject to MedDO

[36] It is worth noting, however, that the Federal Council may subject certain non-medical products to TPA⁶⁰. In such cases, they are deemed comparable to medical devices in terms of functionality or risk profile⁶¹. The list is included in Annex I MedDO, corresponding to Annex XVI MDR, which consists of a list of product groups not intended for medical use under art. 1 para. 2 MDR (e.g. non-corrective contact lenses, cosmetic implants, UV tanning booths etc.).⁶²

[37] These specific products pose a risk to human health comparable to the risk presented by medical devices. Accordingly, these products must fulfill the same general safety and performance requirements as medical devices.⁶³ As also mentioned by Swissmedic: «The devices that fall under Annex 1 MedDO can pose significant potential health risks to the persons concerned (customers or self-users) as well as professional users. Stricter regulations of manufacturing,

⁵⁶ Swissmedic, Produits combinés (09 January 2025): <https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/kombinationsprodukte.html>; Peter BÜRKL/MIRJAM OLAH/DIMITRI SIDLER, Smart Pills – Qualifikation nach Schweizer Heilmittelrecht, Life Science Recht, LSR 3/2023, pp. 102–115.

⁵⁷ Swissmedic, Produits combinés (09 January 2025): <https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/kombinationsprodukte.html>; Peter BÜRKL/MIRJAM OLAH/DIMITRI SIDLER, Smart Pills – Qualifikation nach Schweizer Heilmittelrecht, Life Science Recht, LSR 3/2023, pp. 102–115.

⁵⁸ Swissmedic, Questions fréquentes dispositifs médicaux, (09 January 2025): <https://www.swissmedic.ch/swissmedic/fr/home/dispositifs-medicaux/reglementation-des-dispositifs-medicaux/faq.html>.

⁵⁹ Federal Act on Protection against Dangerous Substances and Preparations of 12 December 2000, (Chemicals Act, Chema, RS 813.1).

⁶⁰ Swissmedic, Information sheet, Products without an intended medical purpose, 08 December 2023.

⁶¹ URSULA EGGENBERGER STÖCKLI/FELIX KESSELRING, Basler Kommentar Heilmittelgesetz, 2nd ed., Basel 2022 (BSK-HMG), art. 4 N 133; Message TPA 2019 20.

⁶² Message TPA 2019 20; recital 12 MDR.

⁶³ Swissmedic, Information sheet, Products without an intended medical purpose, 08 December 2023, p. 5; Annex I MedDO.

marketing, and use are required to guarantee the safety of those who use or apply these products. This is particularly important given that non-professional users may use some of these products at home. The new regulations are intended to ensure that manufacturing, quality, and surveillance of these products meet the same requirements as for devices with an intended medical purpose.».⁶⁴

[38] This product category could allow the Federal Council to define a legal regime applicable to the Sarco capsule. However, this addition has a political impact and would mean admitting that the Swiss list would be different from the one drawn up by the European Commission, which is the authority that established this list and which Switzerland has decided to align with its practice.

4. In line with the federal case law on assisted suicide

[39] Swissmedic's reasoning on the medical/non-medical purpose is consistent with the recent case law of the Federal Supreme Court of 2021⁶⁵ on the lack of criminal liability of prescribing pentobarbital under the TPA, which is, in our opinion, positive.

[40] However, we also have some fundamental doubts about whether this qualification and differentiation between «medical» and «non-medical» can be made that simply. Namely, if we include palliative care in the reflection, which does *not pursue healing* but pain relief. Palliative care has only recently become generally accepted. – Also, thanks to its clear distinction from assisted dying. But even today, in practice, it is still necessary for a patient to switch from the well-known treating oncologist to palliative care when no cure is possible, which shows that this is «another» domain of medicine – one too close to death.

[41] Then again, to decide this question medical / non-medical wasn't the primary goal of the Supreme Court; the primary goal was not to penalize a doctor with altruist motifs and a (correctly) strictly applied principle of «*nulla poena sine lege*» in a legal order, where soft law leads the procedure of assisted suicide, and remains for non-jurists, meaning for patients and medical professionals, not 100% clear.

Conclusion

[42] There are different possibilities to think of safety rules.

[43] If we agreed that the Sarco capsule is a medical device, according to Art. 48 para. 1 LPTh, the Federal Council may declare that specific medical devices require a medical prescription to protect health. This could be a solution to align the new practice with the traditional medical solution of sodium pentobarbital. This would be an additional safeguard to the medical device regime, providing a conformity procedure and a surveillance regime with the possibility of action by the authorities in case of product non-compliance. Still, we need to consider that 3D printing of the device would remain possible.

⁶⁴ Swissmedic, Information sheet, Products without an intended medical purpose, 08 December 2023, p. 6; Message TPA 2019 12.

⁶⁵ Judgement of the Federal Supreme Court, 6B 646/2020 of 9 December 2021.

[44] If we disagree that it is a medical device, a simple solution would be – as mentioned – to declare it as such, which is possible according to the TPA. A depilatory laser device, for example, is treated as a medical device, although it does not fulfill a medical purpose. Still, the general scope of the TPA to protect humans does not match unless we want the product to guarantee death without more pain or suffering than pentobarbital and not injury/disability (art. 3 TPA on due diligence).

[45] If the person who 3Dprints her/his Sarco capsule is injured, it becomes a liability question. Another solution would be to declare it a highly risky consumer good and regulate strict liability, which requires special legislation. This would be an exceptional course of action, unlikely to be followed in Switzerland. Still, there would be no substantive safeguards such as the proper information and the evaluation of the capacity of the judgment of the person concerned.

[46] A further solution would be legally regulating the entire assisted dying process on a federal level without excessively limiting individual autonomy (art. 36 Federal Constitution) and without necessary medicalizing assisted suicide, but with basic substantive and procedural safety rules to provide for information and functional tools and the capacity of judgment – meaning giving a free consent – of the concerned person.

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