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Challenges in Compliance for Medtech Companies

Navigating the Provisions of Free of Charge Products in the Swiss Medtech Code

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Abstract: In the context of the recently revised Swiss Medtech Code of Ethical Business Practice (SMC), the medical technology industry faces a multifaceted regulatory landscape, especially concerning the provision of free of charge products. This revision, aimed at enhancing ethical standards and aligning with European guidelines, significantly impacts interactions between medical technology companies and healthcare professionals and organizations. This article provides a thorough analysis of regulations governing free of charge products in the SMC such as demonstration items, samples, and evaluation products, and examines these regulations in the context of the legal framework, corresponding agreements between medtech companies and their customers as well as compliance programs.

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I. Introduction

In the rapidly advancing field of medical technology, the intersection of innovation, patient care, and ethical business practices presents a complex and dynamic landscape. The medical technology industry, vital to global healthcare systems, is not just about pioneering life-saving devices and diagnostics; it is equally about ensuring that these advancements reach practitioners and patients in a manner that upholds high ethical standards. This balance is critical in fostering trust, driving sustainable development, and ensuring equitable access to medical innovations.

In the healthcare industry, it is a widespread phenomenon that healthcare professionals ("HCPs") and organisations ("HCOs") receive medical devices free of charge from medtech companies for various purposes, e.g., to demonstrate functionalities, but also for training or evaluation purposes (collectively "free of charge products").[1] These products are not only economically significant but also present substantial legal and ethical[2] considerations. However, Swiss law does not explicitly address these considerations. Contrary to the situation regarding pharmaceutical products, there are no specific rules within the applicable laws governing pecuniary benefits in the area of medical devices, although the Federal Council's competence to regulate this area would include such rules.[3] Consequently, both medical device manufacturers and HCPs require adequate guidance to navigate this complex area.

To address this issue and more, the Swiss Medical Technology Association ("Swiss Medtech"), which

1 Cf. regarding «Gratismuster» (free samples), e.g., Vasella Juana, Das heilmittelrechtliche Vorteilsverbot, Korruptionsbekämpfung im Gesundheitswesen, Diss. Zürich 2016, pp. 60 et seq.

2 For ethical considerations in the area of pharmaceuticals, see, e.g., Brett Allan S./Burr Wayne/Moloo Jamaluddin, Are Gifts From Pharmaceutical Companies Ethically Problematic? A Survey of Physicians, Arch Intern Med. 16/2003, pp. 2213 et seqq.

3 Cf. Art. 55 para. 3 of the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21).

has over 750 members,[4] released the Swiss Medtech Code of Ethical Business Practice ("SMC")[5] on 12 June 2017. As per 25 May 2023, Swiss Medtech revised the SMC in light of MedTech Europe's 2022 revision of its "Code of Ethical Business Practice" ("Medtech Europe Code").[6] Meanwhile, the Advanced Medical Technology Association ("AdvaMed"), a leading medical device trade association based in the U.S., revised its "AdvaMed Code of Ethics" ("AdvaMed Code"), too, as per 1 June 2023.[7] The SMC, due to its nature as a private regulation, constitutes so-called self-regulation.[8] Although enforcement is limited as the SMC is no law, the members of Swiss Medtech (called "Member Company" or "Member Companies" in the SMC[9]) commit themselves to adhere to the SMC, and thus, the SMC has gained significance, especially for questions not explicitly regulated by laws, such as those on free of charge products.

We take the revision of the SMC as an opportunity to provide an overview of the regulation of free of charge products and outline the most important problems and potential solutions in the broader context of considerations for compliance programs. For this purpose, we first show the applicable regulatory framework in the area of medtech compliance (II.). Then, we dive into the rules of the SMC that govern free of charge products (III.). We also take a look at contractual measures medtech companies and HCPs/HCOs may take to further promote compliance (IV.). Subsequently, we contemplate the broader context and provide insight as to which considerations may be relevant for compliance programs (V.). Finally, we summarize key insights and provide further thoughts (VI.).

II. MedTech Compliance: Applicable Regulatory Framework in Switzerland

It is crucial to recognize that the SMC was not created in a vacuum; rather, its principles are deeply rooted in statutory law. Understanding this foundational statutory law is essential for a comprehensive grasp of the SMC, as it informs and shapes the code's directives and ethical guidelines. Having established the dynamic interplay between innovation, patient care, and ethical standards in the medtech industry in our introduction, we now shift our focus to providing an overview of the applicable legal landscape.[10]

A. Health Law

The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA, SR 812.21) contains integrity and transparency provisions in Art. 55 TPA. Further, the Swiss Federal Council enacted the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (TPITO, SR 812.214.31). However, the respective integrity provisions currently only apply to medicinal products.[11] As part of the revision of medical devices legislation, Swiss Parliament decided in March 2019 to extend the integrity provisions to benefits related to the prescription, dispensing and use of medical devices.[12] This requires a partial revision of the TPITO. A timetable is not yet available. This extension of Art. 55 TPA and the TPITO is not expected to enter into force before 2025.[13]

Thus, after this revision, Art. 55 TPA will also be applicable in the context of medical devices. According to Art. 55 para. 1 TPA, persons who prescribe, dispense, use or purchase prescription-only medicinal products for this purpose, and organisations that employ such persons, may not demand, be promised

4 See https://www.swiss-medtech.ch/mitgliederverzeichnis (last retrieved on 31 January 2024).

5 See https://www.swiss-medtech.ch/en/ethics-code-and-documentation (last retrieved on 30 January 2024); this article refers to the English version (PDF) as adopted on 25 May 2023. Please note that in case of legal differences, the German version of the SMC is legally binding and shall prevail (title page of the SMC).

6 In this article, we focus on the SMC and will only highlight the respective provisions of the Medtech Europe Code for informative purposes. We refer to the revised English version (PDF) of 25 March 2022, available here: https://www.medtecheurope.org/resource-library/medtech-europe-code-of-ethical-business-practice/ (last retrieved on 30 January 2024). See for further information on the Medtech Europe Code, e.g., Maderitsch Marcel, MedTech Europe Code of Ethical Business Practice, Ausstieg aus der direkten Kongressfinanzierung, LSR 2018, pp. 91–97.

7 See https://www.advamed.org/member-center/resource-library/advamed-code-of-ethics/ (last retrieved on 30 January 2024), references are made to the PDF version of 1 June 2023.

8 For self-regulation in health law, see, e.g., Jenni Christoph/Schüpbach Mike, Private Normen im Gesundheitsrecht, in: Uhlmann Felix (ed.), Private Normen und staatliches Recht, ZfR – Schriften des Zentrums für Rechtsetzungslehre, Zürich/St. Gallen 2015, pp. 83–105; Explanatory Notes of the Swiss Federal Office of Public Health on the TPITO and the amendment to the Ordinance on Health Insurance, April 2019 ("Explanatory Notes"), p. 8. For self-regulation in general, see, e.g., Brunner Ursula, Rechtsetzung durch Private, Private Organisationen als Verordnungsgeber, Diss. Zürich 1982; Forstmoser Peter/Vogt Hans-Ueli, Einführung in das Recht, 5th ed., Bern 2012, § 7 N 67 et seqq.

9 See glossary in part 3 of the SMC (p. 31).

10 We limit ourselves to Swiss laws. On the relationship between Swiss laws and EU regulation see, e.g., Isler Michael/Schweikhard Christine, The EU Medical Device Regulations and Switzerland, Transitional Regime for Swiss and Foreign Manufacturers of Medical Devices, LSR 2020, pp. 111–119.

11 Muresan Remus/Fuchs Philippe, Interaktionen zwischen Medizinprodukteherstellern, Ärzten und Spitälern, LSR 2020, pp. 127–153, p. 129. For details, see Kesselring Felix, Vorteile und Vergünstigungen im Heilmittel- und Versicherungsrecht, Kommentar zu Art. 55 und 56 HMG (Heilmittelrechtliche Integrität und Transparenz) und Art. 56 Abs. 3 lit. b und Abs. 3bis KVG (krankenversicherungsrechtliche Weitergabepflicht), Zürich/St. Gallen 2018, pp. 122 et seqq.

12 See AS 2020 2961. On this extension see Kesselring, pp. 379 et seqq. Such extension has been called for quite a while, see, e.g., Müller Tremonte Caroline, Ungleiche Korruptionsbekämpfung in der Arzneimittel- und Medizinproduktebranche, in: Jusletter 18. August 2014.

13 https://www.bag.admin.ch/bag/de/home/gesetze-und-bewilligungen/gesuche-bewilligungen/itw-geldwerte-anreize/integr-transp-obligation.html (last retrieved on 30 January 2024).

or accept any undue advantage for themselves or for the benefit of a third party. The concept of "undue advantage" corresponds in principle to that of criminal law on corruption. Advantages are all gratuitous benefits of a material or immaterial nature. A benefit is not due if the recipient is not entitled to the benefit or if it is not legally owed. It can be assumed that "contributions" and "benefits" within the meaning of Art. 55 para. 2 TPA may also include those in the form of material, in particular medical devices, after the revision.[14] Art. 55 TPA will therefore become relevant for medical device manufacturers as well. Thus, respective companies, but also their bodies and employees, should be aware of administrative measures and criminal sanctions under the TPA.[15]
Further, companies are obliged to specifically label devices intended solely for demonstration and presentation purposes; the information must be clearly visible and comprehensible (Art. 16 para. 6 of the Medical Devices Ordinance [MedDO], SR 812.213). In addition, health insurance law requires that the "service providers", i.e., HCPs or HCOs, pass on "benefits" that they receive to the debtor of the healthcare service, i.e., the patient or the insurance company.[16]

B. Laws Governing Professions

In relation to HCPs, laws governing professions are relevant. The Swiss Medical Professions Act ("MedBG", SR 811.11) and the Swiss Health Professions Act ("GesBG", SR 811.21) are authoritative. In the present context, Art. 40 MedBG is relevant as it regulates the professional duties of medical professionals working under their own professional responsibility. Among other things, HCPs must practice their profession carefully and conscientiously (Art. 40 lit. a MedBG), always safeguard the rights of patients (Art. 40 lit. c MedBG) and, when collaborating with members of other healthcare professions, exclusively safeguard the interests of patients and act independently of financial gain (Art. 40 lit. e MedBG). The professional duty to act independently of financial gain covers all benefits, including those granted by third parties such as medical device manufacturers.[17]

C. Criminal Law

Misconduct by a HCP in an interaction with a medical device manufacturer may fulfil the elements of an offence under the Swiss Criminal Code (SCC, SR 311.0). This includes corruption offences such as passive bribery of Swiss public officials (Art. 322^{quater} SCC) and private bribery (Art. 322^{novies} SCC), as well as forgery (Arts. 251 et seqq. SCC)[18], depending on the circumstances of the case at hand.

If offences are committed in the context of HCOs, the HCO's potential criminal liability may arise instead of or in addition to the HCP's criminal liability. This liability would have to be assessed in accordance with the rules on so-called "corporate criminal liability" (Art. 102 SCC) and – in light of the revision of Art. 55 TPA – according to specific criminal provisions in the TPA and the Swiss Federal Act on Administrative Criminal Law (SR 313.0).[19]
Certain interactions between HCPs/HCOs and medical device manufacturers may also result in criminal penalties against medical device manufacturers. A misconduct on the part of bodies or employees of medical device manufacturers may, for example, constitute corruption offences (Arts. 322ter, 322^{octies} SCC) or, in the future, criminal offences under the TPA.[20]
It follows from the offences of corruption that a medical professional who is an employee of a (public) hospital or a contractor may not be offered, promised or granted any undue advantage for an action that is discretionary; otherwise the person acting accordingly is guilty of active bribery. Criminal behaviour may also be attributed to medical device manufacturers.[21] In light of these risks of criminal liability, medical device manufacturers are advised to take special measures to ensure compliance.

D. Principles and Standards of Non-Governmental Institutions

As introduced in section I., the Swiss industry association Swiss Medtech has issued the "Swiss Medtech Code of Ethical Business Conduct" (SMC), which is oriented towards the "Medtech Europe Code of Ethical Business Practice" from the European industry association, of which Swiss Medtech is a member. The Swiss Medtech Code contains rules on interactions between medical device manufacturers and HCOs/HCPs in the first part, divided into ten chapters, and rules on interpretation and mediation in the second part.
As transparency is a fundamental principle of the SMC[22] and other self-regulation, this crucial issue deserves particular attention. Swiss Medtech published the SMC, certain Q&As[23], as well as transparency guidelines.[24] However, recommendations of the SMC's Commission to Swiss Medtech members are not published[25], also not anonymised. Thus, there is

14 Muresan/Fuchs, 130.
15 Cf. Muresan/Fuchs, 137.
16 See Art. 56 para. 3 lit. b of the Federal Health Insurance Act (SR 832.10). See also Explanatory Notes, p. 4.
17 Muresan/Fuchs, 132 et seq. with further references.
18 Muresan/Fuchs, 133 with further references.
19 Muresan/Fuchs, 136.
20 On the relationship between the administrative law provisions of the TPA and the criminal laws on corruption, see, e.g., Explanatory Notes, p. 6 with further references.
21 Similarly, as HCOs may be found liable; currently under Art. 102 Swiss Criminal Code, in the future probably under the TPA or the Swiss Federal Act on Administrative Criminal Law. See also, e.g., Explanatory Notes, p. 7 with further references.
22 See Introduction, Aims and Principles of the SMC, p. 6.
23 Chapter 13, para. 3 SMC (p. 27).
24 See above footnote 5.
25 Cf. chapter 13, para. 2 SMC (p. 27).

potential for improving transparency in order to further strengthen transparency as an industry standard, help other Swiss Medtech members to improve their compliance more easily and enhance the industry's trustworthiness in the public.
Further, relating to HCPs, the ethics code of the FMH[26] – the Association of Swiss Physicians – is of particular importance, as it contains rules on compensation for scientific studies, the acceptance of gifts or training events and sponsorship. The FMH code of ethics also refers to several guidelines of the Swiss Academy of Medical Sciences, including the guideline "Cooperation between the medical profession and industry"[27], which also regulates the acceptance of donations, among other things.[28]

E. Internal Guidelines

Building upon the SMC's role as a pivotal self-regulatory framework, the integration of internal guidelines further empowers medtech companies to effectively navigate the complexities of anti-bribery laws. Internal guidelines, aligned with the SMC, can act as a contractual agreement on explicitly agreed benefits, as outlined in Art. 322^{decies} para. 1 lit. a of the SCC.
Art. 322^{decies} para. 1 lit. a SCC stipulates that benefits contractually agreed upon by the principal are not undue. Internal guidelines could constitute such an agreement between the agent (employee) and the principal (employer) and could delineate certain permissible benefits, like minor gifts, preventing them from being deemed undue.[29] It is crucial for management to provide clear directives on both accepting and offering gifts. Frequently, there is a regulation on a monetary threshold up to a certain amount (e. g., CHF 100) and a threshold in the event of recurrence (e. g., a maximum of five times per year up to CHF 100 to the same person). Gifts of a higher value should be submitted to superiors for approval. Seeking the compliance department's guidance in ambiguous situations is advised.

The alignment of SMC regulation and internal guidelines not only underscores a commitment to ethical practices but also provides a tangible defense mechanism against potential criminal proceedings related to bribery. By embedding the SMC's provisions into their internal guidelines, companies ensure a dual layer of compliance – adhering to both the specific industry standards and the broader legal requirements, thus minimizing the risk of legal infractions and reinforcing ethical integrity within their operations.

III. Regulation of Free of Charge Products in the Swiss Medtech Code

A. Types of Free of Charge Products

In principle, gifts of medical device manufacturers to HCPs/HCOs are prohibited. Yet, this principle does not apply to the "legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples"[30]. Thus, for the purposes of the present article, we consider three types of free of charge products: demonstration products ("demos"), evaluation products, and samples.[31]
Demos are "either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use".[32] Samples are "single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use."[33] Evaluation products are "either single-use or multiple-use products and/or equipment provided free of charge to a HCO by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a de-

26 Available in German, French and Italian at https://www.fmh.ch/ueber-die-fmh/statuten-reglemente.cfm# (last retrieved on 30 January 2024). For further details, cf., e. g., Vasella, p. 542 with further references.
27 Available in German, French and English at https://www.samw.ch/en/Publications/Medical-ethical-Guidelines.html (last retrieved on 30 January 2024). For further details, cf., e. g., Vasella, pp. 539 et seqq. with further references.
28 This guideline on collaboration between medical professionals and industry, issued by the Swiss Academy of Medical Sciences (SAMS), contains a section 6.3 on "Medical device samples" which reads as follows: "Companies may make available, free of charge, an appropriate number of medical device samples to medical professionals or medical institutions, so that they can familiarise themselves with and gain experience with safe and effective use of the device or medical service in clinical practice. Medical institutions must clearly document their use of medical device samples and undertake not to charge the patient/health insurer for them."
29 Pieth Mark, Anti-Korruptions-Compliance, Praxisleitfaden für Unternehmen, Zürich/St. Gallen 2011, 81.
30 Chapter 8, last paragraph SMC (p. 24). For the advantages of providing free of charge products in general, see section XII of the AdvaMed Code (p. 33).
31 The SMC also contains rules on "Educational Items and Promotional Items" (chapter 8 SMC, p. 24) which may be provided to HCPs/HCOs free of charge (see also chapter 8 of the Medtech Europe Code and section VIII of the AdvaMed Code). However, due to the fact that demos, samples and evaluation products are in particular likely to be economically relevant, we limit our comments to these three types. Further, free of charge products as referred to in this article do not include (1) products provided at no charge as part of a charitable donation or as part of a research or educational grant, or (2) products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e. g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement (cf. glossary in part 3 of the SMC, p. 29, 30, 32).
32 Glossary in part 3 of the SMC (p. 29).
33 Glossary in part 3 of the SMC (p. 32).

fined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs."[34]

B. Rules for Providing Free of Charge Products

1. Demos and Samples

According to the SMC, the purpose of demos and samples is "to enable HCPs and/or HCOs […] to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality" of certain medical devices and/or related services and "to determine whether, or when, to use, order, purchase, prescribe or recommend" such devices and/or services in the future.[35]

As a rule, a medtech company may only provide its own products as demos and samples. Exceptionally, products from another company may be provided in conjunction with the demos and samples if the products of the other company "are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company".[36] In such cases, the medical device manufacturer is well advised to carefully clarify which products it has to make available to the HCP/HCO in addition to its own product and whether it is authorised to do so. If necessary, it should be clarified with the third-party company whether the corresponding software may be used free of charge by the HCP or HCO for demonstration purposes.

Provision of demos and/or samples "must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure member companies' products or services".[37] The question of whether a HCP/HCO has independently "determine[d]"[38] that it wishes to purchase or lease a demo product in the future, or whether it has been "encourage[d]"[39] to do so in an improper manner, is not easy to answer and requires an analysis in each individual case. Although Art. 55 TPA is not (yet) directly applicable to this question, the practice of Art. 55 TPA is useful to interpret such provisions.

Companies must record the provision of demos and/or samples, e.g., proof of delivery for any demos and/or samples provided and receipt of return for multiple-use demos and/or samples. They also have to record and disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demos and/or samples in writing no later than the time of the supply.[40] Such conditions should be stipulated in an agreement between a medtech company and respective HCPs and/or HCOs.[41] It is noteworthy that the AdvaMed Code provides for specific guidance according to which companies should consider to put in place certain controls not only for products for charge, but also for free of charge products. This means, e.g., "written policies, procedures and work instructions that govern when assets can be supplied to a HCP, including related auditing and monitoring; specialized training and education for Company representatives; and clear documentation, recordkeeping, and asset tracking requirements, including any obligations to compensate or return Medical Technology to the Company, as appropriate."[42] Such internal guidelines, processes, training, controls and the subsequent implementation of improvements are key to avoiding improper rewards or inducements and ensuring compliance.[43]

Further, it is important to note that demos shall (only) be used to increase awareness of HCPs and patients, for educational and training purposes. A HCP may use a demo "to show a patient the type of technology which will be implanted in the patient or may use the demo to train other HCPs in the use of the product".[44] Demos may not be used "for clinical use in any patient care" or on-sale or other transfer.[45] Thus, the potential use of demos is limited by the aforementioned purposes. In order to be able to comply with these regulations and thus also with the legal requirements, such as professional law (section II. B. above) and criminal law (section II. C. above), medical device manufacturers and their employees as well as HCOs and HCPs should be (made) aware of these limited uses of demos.

The SMC stipulates specific rules on the quantity of free of charge samples. A reasonable amount of samples may be provided to "allow HCPs and/or HCOs to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future".[46] The quantity of single-use samples "provided for purposes of familiarisation must not exceed the amount reasonably necessary for the HCPs/HCO to acquire adequate experience in deal-

34 Glossary in part 3 of the SMC (p. 30).
35 Chapter 9, clause 1, para. 1 of the SMC (p. 25). See also chapter 9, clause 1 of the Medtech Europe Code (p. 57).
36 Chapter 9, clause 1, para. 2 of the SMC (p. 25).
37 Chapter 9, clause 1, para. 3 of the SMC (p. 25).
38 Chapter 9, clause 1, para. 1 of the SMC (p. 25).
39 Chapter 9, clause 1, para. 3 of the SMC (p. 25).
40 Ibid.
41 For a closer look at such agreements, see IV.
42 Section XII of the AdvaMed Code (p. 34).
43 For a closer look at compliance programs, see V.
44 Chapter 9, clause 2, para. 1 SMC (p. 25). Similarly, see chapter 9, clause 2 of the Medtech Europe Code (p. 58) and section XII of the AdvaMed Code (p. 34).
45 Chapter 9, clause 2, para. 2 SMC (p. 25). See also section XII of the AdvaMed Code (p. 34); according to AdvaMed, this is typically labelled through designations like "Sample" or "Not for Human Use" on the product, the packaging, or accompanying documentation (ibid.).
46 Chapter 9, clause 3, para. 1 SMC (p. 25 et seq.). See also chapter 9, clause 3 of the Medtech Europe Code (p. 58).

ing with the products".[47] The specific length of time necessary for a HCP to familiarise himself or herself with a multiple-use sample depends "on the frequency of anticipated use, the duration of required training, the number of HCPs who will need to acquire experience in dealing with the product and similar considerations".[48] Member companies have to ensure they retain title to multiple-use samples and remove such samples "from the HCP's location at the conclusion of the familiarisation period".[49] Based on the above, it is probably more difficult to handle samples than demos in compliance with the SMC and potentially relevant laws. While the rules for demos appear to be relatively clear and restrictive, the wording of the rules for samples leaves a lot of room for interpretation, which is not minimised by any references in the Q&A. For example, it is difficult to determine what a "reasonable amount" is or how long HCPs need to familiarise themselves with a product. The answers to such questions are heavily dependent on the circumstances of the individual case. This opens up compliance risks that should be countered with appropriate monitoring.

2. Evaluation Products

The purpose of evaluation products is to help assess medical devices, therapies and/or related services once such product or service has been introduced into the market.[50] For example, third-party funders may provide research with equipment, facilities or laboratory tools on loan for free, without expecting anything in return. This funding practice is particularly widespread in university medicine.[51] This can support research, improve patient care and facilitate hospital operations. The devices are regularly also used in everyday clinical practice and often remain in the hospital even after the research project has been completed. This may be a contractual ancillary service provided by the manufacturer in order to be able to use, maintain or test its main product. Often, the manufacturer also has a motivation of an economic nature. If, for example, manufacturers of pacemakers provide some university hospitals with treadmills free of charge in order to carry out stress electrocardiograms (ECGs), the aim is to familiarize the institution with the product's capabilities. This exposure may enhance the likelihood of the hospital purchasing pacemakers from the medtech company after identifying a need through diagnosis.[52]

The prerequisite for providing evaluation products is a "legitimate business need".[53] The SMC defines such need as "a current and actual business objective pursued by a Member Company such as the advancement of medical education, Clinical Research and/or the safe and effective use of the Member Company's Medical Technology".[54] This leaves room for interpretation. According to AdvaMed, examples of appropriate reasons for providing single-use or multiple-use evaluation products to a HCP include that the HCP may have not recently purchased or used the products, i.e., the HCP is not familiar with the product, or the product is marketed for a new indication or new surgical technique.[55] The AdvaMed Code also contains further insights on when a "legitimate need" is present in the context of consulting services provided by a HCP. In this context, a legitimate need arises when a HCP is tasked to achieve a "specific objective", such as training on technical components to safely and effectively use a product, or when there is a need for clinical expertise in conducting product research and development, or when there is a need for a physician's expert judgment on clinical issues associated with a product. However, such arrangements are not considered to represent legitimate needs if their purpose is to generate business or to reward referrals from the contracted HCP.[56] In our view, the aforementioned considerations as they are presented in the AdvaMed Code provide useful guideline on how to substantiate a legitimate business need. Documenting the rationale behind determining a "legitimate business need" is not only advisable but essential, as it lays the groundwork for robust compliance controls and ensures alignment with ethical standards outlined in the SMC.

Furthermore, several formal requirements have to be fulfilled in order to properly provide evaluation products. There needs to be a written contract in which it is stipulated that the provision is "on a no charge basis in return for the requested user feedback from HCPs at the HCO, which must be formally described in a written protocol or questionnaire forming part of the contract".[57] This contract should also contain the evaluation period. The duration of the period of time necessary for evaluation in case of multiple-use products depends on the anticipated frequency of use, the nature of evaluation feedback requested, the duration of any required training and similar, reasonable considerations.[58]

In addition to the foregoing, Member Companies must ensure that they retain title to multiple-use evaluation products and that they have a process in place for promptly removing multiple-use evaluation products and/or any unused single-use evaluation products

47 Chapter 9, clause 3, para. 2 SMC (p. 26).
48 Chapter 9, clause 3, para. 3 SMC (p. 26).
49 Ibid.
50 Chapter 6, clause 3, para. 1 SMC (p. 22). See also chapter 6, clause 2 of the Medtech Europe Code (p. 48).
51 Cf. Vasella, p. 60, with further references.
52 Cf. Vasella, p. 60, including ibid., footnote 362.
53 Chapter 6, clause 3, para. 1 SMC (p. 22).
54 Glossary in part 3 of the SMC (p. 31).
55 Section XII of the AdvaMed Code (p. 33).
56 Cf. section II of the AdvaMed Code (p. 9).
57 Chapter 6, clause 3, para. 1 SMC (p. 22). For a closer look at such contracts, see IV.
58 Chapter 6, clause 3, para. 2 SMC (p. 22). See also section XII of the AdvaMed Code (p. 34).

from the HCO's location at the conclusion of the evaluation period, unless these are purchased or leased by the HCO.[59] While the SMC, similar to other codes, remains silent on the specific conditions or circumstances under which such subsequent purchases or leases are allowed, it is understood that the general principles of the SMC still govern these transactions. Any purchase or lease agreement by the HCO should be conducted under standard market conditions and must be structured accordingly to avoid creating any undue incentives. This ensures that such agreements align with the overarching ethical framework of the SMC, promoting integrity and fairness in dealings between Member Companies and HCOs.

Finally, as with the provision of demos and samples, provision of evaluation products and/or related services "must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or related services".[60] However, delineating a clear boundary can be challenging, particularly when it comes to the options available to HCOs for purchasing or leasing evaluation products at the end of an evaluation period. Such transaction risks being perceived as incentives, subtly influencing the HCO's decisions to, for instance, purchase or lease evaluation products. To mitigate this, it is crucial to have explicit internal guidelines on post-evaluation acquisitions, ensuring a strict separation between evaluation and procurement processes to avoid perceived undue incentives.

IV. Agreements Between Medtech Companies and HCPs/HCOs

It is imperative for companies and HCPs/HCOs to formally outline the terms governing the transfer of free of charge products through a mutually agreed-upon contract.[61] In case of free of charge products, such an agreement may be considered a gift contract under Swiss law pursuant to Arts. 239 et seqq. Swiss Code of Obligations, for example in the case of single-use samples, or a loan for use pursuant to Arts. 305 et seqq. Swiss Code of Obligations, for example in the case of multiple-use evaluation products. The specifics of the contract should be tailored to the unique context of each case, with a strong emphasis on ensuring compliance. For companies, incorporating provisions related to compliance and anti-corruption within these agreements is an important measure to reinforce ethical practices and mitigate risks. A provision covering several points could read, e.g.: "The parties undertake to comply with all applicable legal provisions within the scope of this contract (e.g. Therapeutic Products Act, Health Care Insurance Act, Data Protection Act). The contractual partner confirms compliance with Art. 56 of the Health Care Insurance Act on the full or partial passing on of direct and indirect benefits and that the agreed delivery conditions have no influence on the choice of treatment of its patients."[62] If the free of charge products can be used multiple times (multiple-use products), the time necessary for, e.g., evaluation and return should be stipulated.[63] This period of time should be "reasonable under the circumstances to allow an adequate evaluation and consistent with any applicable transparency reporting requirements".[64] In this context, it is crucial to monitor the respective return of evaluation products after the evaluation period.[65]

V. Considerations for Compliance Programs Taking into Account Free of Charge Products

Understanding the rules is just the first step; the crucial challenge lies in effectively integrating these principles into everyday business practices. Here, we aim to equip companies with actionable strategies to ensure that the compliance programs not only align with the SMC's standards but are also effective.[66]

In order to ensure compliance, taking into account particularities regarding free of charge products, the following measures are advisable:

– *Put in place comprehensible and harmonised compliance regulations:* An initial core element should be a Code of Business Conduct and Ethics.[67] This code should be binding for all employees.[68] In case of a group of companies, global guidelines that apply to all group companies should be added. Further, Standard Operating Procedures (SOPs) may serve to regulate individual processes and are valid within a specific area. They should contain instructions in plain English regarding collabo-

59 Chapter 6, clause 3, para. 2 SMC (p. 22). See also section XII of the AdvaMed Code (p. 34).
60 Chapter 6, clause 3, para. 3 SMC (p. 22).
61 For such contracts in general, see, e.g., Gattiker Monika, Arzt und Medizinprodukte, in: Kuhn, Moritz W./Poledna, Tomas (Hrsg.), Arztrecht in der Praxis, 2nd ed., Zürich 2007, pp. 495 et seqq., pp. 530 et seqq.
62 See above on the passing on of benefits in section II.A.
63 If no reservation of title is made and no loan period is agreed on, statutory laws may apply, e.g. Arts. 309 et seq. Swiss Code of Obligations.
64 Section XII of the AdvaMed Code (p. 33).
65 Cf. section XII of the AdvaMed Code (p. 34).
66 For compliance and compliance management in general, see, e.g., Wieland Josef/Steinmeyer Roland/Grüninger Stephan (eds.), Handbuch Compliance-Management, Konzeptionelle Grundlagen, praktische Erfolgsfaktoren, globale Herausforderungen, 3rd ed., Berlin 2020; Lengauer Daniel, Compliance, Zürich 2019; Lengauer Daniel/Ruckstuhl Lea, Compliance, Recht für die Praxis, Zürich 2017.
67 Cf., e.g., Pieth, 63.
68 Furthermore, this can also make it easier for companies to provide evidence in criminal proceedings, see Graf Damian K., Compliance und Strafrecht, Anwaltsrevue 2022, pp. 151–154, pp. 153 et seq.

ration with HCPs/HCOs and, conversely, with medtech companies. In any case, benefits with a value of CHF 300.– or more per person should be documented for monitoring purposes, i. e., to check whether such advantage is undue.[69] Accordingly, receipt of any free of charge product constituting such a benefit should be documented. Also, such SOPs should prohibit the resale of free of charge products as such behaviour would contradict the purposes of free of charge products.[70] Finally, work instructions govern individual steps and responsibilities of everyone involved in a certain process.

- *Training:* It is not enough to simply issue compliance regulations – training is also required to ensure that these are put into practice. Employee training should consist of several parts, depending on the specific circumstances. In general, when an employee joins the company, it is advisable to carry out general training (online or web-based). Subsequently, training on the Code of Conduct is advisable. Such training should be repeated, e. g., every six months or annually for refresher purposes. The need for further training on specific guidelines and directives depends on different factors (e. g., the size of the company/group, regional differences, differences in the activities or functions of employees). Especially with regard to free of charge products, zero tolerance regarding the granting of undue advantages must be continuously communicated and implemented at all levels and to third parties. The aforementioned SOPs may be a useful tool for training.[71]
- *Creation of proper records:* The creation of verifiable records is the prerequisite for effective monitoring as it enables the handling of free of charge products to be retraced. Such records should be kept for at least ten years.[72]
- *Monitoring, reporting and implementation of improvements:* Compliance processes and records need to be monitored in order to detect problematic incidents. In case such incidents are discovered, they should be reported and measures determined in order to prevent further incidents from happening and, if necessary, sanction such behaviour.
- *Organisational measures:* In order to carry out training and monitoring, at least one person should be designated who is responsible for training and monitoring the implementation of compliance regulations. This person should have sufficient time and resources within the scope of their work to actually fulfil this demanding task. In larger organizations, it may be necessary to set up cross-divisional teams consisting of members from quality assurance, regulatory affairs and lawyers to ensure well-founded risk assessment and effective implementation of the compliance strategy.[73]
- *Speak-up culture:* Training and monitoring are powerful tools, yet we believe they should be accompanied by a lived speak-up culture. This means that a corporate culture should be fostered which encourages employees to speak up if they come across violations of compliance regulations, or are unsure about the integrity of certain incidents. Such a culture may be introduced and/or cared for through speak-up campaigns.

Finally, it should also be pointed out that any compliance program creates costs. In light of potentially tight budgets, medtech companies, HCOs and HCPs may be faced with the challenge of investing enough resources in compliance. However, even with simple measures, if implemented effectively, much may be achieved after all. When weighing up costs and compliance, it should also be noted that although non-compliance with the SMC can only lead to recommendations and Swiss Medtech cannot issue any sanctions[74], laws (in particular laws governing professions and criminal law, see above sections II. B. and II. C.) could potentially be violated. Further, reputational risks should not be underestimated: If cases of corruption become public, reputation of involved actors potentially suffers immensely and damage could be severe.

VI. Conclusion

Navigating compliance, especially regarding free of charge products, demands addressing several critical issues. A deep understanding of the regulatory landscape is essential. The SMC's nuanced approach to different types of free of charge products – such as demos, samples, and evaluation products – underscores the need for specific company guidelines. Drafting agreements for these products requires meticulous attention to ensure compliance, which should form a component of a comprehensive com-

69 For pharmaceuticals, see Art. 3 para. 1 TPITO and, e. g., Explanatory Notes, p. 13, which refers to jurisprudence on Art. 172ter of the Swiss Criminal Code, see, e. g., in Weissenberger Philippe, in: Niggli Marcel Alexander/Wiprächtiger Hans (eds.), Basler Kommentar Strafrecht, Strafgesetzbuch, Jugendstrafgesetz, 4th ed., Basel 2019, Art. 172ter N 29 with further references.

70 This is applicable law in the area of medicinal products, see Art. 9 TPITO and Explanatory Notes, pp. 19 et seq.

71 General resources may be found online. Cf., e. g., for the Medtech Europe Code, https://www.ethicalmedtech.eu/resources/available-material/ (last retrieved on 30 January 2024), a website created by MedTech Europe.

72 Cf., for the area of pharmaceuticals, Art. 11 lit. b TPITO and Explanatory Notes, p. 20.

73 Cf. Halbach Ralf P., Innovation im MedTech-Bereich im Zeitalter der "Medical Device Regulation", LSR 2023, pp. 179–181, 181; regarding risk assessment see also, e. g., Pieth, pp. 65 et seqq.; regarding compliance organization, ibid., pp. 69 et seqq.

74 Cf. part 2 of the SMC on "Interpretation and Mediation Procedures" (pp. 27 et seq.).

pliance program, designed and executed with precision to uphold ethical standards and legal obligations.

Our exploration of the SMC reveals numerous unanswered questions, particularly concerning free of charge products. This article has offered insights and strategies for addressing these uncertainties. For instance, determining the appropriateness of purchasing or leasing multi-use evaluation products post-evaluation to avoid undue incentives poses a challenge. In this regard, ensuring transactions for such products adhere to standard market conditions, with proper documentation, can mitigate perceptions of undue influence. Furthermore, while no ruleset can address every specific issue exhaustively, publishing the SMC Commission's recommendations and seeking legal guidance could enhance compliance.

In summary, navigating the provisions of the SMC, especially regarding free of charge products like demos, samples, and evaluation products, reveals a complex interplay of ethical considerations and practical applications. The SMC emphasizes the importance of maintaining ethical integrity while facilitating medical advancements through these products. A critical challenge lies in ensuring these products serve their educational and evaluative purposes without influencing HCPs and HCOs' decisions. Further, the rapid evolution of the medical technology field necessitates that regulatory and ethical frameworks evolve correspondingly. Ongoing dialogue among stakeholders, including medtech companies, HCPs, HCOs, legal professionals and regulatory bodies, is essential to adapt these frameworks to emerging technologies and healthcare developments.