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Federal Food Safety and Veterinary Office (FSVO)

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swissmedic

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Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products

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I. Introductory remarks

The increase in recent years in the number of foodstuffs being placed on the market that are advertised as having a positive effect on health by virtue of their ingredients or constituents is having the particular effect of constantly confronting both the Swiss and European authorities and courts with the issue of distinguishing foodstuffs from therapeutic products (medicinal products and medical devices). This is the case even though explicit regulations for such products exist in both Switzerland and Europe. At European level, the fact that each Member State continues to categorise products that are distributed and dispensed within its territory independently of the others means that the same product may be regarded as a foodstuff in one Member State, but as a therapeutic product in another, despite the existence of harmonised definitions. This is an area where Swiss legislation has been largely aligned with European legislation.

The issue of distinction is not just a theoretical one. For example, the requirements governing quality, manufacturing, processing, advertising, promotion, distribution, dispensing and monitoring of a product are regulated differently in foodstuffs legislation and therapeutic products legislation. The authorities responsible for enforcement are also different, as are the measures and possible sanction available to them. Finally, the authorisation procedures for medicinal products can be costly for manufacturers – unlike the procedures for foodstuffs and medical devices – and have considerable financial implications for them. Furthermore, the compliant placing on the market of medical devices is subject to specific requirements (see comments in section II no. 1 point 1.2 let. a). For these reasons, the issue of whether a product is categorised as a therapeutic product or foodstuff is of considerable significance to its manufacturer or distributor.

A product that falls in the grey area between foodstuffs and therapeutic products legislation is always subject to one of the two. However, this does not mean that the product in question can also actually be marketed as a medicinal product, medical device or foodstuff. In fact, it is entirely possible that a product that can be classified as a foodstuff and is therefore subject to foodstuffs legislation cannot be marketed as such because it does not satisfy the requirements of the relevant acts or ordinances for placing on the market.
Conversely, a product may fail to satisfy the requirements for medicinal products (e.g. proof of efficacy) or medical devices (e.g. successful completion of a conformity assessment procedure). Such products could not therefore be placed on the market as medicinal products because they had not been authorised or as medical devices because they do not conform.

This report deals only with orally administered products. It does not cover injectables, implants, ointments or in vitro diagnostics.

It should be noted that the only products exempt from chemicals legislation are finished ones (Art. 1 para. 5 let. c of the Chemicals Ordinance (ChemO; SR 813.11)). Raw materials in particular are therefore subject to the provisions of chemicals legislation. This does not exclude the likelihood of foodstuffs and therapeutic products legislation generally also imposing requirements that raw materials have to fulfil for use in foodstuffs and therapeutic products. It should also be noted that finished products are also subject to provisions intended to restrict the use of certain substances in the European Union (EU). These provisions are set out in the REACH Regulation (EC) No 1907/2006[1] and CLP Regulation (EC) No 1272/2008[2]. Switzerland has adopted provisions to equivalent effect either in the Chemical Risk Reduction Ordinance (ORRChem; SR 814.81) or in the relevant special legislation.

A working group made up of representatives of the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Food Safety and Veterinary Office (FSVO), investigated the issues involved in distinguishing therapeutic products from foodstuffs with reference to the existing legislation for each. This report summarises its findings.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353 of 31.12.2008, p. 1

The report provides an overview of the relevant legal framework in Switzerland and Europe and summarises Swiss and European case law on this issue. It concludes by presenting what the working group regards as the key distinction criteria. These are intended to provide the shared foundation for cooperation between Swissmedic and the FSVO in determining which legislation is to be applied in specific cases[3].

[3] See Art. 7 ff of the Federal Act on Administrative Procedure (APA; SR 172.021) for details of responsibilities in connection with administrative proceedings.

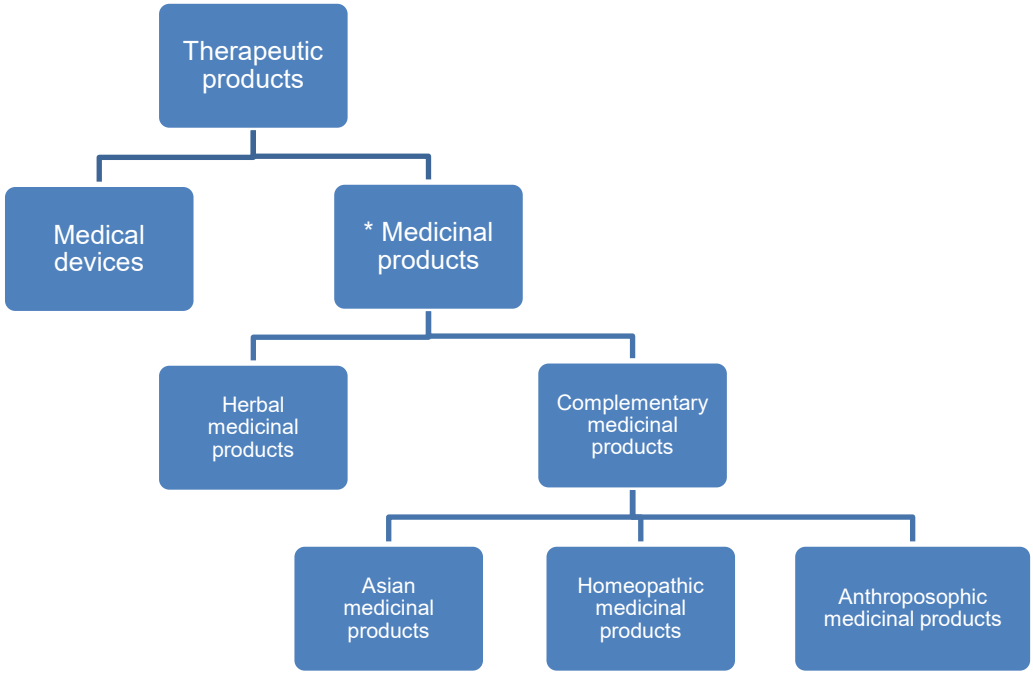
II. Current situation in Switzerland

1. Legal framework and explanations

1.1. Products

a) Therapeutic products

The term “therapeutic products” is applied to both medicinal products and medical devices.



* This is not an exhaustive list of medicinal products. Herbal and complementary medicinal products are specifically included because they are mentioned below.

a.1 Medicinal products

Art. 4 para. 1 let. a of the Therapeutic Products Act (TPA, SR 812.21) defines medicinal products as *“products of chemical or biological origin which are intended to or claimed to have a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products”*.

Detailed definitions of particular medicinal product groups can be found in Art. 4 para. 1 let. a^{bis} ff. TPA or in Art. 4 of the Complementary and Phytotherapeutic Products Ordinance (CPTPO; SR 812.212.24). In terms of distinction criteria, the definitions that apply to medicinal product groups that are consistently the cause of debate for the purposes of distinction are relevant here.

This applies notably to complementary and herbal medicinal products. Complementary medicinal products are medicinal products that are manufactured according to the manufacturing regulations for complementary medicinal therapies such as homeopathy, anthroposophic medicine or traditional Asian medicine and whose field of application is determined according to the principles of the corresponding therapy approach (Art. 4 para. 1 let. a^{ter} TPA). In all cases in which special manufacturing processes or regulations are used in the therapy approach in question (Art. 4 para. 1 let. a^{ter} TPA and Art. 4 para. 3 let. a ff. CPTPO), products containing corresponding ingredients are automatically categorised as medicinal products by virtue of the way they are manufactured.

Many cases in which complementary medicine is used involve individual therapy, i.e. a particular patient receives treatment in the form of a complementary medicinal product on the basis of a comprehensive medical history in accordance with a specific principle (Art. 4 para. 1 let. a CPTPO). This individual therapy is based on the assumption that medicinal products with no specific field of application or indication (complementary medicines without indications as defined in Art. 4 para. 1 let. a^{quater} TPA) will be available in the relevant medicinal product groups. However, their intended use still qualifies such products as medicinal products.

Herbal medicinal products are medicinal products exclusively containing as active substances one or more herbal substances or one or more herbal preparations and which are not classified as complementary medicines (Art. 4 para. 1 let. a^{quinquies} TPA). Herbal medicinal products always have a medicinal indication. The following are not considered to be herbal medicinal products: medicinal products with pure substances isolated from plants as their active substance (for example atropine or digoxin); medicinal products with synthetic or partially synthetic active substances, even if these are synthesised from plant-based raw materials (for example codeine, troxerutin or menthol) or medicinal products additionally containing vitamins or minerals as active substances[4].

a.2 Medical devices

Art. 4 para. 1 let. b TPA defines medical devices as "*products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medicinal use and whose principal effect is not obtained with a medicinal product*." A more detailed definition of medical devices that is identical to that used in European law (see explanations in section III no. 1 point 1.1 let. b or the definition according to Art. 2 para. 1 of Regulation (EU) 2017/745[5]) can be found in Art. 3 para. 1 of the Medical Devices Ordinance (MedDO, SR 812.213). This states that medical devices are "*instruments, apparatus, appliances, software, implants, reagents, materials or other objects:*

a. that are intended by their manufacturer for use on human beings;
b. that do not achieve their intended principal action in or on the human body by pharmacological, immunological or metabolic means, but which action can be assisted by such means; and
c. that serve to fulfil one or more of the following specific medicinal purposes either alone or in combination:
   1. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
   2. diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,
   3. investigation, replacement or modification of the anatomy or of a physiological or pathological process or condition,
   4. acquisition of information by means of in vitro investigation of samples obtained from the human body, including donated organs, blood or tissue."

Contraceptive or fertility-enhancing products and products and items intended specifically to clean, disinfect or sterilise the devices listed in Art. 1, para. 1 MedDO (medical devices and accessories and product groups without a medicinal intended purpose; see below for more information) are also classified as medical devices under Art. 3 para. 2 MedDO.

Medical devices are distinguished from medicinal products by the way in which they fulfil the purpose intended for them by their manufacturer and not solely by virtue of their composition in terms of materials. Whereas the primary effect of medicinal products is pharmacological, immunological or metabolic in nature, medical devices must on no account possess such primary effects. The typical primary effects of a medical device are mechanical, physical or physicochemical in nature[6]. Since it is not always possible to draw a clear distinction between medical devices and medicinal products, the key criterion in making a decision is whether the product achieves its principal intended action in or on the human body by pharmacological, immunological or metabolic means. If it does, the product qualifies as a medicinal product.

a.3 Products without an intended medicinal purpose that are subject to medical devices legislation

Under both Regulation (EC) 2017/745[7] (Art. 1 para. 2 in conjunction with Annex XVI; see explanations in section III no. 1 point 1.1. let. c) and the Medical Devices Ordinance (Art. 1 para. 1 let. b in conjunction with Art. 106 and Annex 1 MedDO), certain product groups without an intended medicinal purpose that have a similar risk profile to medical devices but are not medical devices are subject to medical devices legislation from the time that common specifications designated by the European Commission or Swissmedic take effect. Products of this kind may therefore only be placed on the

[4] See also the guidance document Authorisation of herbal medicinal products HMV4; https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl101_00_008d_wlzulassungphytoarzneimittel.pdf.download.pdf/ZL101_00_008e_WL%20Guidance%20document%20Authorisation%20of%20herbal%20medicinal%20products%20HMV4.pdf
[5] 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, OJ L 117 of 5.5.2017, p. 1.
[6] See FAC verdict C-2093/2006 of 12 December 2007 E 3.5.
[7] See footnote 5.

market if they have undergone a conformity assessment procedure and have had any conformity certificate (EC certificate) that may be necessary issued by a conformity assessment body.

a.4 Intended use of medicinal products, medical devices and products subject to medical devices legislation

With the exception of products without an intended medicinal purpose that are subject to medical devices legislation under Art. 1 para. 1 let. b in conjunction with Annex 1 MedDO, regardless of the existence of an intended medicinal purpose, the intended use of both a medicinal product and medical device must be a medicinal effect on the human organism or use in or on the human body. This applies particularly in connection with the typical fields of application of diagnosis, prevention and treatment (including cure and alleviation) of diseases and disabilities. The list of fields of application is not exhaustive.

The purpose of a product may be objective (i.e. a product that by the very nature of its active substances or intended use can only be used for its medicinal effect or application) or subjective (i.e. the intended purpose attributed to the product primarily by its manufacturer or distributor). The criterion of promotion or designation means that therapeutic products legislation not only applies to products that genuinely have a therapeutic or medicinal action or use, but also to products that are not sufficiently effective to an extent that consumers might expect by virtue of the way they are promoted. This is intended to protect consumers not only against harmful or dangerous therapeutic products, but also against ineffective products that are promoted as medicinal products or medical devices, but whose quality, safety and efficacy fall short of legal requirements. Furthermore, there is a danger of such products being used instead of suitable therapeutic products because of the way they have been promoted.

It should also be noted that in terms of dispensing and use, promoting a product as a therapeutic product is not a sufficient criterion for it to fall within the scope of the Therapeutic Products Act. It may at most be an indication that a product should be categorised as a therapeutic product. The use or dispensing of a product outside its customary field of application does not necessarily affect its original categorisation. Medical or healthcare professionals are responsible for the use they put products to (e.g. placebo, vitamins, etc.) Use of a product must take account of the current state of medical science and technology and comply with the applicable legal requirements.

b) Foodstuffs

b.1 General

Art. 4 para. 1 of the Foodstuffs Act (FoodA; SR 817.0) defines foodstuffs as any substances or products that are intended for consumption by, or that can reasonably be expected to be consumed by, humans in processed, partially processed or unprocessed form.

Medicinal products are not regarded as foodstuffs (Art. 4 para. 3 FoodA), nor are medical devices. Although Art. 4 para. 3 FoodA does not explicitly mention this, it derives from Art. 2 para. 4 let. d FoodA, which states that the Foodstuffs Act does not apply to products that fall within the scope of therapeutic products legislation.

All foodstuffs that are placed on the market must be safe. Foodstuffs are not deemed to be safe if it can be assumed that they are harmful to health or not suitable for human consumption (Art. 7, para. 1 and 2 FoodA). The Foodstuffs Act (Art. 7 para. 3 FoodA) and Art. 8 of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02) clarify how the terms *“harmful to health”* and *“unsuitable”* are to be interpreted.

Furthermore, Art. 15 para. 1 FUAO stipulates that foodstuffs that were not used for human consumption in any appreciable quantity before 15 May 1997 in either Switzerland or an EU Member State and which fall into one of the categories listed in the paragraph (what are known as novel foods) have to be approved either through an ordinance or by the FSVO.

b.2 Plants, plant parts and preparations derived from them (botanicals)

Herbal substances or herbal preparations can be used both as components with a supporting function in medical devices or medicinal products with specific indications and as foods – in this case without such indications – particularly in dietary supplements. In food and dietary supplements, herbal substances and preparations derived from plants, algae, fungi or lichen are known as botanicals.

Certain botanicals can present a safety risk in food. Plants containing pharmacologically active substances or substances that have toxic properties in the dosages used are particularly problematic. Manufacturing and dosage are both particularly relevant when assessing botanicals as foodstuffs or ingredients of foodstuffs. For example, extracts may display considerable differences in their composition and nutritional, pharmacological and toxicological properties, depending on the manufacturing process and extractant used.

Since 1 May 2017, Annex 1 of the FDHA Ordinance on Foodstuffs of Vegetable Origin, Fungi and Table Salt (VFO, SR 817.022.17) has contained a list of plants, plant parts and preparations derived from them that must not be used in foodstuffs because of their known risks. Inclusion in the list is determined by toxicity at low doses. The use of pharmacologically active doses of medicinal plants in foodstuffs is not permitted, regardless of whether the plants in question, parts of those plants or preparations derived from them appear in the VFO list. This list does not apply to the manufacturing of flavourings, which is governed by the FDHA Ordinance on Flavourings and Food Ingredients with Flavouring Properties in or on Foodstuffs (SR 817.022.41).

Under Art. 95 FUAO, the composition and labelling of foodstuffs are subject to a transitional period of four years from the entry into force of the new foodstuffs legislation. This stipulates that foodstuffs and utility articles produced and labelled under the previous legislation can only be sold to consumers until stocks are exhausted. However, that does not mean that the list of prohibited substances in Annex 1 VFO will only take effect in four years' time because current legislation also stipulates that foodstuffs must not jeopardise health. The plants, plant parts and preparations derived from them that have now been added to Annex 1 VFO could not be placed on the market under the previous legislation for toxicity reasons. For this reason, they are excluded from the transitional period under Art. 95 para. 2 FUAO.

b.3 Dietary supplements

The provisions specific to dietary supplements are set out in the Ordinance on Dietary Supplements (DietSO; SR 817.022.14). Dietary supplements are foodstuffs intended to supplement the normal diet. They consist of concentrated sources of vitamins, minerals or other substances, alone or in combination with a specific nutritional or physiological effect and are marketed in dosed form. They have to be prepackaged and supplied for use in measured small quantities in various presentations, such as capsules, tablets or liquids (Art. 1 and 2 DietSO).

In accordance with Art. 2, para 3 let. a DietSO, dietary supplements may contain the vitamins and minerals listed in Part A of Annex 1 DietSO subject to the conditions stated therein (e.g. compliance with maximum levels). In addition, conditions of use apply to certain other substances in Part B of Annex 1 of DietSO. The permitted combinations of vitamins, minerals and other substances are set out in Annex 2 of DietSO. Substances other than those listed in Part B of Annex 1 of DietSO may be contained in dietary supplements, subject to fulfilment of the following requirements:

- Food safety must be guaranteed (Art. 7 FoodA; Art. 8 FUAO);
- The substance and product must not fall under the scope of therapeutic products legislation (Art. 2 para. 4 FoodA);
- The definition of a foodstuff must be fulfilled (Art. 4 FoodA);
- The definition of and requirements for a food supplement must be fulfilled (Art. 1 and 2 DietSO);
- The provisions for "novel foods" must be fulfilled (Art. 15–19 FUAO, Ordinance on Novel Foods; SR 817.022.2).
- The plants, plant parts or preparations derived from them listed in Annex 1 VFO and the substances listed in Annex 4 of the Ordinance on the Addition of Vitamins, Minerals and other Substances to Foodstuffs (AVMO; SR 817.022.32) may not be added.

Compliance with these requirements must be ensured as part of self-supervision activities.

b.4 Food for special medical purposes (FSMP)

Food for special medical purposes is governed by Art. 23ff of the FDHA Ordinance on Foodstuffs for Persons with Special Dietary Requirements (SDRO; SR 817.022.104). FSMP is intended for patients with:

a. restricted, impeded or impaired ability to consume, digest, absorb, metabolise or excrete conventional foods or certain nutrients contained in such foods, including their metabolites; or

b. another medically necessary nutrient requirement that cannot be met by modifying the normal diet, by means of different foods intended for the nutrition of particular groups of people or a combination of both.

Unlike therapeutic products, such foodstuffs are therefore not intended to have a medicinal effect or application in the human organism, but are instead designed for dietary management of a disease, disorder or other condition.

1.2. Market access

a) Therapeutic products (medicinal products, medical devices and products subject to medical devices legislation)

Medicinal products may only be distributed in Switzerland if they have been authorised by Swissmedic and if the natural person or legal entity that manufactures, imports or exports them, conducts wholesale trading in them or trades in them abroad holds an establishment licence issued by Swissmedic.

By contrast, there is no state authorisation procedure for medical devices. Medical devices can only be placed on the market or put into service in Europe or Switzerland if they carry a CE mark. This legal requirement also applies to medical devices that are issued free of charge, rented out or used directly on patients and to product groups without an intended medicinal purpose as defined in Art. 1 para. 1 let. b in conjunction with Annex 1 MedDO. The CE mark may only be attached if the products fulfil the prescribed general safety and performance requirements (Art. 6 para. 2 MedDO) and the prescribed conformity assessment procedure has been completed either with or without the involvement of a conformity assessment body (Art. 23 and Art. 24 para. 1 MedDO).

b) Foodstuffs

Foodstuffs may generally be placed on the market without the need for approval if they are safe and do not mislead consumers. However, there are still areas in foodstuffs legislation that are subject to positive lists (e.g. the final list of vitamins and minerals in Annex 1 of the FDHA Ordinance on Dietary Supplements, SR 817.022.14), negative lists (e.g. the list of the plants, plant parts and preparations derived from them that may not be used in foodstuffs in Annex 1 of the FDHA Ordinance on Foodstuffs of Vegetable Origin, Fungi and Table Salt, SR 817.022.17) or an approval requirement (e.g. approval requirement for novel foods in Art. 15 FUAO). However, foodstuffs are not subject to a blanket requirement to obtain state authorisation in the way that medicinal products are. Nevertheless, to ensure food safety, anyone who manufactures, processes, stores or transports foodstuffs, places them on the market, exports, imports or carries them in transit is obliged to comply with the legal requirements (obligation to self-supervise). Official supervision does not absolve from the duty to self-supervise (Art. 26 FoodA).

1.3. Fraud prevention/non-permissible health claims

a) Therapeutic products in general

Art. 1 para. 2 let. a TPA establishes the principle that consumers of therapeutic products are to be protected against fraud. The dispatch of 1 March 1999 on a Federal Act on Medicinal Products and Medical Devices (TPA Dispatch; Federal Gazette *1999* 3485) states that in particular, misleading expectations concerning the quality, efficacy, composition and safety of a therapeutic product must not be aroused.

b) Specific points concerning medicinal products

In compliance with Art. 9 para. 4 of the Therapeutic Products Ordinance (TPO; SR 812.212.21), Swissmedic will reject applications for authorisation of a ready-to-use medicinal products if they fail to satisfy the specified requirements or if the product name or the design of the container or packaging material breaches public order or decency, could be misleading or could cause confusion.

Finally, the Medicinal Products Advertising Ordinance (MPAO; SR 812.212.5) contains various provisions intended to protect professionals and consumers from misleading specialist or mass-market advertising (e.g. Art. 5 para. 3, Art. 22 let. i and m MPAO).

Under the Therapeutic Products Licensing Requirements Ordinance (TPLRO, SR 812.212.22), complementary and herbal medicinal products must also carry information on the product group they are

categorised under (e.g. herbal medicinal product, homeopathic medicinal product, anthroposophic medicinal product). This requirement also applies to complementary medicine without indications.

c) Specific points concerning medical devices and products subject to medical devices legislation

Art. 69 para. 1 MedDO states that promotion for products subject to medical devices legislation must only contain claims that correspond to the product information. According to Art. 69 para 2 MedDO, misleading statements, particularly concerning the intended purpose, safety and performance of a device, are prohibited.

d) Foodstuffs

In execution of Art. 18 and 19 FoodA, Art. 12 para. 1 FUAO stipulates that the names used, details, illustrations, wrappings, packaging, wording on wrappings and packaging, presentation types, advertising and foodstuffs information used for foodstuffs must correspond to the facts and not be liable to mislead as to the nature, origin, manufacture, method of production, composition, content or storage life of the foodstuffs in question.

In particular, Art. 12 para. 2 let. a FUAO prohibits information on effects or properties of a foodstuff that current scientific knowledge indicates that foodstuff does not even possess or for which there is insufficient scientific evidence. Moreover, let. c prohibits any kind of reference ascribing to a foodstuff properties capable of preventing, treating or curing human disease or giving rise to the impression that the foodstuff possesses such properties ("health claims prohibition"). By contrast, references to the action of substances with a nutritional or physiological effect added to foodstuffs[8] and nutritional and health-related information are permitted[9]. Art. 12 para. 2 let. d FUAO further prohibits presentations of any kind that give a foodstuff the appearance of a therapeutic product. As mentioned under 1.1. above, the labelling of FSMP may carry references to a disease. However, these must be restricted to the dietary management of the disease in question and must not refer to prevention, cure or alleviation.

The permissibility of nutritional and health claims is governed by Articles 299ff of the FDHA Ordinance on Information on Foodstuffs (FoodIO, SR 817.022.16). Such information is permissible in connection with foodstuffs provided that Annex 13 or 14 FoodIO makes explicit provision for it. Health claims that are not listed in Annex 14 FoodIO must be approved by the FSVO. Foodstuffs legislation prohibits health claims (see Art. 12 para. 2 let. c FUAO).

2. Case law and principles of the distinction between therapeutic products and foodstuffs in Switzerland

The Dispatch on the TPA states that the distinction between therapeutic products and foodstuffs should essentially be a matter for the supplier, saying that *"suppliers should be free to place their product on the market as either a therapeutic product or foodstuff"*[10].

However, the Federal Supreme Court's case law has corrected the entirely subjective approach of the Federal Council's dispatch by firmly qualifying it.

In judgement 2A.565/2000[11], the Federal Supreme Court settled on the following distinction criteria. "*When authorising a product as a foodstuff, the primary attribute to be considered – as provided for in Art. 3 para. 3 FoodO – is its composition (taking account of international standards and foreign legislation). In doing so, consideration must be made of whether, and to what extent, side effects that are both undesirable and possibly even dangerous to health may be associated with the product (see Art. 13 para. 1 FoodA, which specifies that food must not present a risk to health when used in the intended way). From the perspective of intended use, the question to be asked with reference to the nature of the foodstuff is to what extent a product contributes to the development or maintenance of the human body. If it also has curative properties, these need to be qualified; the more the primary purpose is nutrition, the more the product is a foodstuff. Conversely, if the product is promoted as a*

[8] Art. 25 FUAO.
[9] Art. 38 FUAO.
[10] Federal Gazette 1999 *3481* no. 134.2.
[11] Federal Supreme Court judgement 2A.565/2000 E. 4 b) cc)

therapeutic product or is generally known as such, this can provide an indication that primary significance should be attributed to its pharmacological effects. If there are both curative properties and detrimental side effects, health regulatory considerations speak against approval as a foodstuff; however, authorisation as a therapeutic product would still be possible on the grounds of stricter supervision to the extent that the desired pharmacological effect makes this justifiable. A product should specifically no longer be considered a foodstuff if its curative properties predominate when weighed against its contribution to the development or maintenance of the body and if consumption of normal quantities may cause side effects that are detrimental to health (unpublished verdict of 4 November 1991, according to H. AG, E. 3e)".

In judgement 6B_979/2009, the Federal Supreme Court ruled that there was no legal loophole between foodstuffs legislation and therapeutic products legislation. However, a preparation was not automatically a medicinal product because it contained an active substance that appeared in the substance lists prepared by the Agency for Therapeutic Products. The *overall circumstances of the individual case* were decisive. In view of this, it was possible that if there were two different products with an identical composition, one could be classified as a foodstuff and the other as a medicinal product by virtue of the other circumstances. The key circumstances for the purpose of distinction included product composition, pharmacological effects including adverse reactions and the intended use as perceived by the average consumer. The impression that the average consumer would have in terms of intended use would depend on a variety of circumstances. Significant factors would include the way the product was presented, its actual presentation, form of administration and distribution channels.

Elaborating on Supreme Court case law, the Federal Administrative Court noted in judgement C-4612/2011 that subordinating products to a particular class of legislation was of major health regulatory significance because placing on the market and market surveillance were subject to different requirements depending on the applicable law in each case, and correct categorisation was the only way of ensuring that users and consumers were protected against inadequately tested products (E 3.1). In addition, products could generally only belong to one of the product categories and be subject to that particular legislation (E 3.2). Furthermore, the Federal Administrative Court's judgement states that whether or not a product should be classified as a medicinal product depends on whether it was primarily intended from an objective viewpoint for medicinal use, and that this should be determined on the basis of its composition, the associated product properties and its normal use as generally perceived by consumers. Finally it also pointed out that the criteria developed to distinguish medicinal products from foodstuffs could also be applied analogously to distinguish therapeutic products from various other product categories given the similarities between the issues (E 3.3).

In judgement C-900/2007 of 19 October 2009 (E. 6.3.3), the Federal Administrative Court held that when determining predominant intended use for the purpose of distinguishing medical devices from biocidal products, this intended use was to be determined not only by the (predominant) purpose intended by the manufacturer, but also from the impression that consumers in particular gain of the intended use of the product.

As far back as judgement 2A.565/2000[12], the Supreme Court held that advertising or publications containing health claims for a certain product that were not attributable to its manufacturer or supplier were generally insufficient to qualify the product as a medicinal product subject to authorisation. Consumers could not be relieved of a certain amount of personal responsibility. "*Remote possibilities and speculation by the regulatory authorities to the effect that* '*consumers' would be* '*highly likely to use' the product generally as a popular or natural remedy because of articles and works directed at a specific target audience are not at all sufficient to exclude its authorisation as a foodstuff*".

In summary, both the Supreme Court and the Administrative Court have adopted the stance that the decision on whether a product falls under the Foodstuffs Act or the Therapeutic Products Act should be made on the basis of a *holistic view* and applying *objective criteria*. The existence of a health claim does not automatically qualify a product as a therapeutic product.

The entry into force of the new Foodstuffs Act on 1 May 2017 raised the question of which principles from the existing case law handed down by Swiss courts could be applied to the new legislation and which could not. It should be noted in this context that the requirement of adopting a holistic view to determine whether a product falls under the Foodstuffs Act or Therapeutic Products Act has not changed in any way. Similarly, the hierarchy of both Acts has not changed either. If a product falls

[12] Federal Supreme Court judgement 2A.565/2000 E. 5 b) cc)

under the Therapeutic Products Act, it is not subject to the Foodstuffs Act (Art. 2 para. 4 let. d FoodA). A further thing that remains the same is the lack of legal loopholes between the two sets of legislation.

What has changed is the definition of foodstuff, which has been expanded because it no longer requires products to *"further the development or maintenance of the human body"*. This has no impact on whether a product is classified under foodstuffs legislation or therapeutic products legislation, but it does affect whether a product can be marketed as a food under the Foodstuffs Act.

Because the requirement to "*contribute to the development or maintenance of the human body*" no longer exists, the question could arise as to whether the criterion of predominant intended purpose also no longer exists as a way of distinguishing the two product categories. This is not the case, however. If a product serves purposes that fall predominantly under the scope of therapeutic products legislation and if this aligns with the outcome of a holistic appraisal (which might generally be the case), foodstuffs legislation will not apply by virtue of Art. 2 para. 4 let. d FoodA.

Finally, the interpretation documents issued by the European Commission can also be helpful when distinguishing and classifying products that are or could be subject to the Medical Devices Ordinance, particularly the *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices*[13] and the MEDDEV guidelines[14], particularly MEDDEV 2.1/6 (*Qualification and Classification of stand alone software*), MEDDEV 2.4/1 (*Guidelines for the Classification of Medical Devices*) and MEDDEV 2.1/3 (*Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative*). Although not legally binding, these interpretation documents were produced as part of a consultation process involving the relevant authorities, European Commission, conformity assessment bodies, industry representatives and further stakeholders, and as such provide guidelines for the harmonised application of the relevant European regulations on medical devices. Furthermore, they reflect the latest scientific and technological findings.

Although these interpretation documents can only be used in the context of the medical devices directives at present, it can be assumed, given the importance of the interpretation documents, that products governed by MDR will also be included in any further update. Interpretation documents for MDR and IVDR are published by the Medical Device Coordination Group (MDCG)[15]: e.g. MDCG 2019-11 (Qualification and classification of software).

[13] DocsRoom - European Commission (europa.eu)
[14] md_guidance_meddevs.pdf (europa.eu)
[15] Guidance - MDCG endorsed documents and other guidance | Public Health (europa.eu)

III. The current situation in the European Union

1. Legal framework and explanations

1.1. Products

a) Medicinal products

According to Art. 1 no. 2 let. a and b of Directive 2001/83/EC[16] in the version amended by Directive 2004/27/EC[17] (hereinafter: Directive 2001/83/EC), medicinal products are *"Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"*.

Like Switzerland, the EU also has detailed definitions for certain medicinal product groups and these are set out in the further provisions of Directive 2001/83/EC.

Art. 1 no. 5 of Directive 2001/83/EC defines a homeopathic medicinal product as *"Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles"*.

As in Switzerland, homeopathic medicinal products with and without indications are classified as homeopathy if they have been manufactured according to the appropriate manufacturing specifications and should therefore be categorised as medicinal products.

Art. 1 no. 30 of Directive 2001/83/EC defines a herbal medicinal product as *"Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations"*. This corresponds largely to the Swiss definition of herbal medicinal products.

In summary, in the EU, as in Switzerland, the decisive criteria for qualification as a medicinal product are firstly effective pharmacological, immunological or metabolic action of the product (medicinal product by function) and secondly the designation of the product as such (medicinal product by presentation). There is only one exception: homeopathic medicinal products' classification as medicinal products is determined by their manufacturing process as well as their intended use.

b) Medical devices

Art. 2 para. 1 of Regulation (EU) 2017/745[18] defines a medical device as "*any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) (medical devices, accessories for medical devices and product groups without*

[16] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; OJ. L 311 of 28.11.2001, p. 67.
[17] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
[18] Cf. footnote 5.

an intended medical purpose; more on these below) and of those referred to in the first paragraph of this point."

As in Switzerland, the intended purpose of medical devices must be medicinal and therapeutic use on the human organism, especially in the context of the typical fields of application of diagnosis, prevention and treatment (including cure and alleviation) of diseases or diagnosis, treatment (including cure, alleviation and compensation) of injuries or disabilities. Also as in Switzerland, medical devices are distinguished from medicinal products by the way they achieve the effect attributed to them. Whereas the primary effect of medicinal products is pharmacological, immunological or metabolic in nature, medical devices must on no account possess such primary effects. Typical primary effects of a medical device are mechanical or physical in nature.

c) Products without an intended medicinal purpose that are subject to medical devices legislation

As in Switzerland (see comments in section II no. 1 point 1.1 let. a subletter a.3), the EU also subjects certain product groups without an intended medicinal purpose and which are not medical devices, but have a similar risk profile to medical devices, to medical devices legislation from the time the common specifications issued by the European Commission in accordance with Art. 1 para. 2 in conjunction with Annex XVI of Regulation (EC) 2017/745[19] enter into force. Accordingly, products of this kind may only be placed on the EU market if they have undergone a conformity assessment procedure and have had any conformity certificate (EC certificate) that may be necessary issued by a conformity assessment body.

d) Foodstuffs

Art. 2 of Regulation (EC) No. 178/2002[20] defines foodstuffs as follows: *"For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (...)"*. This definition explicitly excludes medicinal products from the foodstuffs category.

Art. 14 para. 1 of Regulation (EC) No 178/2002 prohibits the placing on the market of unsafe foodstuffs. Foodstuffs are deemed to be unsafe if they are considered to be injurious to health or unfit for human consumption. In determining whether a foodstuff is injurious to health, consideration must be given to the probable short-term and probable long-term effects of that foodstuff on health (para. 4).

Certain foodstuffs and foodstuff ingredients that were not consumed to a significant degree by humans in the Member States of the European Union before 15 May 1997 ("novel food") have to undergo a health evaluation and obtain authorisation before they can be placed on the market. Examples of novel food include new sources of vitamins or minerals, new microorganism cultures (e.g. certain probiotic bacteria), exotic seeds or fruit (e.g. chia seeds or noni fruit) or food derived from new production processes (e.g. UV-treated baker's yeast used for vitamin D enrichment). Details can be found in Regulation (EC) 2015/2283[21].

1.2. Fraud prevention/non-permissible health claims

a) For medicinal products

Fraud protection for medicinal products is primarily ensured by means of advertising regulations (see Art. 87 para. 3 and Art. 90 let. j and k of Directive 2001/83/EC[22]).

b) Medical devices and products subject to medical devices legislation

Article 7 of Regulation (EU) 2017/745[23] stipulates that "*In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names,*

[19] Cf. footnote 5.
[20] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ. L 31 of 1.2.2002, p. 1.
[21] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327 of 11.12.2015, p. 1.
[22] Cf. footnote 19.
[23] Cf. footnote 5.

trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

a) *ascribing functions and properties to the device which the device does not have;*
b) *creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;*
c) *failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;*
d) *suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out*."

c) Foodstuffs

Art. 8 and 16 of Regulation (EC) 178/2002[24] contain general provisions to protect consumers against fraud that are equivalent to those in Swiss law. Art. 8 defines protection of consumer interests as one of the aims of food law and the basis for consumers to make free, informed choices in relation to the foods they consume. Art. 16 contains general provisions stipulating that the labelling, advertising and presentation of foodstuffs must not mislead consumers.

Art. 7 para. 1 of Regulation (EC) 1169/2011[25] states that food information must not be misleading. Furthermore, food information must not attribute to any food the property of preventing, treating or curing a human disease, nor must it make reference to such properties (para. 3). The same applies to the presentation of foodstuffs and advertising (para. 4). Natural mineral waters and foods for particular nutritional uses are subject to special regulations.

Regulation (EC) 1924/2006[26] governs the permissibility of nutrition and health claims made on foods. The term "*nutrition claims*" refers to claims such as *"low-fat"*, *"high fibre"* or *"high in vitamin C"*, for which the Annex of the Regulation provides a list setting out the conditions under which such claims may be used. The term *"health claims"* applies to any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. In terms of the issue of distinction, it is interesting to note that "reduction of disease risk claims" are permissible. "*Reduction of disease risk claims*" means any claim that states, suggests or implies that the consumption of a food or one of its constituents significantly reduces a risk factor in the development of a human disease. Reduction of disease risk claims and any other health claims may only be made if they are authorised under Regulation (EC) 1924/2006.

2. Case law and principles of the distinction between therapeutic products and foodstuffs in the European Union

The ECJ already made pronouncements on the distinction between foodstuffs and therapeutic products in various past judgements[27]. More recent judgements on the subject include C-319/05 (Garlic Capsules) and C-140/07 (Red Rice), which European Courts' current case law often still cites as "leading cases". ECJ judgement C-358/13 of 10 July 2014 (Cannabis) is also significant since it refers to the criterion of direct or indirect conduciveness to human health. The core statements of these judgements may be summarised as follows:

Medicinal products by function:

- A product is deemed to be a medicinal product by function if, having regard to its composition – including its content in active substances – and provided it is used as intended, it is capable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action (judgement C-140/07 paras 38 to 45). In its judgement of 2 November 2017[28], the Lüneburg Higher Administrative Court dealt in detail with the issue of

[24] Cf. footnote 23.
[25] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004; OJ. L 304 of 22.11.2011, p. 18.
[26] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404 of 30.12.2006, p. 9.
[27] Cf. Van Bennekom, para. 29 of 21 March 1991 in case C-369/88, Delattre, ECR 1991, I-1487, paras. 26 and 35, and in case C-60/89, Monteil and Samanni, ECR 1991, I-1547, para. 29 of 16 April 1991 in case C-112/89 Upjohn, "Upjohn I", ECR 1991, I-1703, para. 23 of 20 May 1992 in case C-290/90, Commission vs Germany, ECR. 1992, I-3317, para. 17 of 29 April 2004 in case C-150/00, Commission vs Austria, ECR. 2004, I-3891, para. 64.
[28] Lüneburg HAC 13th chamber, judgement of 2 Nov. 2017, 13 LB 31/14.

what constitutes a pharmacological effect, finding in this context that an effect of this type does not necessarily have to be associated with a therapeutic effect.

- Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions (judgement C-319/05 para. 61).
- Substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions are not medicinal products by function (judgement C-319/05 para. 60).
- Any product whose effect on physiological functions is no greater than the effects that a foodstuff consumed in a reasonable quantity may have on those functions does not have a significant effect on the metabolism and cannot be classified as a product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83 (judgement C-319/05 paras 60 and 68).
- It is not sufficient that a product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease (judgement C-319/05 para. 64).
- Substances whose effects are limited to merely influencing physiological functions and are not directly or indirectly conducive to human health are not classified as medicinal products (judgement C-358/13 para. 38).
- Products that are generally recognised as foodstuffs and which are also acknowledged to possess beneficial effects on health and which may objectively serve therapeutic purposes are not medicinal products by function (judgement C-319/05 para. 65).
- The provision covering cases of doubt in Art. 2 para. 2 of Directive 2001/83/EC is not applicable to products whose properties have not been proven to comply with the definition in Art. 1 no. 1 let. b of this Directive, i.e. a product whose suitability to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis has not been scientifically demonstrated (judgement C-140/07 para. 26).
- The national authorities must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail, whether a product falls under the definition of a medicinal product by function within the meaning of Directive 2001/83 (judgement C-140/07 para. 39).
- Under current Community law, it is possible for differences to exist in whether Member States classify products as medicinal products or foodstuffs. For this reason, there is the possibility that one Member State may regard a product as fulfilling the requirements for a medicinal product by function, whereas another takes the view that the current scientific evidence does not prove that it is a medicinal product by function (judgement C-140/07 para. 28). The same applies to classifying a product as a medicinal product or medical device. Here again, the fact that a product is classified as a medical device in accordance with Directive 93/42[29] does not prevent another Member State recognising it as a medicinal product within the meaning of Directive 2001/83 if it possesses the relevant features (judgement C109/12 para. 45 and 47).

Medicinal products by presentation

- A product is deemed to be a medicinal product by presentation either if it is expressly *"presented for treating or preventing disease in human beings"* or whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question (judgement C-319/05 paras 44 and 46).
- However, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the

[29] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169 of 12.7.1993, p. 1.

sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered (judgement C-319/05 para. 52).

Finally, the interpretation documents issued by the European Commission can once again be helpful when distinguishing and classifying products that are or could be subject to the Medical Devices Ordinance with regard to the EU, particularly the *Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices*[30], the MEDDEV guidelines[31] or the new interpretation documents published by the Medical Device Coordination Group (MDCG) for MDR and IVDR[32] (see also the explanations in section II no. 2 on page 12).

IV. Comparison of Switzerland and the EU

As will be apparent from the explanations above, the process used in the EU to distinguish foodstuffs from therapeutic products (medicinal product, medical devices and products subject to medical devices legislation) is essentially the same as the process used in Switzerland. The Swiss definition of foodstuff that applied until 30 April 2017 included the limitation that food products had to further the development or maintenance of the human body. This limitation is absent from the definition of foodstuff that has applied since 1 May 2017. The central criterion now is whether a substance or product is intended for human consumption or its consumption can be reasonably foreseen. This qualifies the criterion of predominant intended use by adopting the EU's definition of a foodstuff. However, the predominant public perception – or rather consumers' perceptions of how a substance or product is categorised – are still relevant when determining whether a product is a medicinal product by presentation.

As in Switzerland, the EU distinguishes medical devices from medicinal products by the way they achieve the effect attributed to them (see section II no. 1 point 1.1 let. a above).

Categorising *medicinal products by presentation* as therapeutic products is in line with the Swiss regulatory practice of applying the Therapeutic Products Act to products of chemical or biological origin that are *promoted* as having a medicinal effect on the human or animal organism (see the definition of *medicinal product* in Art. 4 para. 1 let. a TPA and the definition of *medical device* in Art. 4. para. 1 let. b TPA). Both Swiss and European case law treat the issue similarly, concluding that it is impossible to definitively categorise a product as a foodstuff or therapeutic product **solely** on the basis of a (prohibited) claim of a cure.[33]

Categorising *medicinal products by function* as therapeutic products is also in line with the Swiss regulatory practice of applying the Therapeutic Products Act to products of chemical or biological origin that are *intended* to have a medicinal effect on the human or animal organism (see the definition of *medicinal product* in Art. 4 para. 1 let. a TPA and the definition of *medical device* in Art. 4. para. 1 let. b TPA). Here again, Swiss and European case law treat the issue similarly, concluding that the decision on whether a product is classed as a medicinal product should be guided by whether, in objective terms, it is primarily intended for medical use. This should be determined by its composition, associated properties and consumers' perception of its normal use. Alternatively a product may be deemed to be a medicinal product by function if, having regard to its composition – including its content in active substances – and provided it is used as intended, it is capable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

The European Court of Justice's case law on the distinction between foodstuffs and therapeutic products is now increasingly being adopted in Swiss courts' judgements. However, the Federal Supreme Court has recently had almost no opportunity to pronounce on the issue. In contrast, the Federal Administrative Court's deliberations reveal that it takes account of the European Court of Justice's case law when reaching its judgements (see for example point E. 3 of judgement C-4612/2011).

[30] DocsRoom - European Commission (europa.eu)
[31] md_guidance_meddevs.pdf (europa.eu)
[32] Guidance - MDCG endorsed documents and other guidance | Public Health (europa.eu)
[33] See Kiethe/Groeschke, p. 975.

V. Procedure for determining the marketability of a product

During the revision of the new foodstuffs legislation that entered into force on 1 May 2017, both parliament and the Federal Council expressed their intention to make the Swiss Foodstuffs Act compatible with European legislation and to draft it in such a way as to avoid trade barriers in goods traffic between Switzerland and the EU. The same also applied to the full revision of the Medical Devices Ordinance, which entered into force on 26 May 2021. The procedure recommended below for distinguishing the boundaries for foodstuffs and therapeutic products legislation takes account of this intention. It has been guided primarily by the landmark rulings issued to date by the Federal Supreme Court and Federal Administrative Court and takes account of the definitions adopted from EU law for the purposes of interpretation, as well as the European Court of Justice's case law.

There are two major steps in the process of determining whether a product is classified as a foodstuff, medicinal product, medical device or product without an intended medicinal use that falls under the Medical Devices Ordinance:

1. Does the product fall under the Foodstuffs Act or the Therapeutic Products Act (step 1)?

2. Does it meet the requirements for placing on the market under the relevant Act (step 2)?

About step 1:

Does the product fall under the Foodstuffs Act or the Therapeutic Products Act?

Subordinating products to a particular class of legislation is of major health regulatory significance because placing on the market and market surveillance are subject to different requirements depending on the applicable law in each case, and correct categorisation is the only way of ensuring that users and consumers are protected against inadequately tested products[34]. For this reason, Art. 2 para. 4 let. d FoodA stipulates that the Foodstuffs Act is not applicable to substances and products that fall under therapeutic products legislation. If a product is covered by the Therapeutic Products Act, it cannot simultaneously be covered by foodstuffs legislation. There are no legal loopholes between foodstuffs and therapeutic products legislation[35].

With the exception of products without an intended medicinal purpose that are subject to medical devices legislation under Art. 1 para. 1 let. b in conjunction with Annex 1 MedDO, regardless of the existence of an intended medicinal purpose, the composition of a product and its intended use in the eyes of the average consumer must be considered when categorising it. Significant factors here include how the product is presented, its actual presentation, pharmaceutical form and distribution channels[36]. In the case of medical devices, the intended purpose is key (see let. b below).

When applying a **holistic view** of this type, the following points must be observed:

a. Composition

General:

- Whether or not a product is intended to have a medicinal effect on the human organism within the meaning of the definition of a medicinal product in Art. 4 para.1 let. a TPA can be determined by objective criteria[37].

[34] See Federal Supreme Court judgement 2C_590/2008 (E. 2.2) and Federal Administrative Court judgement C-4612/2011 (E. 3.1).
[35] Federal Supreme Court judgement 6B_979/2009 (E. 4.2).
[36] Federal Supreme Court judgement 6B_979/2009 (E. 4.2).
[37] Federal Supreme Court judgement 6B_979/2009 (E. 4.2).

- All the product's characteristics must be considered, particularly its composition[38], its pharmacological, immunological or metabolic properties, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail[39].
- The *"normal conditions of use"* are key when assessing the risks associated with consumption (Art. 7 para. 3 FoodA).
- Any product that contains a substance that can be consumed with normal nutrition should not be regarded as a medicinal product if that product does not produce any significant modification of metabolism compared with the effects of normal nutritional intake[40].
- Substances whose effects are limited to merely modifying physiological functions and are not directly or indirectly conducive to human health are not classified as medicinal products[41].

A product should be classified as a medicinal product under the Therapeutic Products Act if it satisfies all the following conditions:

- The product must be capable by virtue of its composition – including its content in active substances – and if used as intended, of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action[42].
- The required pharmacological, immunological or metabolic effect must have been scientifically demonstrated[43]. This requirement does not apply to complementary medicinal products in particular, since the manufacturing process is key here.
- It is not sufficient that the product has properties beneficial to health in general, but it must genuinely have the function of treating or preventing disease[44].

If it is not possible to conclusively categorise the product on the basis of composition alone, its intended use should be determined on the basis of all the available evidence.

b. Intended use

- Determining intended use entails assessing how the product is presented, its actual presentation, pharmaceutical form, distribution channels, etc. in a holistic appraisal. Not all evidence carries equal weight. One particular piece of evidence (e.g. pharmaceutical form) may carry a different weight depending on the case in question. It is generally not possible to arrive at a definitive qualification on the basis of just one item of evidence. Instead, all the criteria that speak in favour of or against a particular classification should be factored in and considered.
- The crucial factor in categorising a product as a therapeutic product or foodstuff is its predominant intended use, as derived from its objective properties by an averagely well informed, attentive and knowledgeable average consumer[45].
- While a health claim or other information may provide evidence for distinguishing products, it does not generally permit a reliable qualification in its own right[46].

[38] This should primarily be the composition stated on the packaging, the product or the package inserts. If this does not produce any accurate information that is suitable for the purposes of categorisation, the competent authority (e.g. Swissmedic) can compel the facility or party responsible for the product to provide accurate details of its composition on the basis of Art. 58 para. 4 TPA (Duty to cooperate and provide information). Laboratory testing is generally not required, since a product can also be qualified on the basis of the other criteria (see let. b below) and because in most cases analyses of this type are generally disproportionately expensive and labour-intensive. Art. 29 para. 1 FoodA imposes a duty to cooperate and provide information on foodstuffs manufacturers and dealers.
[39] ECJ judgement C-140/07 (para. 39).
[40] ECJ judgement C-358/13 (para. 38).
[41] ECJ judgement C-358/13 (para. 38).
[42] ECJ judgement C-140/07 (para. 38–45).
[43] ECJ Judgement C-319/05 (para. 61).
[44] ECJ judgement C-319/05 (para. 64).
[45] Judgement I ZR 288/01 of 22.07.2004 of the German Bundesgerichtshof [Supreme Court](para. 20).
[46] Federal Supreme Court judgement 2A.456/2000 (E. 3a)aa)) and Federal Administrative Court judgement C-5554/2007 (E. 3.2.5).

- However, the external form given to a product, although it may serve as strong evidence of an individual's intention to market it as a medicinal product, cannot be the sole or conclusive evidence, since certain food products which are traditionally presented in a similar form to medicinal products would otherwise also be covered [47].
- The decisive factor in distinguishing medical devices from other products is their predominant intended use. The existence of an intended medicinal use is a prerequisite for qualification as a medical device, as stipulated in Art. 3 para. 1 let. c MedDO. This does not apply to products without an intended medicinal use that are already subject to medical devices legislation under Art. 1 para. 1 let. b in conjunction with Annex 1 MedDO by virtue of their risk profile.
- The intended use is defined by the manufacturer and is the use for which the medical device is intended in the manufacturer's labelling, instructions for use or advertising materials.
- Determining the predominant intended use does not only depend on the (predominant) purpose that the manufacturer or distributor intends the product to fulfil, but rather on the impression that the market segments for the product, notably its consumers, obtain about its intended purpose[48].
- For the purpose of the authorities' decision, disclaimers such as *"This is not a medical device"* are meaningless if the manufacturer specifies an intended medicinal use in its labelling, instructions for use or advertising materials.
- The decision on whether a product is a medicinal product or medical device must take particular account of the principal intended action, which is to be determined by applying objective criteria.

About step 2:

Does it meet the requirements for placing on the market under the relevant Act?

Once the product has been assigned to foodstuffs or therapeutic products legislation, the next step is to determine whether it fulfils the requirements set out in the relevant legislation for placing on the market.

Classification as a therapeutic product obliges the manufacturer to carry out a further assessment to determine whether the product should be placed on the market as a medicinal product or medical device. Any product with health claims or medicinal indications as well as a pharmacological, immunological or metabolic primary effect must be placed on the market as a medicinal product. Conversely, any product with health claims or medicinal indications and a mechanical, physical or physicochemical primary effect should be placed on the market as a medical device.

[47] ECJ Judgement C-319/05 (para. 52).
[48] Federal Administrative Court judgements C-4612/2011 (E. 3.3) and C-900/2007 (E. 6.3.3).

Evaluation of product marketability

Step 1: Does the product fall under the Foodstuffs Act or the Therapeutic Products Act?

Holistic appraisal

Composition (section V let. a)
- Is the product, having regard to its composition – including its content in active substances – and if used as intended, capable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action?
- Has this action been scientifically proven?
- Risks
- etc.

If it is not possible to conclusively categorise the product on the basis of composition alone, its intended use should be determined on the basis of all the available evidence. Intended use is the primary consideration for medical devices.

Intended use (section V let. b)
- Assessment of how the product is presented, its actual presentation, pharmaceutical form, distribution channels, etc. in a holistic appraisal
- Predominant intended use derived from objective characteristics
- Extent of distribution
- Impression gained by an averagely well informed, attentive and knowledgeable average consumer

Step 2: Does it meet the requirements for placing on the market under the relevant Act?

Points to review (not exhaustive):
Therapeutic Products Act
– Medicinal product, medical device or product subject to the Medical Devices Ordinance?
– Authorisation required?
– Licence required?
– Complies with general safety and performance requirements?
– Conformity assessment procedure conducted correctly?
– Compliant labelling?
– Etc.

Foodstuffs Act
– Food safety guaranteed?
– Compliant labelling?
– Licence required?
– Etc.

Indications or evidence that could point to a therapeutic product:

Warnings
- *Warning for epileptics*
- *References to contraindications (pregnancy, certain diseases)*
- *References to interactions*

Advertising statements
- *Primary use is elimination of a health disorder*
- *Mechanism of action of a substance is described*
- *Processes within the body are described*
- *Disease-related statements that are not health claims permissible under foodstuffs legislation.*
- *Alleviation or treatment of pain*

Presentation
- *Packaging design typical of therapeutic products or with depiction of organs*

Indications or evidence that could point to a foodstuff:

Advertising statements
- Optimal nutrient delivery for the purpose of good health
- Use of a health claim permissible under foodstuffs legislation
- Non-specific health claims combined with specific claims such as *"beneficial to health"* or *"important for eyesight and skin"*

Product name and labelling
- *"Consumption"* or *"nutritional information*

The following should also be reviewed:

- Categorisation of comparable products on the market
- Intended use as perceived by an averagely well informed, attentive and knowledgeable average consumer.
- Distribution channels and sales price (very rarely acknowledged as evidence in current case law, however).