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Criteria for the demarcation of cosmetic products from therapeutic products and biocidal products

TABLE OF CONTENTS

I. Preliminary remarks

Some products present on the Swiss market are often considered by consumers as cosmetic products (that fall under the category of utility articles), although in reality they are medicinal products, medical devices or biocidal products. However, in order to protect public health, it is important that products be assigned to their correct category. Accordingly, the present document focuses on the demarcation of cosmetic products from medicinal products, medical devices or biocidal products.

The issue of demarcation is not simply a purely theoretical question, because the assignment of a product to one or other category has extensive repercussions. Thus, Food Legislation, Therapeutic Product Legislation (medicinal products and medical devices) and Chemicals Legislation govern differently the requirements for production, treating, publicity, purpose, distribution, supply and monitoring of a product. Moreover, those authorities responsible for enforcement are different; likewise measures and sanction possibilities available to them also differ. In particular, in contrast to cosmetic products, those authorisation procedures required for placing on the market therapeutic products and biocidal products involve enormous economic resources. For these reasons the correct classification of a product is highly significant for the manufacturer or distributor.

The definition of a cosmetic product is harmonised in Europe and Switzerland. However, certain differences sometimes exist between the EU Member States and Switzerland in the interpretation of the provisions relating to the demarcation. The present report has been drawn up focusing on cosmetic products. Consequently, criteria for the demarcation between therapeutic products and biocidal products and for other utility articles have not been made.

It should also be noted that in the European Union (EU) certain raw materials used for therapeutic products, cosmetic products and other utility articles are subject to the regulations on chemicals (REACH Regulation (EC) no 1907/2006[1], CLP Regulation (EC) no 1272/2008[2]). Switzerland has adopted corresponding provisions into the Swiss Chemicals legislation. Of particular concern here are propellants and technical auxiliaries, precursors or carrier substances for cosmetic products and medicinal products as well as utility articles or medical devices, which contain substances of very high concern.

A working group, composed of representatives of Swissmedic, the Federal Office of Public Health (FOPH) and the Federal Food Safety and Veterinary Office (FSVO) has closely examined the existing problems of demarcation between the Foodstuffs Act for cosmetic products, the Therapeutic Products Act and the legislation on biocidal products. The present report is a summary of the work of this group; this updated version is largely inspired by that relating to “The Criteria for the Demarcation between Therapeutic products and Foodstuffs in regard to orally administered products” [3], revised at the end of 2018, and which served as the basis of the structural outline.

The present document provides a review of the relevant legal bases in Switzerland and Europe and summarises the Swiss and European jurisprudence in regard to the demarcation issues on cosmetic products. The report then presents the working group’s indication of significant procedures, typical classification indications as well as a reference to the “Borderline Manual”, recently published by the European Commission, on the scope of application of the Cosmetics Regulation with practical examples (cf Chapter V and Annex). It is intended to serve as a common basis for collaboration between Swissmedic, FOPH and FSVO so as to clearly define the legislation to be applied in a given case.

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[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, 31.12.2008, p. 1.*

[3] Link: https: //www. blv. admin. ch/blv/de/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-und-vollzugsgrundlagen/abgrenzungskriterien. html

[4] Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009, revised version of September 2020.
Link: https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en / Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) (September 2020, Version 5. 2)

II. The current situation in Switzerland

1. Legal bases and explanatory notes

1.1. Products

a) Cosmetic products

According to Art. 5 let. b of the Foodstuffs Act (FoodA; SR 817.0) cosmetic products and other articles, substances and preparations which, when used as normally intended, come externally into contact with the body, teeth or mucous membranes, are utility articles. A more precise definition of cosmetic products is given in Art. 1 of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02) according to their application site and purpose. Accordingly*, "cosmetic products"* are defined as *"any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".*

It is likewise clearly stated that substances or preparations, which are products "intended to be ingested, inhaled, injected or implanted into the human body do not come under the field of cosmetics" (Art 53 para. 2 FUAO).

According to Art. 2 para. 4 let. d FoodA this Act does therefore not apply to substances and articles, which fall under the Therapeutic Products Act.

Only safe utility articles (inter alia cosmetic products) may be placed on the market (Art. 15 para. 1 FoodA). A utility article is deemed safe if, when used in a normal or reasonably foreseeable manner, it does not pose or poses solely minimal risks or only those that are compatible with its normal usage and which maintain an acceptable high level of protection for the health of consumers and third parties (Art. 15 para. 2 FoodA).

Utility articles (and thereby also cosmetic products), which because of their shape, colour, odour, appearance, presentation, labelling, volume or size may be expected to be mistaken for food and thereby endanger health shall not be dispensed to consumers (Art. 45 FUAO).

A non-exhaustive, exemplary list of products that may be deemed as cosmetic products can be found in Annex 1 of the Ordinance on Cosmetics (CosmO; SR 817.022.31).

b) Therapeutic products

The term therapeutic product applies to medicinal products as well as to medical devices.

aa) Medicinal products

Therapeutic products are defined in Article 4 paragraph 1 letter a of the Therapeutic Products Act, TPA, SR 812.21) as "*products of chemical or biological origin, which are intended for or claimed to be for the medicinal action on the human or animal organism, in particular for the diagnosis, prevention or treatment of illnesses, injuries and disabilities; blood and blood products are also considered to be medicinal products"*.

For more detailed definitions of specific medicinal product groups reference is made to Art. 4 para. 3 and 4 of the Complementary and Phytotherapeutic Products Ordinance (KPTPO; SR 812.212.24) and Art. 4 para. 1 let. a – a^{decies} TPA. In regard to the demarcation criteria, the definitions that apply to medicinal product groups are particularly pertinent as their demarcation from other products time and again leads to further discussions. In all cases in which specific manufacturing processes or regulations are applied to complementary medical therapies, then the products containing the corresponding ingredients are classified as medicinal products already defined by the manufacturing process.

bb) Medical devices

According to Art. 4 para. 1 let. b TPA medical devices are defined as *"products including instruments, apparatuses, in-vitro diagnostics, software and other articles or materials, which are intended or promoted for medical use and whose principal main action is not obtained by a medicinal product".*

A more detailed definition of medical devices, which is identical to that according to European law (cf statements under chapter III no 1 point 1.1 let. b or the definition according to Art. 1 para. 2 let. a of the Guideline 93/42/EEC[5]) can be found in Art. 1 para. 1 of the Medical Devices Ordinance (MedDO; SR 812.213). Accordingly, 'medical devices' mean any instrument, apparatus, appliance, material or other medical article, whether used alone or in combination, including the software and accessories, intended to be used for human beings and whose intended principal action in or on the human body cannot be achieved by pharmacological, immunological or metabolic agents, but whose mode of action may be supported by such agents and which serve the purpose in humans of:

a. diagnosis, prevention, monitoring, treatment or alleviation of disease;

b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

c. investigation, replacement or modification of the anatomy or of a physiological process:

d. control of conception or diagnoses in connection with the conception.

Medical devices differ from medicinal products by the manner in which they fulfil the purpose intended by the manufacturer and not purely based on the material composition. Whereas medicinal products develop a pharmacological, immunological or metabolic principal action, these actions must not be the primary actions of medical devices. Typical primary actions of a medical device are of the mechanical, physical or physical-chemical type[6].As the demarcation between medical devices and medicinal products is not always straightforward it is critical for an assessment whether the intended principal action in or on the human body is achieved by pharmacological, immunological or metabolic means. In this case the product would be qualified as a medicinal product. Finally, it should be noted that pursuant to the Regulation (EU) 2017/745[7] product groups without a medicinal purpose may from now on also be subject to this Regulation, if they have a risk profile analogous to medical devices but are not medical devices.

cc) Intended use of therapeutic products

The intended use of a medicinal product and a medical device must be the medical and therapeutic action or use on the human organism. This is in particular in the context of the typical application fields of detection, prevention and treatment (including healing and alleviating) illnesses and handicaps. This list of application fields is not exhaustive.

The aim of a therapeutic product can be either objective (a product that due inherently to its active principles or to its intended use may serve solely for a medical effect or use) or subjective (i.e. the effective intended purpose is primarily defined by the manufacturer or distributor. The criterion of the presentation or the designation of the article means that the therapeutic product legislation applies not only to products that actually do have a therapeutic or medicinal action, but also to articles that do not satisfy the expectations that consumers could have expected from the presentation. Consumers should therefore be protected not only from harmful or dangerous therapeutic products, but also from ineffective articles that are presented as medicinal products or medical devices, but which do not meet the legal regulations in regard to quality, safety and efficacy. This is also because the danger exists for such products that, based on the advertising, they may be used instead of a suitable therapeutic product.

It should also be noted in regard to presenting a product as a therapeutic product one should not solely follow the presentation given by the distributor or the supplier[8]. This may, however, serve as an indication for qualification.

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[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, *OJ L 169, 12.*7.1993, p. 1.

[6] See ruling C-2093/2006 of the Federal Administrative Court of 12 December 2007 E 3.5

[7] 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, 5.5.2017, p. 1

[8] The use or the supply of a product outside the usual field of use has no bearing on its original qualification. Physicians, pharmacists and chemists are (relatively) free to decide how a product may be used (e.g. placebo, vitamin, etc.). Medical personnel or health professionals assume themselves the responsibility and are bound by the medical and technical state of the art for the usage at the time (Art. 3 and 26 TPA). If medical personnel or health professionals supply their patients with foodstuffs or utility articles in accordance with food legislation, then in all cases they have to respect the provisions of the food law. 9.

c) Biocidal products

The Chemicals Act defines biocidal products as follows (Art. 4 para. 1 let. d Chemicals Act, ChemA[9]):

"Biocidal products: means active substances and preparations that are not plant protection products and which are designed to:

1. *Deter, render harmless, destroy or otherwise control harmful organisms, or*
2. *Prevent damage from being caused by harmful organisms".*

The Ordinance on Biocidal Products (OBP) [10] further specifies the term (Art. 2 para. 1 let. a OBP):

"Biocidal products:

1. *Substances, preparations or objects, in the form in which they are supplied to the user, consisting of, containing or generating one or more active substances, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.*
2. *Substances or preparations generated from substances or preparations which are not themselves biocidal products as defined in number 1, and which are intended for the purpose for which biocidal products as defined in number 1 are intended".*

Articles that contain or release biocidal products and which are primarily intended to have an effect on harmful organisms outside these articles also represent biocidal products.

The OBP does not apply to biocidal products or treated articles which are placed on the market solely in accordance with legislation on therapeutic products, foodstuffs, feedstuffs or plant protection products for the specified purposes (Art. 1*a* para. 3 let. a OBP). Biocidal products, which although covered thematically in the scope of another legislation, but not placed on the market and used for one of the therein intended purposes, fall into the scope of the OBP. As in Europe, products that have a primary biocidal function fall in principle under the Biocidal Product Regulation. These include for example products presented as disinfectants (e.g. ethanolic hand gels as a hand disinfectant). The use of conservation agents (biocidal substances) in cosmetic products is not regulated by biocidal law, but by cosmetics law, if the agents are used exclusively for conserving the cosmetic product. If biocidal products or active substances whose biocidal function is only secondary ("*secondary claims*"[11]) to the primary cosmetic function or if the function is inherently with the cosmetic function, then they again do not fall into the scope of the OBP (Art. 1 *a* para. 3 let. a OBP) when added to cosmetic products.

1.2. Market access

a) Cosmetic products

Cosmetic products sold in Switzerland do not require an authorisation from the cantonal or federal authorities. However, the products have to fulfil the requirements of food law. Whosoever manufactures, treats, stores, places on the market, imports, exports or carries in transit cosmetic products must ensure that the statutory requirements are complied with (obligation to self-supervision). Official inspection does not imply an exemption from the obligation to carry out self-supervision (Art. 26 FoodA).

b) Therapeutic products (medicinal products and medical devices)

In Switzerland medicinal products may only be commercialised if they have been authorised by Swissmedic and if the legal or natural person who has manufactured, imported, exported or carried out wholesale trade or traded them abroad possesses an operating license from Swissmedic.

In contrast to medicinal products there exists no national accreditation for medical devices. In order to commercialise or put into service medical devices in the European or Swiss markets the devices have to bear the CE marking. This legal requirement also applies to medical devices that are provided

Federal Act of 15 December 2000 on Protection against Dangerous Substances and Preparations (ChemA, SR 813.1)

[10] Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (OBP, SR 813.12)

[11] See footnote 4.

free of charge, rented or used directly on patients. The CE marking may be affixed only if the devices satisfy the essential requirements defined in the relevant European Directives – which also apply in Switzerland (Art. 4 para. 1 MedDO) – and if the prescribed evaluation procedure for compliance has been carried out – with or without recourse to a conformity assessment body (Art. 10 para. 1 and 2 MedDO).

Since 26 November 2017 medical devices that satisfy the requirements of the Regulation (EU) 2017/745[12] may also be placed on the market in Switzerland (Art. 22*a* MedDO).

c) Biocidal products

In principle, biocidal products may be placed on the market in Switzerland or used professionally or commercially only when they have been granted a valid authorisation in Switzerland. The various types and possibilities of authorisations are described in the form of guidance documents on the internet pages of the Chemicals Notification Authority[13].

Biocidal products authorised in the EU may be authorised in Switzerland by means of recognition procedures.

All products that are authorised to be placed on the market in Switzerland are listed in the Chemicals Product Register (CPR) (internet address: see Chapter "*Competence and Information on Biocidal Products*"). The authorisation number registered therein must be the same as the number on the label. The products may be placed on the market only with the agreement of the authorisation holder. Parallel imports are allowed only with prior approval.

Certain biocidal products may not be supplied to the general public. The criteria for this ban are defined in Art. 11d OBP (e.g. carcinogenic, mutagenic or toxic to reproduction category 1A or 1B). Likewise, the prohibitions and requirements of the Chemical Risk Reduction Ordinance (ORRChem; SR 814.81)[14] on the import, distribution and possession of products containing certain substances, should be noted.

Specific permits are necessary for various professional uses of biocidal products (see link to the legal bases of the chemicals law, and to the information sheets of Chemsuisse[15]).

1.3. Advertising and ban on deception

a) For cosmetic products

The prevention against deception for cosmetic products was newly introduced with the revision of FoodA (Art. 18). All information relating to these products has now to be based on fact. The impression made on the average consumer by the information is critical.

Pursuant to Art. 10 para. 1 CosmO and in the application of Art. 18 FoodA and Art. 58 FUAO, product claims in the form of texts, names, trademarks, pictures and figurative or other signs shall not be used explicitly or implicitly to indicate properties or functions that they do not possess.

In addition, a new condition was introduced that product claims relating to cosmetic products would only be allowed if the claims also complied with the six common criteria as defined in the European legislation[16]: *"legal compliance", "truthfulness", "evidential support", "honesty", "fairness" and "informed decision-making".* The particulars of these criteria are presented in Art. 10 and in Annex 6 of CosmO. The criteria are intended to guarantee a high level of protection for consumers, in particular against misleading claims.

Concerning the labelling of cosmetic products, the Art. 95 para. 2 FUAO stipulates, however, a transitional period up to 30 April 2021.

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[12] See footnote 7.

[13] Link: https://www.anmeldestelle.admin.ch/chem/de/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html

[14] Link: https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2005/478/20201101/de/pdf-a/fedlex-data-admin-ch-eli-cc-2005-478-20201101-de-pdf-a.pdf

[15] Link: https://chemsuisse.ch/de/merkblaetter/10-merkblaetter

[16] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products *OJ L 190, 11.7.2013, p. 31*.

Finally, pursuant to Art. 47 para. 3 FUAO, as already laid down in previous legislation, indications of any kind are forbidden that attribute illness healing, relief or prevention to utility articles (e.g. medicinal or therapeutic properties, disinfecting or anti-inflammatory actions). For dental and oral care products indications regarding caries prevention as well as other properties relating to dental medicine are authorised as long as they can be proved scientifically (Art. 47 para. 4 FUAO).

b) For therapeutic products in general

Art. 1 para. 2 let. a TPA establishes the principle that consumers of therapeutic products shall be protected against fraud. According to the message of 1 March 1999 on the Federal Act on Medicinal Products and Medical Devices (message TPA; BBl 1999 3485) it should be particularly prevented that false hopes be awakened in regard to the quality, efficacy, composition or innocuousness of a therapeutic product.

c) For medicinal products in particular

According to Art. 7 para. 3 of the Therapeutic Product Ordinance (TPO; SR 812.212.21) the Institute rejects an application for the authorisation of a ready-for-use therapeutic product if the conditions are not fulfilled or if the name of the preparation is contrary to public order or morality, is misleading or may create confusion.

Finally, the Medicinal Products Advertising Ordinance (MPAO; SR 812.212.5) contains various provisions to protect specialists and consumers against misleading specialist or public advertising (e.g. Art. 5 para. 3, Art. 22 let. i and m MPAO).

d) For medical devices in particular

According to Art. 21 para. 1 MedDO publicity for medical devices, destined to be supplied directly to the public or to be used directly by the public, shall only contain claims corresponding to information on product use, performance and efficacy. According to Art. 21 para. 2 MedDO misleading information on the efficacy or performance of a medical device is forbidden.

Advertising to the public is forbidden for those medical devices (Art. 21 para. 3 MedDO) that a) may only be medically prescribed or b) are placed on the market for the exclusive use of professional specialists.

e) For biocidal products

False, misleading or incomplete information or facts, which could deceive the purchaser in regard to the nature, type of composition or utilisation of a biocidal product, are forbidden. In the absence of an authorisation, no product may be claimed to be a biocidal product. Labelling is subject to detailed provisions.

Authorised biocidal products may be commercialised on the internet. In such cases, however, the publicity shall respect the specific provisions of Art. 50 OBP, i.e. anyone who advertises dangerous biocidal products which the general public can purchase without seeing the labelling beforehand must indicate their hazardous properties in a comprehensible and clearly legible or audible manner.

Like the labelling, no misleading information such as "*low-risk biocidal product", "non-toxic", "not harmful to health", "natural", "environmentally friendly"* or other similar indications may be made. Unfair competitive publicity is forbidden.

More detailed information may be found in the guideline "Publicity" on the internet page of the Chemicals Notification Authority[17].

[17] Link: https://www.anmeldestelle.admin.ch/chem/de/home/themen/recht-wegleitungen/wegleitungen-interpretation-shilfen.html

2. Jurisprudence and principles for the demarcation of cosmetic products/therapeutic products/biocidal products in Switzerland

2.1. Cosmetic products – Therapeutic products

The great majority of federal court decisions do not concern the demarcation between therapeutic products and cosmetic products, rather only with the ban that healing properties can be claimed for cosmetic products. In these cases subordination to the food legislation was not disputed.

The Federal Court dealt with the demarcation of therapeutic products and cosmetic products in its decision 2C_413/2015. It considered that a product recognised by the average member of public mainly for its quality as a medicinal product should be classified as a medicinal product (E 3.1). The impression that a product evokes in consumers depends on various objective factors: significant factors, inter alia, are the nature of its presentation, the packaging, its pharmaceutical form and its distribution channels (E 3.2). In order to foster the appearance of a therapeutic product and therefore to imply that it is subject to the regulations of the TPA as a presentation medicinal product, the legal characteristics of the medicinal product have to predominate according to the standards. From the outset health claims do not lead to a qualification as a therapeutic product, insofar as they are based on supportable facts and are not likely to mislead the average member of the public of their possible healing, soothing or prophylactic properties. However, even claims that are subject to an actual ban on advertising still do not lead *per se* to a qualification as a medicinal product by its presentation. The criterion of the predominant chosen purpose according to the commercial conception thus ultimately differentiates the material scope of the TPA from that of the FoodA (E 3.2).

As cosmetic products are seen as utility articles they are also subject to the Foodstuffs Act; in order to differentiate between cosmetic products and therapeutic products one can refer back to the bases of the Federal Court and the Federal Administrative Court for the demarcation between foodstuffs and therapeutic products.

In a further development of the Federal Court case-law the Federal Administrative Court remarked in its ruling C-4612/2011 that from the view point of sanitary law it is highly important to know whether a product is subject to one law or to another because the requirements of the applicable law may differ for market placement and surveillance and that only a correct classification would guarantee the protection of users and consumers against insufficiently tested products (E 3.1). Moreover, a product may generally belong only to one product category and therefore be subject to the corresponding legislation (E 3.2). The Federal Administrative Court also ruled in its decision that the qualification of a product as a medicinal product depended on whether objectively it was primarily considered for medical use, this being based on its composition, on the associated product characteristics and on the commercial conception as perceived by consumers. Finally, it remarked that in view of the similar nature of the questions, the criteria for demarcation between foodstuffs and medicinal products can likewise be applied by analogy to the demarcation of therapeutic products from various other product categories (E 3.3).

According to the message on the TPA, the demarcation between therapeutic products and foodstuffs is fundamentally to be based on the wishes of the supplier. Accordingly, "*it should be up to the supplier to place their product on the market as a therapeutic product or as a foodstuff*".

However, the case-law of the Federal Court corrected and strongly qualified this purely subjective point of view of the Federal Council:

The most important criteria for demarcation are summarised in the ruling 2A.565/2000 of the Federal Court. "When authorising a product as a foodstuff – *as laid down in Art. 3 para. 3 FoodO – the primary consideration (taking into account international standards and foreign legislations) is its composition. It should be noted whether and to what extent unwanted and even harmful side effects may be associated with them (cf Art. 13 para. 1 FoodA, according to which, foodstuffs when used as normally intended must not present a risk to health). In regard to the intended use, the question should be asked about the nature*

[18] Ruling 2C.413/2015 of 10. March 2016

[19] BBl 1999 3481 let. 134.2.

[20] Decision of the Swiss Federal Supreme Court 2A.565/2000 E. 4 b) cc).

*of the foodstuff - to what extent a product contributes to develop or maintain the human body. If the product also possesses healing effects, they have to be put into perspective; the more the nutritional purpose preponderates, the more likely it is that it concerns a foodstuff. On the other hand, if the product is presented as a therapeutic product or is generally known as such, then this may favour the contrary stance, such that greater significance is afforded to the pharmacological effects. If both healing effects as well as adverse side effects exist, then the authorisation of the product as a foodstuff needs to be evaluated in accordance with health protection requirements; in contrast, authorisation as a therapeutic product remains possible as long as the pharmacological effect justifies this, although stricter controls do indeed apply to therapeutic products. A product cannot be considered as a foodstuff if the therapeutic effects manifestly surpass the contribution to the development or maintenance of the body, and if detrimental side effects may result from consuming normal amounts (*unpublished ruling of 4 November 1991 *(i.S.H. AG, E. 3e)"*

In its judgement 6B_979/2009 the Federal Court found that no legal vacuum existed between the food legislation and the therapeutic product legislation. Consequently, a preparation is not necessarily a medicinal product because it contains an active substance that is cited in the list of substances established by the Agency for Therapeutic Products. Given that the *overall circumstances of the particular case* are the determining factor, then it could be possible that for two different products having the same composition, but for which the overall circumstances differ, one could be qualified as a foodstuff and the other as a medicinal product. Decisive circumstances for demarcation include the product composition, the pharmacological effects (including the undesirable side effects) and the intended use as perceived by the average consumer. The consumers' perception in regard to the intended use would seem to depend on various factors. The nature, inter alia, of the product presentation, the packaging, the pharmaceutical form and the distribution channels would be of significance.

In its judgement C900/2007 of 19 October 2009 (E. 6.3.3) the Federal Administrative Court found that when demarcating medical devices from biocidal products the determination of the predominant intended use must not only take into account the (predominant) use of the product as defined by the manufacturer, but also the perception held by consumers in regard to the intended use of the product.

In its ruling 2A.565/2000[21] the Federal Court already found that publicity or publications originating from third parties, and which extol health claims for a specific product, are generally insufficient grounds to qualify the product as a medicinal product subject to authorisation. *A certain individual responsibility should not be taken away from the consumer. "Remote possibilities and speculations by the approval authorities that the "consumer" - as the result of articles and studies aimed at a specific segment of the public - would generally use the product "most probably" as a popular and natural remedy, are not sufficient grounds to exclude its authorisation as a foodstuff".*

In its ruling C-3525/2012 the Federal Administrative Court under E. 2.5 found: *"In regard to the composition, it is crucially important to know whether and to what extent the product could trigger unwanted and even dangerous-to-health effects" …." Consequently, the composition of the product (active principles and ingredients), the habitual use of the active principle (as an indication here, for example, the inclusion in a list of active principles) as well as possible risks associated with its habitual use are to be examined. Furthermore, the composition provides information on product properties and effects. The products may also display multiple and varied effects, even healing effects or health-promoting effects as well. Consequently, a correct demarcation should be based on the principle effect, i.e. the primary and most significant effect"…. "In order to determine the intended use one should take an objective view. The various uses of the product must be considered in relation to each other, so as to categorise the intended uses as primary or secondary. When identifying the predominant intended use it should not necessarily be assumed that the (predominant) use of the product is that given by the manufacturer. Rather, in order to classify a product, one should consider the opinion of the consumers and the public conception; the question to be answered is how the averagely informed, reasonably observant and circumspect consumers judge the product and what they expect from it. The prevailing opinion of the consumer is regularly found to adhere to an already existing opinion of the purpose of comparable products and their usage, which again depends on the possible uses of the products as a function of their nature in normal usage".*

[21] Decision of the Swiss Federal Supreme Court 2A.565/2000 E. 5 b) cc).

In summary, the Federal Court and the Federal Administrative Court consider that the classification within the scope of either the food law or the therapeutic product law has to be carried out based on an *overall consideration* and in an *objective manner*. The presence of a health claim does not automatically make a product a therapeutic product.

The entry into force of the new Foodstuffs Act on 1 May 2017 brought up the question of which bases of the previous case-law of the Swiss Courts were applicable or not to the new law. In this context it should be noted that nothing had changed in regard to the requirement to classify a product on the basis of an overall consideration to either the scope of the Foodstuffs Act or the Therapeutic Products Act. This also applied to the hierarchy of the two acts. If a product were subject to the scope of the Therapeutic Products Act, then the Foodstuffs Act would not apply (Art. 2 para. 4, let. d FoodA). The absence of a legal vacuum between the two legislations remains unchanged.

2.2. Cosmetic products – Biocidal Products

As yet there is still no case-law from the Federal Courts regarding the demarcation of biocidal products from cosmetic products. However, some rulings concerning similar products in the EU may serve as a guide.

In its ruling C-900/2007 (E 6.3) the Federal Administrative Court found that those criteria developed by the Federal Court and the European Courts for the demarcation of therapeutic products on the one hand, and foodstuffs and utility articles on the other hand, may be used to demarcate biocidal products and therapeutic products, insofar as the demarcation is objectively justified. In its ruling C-4612/2011 (E 3.3) it was remarked that in view of the similar nature of the questions, the criteria for demarcation between foodstuffs and medicinal products can likewise be applied by analogy to the demarcation of therapeutic products from various other product categories.

In accordance with the case-law of the Federal Administrative Court the criteria used to demarcate therapeutic products and foodstuffs/utility articles or to demarcate therapeutic products and biocidal products could be used to demarcate cosmetic products from biocidal products (cf chapter 2.1 above). Accordingly, an overall objective view of the product should be undertaken in order, in particular, to take account of its composition, its properties that depend on its composition, its actual purpose and field of application as perceived by the consumers.

In the EU the European Commission, having regard to Article 3(3) of the European Regulation (EU) no 528/2012 (BPR), can decide, when requested by a Member State, whether a given product is a biocidal product, treated goods or neither of these. Such decisions are published as an act of implementation by the European Commission. Pursuant to the existing bilateral agreement with the EU (MRA), the Swiss authorities, in regard to questions of demarcation in the field of biocidal products, comply with the published decisions of the Commission.

III. The Current Situation in the European Union

1. Legal bases and explanatory notes

1.1. Products

a) Cosmetic products

The definition of cosmetic products according to Art. 2 para. 1a of the EU Regulation no 1223/2009 is identical to the definition of cosmetic products in Switzerland (see 1.1a). As in the Swiss legislation the EU

[22] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products *OJ L 167, 27.6.2012, p. 1*; last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council, *OJ L 103, 5.4.2014, p. 22*

[23] Agreement between the European Community and the Swiss Confederation on the mutual recognition in relation to conformity assessment, chapter 18: biocidal products (SR 0.946.526.81)

[24] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products *OJ L 342, 22.12.2009, p. 59;* last amended by Commission Regulation (EU) 2020/1684 of 12 November 2020; OJ L 379, 13.11.2020, p. 42

Regulation applies only to cosmetic products and not to medicinal products, medical devices or biocidal products (sixth Recital).

The seventh Recital of the EU Regulation no 1223/2009 contains a non-exhaustive list of products that can be cosmetic products.

In contrast to the Swiss legislation cosmetic products in Europe have to be registered in a centralised electronic database (Cosmetic Products Notification Portal, CPNP) when they are placed on the market, and a system for monitoring cosmetic products has been set up in which serious undesirable effects must be reported to the Commission.

b) Medicinal products

According to Art. 1 no. 2 let. a and b of the Directive 2001/83/EC medicinal products are "*Any substance or combination of substances presented for treating or preventing disease in human beings, or any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings*".

As in Switzerland, detailed definitions also exist in the EU for certain groups of medicinal products in the further provisions of Directive 2001/83/EC.

In summary, it can be concluded that as in Switzerland, in the EU the qualification of a product as a medicinal product depends on the one hand on the effective pharmacological, immunological or metabolic action of the product (functional medicinal product), but also, on the other hand, the presentation of the product as such (presentational medicinal product). Unique exception: For homeopathic medicinal products the composition plays no part, thus the manufacturing process and the intended purpose are the determining factors in such cases.

c) Medical devices

According to Art. 1 para. 2 let. a of the European Directive 93/42/EEC medical devices mean "*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- *investigation, replacement or modification of the anatomy or of a physiological process;*
- *control of conception,*

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

The Regulation (EU) 2017/745 also contains a definition of the term "*medical device*" in Art. 2 para. 1.

As in Switzerland, the intended purpose of a medical device must be its medico-therapeutic usage on the human organism. This, in particular, is in the context of the typical application fields of detection (diagnosis), preventing and treating (including healing and alleviating) illnesses or of detection, treating (including healing, alleviating and compensating) injuries or handicaps. Likewise, as in Switzerland, medical devices differ from medicinal products by the manner in which they achieve their claimed effect or their claimed action. Whereas medicinal products develop a pharmacological, immunological or metabolic principal action, these actions do not have to be primary in the case of a medical device. Typical primary actions of a medical device are of a mechanical or physical nature.

[25] 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, 28.11.2001, p. 67*.
[26] See footnote 5.
[27] See footnote 7.

d) Biocidal Products

The definition according to Art. 3 para. 1 let. a of the Regulation (EU) no 528/2012 (BPR) reflects the definition according to Art 2 para. 1 let. a OBP (see Chap, 3.1.1.d).

Switzerland and the EU have an agreement on the mutual recognition of authorisations for biocidal products (Mutual Recognition Agreement, MRA). The provisions in regard to the regulation of biocidal products are technically equivalent in the EU and Switzerland. When interpreting the provisions the Swiss authorities are guided by the interpretation in the EU (in accordance with Art. 50a OBP).

1.2. Advertising and ban on deception

a) For cosmetic products

The general provisions on the protection of consumers against deception comprised in Art 20 of the EU Regulation (EC) 1223/2009 correspond to Swiss law. Art. 20 prohibits the assignment of characteristics or functions to a cosmetic product that it does not possess and notes that common criteria have to be met to justify such claims. However, as in Switzerland, no list of authorised claims for cosmetic products exists; this leaves scope for interpretation in the various Member States.

b) For medicinal products

In the field of medicinal products protection against deception is ensured primarily by provisions relating to advertising (see Art. 87 para. 3 and Art. 90 let. j and k of Directive 83/2001/EC).

c) For medical devices

The European Directives (Directive 93/42/EEC[31], 98/79/EC[32] and 90/385/EEC[33]) do not contain any explicit ban on deception or misleading statements. Such a ban, however, is explicitly integrated in Art. 7 of the new Regulation (EU) 2017/745 that will replace Directives 93/42/EEC and 90/385/EEC as of 26 May 2021. However, according to the concept of the European medical devices law the manufacturer is obliged to define the intended purpose and to attest to their medical device; this has the result that anyone who modifies this intended purpose, inter alia by deceiving or misleading indications, will be considered as the new manufacturer of the device.

d) For biocidal products

The European Biocidal Product Regulation (BPR) lays down in Articles 69(2) and 72 that misleading claims for biocidal products are prohibited, and also specifies which information is mandatory. Certain specific claims are listed which must never be used (see Chapter II point 1.3 let. e). As a result of the technical equivalence of the BPO with the BPR the same provisions apply in Switzerland and in the EU (Art. 38 para. 1 and Art. 50 BPO).

In Switzerland, as in the EU, however, no exhaustive list of authorised and/or prohibited claims exists for biocidal products, thus complicating any uniform implementation of the provisions.

2. Jurisprudence and principles for the demarcation of cosmetic products/therapeutic products/biocidal products in the European Union

In the current state of Community law it is still possible for differences to exist between Member States in regard to the classification of products as cosmetic products, medicinal products or biocidal products. Thus, it cannot be ruled out that one Member State may consider it established that a product is a medic-

[28] See footnote 22.

[29] See footnote 23.

[30] 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, 28.11.2001, p. 67*.

[31] See footnote 5.

[32] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; *OJ L 331, 7.12.1998, p. 1*

[33] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; *OJ L 189, 20.7.1990, p. 17*.

[34] See footnote 7.

inal product by function whereas another Member State may take the view that, according to current scientific knowledge, it has not been proved that that product is a medicinal product by function (Judgement C-140/07 point 28).

The European Commission has published a "Borderline Manual" on the scope of application of the Cosmetics Regulation (EC) no 1223/2009 and which delimits which products fall under the cosmetics law. This manual is regularly updated and is very helpful for assessing individual cases (see Annex).

2.1. Cosmetic products – Therapeutic products

According to the guidelines of the EU Commission on the demarcation between cosmetic products and medicinal products, a product, even when it corresponds to the definition of the EU Regulation no 1223/2009, is assessed as a medicinal product and subject to the corresponding regulation, if it is designated as a product for healing or preventing diseases or is intended to be applied to restore, correct or modify a physiological function (*principle of non-cumulation*).

The European Court of Justice (ECJ) in the judgements "Upjohn" and "Commission vs the Federal Republic of Germany" found that the Member States, when assessing whether the product is a medicinal product or not, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological 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.

In a case where one has to determine and demarcate whether a product is a cosmetic product or a medicinal product, then firstly the examiner must check whether the conditions laid down in the Medicinal Product Directive are met. If these conditions are not met then the examination is effected with a view to classifying the product as a cosmetic product according to the EU Cosmetic Product Regulation.

In its judgement of 15 January 2009 the Court of Justice (ECJ) found that Art. 1 no 2 let. b of the Directive 2001/83/EEC, as amended by the Directive 2004/27/EEC, must be interpreted as meaning that a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

On medicinal products by function:

- A product is considered to be a functional medicinal product where, having regard to its composition – including its content in active substances – and if 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 points 38 to 45). In its judgement of 2 November 2017 the Administrative Court of Appeal of Lüneburg (Oberverwaltungsgericht, OVG) analysed in detail the question of the meaning of "pharmacological action", and found that it was not necessarily linked to a therapeutic action.

- 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,

[35] See footnote 4.

[36] Guidance Document on the Demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the commission services and the competent authorities of member states.

[37] ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703

[38] ECJ, C-290/90 of 20 May 1992, Commission of the European Communities versus Federal Republic of Germany, Slg. 1992, Rn. 14

[39] Judgment of the Court (First Chamber) of 15 January 2009. Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg

[40] OVG Lüneburg 13. Senate, ruling of 02.11.2017, 13 LB 31/14.

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 point 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 a medicinal product by function (Judgement C-319/05 point 60).

- 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 point 64).

- Substances whose effects merely modify physiological functions and which are not such as to entail immediate or long-term beneficial effects for human health are not considered to be medicinal products (Judgement C-358/13 point 38).

- The provision of doubt according to Art. 2 para. 2 of Directive 2001/83/EC does not apply to a product in respect of which it has not been established that it is a medicinal product within the meaning of Article 1(2)(b) of that directive, that is to say, a product in respect of which it has not been scientifically established that it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or that it may be used to make a medical diagnosis(Judgement C-140/07 point 26).

- For the purpose of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the competent national authority 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 (Judgement C-140/07 point 39).

On medicinal products by presentation:

- A product is considered to be a medicinal product by presentation when either it is expressly indicated as a “product for treating or preventing human diseases” 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 points 44 and 46).

- 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 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 point 52).

2.2. Cosmetic products – Biocidal products

In contrast to cosmetic products, biocidal products are subject to authorisation prior to being placed on the market in the EU or in Switzerland. In principle, an authorisation granted by a Member State is recognised by the other Member States following a defined procedure. A harmonised demarcation between cosmetics and biocides is therefore highly important.

Demarcation questions are generally based on the primary function, the claims, the intention and the composition of the product as well as on the expectations of consumers.

In cases that are not clear-cut a Member State may submit an application in accordance with Article 3(3) BPR to the Commission for a decision on whether the product falls under the scope of the BPR or not. The Commission may obtain a scientific opinion from ECHA for this decision. The Commission submits a draft for its decision to the Standing Committee of Biocidal Products, which is composed of representatives of all EU Member States. The drafts are commented on and put to a vote. States of the European Economic Area (EEA) and Switzerland likewise have a seat on the Standing Committee and are able to express their opinion, but have no voting right.

Up to now the Commission has published nine decisions in the form of implementation decisions based on Article 3(3) BPR. They also serve as precedents for similar products.

It has, however, also been found that in some cases the Member States could not agree. The Commission then takes no decision and each Member State makes its own decision. This then leads to a non-harmonised interpretation within the EU/EEA.

IV. Comparison CH - EU

In Switzerland, the demarcation of cosmetic products from therapeutic products or biocidal products occurs essentially as in the EU. Moreover, Switzerland and the EU have an agreement on the mutual recognition of authorisations for biocidal products (Mutual Recognition Agreement, MRA). Consequently, demarcations for biocidal products have to be harmonised and identically implemented as in the EU. However, because the demarcation is always made on a case-by-case basis, certain differences in appreciation may possibly occur in each EU Member State as well as in Switzerland.

With the revision of the Food Act in 2017 Switzerland harmonised its legislation with EU law. The aim was to limit divergences and to ensure an equivalent safety level in Switzerland in the field of cosmetic products.

The re-interpretation of the definition of a biocidal product in regard to its primary end use and the recently created possible secondary end use (e.g. antibacterial properties) has enabled the elimination of numerous differences that had arisen in practice between Switzerland and Europe.

Both in Switzerland and the EU, medical devices differ from medicinal products by the manner in which they achieve their claimed effect or their claimed action (see Chapter II no 1 point 1.1, under b)).

The classification of “medicinal products by presentation” as therapeutic products corresponds to the Swiss regulatory approach, whereby products of chemical or biological origin, presented as being intended for their medicinal action on human or animal organisms, are subject to the law on therapeutic products (cf the definition of the term “medicinal product” in Art. 4 para. 1 let. a TPA and that of “medical device” in Art. 4 para. 1 let. b TPA). In both Swiss and European case-law this is considered in a similar manner with the conclusion that the fact of presenting a prohibited health claim is sufficient grounds to prevent a definitive classification of a product as a foodstuff or as a therapeutic product.

Moreover, the case-law of the ECJ on the demarcation between food law and therapeutic product law is increasingly cited in the judgements of the Swiss courts. However, the Federal Court has not recently been called upon to rule on this question. On the other hand, the considerations of the judgements of the Federal Administrative Court indicate that it concurs with the legal interpretation of the European Court of Justice in its deliberations (see in this context for example the judgement C-4612/2011 under E.3). Since the entry into force of the new Food Law on 1 May 2017, it could be expected that the Swiss judicial decisions in the future will also reflect to a greater degree the case-law of the ECJ.

V. Procedure to clarify the marketability of a product as a cosmetic product, therapeutic product or biocidal product

In the context of the revision of the new legislation on foodstuffs, the Parliament and the Federal Council have expressed the will to interpret and render the Swiss Foodstuffs Act euro-compatible, such that barriers to trade in goods may be obviated between Switzerland and the EU. The following recommended procedure to demarcate cosmetic products, therapeutic products and biocidal products forms part of this concern. It is based primarily on rulings already made by the Federal Court and the Federal Administrative Court in this field and takes into account the case-law of the ECJ for the interpretation of the definitions adopted by EU law.

To clarify the question of marketability of a product as a cosmetic product, therapeutic product (medicinal product or medical device) or biocidal product, two main steps are involved:

[41] See footnote 23.

[42] See Kiethe/Groeschke, p. 975.

1. Does the product fall into the scope of the foodstuffs law (cosmetic product), of the therapeutic product law (medicinal product or medical device) or the chemicals law (biocidal product) (step 1)?

2. Does it meet the requirements for the placement on the market in accordance with the relevant law (step 2)?

On step 1: Does the product fall into the scope of the foodstuffs law (cosmetic product), of the therapeutic product law (medicinal product or medical device) or the chemicals law (biocidal product)?

From the view point of sanitary law it is highly important to know whether a product is subject to one law or to another because the requirements of the applicable law may differ for market placement and surveillance and that only a correct classification would guarantee the protection of users and consumers against insufficiently tested products. According to Art. 2 para. 4 let. d FoodA this Act does therefore not apply to substances and articles, which fall under the therapeutic products legislation. In the case that a product falls into the scope of application of the Therapeutic Products Act, it cannot at the same time also fall into the scope of the foodstuffs legislation. No legal vacuum exists between the scopes of application of the foodstuffs legislation and the therapeutic product legislation.

When qualifying a product, the primary considerations (taking into account international standards and foreign legislations) are its composition, its properties that depend on its composition, its actual purpose and field of application as perceived by consumers (Judgement of the Federal Administrative Court of 24.08.2012; C-7143/2010, E 3.2) In this context, significant factors include, inter alia, the nature of its presentation, the packaging, its pharmaceutical form and its distribution channels.

For this **overall view** of the product the following is to be considered on a case-by-case basis:

a. Composition

Generalities:

- Whether a product is intended to act medicinally on the human organism in accordance with the sense of the definition of the term 'medicinal product' in Art. 4 para. 1 let. a TPA, is to be considered according to objective criteria.

- All characteristics of the product are to be taken into account, in particular its composition, 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.

- When examining the risks associated with its use, '*the normal conditions of use*' are applicable (Art. 15 para. 2 FoodA).

- Certain substances may be used both in cosmetic products and in therapeutic products, such as e.g. menthol (ethereal oils), fluorine or chlorhexidine. Based on the formulation, it must be determined whether the substances comprised in the product, in the given amounts, have pharmacological, immunological or metabolic properties.

[43] Rulings 2C_590/2008 (E. 2.2) of the Federal Court and C-4612/2011 (E. 3.1) of the Federal Administrative Court

[44] Ruling 6B_979/2009 (E. 4.2) of the Federal Court

[45] Ruling 6B_979/2009 (E. 4.2) of the Federal Court

[46] For actual examples of indications that may be considered in the framework of the overall assessment, see the Annex.

[47] Ruling 6B_979/2009 (E. 4.2) of the Federal Court

[48] One should begin with the composition provided on the packaging, on the product or in the prospectus. If this does not provide enough information for an exact classification of the product, then the competent authority, e.g. Swissmedic, on the basis of Art. 58 para. 4 TPA (duty of cooperation/duty of disclosure) is able to oblige to company in question to provide the exact composition of the product. In general, it is not necessary to revert to laboratory analyses because a product may also be qualified on the basis of other criteria (see let. b below) and because in most cases such analyses are disproportionately expensive and complex. Art. 29 para. 1 FoodA likewise stipulates that manufacturers and traders have a comparable duty of cooperation/duty of disclosure in the domain of foodstuffs and utility articles.

[49] Ruling C-140/07 (Rn. 39) of the ECJ

- Substances whose effects merely modify physiological functions and which are not such as to entail immediate or long-term beneficial effects for human health are not considered to be medicinal products.

- Antimicrobially active substances may be incorporated into a cosmetic product in order to inhibit the development of microorganisms in the product (see Art. 54 para. 4 FoodO in relation to Annex V of the EU Regulation no 1223/2009). As preservatives they act to preserve the product without any external effect such as e.g. cleaning the skin. They may also be used for other specific purposes, however, such as e.g. deodorants in soaps or as antidandruff agents in shampoos (see Art. 54 para. 2 FoodO in relation to Annex III of the EU Regulation no 1223/2009).

- Preservatives for cosmetic raw materials are considered to be biocidal products.

A product is to be classified as a medicinal product within the scope of application of the Therapeutic Product Act when the following conditions are cumulatively met:

- The product, having regard to its composition – including its content in active substances – and if used as intended, must be capable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

- The claimed pharmacological, immunological or metabolic effect must be scientifically substantiated. Homeopathic medicinal products are excluded here; the primary determining factor being the manufacturing process in such cases

- It is not sufficient that a product has properties beneficial to health in general, rather it must strictly speaking have the function of treating or preventing disease.

If the composition of the product does not allow a conclusive classification to be drawn, then its intended use is to be determined based on all available indications.

b. Intended use

- The assessment of the intended use requires an overall examination of the nature of the presentation of the product, its packaging, pharmaceutical form, distribution channel, etc. Not all indications have equal weighting. A given indication (e.g. the pharmaceutical form) may also be differently weighted depending on the particular case. In general, it is not possible to qualify a product based on only a single indication. Rather, all indications that tend to be for or against a particular classification are to be considered and evaluated,

- The decisive element that enables a product to be classified as a cosmetic product, therapeutic product or biocidal product is determined objectively by its predominant intended purpose, as perceived by an averagely informed, reasonably observant and circumspect consumer.

- In order to demarcate cosmetic products from other products the decisive element is the exclusive or predominant use of the product. A product is to be classified as a cosmetic product when its intended use corresponds to the definition of a cosmetic product, i.e. to clean, to perfume, to change the appearance, to protect, to keep a good condition or to correct body odours (Art. 53 FUAO). Moreover, the application site is to be checked, i.e. whether the product, pursuant to the definition of a cosmetic product, comes into contact with certain parts of the human body (skin, hair system, nails, lips or external genital organs) or with the teeth and the mucous membranes of the oral cavity.

- A health claim or other statement may indeed serve as an indication for the demarcation of products, but generally by itself does not enable a reliable qualification[55]. Rather, the health claim must be suitable to crucially determine the predominant intended purpose and consequently the general trade usage.

[50] Ruling C-358/13 (Rn. 38) of the ECJ
[51] Ruling C-140/07 (Rn. 38-45) of the ECJ
[52] Ruling C-319/05 (Rn. 61) of the ECJ
[53] Ruling C-319/05 (Rn. 64) of the ECJ
[54] Ruling ZR 288/01 of 22.07.2004 of the German Federal Court (Rn. 20)
[55] Rulings 2A.456/2000 (E. 3a) aa)) of the Federal Court and C-5554/2007 (E. 3.2.5) of the Federal Administrative Court

- 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 sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered.

- When demarcating medical devices from other products the predominant intended purpose is decisive. The qualification of a device as a medical device implies that its intended purpose is medical, as defined in Art. 1 para. 1 let. c nos 1-4 MedDO.

- The intended purpose is defined in principle by the manufacturer; it is the use for which the medical device is intended as stated on the label, in the instructions for use or in publicity materials.

- The determination of the predominant intended purpose must not only take into account the (predominant) use of the product as defined by the manufacturer or distributor, but also the perception held by those involved in its intended use, particularly the consumers[57].

- Disclaimers such as e.g. the statement "*This is not a medical device*" are to be ignored by the authorities in their decision-making if an intended medical purpose is given or imparted by the manufacturer on the label, in the instructions for use or in publicity materials.

- What is to be understood as a cosmetic product is illustrated by the examples in Annex 1 CosmO, for example anti-wrinkle cream.

- To demarcate biocidal products and cosmetic products (personal hygiene products) one needs to check whether the principal claim is the biocidal action of the product (combating harmful organisms such as microorganisms, fungi or parasites as well as eliminating damage by harmful organisms or repellent action).

- When a product exhibits a biocidal function that is inherent to its cosmetic function (for example in tooth pastes or deodorants) or when this biocidal function is considered to be a secondary property of a cosmetic product, then the product is deemed to be a cosmetic product. Consequently, biocidal (e.g. antibacterial or antimicrobial) properties are allowed in a cosmetic product if they are secondary and the principal useage of the product remains cosmetic in nature.

On step 2: Does it meet the requirements for market placement according to the relevant law?

After having classified the product into the scope of the foodstuffs legislation (cosmetic product), the therapeutic product legislation (medicinal product or medical device) or the chemicals legislation, one has to determine whether it meets the requirements for market placement laid down in the relevant legislation[58].

If the product has been classed as a therapeutic product the manufacturer is obliged to carry out a further assessment to determine whether the product will be commercialised as a medicinal product or a medical device. A product having health claims or medical indications and a pharmacological, immunological or metabolic principal effect must be placed on the market as a medicinal product. On the other hand, a product having health claims or medical indications and with a mechanical, physical or physico-chemical principal action must be placed on the market as a medical device.

The following federal authorities are competent to answer questions on these three product categories:

- The Department "Food and Nutrition" of the FSVO is responsible for questions on cosmetic product legislation, and the cantonal chemists are responsible for controls.

- Further information:
https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/kosmetika-schmuck/kosmetika.html

www.kantonschemiker.ch

[56] Ruling C-319/05 (Rn. 52) of the ECJ
[57] Rulings C-4612/2011 (E. 3.1) and C-900/2007 (E. 6.3.3) of the Federal Administrative Court
[58] Decision of the Swiss Federal Supreme Court 2A.456/2000, E. 3a) aa).

- The Swiss Agency for Therapeutic Products Swissmedic is responsible for therapeutic products www.swissmedic.ch

- The Chemicals Notification Authority or the Cantonal Chemicals Inspectorate are responsible for biocidal products.
Further information:
https://www.anmeldestelle.admin.ch/chem/de/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html

www.chemsuisse.ch

https://www.anmeldestelle.admin.ch/chem/de/home/themen/pflicht-hersteller/zulassung-biozidprodukte/abgrenzungsfragen/kosmetika.html

www.cheminfo.ch

Flow Chart for the marketability of a product as a cosmetic product, therapeutic product or biocidal product

Step 1:
Does the product fall under the scope of application of the Foodstuffs Act, the Therapeutic Product Act or the Chemicals Act?

Overall assessment

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

If the composition of the product does not allow a conclusive classification to be drawn then its intended use is to be determined based on all available indications.

Intended use (Ch. V, let. b)
- Overall examination of the nature of the presentation of the product, its packaging, pharmaceutical form, distribution channel, etc.
- Is the product claimed to have a principal biocidal action, (combating harmful organisms such as microorganisms, fungi or parasites as well as eliminating damage by harmful organisms or repellent action)?
- Predominant intended use from objective features
- Scale of distribution
- predominant intended purpose, as perceived by an averagely informed, reasonably observant and circumspect consumer
- etc.

Step 2:
Does it meet the requirements for market placement according to the relevant law?

Check list (non-exhaustive list):

Cosmetic product: Foodstuffs Act (FoodA)
- Product information file (PIF) with composition, statement on compliance with good manufacturing practice, safety report
- Advertising claims in conformity with the common criteria, protection against misrepresentation?
- Banned therapeutic claims?
- Labelling conform?
- Manufactured in accordance with GMP?
- Substances and their concentrations?
- etc.

Therapeutic product: Therapeutic Product Act (TPA)
- Medicinal product or medical device?
- Authorisation required?
- Authorisation for manufacture required?
- Compliance with fundamental requirements?
- Conformity assessment procedure carried out correctly?
- Labelling conform?
- etc.

Biocidal product: Chemicals Act (ChemA)
- Is the product authorised in Switzerland according to OBP?
- Is the product labelled correctly in accordance with OBP?
- Compliance with fundamental requirements?
- Advertising claims in conformity with the six common criteria, protection against misrepresentation?
- etc.

Annex

Overall assessment

Compilation of practical examples for a case-by-case assessment for the scope of application of the legislation concerning cosmetic products:

The European Commission has published a **"Borderline Manual"** [59]on the scope of application of the Cosmetics Regulation (EC) no 1223/2009 and which delimits which products fall under the Cosmetics Law. This manual is regularly updated and is very helpful for assessing individual cases by taking into account the nature of the product (substance or mixture), the application site and the envisaged cosmetic purpose. This document thus contains indications that are helpful to demarcate cosmetic products from other products. In all cases, however, the national competent authorities and national courts make the definitive decision.

Criteria and indications which may point towards a cosmetic product

Intended purpose

- Statements relating to protecting or keeping in good condition such as "caring"
- Protection of the skin, e.g. sunbathing products
- Cleaning, perfuming or deodorising
- Improving the appearance
- Well-being
- Note such as "relaxing", "invigorating", "restorative" or "repair"
- Anti-dandruff

Criteria and indications which may point towards a therapeutic product

Intended purpose

- Principally for eliminating a health disorder
- Disease-related or therapeutic statements
- Disinfection of diseased skin, wounds, for preparing incisions
- Medical or therapeutic purposes

Labelling and presentation

- Typical packaging for medicinal products or with illustrations of organs
- Syringes, used for inhalation, injections
- Product name and labelling with medical attributes, e.g. Asclepios' staff
- Designation: "Strong" or "retard" action
- Information destined for professionals and patients
- Declaration of the composition in Latin, indications on the dosage of active substances, indications on excipients with e.g. "excip. ad emuls".

Application sites

- Ear canal, nasal mucosa, eyes, throat, internal genital regions

[59] See footnote 4.

Warnings

- "Caution do not use in the case of illness x"
- Warning for contraindications (pregnancy)
- Warnings for interactions
- Indications for the prevention of illnesses (e.g. skin diseases)

Criteria and indications which may point towards a biocidal product

Intended purpose

- Repelling, neutralising, combating or eliminating harmful organisms as the principal intended use without a medicinal use
- Skin disinfection (e.g. hands, including surgical hand disinfection) or scalp disinfection of intact skin (no disinfection of wounds or preoperative disinfection)
- Repellents

Other demarcation criteria that are to be checked in all cases:

- Classification of comparable products available on the market
- Risk phrases (R-phrases)
- Intended use, as perceived by an averagely informed, reasonably observant and circumspect consumer.
- Distribution channels and sales price (although hardly still recognised today as an indication by case-law)
- Other possible criteria

[60] Pursuant to Commission Implementing Decision (EU) 2016/904 of 8 June 2016.