

Expert Panel for Delimitation Questions

Swissmedic, Swiss Agency for Therapeutic Products

Federal Office of Public Health FOPH

Federal Food Safety and Veterinary Office FSVO

Association of Cantonal Pharmacists KAV

Association of Swiss Cantonal Chemists VKCS

POSITION PAPER: Parenterals without an intended medical purpose – Enforcement at product level

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1 Introduction

This document is intended for enforcement authorities, medical professionals, specialists and other interested parties, e.g. from the cosmetics and lifestyle sectors, and clarifies the enforcement practice for parenterally administered human products (for definition see section 2.1), focusing on the actual **products**.

The existing legal provisions allow for a certain degree of interpretation in the classification of parenterals with an aesthetic purpose or without an intended medical purpose. In this position paper, the Expert Panel for Delimitation Questions provides guidance to the parties concerned.

Due to the risk potential of these invasive products, the Expert Panel for Delimitation Questions classifies these products as being subject to the Therapeutic Products Act (TPA)¹. Before these products can be lawfully placed on the market in Switzerland, they must therefore either possess a marketing authorisation that is valid in Switzerland or – as is the case, for example, for products listed in Annex 1 of the Medical Devices Ordinance (MedDO)² – undergo the relevant conformity assessment procedure.

Otherwise, the above-mentioned products may not be marketed in Switzerland, and the appropriate measures will be taken in accordance with the Therapeutic Products Act.

2 Description of the problem

Products for parenteral administration that have no intended medical purpose, but that are to be used in the lifestyle or cosmetic sector are increasingly being imported into Switzerland, distributed, dispensed, used or even manufactured here. Since they have no medical purpose, these products are not authorised as medicinal products and, as a result of their administration route, they cannot be classified as cosmetics.

2.1 What are parenterals?

Products for parenteral administration (i.e. bypassing the digestive tract, for example administered as an injection or infusion)³ are sterile preparations that are designed to be injected, infused or implanted into the body. They can be given intravenously, subcutaneously or intramuscularly⁴.

Numerous requirements must be met in the manufacture of parenterals (as medicinal products)³. For example, the products must not only be sterile, isotonic, pyrogen-free, etc., but the containers, storage, labelling or the water used must also satisfy various strict requirements.

Moreover, according to [Art. 42 let. e of the Therapeutic Products Ordinance \(TPO\)](#)⁵, a medicinal product intended for parenteral use is available on a prescription-only basis.

¹ Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21)

² Medical Devices Ordinance (MedDO, SR 812.213)

³ European Pharmacopoeia 11th edition

⁴ <https://www.pharmawiki.ch/wiki/index.php?wiki=Injektionen>

⁵ Ordinance on Therapeutic Products (Therapeutic Products Ordinance, TPO; SR 812.212.21)

2.2 Risks of products for parenteral administration

Compliance with GMP guidelines⁶ is of crucial importance for the manufacture of parenterals. Since errors and deviations at this stage can directly affect patient well-being, the manufacture of sterile medicinal products is also the focus of monitoring by the relevant authorities.⁷

Since the administered product can enter the bloodstream very quickly during an injection or infusion, the risk of adverse reactions and damage is very high if it is not injected correctly. Furthermore, any contamination can cause infections, particles can lead to embolisms or other health complications, bacterial endotoxins and pyrogens can trigger feverish reactions, and defective closures can contaminate the preparation, etc.

These aspects highlight the need to minimise the high risks associated with the manufacture and use of parenterals through strict controls and tests in order to ensure customer safety.

2.3 Classification of products for parenteral administration without an intended medical purpose

The existing legal provisions allow for a certain degree of interpretation in the classification of parenterals without an intended medical purpose. When assessing the overall situation, particular attention should be paid to the intended purpose of the product and the site of administration or the depth of the injection.

Cosmetic products are defined in Art. 53 para. 1 of the Ordinance on Foodstuffs and Utility Articles (FUAO)⁸ and are intended to come into **external** contact with parts of the human body, such as the skin (epidermis), and are exclusively, or primarily, intended to clean, perfume or change the appearance of these body parts, to protect them, keep them in good condition or affect body odour. If the method of administration only results in superficial penetration of the product into the epidermis, it may be a cosmetic product whose safety needs to be assessed taking this method of administration specifically into account.

According to [Art. 53 para. 2 FUAO](#), substances or preparations intended to be swallowed, inhaled, injected or implanted in the human body do not qualify as cosmetic products.

The same applies to other parenterals, for example vitamin infusions: Although vitamins can be marketed as nutritional supplements, the food legislation does not permit any route other than through the gastrointestinal tract. Consequently, they may not be marketed as infusions, see Art. 4 of the Foodstuffs Act (FoodA)⁹, where the route of ingestion is indisputably clear, particularly in the French version:

⁶ GMP (Good Manufacturing Practice) refers to the part of quality assurance that ensures consistent quality standards in the production and testing of medicinal products or active substances.

⁷ <https://www.gmp-navigator.com/gmp-news/zusammenstellung-der-wichtigsten-richtlinien-und-normen-zur-ueberwachung-der-gmp-gerechten-herstellung-steriler-arzneimittel>

⁸ Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02))

⁹ Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FoodA; SR 817.0)

*« On entend par denrées alimentaires l'ensemble des substances ou des produits transformés, partiellement transformés ou non transformés qui sont destinés à être **ingérés** ou dont on peut raisonnablement s'attendre à ce qu'ils soient **ingérés** par l'être humain. »*

According to Federal Supreme Court case law (BGE 127 II 91 E 3a/bb¹⁰), products may not fall into a legal loophole, but must be covered by some kind of legislation.

Based on this case law and taking into account both the aforementioned risk profile of such products and the ruling in Art. 53 para. 2 FUAO, the Expert Panel for Delimitation Questions is of the opinion that parenterals with a purely aesthetic purpose or without an intended medical purpose should fall within the scope of therapeutic products legislation.

3 Overview of various categories of products for parenteral administration

3.1 Parenterals containing a pharmacologically active substance

Parenterals containing a **pharmacologically** active substance (for example botulinum toxin) are classified on the basis of their composition as medicinal products by function¹¹.

They must have an intended medical purpose in order for them to be authorised as medicinal products and placed on the market and used on this basis. In other words, if such products are intended not for medical but for aesthetic purposes (for a cosmetic wrinkle treatment, for example) they cannot be authorised for this use by Swissmedic. Injectable products containing pharmacologically active substances can therefore be used for purely aesthetic purposes only in the context of the off-label use of an **authorised** product (authorised for a different purpose). The responsibility for such unauthorised use of the medicinal product therefore lies solely with the healthcare professional providing the treatment.

At present, **pharmacologically active parenterals** with an **exclusively aesthetic purpose** cannot be authorised in Switzerland as **medicinal products** and therefore may not be placed on the market.

Since their route of administration and mode of action do not correspond to those of a cosmetic product, they also cannot be placed on the market as cosmetics.

3.1.1 Non-standardised medicinal products¹²

Non-standardised medicinal products are patient-specific preparations that cannot be standardised to the same extent as industrially produced medicinal products because of their origin or biological variability.

Art. 54 para. 1 FUAO prohibits the use of tissues, cells or other substances of human origin in cosmetic products, and such preparations could not be placed on the market as cosmetics.

¹⁰ [127 II 91 - Swiss Federal Supreme Court](#)

¹¹ Medicinal product by function: The effective pharmacological, immunological or metabolic action of the product

¹² <https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/besondere-arzneimittelgruppen--ham-innovation/informationen/anpassung-merkblatt-nichtstandardisierbare-am.html>

If such preparations are ingested, inhaled, injected or implanted into the human body, they are also not deemed to be cosmetic products (Art. 53 para. 2 FUAO), but fall within the scope of the TPA on the basis of their route of administration.

For non-standardised medicinal products with a purely aesthetic purpose included in the list in Annex 3 of the Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO)¹³, the following applies:

Such preparations may not be placed on the market in Switzerland until their manufacturing process has been authorised by Swissmedic. They include, for example, injectable platelet preparations used for wrinkle treatment or other aesthetic purposes (e.g. PRP, vampire lifting).

However, the manufacture and dispensing of non-standardised medicinal products for purely aesthetic purposes not listed in Annex 3 TPLO are not exempt from regulatory oversight, their manufacture must also be licensed and/or is subject to other cantonal requirements.

3.2 Parenterals with a primarily physical action

This applies, for example, to devices that fall within the remit of the Medical Devices Ordinance.

Unlike medicinal products, there is no official authorisation for medical devices. In Switzerland, medical devices may, in principle, be placed on the market if they have successfully completed the relevant CE conformity assessment procedure and carry a conformity marking (CE marking or MD marking)¹⁴.

3.2.1 Products with an intended medical purpose

Medical devices do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means¹⁵. They **fulfil** (among others) one or more of the following specific **medical purposes**:

Treatment or alleviation of diseases, treatment, alleviation of, or compensation for, injuries or disabilities, replacement or modification of the anatomy or of a physiological or pathological process or state.

Consequently, the manufacturer's intended purpose is a decisive factor in the classification as a medical device or medicinal product. The intended purpose refers to the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation¹⁶.

¹³ Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO; SR 812.212.23)

¹⁴ Art. 21. 2 [MedDO](#); Art. 13 para. 1 [MedDO](#) in conjunction with Annex 5 [MedDO](#) and Annex V [EU-MDR](#)

¹⁵ Art. 3 para. 1 let. b [MedDO](#), Art. 4 para. 1 let. b [TPA](#)

¹⁶ Art. 4 para. 2 [MedDO](#) in conjunction with Art. 2 no. 12 [EU-MDR](#)

Products with a predominantly physical action basically fall within the scope of the MedDO, only if they have an intended medical purpose¹⁷, or are intended to have, or are presented as having, a medical use¹⁸ and may be placed on the market only if they have successfully completed the relevant conformity assessment procedure and carry a CE mark or MD mark.

3.2.2 Products without an intended medical purpose: Products listed in Annex 1 MedDO¹⁹

According to Art. 1 para. 1 let. b MedDO, the MedDO also applies to certain groups of products **without an intended medical purpose** and with a predominantly physical mode of action and listed in Annex 1 MedDO²⁰.

These include substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling (subsequently referred to as **fillers**) by subcutaneous, sub-mucous or intradermal injection or other introduction, excluding those for tattooing (Annex 1, no. 3 MedDO). For more detailed information please refer to the information sheet "Injectable products for wrinkle treatment" on the Swissmedic website²¹.

3.2.3 Products without an intended medical purpose and with a physical mode of action, but which are not medical devices listed in Annex 1 no. 3 MedDO

In the context of therapeutic products legislation, products without an intended medical purpose and with a predominantly physical mode of action, such as parenterals with a purely aesthetic purpose that are also not fillers, do not usually fall within the scope of MedDO, since they satisfy neither the legal definition according to Art. 3 para. 1 MedDO, nor the criteria stated in Annex 1 MedDO.

Such parenterals may not be placed on the market either as medical devices or as cosmetics.

In view of their invasive route of administration or mode of action, they pose risks comparable with those of medicinal products or medical devices. Due to the risk potential of these invasive products, the Expert Panel for Delimitation Questions classifies these products as being subject to the Therapeutic Products Act (TPA) (see section 4).

3.3 Transplants and transplant products

The above-mentioned products should be distinguished from

¹⁷ Art. 3 para. 1 let. c [MedDO](#)

¹⁸ Art. 4 para. 1 let. b [TPA](#)

¹⁹ <https://www.swissmedic.ch/swissmedic/en/pomz.html>

²⁰ For the transitional provisions (Art. 106 [MedDO](#)) see [information sheet MU600 00 007 MB, Products without an intended medical purpose](#)

²¹ <https://www.swissmedic.ch/swissmedic/en/home/services/questions-on-delimitation/humanbereich.html>

- Products comprising or containing living human or animal organs, tissues or cells and intended for transplantation to humans ("transplant products"²²),
- living human cells, tissues and organs intended for transplantation to humans ("transplants").

The handling of transplant products is governed by the Transplantation Act²³, the TPA and additionally by the Human Research Act (HRA)²⁴.

The handling of autologous and allogeneic²⁵ transplants is governed by the Transplantation Act and the Human Research Act.

Although the Transplantation Act does not specifically foresee medical usage in its definition of **transplant products and transplants**, the Federal Council statement to the Chambers clearly indicates that transplantation, in all its forms, is intended to replace irreversibly damaged tissues or cells by healthy ones. This also includes aesthetic and reconstructive indications, such as the regeneration of the deep layers of skin after excessive exposure to the sun or deep wrinkles.

From the legal standpoint therefore, treatments such as the injection of products based on stem cells are always subject to the Transplantation Act and, under certain conditions, to the Therapeutic Products Act, for example if the cells are subject to substantial manipulation.

Further information can be found on the Swissmedic website.²⁶

3.4 Other examples

3.4.1 "Lipolysis" products

Products that claim to have a so-called lipolytic effect (e.g. "fat-dissolving injections", "lipolysis" or "treatment of local fat deposits and cellulite") cannot be classified as cosmetics based on their intended purpose, since lipolysis is the main purpose and cannot be considered a "minor" change in physiological function (for further details, see the Borderline Manual in the section headed "Products reducing cellulite in the skin"²⁷). Furthermore, such products are generally assumed to produce a

²² Transplant products are tissues and cells that have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. Substantial manipulation processes include cultivation for cell expansion (Art. 2 para. 1 let. d of the Transplantation Ordinance). Accordingly, the following are deemed to be transplant products according to Art. 2 para. 1 let. c of the Transplantation Ordinance:

1. Products comprising or containing human organs, tissue or cells, where the organs, tissue or cells have been subject to substantial manipulation or are not intended to exercise the same function in the recipient as in the donor
2. Products comprising or containing animal organs, tissue or cells

Following this same logic, tissues and cells that are implanted in a way that changes their function in the recipient after administration are also considered to be transplant products.

²³ Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act; SR 810.21)

²⁴ Human Research Act (HRA; SR 810.30)

²⁵ **Autologous transplantation:** The donor and recipient are the same person

Allogeneic transplantation The donor and recipient of organs, tissues or cells are genetically different individuals of the same species.

²⁶ www.swissmedic.ch: [Legal framework governing the use of tissues and cells of human origin](#)

²⁷ Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009, revised version of November 2024. Link: [DocsRoom - European Commission](#)

pharmacological or metabolic effect. Since the desired effect takes place in the deeper layers of the skin, such products always have to be **injected** in order to achieve the claimed effect.

Since this is not external use, such products do not satisfy the definition of a cosmetic (Art. 53 FUAO).

These two aspects mean that the products are classified as medicinal products and may not be placed on the market in Switzerland without authorisation (and they can only be authorised for an intended medical purpose). Corresponding enforcement measures are taken under the TPA.

3.4.2 Permanent make-up (PMU), microblading and tattoos

Tattooing, permanent make-up (PMU) and microblading involve the insertion of pigments into the dermis layer of the skin, resulting in a superficial wound and the associated risk of infection.

The pigments for tattoos and PMU do not need to be licensed and fall within the scope of the FoodA. In this context, certain safety criteria are regulated in the Ordinance on Articles intended for Human Contact (HCO, SR 817.023.41).

The training of personnel who perform tattooing is not currently regulated at federal level, and no corresponding training courses are recognised. Businesses that offer tattooing or permanent make-up must be registered with the competent cantonal enforcement authority²⁸.

3.4.3 Products applied by microneedling

Microneedling is a technique in which the top layer of the skin is perforated with fine microneedles. Various devices with differing injection depths are used for this purpose (e.g. pens, rollers).

Cosmetic products may be used in microneedling only if their penetration is strictly limited to the **epidermis** (definition of a cosmetic according to Art. 53 para. 1 FUAO).

According to the latest scientific findings and the relevant legislation, a product that penetrates through deeper skin layers with this procedure – i.e. **beyond the epidermis**, may **not be classified as a cosmetic product**. In such cases, only conforming medical devices or authorised medicinal products intended for this purpose may be used, and their use is reserved exclusively for physicians who are authorised to practice their profession independently.

For cosmetic products whose penetration is strictly **limited to the epidermis**, e.g. using a derma roller, without reaching the deeper skin layers, compliance with this requirement must be verified on the basis of official documentation (e.g. in the safety report for a cosmetic product) provided by the manufacturer for each product or device used.

There are also products that are **not intended** (i.e. as claimed by the manufacturer) to be applied by microneedling. Like all other products, these are classified taking all their properties into account.

Rollers, derma pens etc. are neither cosmetics nor therapeutic products in themselves, unless they are to be used for medical purposes. Only in this latter case are they considered to be medical devices.

²⁸ <https://kantonschemiker.ch/>

The use of such devices for aesthetic purposes is not currently subject to any specific federal regulations, although cantonal provisions to the contrary may apply.

3.4.4 Other product groups without an intended medical purpose

For certain parenterally administered products with an aesthetic purpose or without a medical purpose (e.g. as in the case of certain vitamin infusions in the lifestyle sector), further clarification is needed as part of an overall assessment.

This concerns products containing one or more constituents whose pharmacological, immunological, metabolic or physical effects at the corresponding dosage have not been demonstrated scientifically and **on a product-specific basis**.

But since these are administered parenterally, they are neither foodstuffs, nutritional supplements, nor cosmetics. They are therefore subject to the provisions of therapeutic products legislation.

4 Swissmedic practice

Considering the principles of therapeutic products legislation, decisions have so far been made on a case-by-case basis in accordance with case law, taking all factors into account. For the sake of legal certainty, and in the interests of consistent and equal legal enforcement, the following procedure is established:

*Because of their risk potential (route of administration and/or mode of action), parenterals with an aesthetic purpose or without an intended medical purpose **are subject to the provisions of therapeutic products legislation** (or for transplants/transplant products also the Transplantation Act) in order to protect consumers. Before these products can be lawfully placed on the market in Switzerland, they must therefore either possess a marketing authorisation that is valid in Switzerland or have successfully completed the relevant conformity assessment procedure (CE or MD marking) in accordance with the Swiss Medical Devices Ordinance.*

Otherwise, the above-mentioned products may not be marketed in Switzerland, and the appropriate measures will be taken in accordance with the TPA.

5 Official responsibilities in enforcement

In accordance with Art. 58 TPA, Swissmedic and the other authorities entrusted with the enforcement of the Act monitor the lawful manufacture, distribution, dispensing, maintenance, and promotion of therapeutic products within the scope of their responsibilities. As well as federal law, the cantonal legislation must also be taken into account.

- Medicinal products: According to Art. 30 TPA, in addition to Swissmedic, the cantons are responsible for licensing dispensing activities and for carrying out periodic inspections of the operations and practices of dispensing points. In addition to the dispensing of therapeutic products (Art. 24 to 26 TPA), their use should also be taken into account. Only a few defined professional groups outside the medical profession are entitled to use prescription-only medicinal products for medical purposes and limited to their area of expertise (see also Art. 52 TPO).

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- Medical devices: According to Art. 76 para. 1 MedDO, Swissmedic is responsible for monitoring devices and their conformity. According to Art. 76 para. 3 MedDO, the cantons are responsible for monitoring the dispensing points.
- Product groups without an intended medical purpose: According to Art. 8 MedDO in conjunction with Annex 1 MedDO and Art. 6 para. 4 MedDO, Swissmedic has the authority to stipulate common specifications for product groups without an intended medical purpose.

The cantons are responsible for supervising their professional use.

6 Overview of marketable product categories for parenterals

Products that are administered parenterally may be placed on the market **ONLY** if they have been correctly classified and meet the legal requirements for the corresponding product category. At present, all parenterally administered products are classified under the Therapeutic Products Act, and, in some cases, also the Transplantation Act.





- Products that do not meet the requirements for the corresponding product category (non-compliant products) may not be placed on the market.
- The use of parenterally administered products as cosmetics is explicitly prohibited (see section 2.3).
- The parenteral administration of products that are not intended or envisaged for parenteral use is not permitted.

Generally speaking, the requirements of therapeutic products legislation ensure that parenterally administered products are of high quality, safe and effective in accordance with their product category²⁹.

²⁹ See [Art. 1 TPA](#), SR 812.21



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Product	Examples	Product category	Legal basis	Condition for placing on the market: If the condition is not met: illegal product
Products of chemical or biological origin (active substances)	Botox Vitamin infusions	Medicinal product	Therapeutic Products Act	<p>Medicinal product authorisation</p> <p>Pharmacological, immunological or metabolic effects at the corresponding dosage have been demonstrated on a product-specific basis and in compliance with the legislation</p> <p>Identifiable by the Swissmedic authorisation number and the pictogram for the dispensing category on the packaging:</p> <div data-bbox="1563 839 1666 943" style="display: inline-block; vertical-align: middle;">  </div> <div data-bbox="1684 839 1787 943" style="display: inline-block; vertical-align: middle;">  </div>
Substances of human or animal origin that cannot be standardised due to their properties	Serum eye drops	Non-standardised medicinal products	Therapeutic Products Act	<p>Authorisation of the manufacturing process</p> <p>Identifiable by the Swissmedic authorisation number and the pictogram for the dispensing category on the packaging:</p> <div data-bbox="1563 1214 1666 1318" style="display: inline-block; vertical-align: middle;">  </div> <div data-bbox="1684 1214 1787 1318" style="display: inline-block; vertical-align: middle;">  </div>

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Product	Examples	Product category	Legal basis	Condition for placing on the market: If the condition is not met: illegal product
Living human cells, tissues and organs intended for transplantation to humans (no substantial manipulation and no functional change).	Adipose tissue for breast enlargement	Transplants	Transplantation Act	Reporting or licensing requirement
Products comprising or containing living human or animal organs, tissue or cells (substantial manipulation or functional change)	Enzymatically prepared adipose tissue for wrinkle treatment Stromal vascular fraction for injection into the epidermis or dermis in order to improve the skin structure	Transplant products	Therapeutic Products Act Transplantation Act	Authorisation Identifiable by the Swissmedic authorisation number and the pictogram for the dispensing category on the packaging: 
Products with a predominantly physical mode of action with an intended medical purpose	Hyaluronic acid for intra-articular injection in arthritis	Medical devices	Therapeutic Products Act	Conformity assessment and marking Example for identification:  (nnnn: number of the notified body)
Certain product groups without an intended medical purpose listed in	Fillers	Medical devices	Therapeutic Products Act	Conformity assessment and marking

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Product	Examples	Product category	Legal basis	Condition for placing on the market: If the condition is not met: illegal product
Annex 1 MedDO and which contain substances with a predominantly physical mode of action				 (nnnn: number of the notified body)

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