Information sheet
Injectable products for wrinkle treatment

Identification number:	MU100_00_001
Version:	3.1
Valid from:	06.06.2023

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Injectable products for wrinkle treatment in beauty salons

Version 3.0, last revised on 1st June 2021

Wrinkle treatments involving injectable products are repeatedly being offered in beauty salons. Since the legal situation regarding these treatment methods is not always clear, leading to uncertainty on the part of both users and consumers, Swissmedic, the Swiss Agency for Therapeutic Products and the Federal Food Safety and Veterinary Office (FSVO) have compiled this information sheet.

The information sheet lists the injectable products, either classified as medicinal products or governed by the provisions of the Medical Device Ordinance, that are most commonly used to treat wrinkles. Different legal provisions apply to these products, depending on their classification. It also deals with the question of who is permitted to use what kind of product under what respective technical and operational requirements.

Due to the federal legislation, cosmeticians are either not allowed to use these products at all or only under restricted conditions.

However, the cantonal legislation must also be taken into account. For this reason, it is always advisable for cosmeticians to contact the competent cantonal health authorities (cantonal pharmacist and/or cantonal medical officer) before they use products of this kind and enquire about any additional regulations that may apply.

Classification of the different injectable products for wrinkle treatment

Although wrinkles are basically not a disease but part of the normal ageing process, injectable products used for wrinkle treatment must be classified, depending on their composition and intended use, as medicinal products or, depending on the mode of application and the associated risks, as medical devices governed by the Medical Devices Ordinance. Different legal provisions apply to these products, depending on their classification.

The main injectable substances or materials used for wrinkle treatment are botulinum toxin and hyaluronic acid, and various fillers containing non-absorbable components such as silicone, polyacrylamide or polymethyl methacrylate. Due to their pharmacological effect Botulinum toxin preparations (such as Botox) are classified as medicinal products requiring authorisation according to Art. 4 para. 1 let. a of the Therapeutic Products Act (TPA; SR 812.21). On the other hand, products containing hyaluronic acid, silicone, polyacrylamide or polymethyl methacrylate, fall under the terms of the Medical Devices Ordinance (Art. 1 para. 1 of the Medical Devices Ordinance [MedDO; SR 812.213]) due to their mainly physical effect. All injectable substances and products for wrinkle treatment are governed by the therapeutic products legislation due to their mode of application (injection). The distribution, dispensing and use of these products are therefore subject to the requirements of the therapeutic products legislation.

It is essential for injectable products containing a pharmacologically active substance (botulinum toxin, for example) to have a medical intended use to enable them to be authorised as medicinal products and to be placed on the market and used on this basis. In other words, if such products are intended not for medical but for cosmetic purposes (for wrinkle treatment, for example) they cannot be authorised for this intended use by Swissmedic. Injectable products containing pharmacologically active substances can therefore only be used for purely cosmetic purposes if an approved product (approved for a different purpose) is used on an off-label basis. In consequence, the responsibility for such unauthorised use of the medicinal product lies solely with the healthcare professional providing the treatment.

On the other hand, injectable products with a mainly physical effect (such as hyaluronic acid or silicone), are governed by the Medical Devices Ordinance in accordance with Art. 1 para. 1 let. b in conjunction with point 3 of Annex 1 of the MedDO, irrespective of whether they have a medical intended use or not. Products of such kind may therefore only be placed on the market and used if they have undergone a conformity assessment procedure and have the necessary conformity certificate (EC certificate).

Injectable products may under no circumstances be classified as cosmetic products since they do not comply with the definition of a cosmetic (cf. definition of a cosmetic product according to Art. 53 para. 1 of the Foodstuffs and Utility Articles Ordinance [FUAO; SR 817.02]). According to this definition, cosmetics are intended to come into external contact with certain parts of the human body (skin, hair system, nails, lips and genitals) or with the teeth and mucous membranes in the oral cavity. Moreover, Art. 53 para. 2 FUAO states explicitly that substances and preparations intended to be swallowed, inhaled, injected or implanted in the human body do not count as cosmetic products.

In summary, it can therefore be stated that all injectable products for wrinkle treatment in Switzerland may only be placed on the market and used, if they have either been authorised as medicinal products by Swissmedic or if they have undergone a conformity assessment procedure as stipulated in the Medical Devices Ordinance and have an EC certificate.

Who is permitted to inject or use products such as botulinum toxin preparations professionally?

Swissmedic has classified botulinum toxin preparations in dispensing category A (restricted prescription-only medicinal products) on the basis of Art. 23 TPA and Art. 40 of the Therapeutic Products Ordinance (TPO; SR 812.212.21) due to their pharmacological and toxicological effects and the associated risks for patients' health; in accordance with Art. 24 TPA in conjunction with Art. 41 TPO they may therefore be dispensed exclusively on the basis of a physician's prescription. Moreover, the Information for healthcare professionals for these preparations explicitly states that they may only be used by suitably qualified physicians who have experience with this treatment and the necessary equipment.

Art. 52 of the Therapeutic Products Ordinance contains special regulations governing the use of this kind of prescription-only product. Accordingly, anyone who wishes to use prescription-only medicinal products on their own responsibility during the exercise of their profession requires a licence from the canton in which they exercise this profession. However, under federal law, this licence – which may also list the medicinal products that the person may use professionally (Art. 52 para. 3 TPO) – may only be issued to persons who have undergone a form of training recognised at the federal level. In accordance with Art. 52 para. 2 let. a to e TPO, these includes, in addition to healthcare professionals, only persons with a Bachelor of Science (from a university of applied sciences – FH) in midwifery, a diploma in dental hygiene (from a technical college – HF), a diploma in chiropractic, a diploma in paramedic science (HF) and specialists in complementary medicine with a federal diploma.

Since cosmeticians are neither healthcare professionals, nor do they feature in the definitive list in Art. 52 para. 2 let. a to e TPO, they are not entitled to use botulinum toxin preparations or other prescription-only medicinal products in dispensing category A or B on their own responsibility professionally.

Side note: Supply of medicinal products to cosmeticians by wholesalers

Art. 2 let. l of the Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1) states that wholesalers may only transfer or provide medicinal products to persons who are authorised to trade in them, process or dispense them or use them professionally. Art. 29 para. 1 TPA in conjunction with Art. 15 para. 2 MPLO states that the rules of good distribution practice (GDP) must be followed during wholesaling activities, according to which the respective products may only be supplied to authorised recipients (point 17 of the Guidelines for GDP of medicinal products for human use). Wholesalers' duty of care therefore requires them to check periodically and in a documented and verifiable manner whether their clients hold one of the authorisations mentioned in Art. 2 let. l MPLO.

Since cosmeticians are not authorised to dispense or use prescription-only medicinal products professionally, wholesalers are not permitted to supply botulinum toxin-containing products or other prescription-only medicinal products to such persons.

Wholesalers are, however, permitted to supply cosmeticians with non-prescription medicinal products (those in dispensing categories D and E) provided they check before doing so that:

- the cosmeticians have undergone training recognised under cantonal law within the meaning of Art. 25 para. 5 TPA, and
- the legislation of the canton concerned stipulates that cosmeticians may also use the medicinal products concerned professionally.

Who is permitted to inject or use products subject to the Medical Devices Ordinance, such as hyaluronic acid, silicone, polyacrylamide or polymethyl methacrylate, professionally?

Note: The following information is based solely on federal law. However, the cantons are responsible for issuing any authorisations relating to the professional practise that may be required. Cosmeticians are therefore advised to obtain information from the cantonal pharmacist and/or cantonal medical officer in the competent canton before they begin such activities.

In including Art. 70 para. 2 and 3 and Annex 6 in the Medical Devices Ordinance, the Federal Council exercised the option granted to it under Art. 48 let. b TPA to make the use of certain medical devices with the potential to harm health dependent on fulfilment of certain technical and operational requirements.

Point 1 of Annex 6 of the MedDO imposes certain technical and operational requirements on the use of injectable products which persist in the body longer than 30 days (long-term devices). These devices may be used solely by a physician or a professional trained in accordance with the requirements stated in point 2 of Annex 6 under the direct supervision and responsibility of a physician. The requirements in point 2 of Annex 6 of the MedDO state that devices of this kind may only be used by persons with a nursing diploma who have undergone the respective further training in the injection of long-term devices.

Since point 1 of Annex 6 of the MedDO only covers the use of injectable products which persist in the human body longer than 30 days, this raises the question of whether products containing hyaluronic acid, silicone, polyacrylamide or polymethyl methacrylate are covered by this provision.

Non-absorbable products or fillers such as silicone, polyacrylamide or polymethyl methacrylate persist in the human body for a long time and are therefore definitely covered by this provision. However, this provision only applies to absorbable fillers such as hyaluronic acid if the injected material persists in the human body longer than 30 days –, i.e. if, 30 days after the injection has been given, residues of the products are still detectable in the human body. If the interval between injections is longer than 30 days, it must be assumed that components of the device also persist in the body longer than 30 days, so that point 1 of Annex 6 of the MedDO applies. On the other hand, if the interval between injections is less than 30 days, it may be possible to use the product without needing to comply with the limitations stated in point 1 of Annex 6 of the MedDO. However, this only applies if the manufacturer has been able to demonstrate scientifically that the material is fully absorbed within 30 days and this is stated in the product information.

Art. 3 TPA requires users of injectable products which are demonstrably absorbed in full by the human body no longer than 30 days after they have been administered to take all the measures required by the state of science and the art to ensure that patients' health is not endangered. In addition, they have a reporting obligation under Article 66 para. 4 MedDO in such cases. This requires them to report all serious incidents involving the use of such products to Swissmedic and the supplier without delay.

In order to fulfil these obligations and avoid endangering patients' health, Swissmedic recommends users always to undergo training in the injection of long-term devices as defined in point 2 of Annex 6 of the MedDO before starting activities of this kind and to obtain further training at regular intervals. Since some patients may experience serious undesirable reactions after injection of such substances, Swissmedic additionally advises the respective users always to use any injectable products under the direct supervision and responsibility of a physician.

Summary and conclusion:

Cosmeticians are not authorised to use botulinum toxin preparations and other prescription-only medicinal products in dispensing categories A and B professionally.

Cosmeticians are not permitted to use injectable products which are subject to the provisions of the Medical Devices Ordinance, such as hyaluronic acid, silicone, polyacrylamide or polymethyl methacrylate, professionally unless:

- these products are demonstrably absorbed in full in under 30 days and this is stated explicitly in the product information, or
- the following points are fulfilled cumulatively:
  - the products are not absorbable or which are absorbed in full over a period of more than 30 days,
  - the person using the product has a recognised nursing diploma and corresponding further training in the injection of long-term devices within the meaning of point 2 of Annex 6 of the MedDO.
  - the product is used under the direct supervision and responsibility of a physician, and
  - the cantonal legislation does not contain a different regulation that forbids cosmeticians to use such products or such invasive techniques or requires them to have an authorisation to do so.

The cantons, represented by the cantonal pharmacists and cantonal medical officers in the canton in which the activity is performed, are responsible for monitoring the dispensing and use of therapeutic products in beauty salons. The cantons are also responsible for issuing authorisations to practise the profession and can therefore determine whether cosmeticians may use these products professionally – and, if so, which ones. It is thus mandatory to contact with the cantonal authorities concerned before using injectable products. If the cantons determine during a retrospective check that the cantonal and/or federal regulations have been violated, it can result in administrative or penal proceedings.

Swissmedic recommends cosmeticians in all cases – i.e. even with regard to using injectable products which are demonstrably absorbed by the human body in no longer than 30 days after they have been injected – to undergo both training and regular further training in the injection of long-term devices as defined in point 2 of Annex 6 of the MedDO and to use the products only under the direct supervision and responsibility of a physician, thus ensuring compliance with the legal requirements governing the professional use of therapeutic products (duty of care according to Art. 3 TPA and reporting obligation according to Art. 66 para. 4 MedDO).

Change history

Version	Change	sig
3.1	New layout, no content adjustments to the previous version.	dei