Schweizerische Eidgenossenschaft
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Federal Department of Home Affairs FDHA

Federal Office of Public Health FOPH
Public Health Directorate

swissmedic

Swiss Agency for Therapeutic Products

The legal framework for therapies with fresh cells and products therefrom, as well as other cell-based products of human or animal origin

Activities or use of fresh cell therapy or products, as well as other cell-based products of human or animal origin, are subject in particular to the following legal provisions:

- **Fresh cell therapy with live animal cells** is a xenotransplantation and is subject to the Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Transplantation Act; SR 810.21). Xenotransplantation requires an authorisation from the FOPH. Granting of this authorisation is subject to strict requirements in order to exclude or minimise the risk of transmitting pathogens from animals to humans. The transplantation of human cells, tissues and organs is also subject to the Transplantation Act, which provides for appropriate authorisations from the FOPH.
- Novel types of cell therapy in which products from cells, tissues or organs are produced, referred to as **transplant products,** are subject to the Transplantation Act and the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21). This results in various licensing and marketing authorisation requirements for transplant products and their preparation in order to ensure their safety, efficacy and quality.
- The Transplantation Act does not apply to **cell extracts (without live cells) of human or animal origin.** These preparations are classified as medicinal products and are subject to the Therapeutic Products Act. Until 2010, these products for fresh cell therapy could be classified as '*magistral formulas'* (for filling a medical prescription), which exempted them from the marketing authorisation otherwise required by the TPA. As '*magistral formula'* medicinal products, these preparations were under the jurisdiction of the respective canton. With the amendment of the Therapeutic Products Act on 1 October 2010, classification of these products as *magistral formulas* is no longer possible, since the cell extracts or fragments used cannot be classified as authorised active substances according to Art. 19d of the Ordinance of 17 October 2001 on medicinal products (Ordinance on Medicinal Products, VAM; SR 812.212.21). For this reason, since then such preparations have been subject to the requirement for marketing authorisation according to Art. 9, para. 1 of the TPA. Marketing authorisation can be granted if the requirements regarding quality, safety and efficacy are met. The manufacture and distribution of such products require a license from Swissmedic. This also applies to their **import, wholesale and export.**
- If certain patients need a particular **medicinal product** that is **not authorised** in Switzerland, its **import** by a health professional requires a permit from Swissmedic for a particular case (Art. 36 Ordinance concerning Authorisations for Medicinal Products, AMBV; SR 812.212.1).
- Given the nature and origin of the starting material as well as the type of application (frequently injection), it is not possible to classify products for fresh cell therapy as **cosmetics** or, if administered orally, as **dietary supplements.**

- The **supervision and control of medical activities in clinics, practices and of medical personnel** who provide or use such treatments continue to be the responsibility of the relevant enforcement agencies of the cantons.
- **Public advertising** of the above-mentioned treatments is subject to national and cantonal legislation on the practice of medicine. Advertising of treatments with transplant products or preparations containing cell extracts must also comply with the requirements of the Ordinance of 17 October 2001 on the advertising of medicinal products (Ordinance on Advertising Medicinal Products, AWV; SR 812.212.5). This applies particularly to the advertising of such treatments on the Internet.
- For the **harvesting of fresh cells from animal fetuses or animal organs,** the provisions of the Animal Welfare Act of 16 December 2005 (Tierschutzgesetz; SR 455) and the Animal Protection Ordinance of 23 April 2008 (Tierschutzverordnung; SR 455.1) must be observed. The Federal Food Safety and Veterinary Office (FSVO) is responsible for these legal issues. The killing of animals that are not to be used as food is classified under animal experimentation and requires an appropriate permit.