Keeping an overview – What distinguishes topical medical devices from cosmetic products

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The care of the skin, the supportive prevention and the therapy of skin diseases requires different products and compositions. They range from cosmetic preparations via topical medical devices up to topical pharmaceuticals. Experience shows that the differentiation between the individual product groups, the application and the effects of the products often is ambiguous. It is difficult for consumers to figure out the complex legal backgrounds, various sources of supply and notorious publicity campaigns.

Medical devices – this sounds like science and sound effects. However do they really contain more effective components and are they of higher quality? The answer sometimes sounds quite surprising.

Approved for dermal application

Within the meaning of the German Ordinance on Medical Devices, that is to be replaced by the EU Medical Device Regulation (MDR), on 26. Mai 2020[1)], topical medical devices rather are a marginal group of class I, which is one of four classes (I, IIa, IIb, III) according to annex IX of the Regulation 93/42/EEC. The classification follows an ascending risk potential regarding the application. There is practically no potential risk involved in class I to which for instance medical instruments, nursing beds, surgical dressings etc., belong to. The following formal criteria for belonging into class I are

- no methodical risks
- low invasiveness
- no or **non-critical skin contact**
- transient use ≤ 60 minutes

For the topical products pertaining to class I the intended use mainly falls under the category "identification, prevention, monitoring, treatment or soothing of diseases". There are further intended uses for medical devices that, however, are not applicable for skin treatments involving the application of preparations listed in class I. In sum, it is the uncritical skin contact combined with prevention, treatment or soothing of diseases that is crucial to the right to exist of topical medical devices.
They can have therapeutic effects – however not within the pharmacological meaning in the manner of topical pharmaceuticals that can inhibit, stimulate or otherwise influence metabolic and biological processes (in the skin). Topical products of class I hence are more or less limited to modify the physical-chemical skin condition in such a way that a therapeutic benefit will result. It is assumed that the classes will be redefined in the context of the impending new EU Medical Devices Regulation. In substance however there will be no changes as to the following statements relating to cosmetic products.
Only in exceptions (see below) the ingredients used in topical medical devices differ from the compositions of the skin care preparations controlled by the European Cosmetic Regulation. In these skin care compositions also an “uncritical skin contact” is implied. In addition to this, banned substances are listed in the annex of the European Cosmetic Regulation. Among them are various pharmaceuticals.

Improving conditions, but no healing

The intended use of cosmetic products is the care of the skin and the improvement of the skin condition however not the healing and soothing of skin diseases. Already in the eighties, the long before well-known experience has been clinically proven which implies that skin care substances can have a major influence on the soothing of skin diseases. The term corneotherapy has been coined which describes the application of suitable cosmetic substances in the case of topical-medical indications. The difference between topical medical devices of class I and cosmetic products with similar composition only consists in the

[1] In May 2020 postponed at short notice by one year to 2021 due to the Corona pandemic (after printing of the present publication)

fact that the cosmetic sector is not entitled to use the terms soothing and healing.

Clinical studies

Medical devices are put on the market on the manufacturer's own authority. Among other preconditions, a conformity assessment procedure and in the case of topical preparations also clinical tests are required which can be applied for at the responsible higher federal authority and an ethics commission where they are also licensed. Monitoring of the products however resides within the federal state authorities.
Required tests for instance are double blind studies according to predetermined regulations. In this process the preparations are physically-chemically compared within a group of test persons versus controls and the resulting influence on a medical indication (skin anomaly, skin disease).

Effects within bounds

In cases where sufficient scientific literature relating to the effects of ingredients and composition is available, such tests can be waived; the presentation of such documentation then is deemed to be adequate – sometimes it only has to be supplied after request of the responsible authority. In comparative studies it can occur that only the trade names of the preparations are mentioned but not the composition at the time of implementing the study.
In practice, the topical treatments with medical devices or cosmetic products cannot exclude indirect influences on the physiology of the skin and the metabolism of the endogenous substances in the skin. In the final analysis, however, they are not supposed to trigger any systemic effects. The manufacturer is responsible for respective examination hereto. The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM) only is responsible for recording and following up on the measures in order to minimize the risks involved with medical devices.

Trade and sales

The topical medical devices of class I are neither subject to medical prescription nor are they available only in pharmacies. In other words, besides pharmacies they can also be sold in supermarkets, health stores, cosmetic institutes or via online stores. Precondition for selling medical devices is the "CE" label according to article 17 and annex XII of the 93/42/EEC.

CE stands for "Conformité Européenne", and only is an administrational symbol used in the EU. The sign printed on label and packaging is supposed to confirm the safety and particularly the orderly classification (conformity) into one of the mentioned risk classes. Depending on the risk class, the compliance with the respective requirements can also be confirmed by a "designated office" such as for instance the Technical Control Board in Germany – TÜV.
When sold in pharmacies, medical devices but also cosmetic products can be registered with a central pharmaceutical number (Pharmazentralnummer – PZN). What consumers usually don't know is that these numbers only are identification codes within the inventory control system of pharmacies and not related to any product features whatsoever. Nevertheless, marketing departments like to use such central pharmaceutical numbers for their campaigns. Also the statement "Without cortisone" is frequently used for promotion purposes although cortisone already is banned for the use in cosmetics according to the list of prohibited substances.

Critical ingredients

As already mentioned, the quality requirements for proofs of efficacy of the medical devices substantially differ from the strongly regulated pharmaceuticals. As far as the referred literature is accessible, it is worth studying the documentation before purchase and application.
In contrast to pharmaceuticals, the differentiation between active agents and additives is not mandatory in the list of ingredients of medical devices. Neither is there a comparable declaration of ingredients according to the INCI declaration (decreasing concentration, standardized coding) of cosmetic products. Also the principle of Good Manufacturing Practice (GMP) is not mandatory for medical devices.
The topical medical devices of class I mostly contain the same ingredients as used in cosmetic products but they are not regulated by lists of prohibited substances or their restricted use. This leads to the fact that they sometimes contain substances that already for a long time have been banned from cosmetic products. Some examples can be quoted from the past as for instance ultrasound gels that still contained the strong contact allergen methyldibromoglutaronitrile (MDBGN) as a preservative. Still today there are comparable products on the market containing this substance, such as lotions for the legs or lotions for intimate hygiene (as of 20.03.2020).
Besides the preserving but rather harmless parabens, ultrasound gels contain chloromethylisothiazolinone which also is a potent contact allergen. Its production costs are relatively

low, though. This also applies to the use of tax-advantaged alcohol (alcohol denat.) denatured with plasticizers such as phthalic acid esters. Also relatively often found is benzyl alcohol in vaginal creams. 5% aqueous potassium hydroxide solution used for the treatment of actinic keratosis also is a harmful substance but not declared as such. Sometimes a grateful description of products does not include the composition or it just incidentally mentions "contains ….as well as emulsifiers, gelling agents and stabilizers" without further details. It also occurs that there only is a list of substances that are not contained.

Misleading statements

Sales promotions quite often act carelessly – particularly in online-shops. It occurs that they claim products to be without parabens while they contain them and on top of it they may even be supplemented with MDBGN. The German consumer organization Stiftung Warentest has justifiably pointed out these serious shortcomings and requested legislation to provide equal conditions for topical medical devices and dermatics in order to improve not only the product quality but also the quality of proofs of efficacy and consumer protection. The responsible federal state authorities are simply overwhelmed with the complex issue. Consequently, such inaccurate legal framework often requires a court decision.
Concluding it should be mentioned that tooth care products are classified as cosmetic products although they should belong to the medical devices. Moreover it can be assumed that many of the skin care products when relating to their effects rather are topical medical devices in disguise which only lack the official documentation.

Medical cosmetics – what is permitted?

In the context of product names often additions from the medical terminology are borrowed. The following issues are worth mentioning:

- "Medical", "dermatological" skin care- or "dermocosmetic" skin care products do neither belong to the pharmaceuticals nor the topical medical devices but to the group of cosmetic products.
- Additions such as "medical", "med" as well as scientific grades of the manufacturer such as "Dr" or "PhD" are permitted in the product name of cosmetics as long as they are not related to a medical indication.

Similar applies to pharmaceuticals: antimycotic active agents for instance are permitted in cosmetic products as long as only the anti-dandruff effects are described but not the athlete's foot treatment.

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