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### **Sales promotion for cosmetics**

# What not to do!

Dr. Silke Granzow of Mann & Schroeder describes the points to observe if you want your cosmetics advertising to avoid falling foul of the legislation covering medicines or pharmaceuticals, or possibly the biocidal products directive, as well as what to note in the tighter attention being paid to the matter of safety evaluation.



A longside §27 of the LFGB (a German law covering the supply and quality of foodstuffs and day to day domestic items) and Article 20 of the EU cosmetics directive there are other legal regulations that impact on the promotion of cosmetic products, in particular the law forbidding unfair competition (UWG) and the law governing the promotion of medicinal products (HWG)

In §5 of the UWG all misleading activities are classified as unfair. Examples include the publication of falsified test results, alleged new products, allegedly unique products or promotions with implied product benefits.

## Cosmetics and the law governing medicinal product promotion

In which cases does the HWG impact on cosmetic products?

Advertising for cosmetic products is subject to the requirements of the HWG if they claim to cure or relieve illness, pain, physical problems or pathological suffering in animals or humans (§ 1 HWG).

However the HWG does not affect promotional messages that promise to guard against something. This means that, depending on the expressions used, either the HWG or the cosmetics directive will come into play, as in the following case:

In the dental care business tooth pastes often promise to prevent paradontosis or caries. In the case of an expressed claim to prevent the problem it is only the cosmetics directive that has to be met. On the other hand, where the product is a mouth wash, that as a pleasant side effect will often soothe inflammation inside the mouth, it is the requirements of the HWG that come into effect. §3 of the HWG regulates misleading claims in the following areas:

- Advertising that makes claims about the product which cannot be met
- 2. Misleading claims with regard to the success of the product when used
- 3. Misleading claims about any potential damaging action
- 4. Hiding of competitive activities
- 5. Misleading claims about the composition or nature of the product
- 6. Misleading claims about personal data

This means that §3 of the HWG applies to cosmetic products only in so far as claims regarding illness or physical problems are concerned. Since such claims are rather rare in the cosmetics business there is, as a rule, no conflict with the HWG.

With a few advertising claims it is much harder to decide whether they do indeed fall under the cosmetics legislation. Expressions such as "care for", "cleanse" or "purify", "perfume", "change the appearance", or "have an effect on body odours", are clearly cosmetics related. However, where do the expressions used indicate a medicinal effect or even a biocidal substance? Is, for example, a cooling gel for the legs, which can, for example, in summer promise a reduction in the swelling of tired legs, still seen as a cosmetic? Is an antibacterial facial tonic already classed as a biocide?

The deciding factor is the overwhelming objective of the product. Assessment criteria that will differentiate the product from a pharmaceutical preparation can be the way that it is sold, or the distribution outlets used, or the way it is presented and its application, the use or non-use of a typical warning regarding side effects etc. as seen on pharmaceutical packaging, or an appropriate product name or manufacturer's name, and, last but not least, the overall promotional concept. But a decisive factor is always the consumer expectation that is awoken by the product.

#### Too close to pharmaceutical advertising

Examples of promotional claims that come close to pharmaceutical advertising can be found in the following categories, as examples:

- itness and massage products:
- that act on the muscles, "promote the circulation" Foot and leg care:

 "reduces swelling", "cares for the veins", "foot care for diabetics"

Medicinal products:

– "combats psoriasis", "combats neurodermatitis"

Menopause products:

-"for a hormone balance", "intimate personal care"

Is a gel to protect blisters still seen as a cosmetic, or is it a pharmaceutical product?

Pharmaceutical products are so formulated that they are used for the prevention of illness or medical complaints (as per §2 para. 1 No. 1 of the German pharmaceuticals legislation – AMG). The wording of the law extensively covers the term "illness" and the products as "any product that even a continuous or temporary disruption of the normal state or normal activity of the body that can be healed, cured or mitigated".

Skin blisters, for example, arise from rubbing and abrasion where the upper layers of skin become loose. The space between the layers that is so produced fills with a low protein tissue fluid and causes pain and perhaps a wound. A skin blister is therefore a disruption of the body's normal state. So does a blister go beyond the normal cosmetic application?

And how is a baby cream to be assessed? E.g. a cream which enhances the massage effect with the help of essential oils of aniseed and caraway, and promises "relaxation for baby's tummy", or "a gentle tummy massage"? Is such a product still regarded as a cosmetic, or is it used mainly as a treatment for the baby's digestive problems ?

Even with aromatherapy products the borderline between cosmetics and pharmaceuticals is not easy to draw. The Kapha body lotion ("beautifully in balance") actually promotes with the message "Discover the 3 life energies of the Ayurveda Indian health cure". The Kapha cure or "dosha brings stability, composure and perseverance", but the "inspiring fragrance of the Kapha XY body lotion offers a harmonised balance. Pamper your body, your mind and your inner self" is a message that for the consumer will surely not give the impression of using a psychotropic drug.

The "Clear Head" aroma roller promises even much more: "It brings a new freshness and increased concentration. As you breathe in the essential oils you feel your mind being freed and a new power of concentration evolving". And for those who cannot fall asleep there is the Aromaroller Relax, which "brings balance and relaxation. Feel the calming effect as you breathe in the essential oils. Sleep easier!"



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### What do you need?

#### The problem of biocides

What are the borderline problems faced by the use of biocides? Products with clear written messages on the pack, such as "disinfecting", "protects against fungal infection", "kills 99.9 % of all germs and bacteria", and "antimycotic", should be labelled in line with the biocides directive. An antibacterial facial tonic for problem skin in young people is, however, not seen as a biocide, because as a rule other benefits are also promoted, such as a clear skin and a refreshed feeling, and the antibacterial action is presented as no more than a pleasant secondary benefit.

#### A deeper safety evaluation

Alongside the problem of defining the borderline, the safety aspects of commercially marketed cosmetics must be considered. Would a misunderstood promotional claim lead to incorrect use of the product, such as using it as a possible pharmaceutical or biocide, or could the product description be misunderstood, or indeed its whole look presented in a misunderstandable way?

The EU cosmetics directive 1223/2009 makes it clear in article 3 regarding safety that only products which are held to be safe in normal, predictable and careful use may be put onto the market. In agreement with the EEC directive 87/357/EWG, reference is made in particular to the overall presentation, the labelling, instructions for use and disposal, and all other data from the responsible person. Hence these criteria must be taken into careful consideration when prepar-

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A cosmetic promotional claim can quickly fall under the pharmaceutical or medicinal legislation, or the biocide directive

ing product data sheets and safety reports.

In comparison with EEC directive 76/768/EWG, which prohibits the manufacture or marketing of cosmetics which are capable of harming the health, this latest move is a stricter requirement. The objective of the EC cosmetics decree 1223/2009 is fundamentally to protect human health.

Even in the advice regarding the conducting of a safety evaluation in the EC cosmetics decree 1223/2009, appendix 1 Safety Report, part A (safety information), 5. Normal, careful and predictable use, this requirement is clearly stated: "The circumstances must, particularly with regard to warnings and other advice, be clearly explained on the label of the cosmetic product".

Also cosmetic preparations should not be so presented that they can be confused with other day-to-day items or foodstuffs. A made-up term such as "shower cream", presented in a certain way, e.g. in a cream dispenser, would be a marginally risky product, if only as a result of this overall look. The same would apply to a body lotion e.g. "Bourbon Vanilla Smoothie" body lotion in a container similar to a yoghurt pot. A shower gel or a body lotion may use the fragrance of exotic fruits, and use colour to make the fruit appealing, but should use packaging that is clearly distinguishable from beverage containers. By the use of warning notes on the pack, such as "Only for external use" or "Not suitable for human consumption" is a way that the safety of the product can be enhanced and that would be legally sufficient. However, not all consumer groups are reached with the use of such measures, e.g. children. Here additional help can be obtained by the use of a clearly unmistakeable design.

But it is not only packaging that can lead to inappropriate product use, but also creative product names. A balsam bath additive that promises "caressably tender skin" thanks to its "creamyrich formulation" would surely not be classed as potentially hazardous by the safety evaluator, but with the further promotional message "Bath and cream



Toothpastes that act to prevent paradontosis or caries are not covered by the pharmaceuticals legislation

2 in 1" it would be necessary to seriously question the overall safety aspect. Does this kind of message leads inevitably to wrong use of the product? It is possible that it is believed to be a bath additive that could also be used as cream.

What is obvious is that promises of efficacy that also involve a safety aspect must be proven in tests, such as SPF claims in the sun protection sector. The evidence of the fastest possible wrinkle reduction is of no real interest within the safety evaluation. With a children's shampoo on the other hand, that is promoted with the message "No more tears at hair washing time", the question is asked whether such a shampoo may be used too freely and so pose a safety risk.

Even though all of these examples show us where the pitfalls are, it is clear that a cosmetics package must have an appealing and unmistakeable look and it should ultimately convince the consumer to try it. It is only by way of plausibility and competence that an attractive product can survive against stiff competition.

Restrictive legal copy on the pack should not be seen as a sales handicap but rather a contribution to a sustained awareness of the product by the consumer and an objective self-assessment of the product's real performance.

The article "Promotional messages – promises and evidence of efficacy" by Dr. Silke Granzow, from COSSMA 3/2012 starting on page 14 as well as references can be found on the Internet (see Internet box)

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