BEAUTY CARE
COMPETENCE PARTNER WITHIN IKW

LETTER TO THE EDITOR of *Pharmazeutische Zeitung* of 24.05.2013

In the *Pharmazeutische Zeitung* of 09.05.2013 and in PZ Online an article under the title “Cosmetics – Pharmacists will soon be liable for errors” was published which according to IKW unfortunately leads to confusion in various respects concerning the content of the new European Cosmetics Regulation. In order to avoid misunderstandings at the interpretation of the Regulation amongst your readers, IKW would like to clarify several points.

Your report first of all gives the wrong impression that the EC Cosmetics Regulation creates basically new responsibilities for pharmacies at the distribution of cosmetic products. As a matter of fact the EC Cosmetics Regulation now contains detailed provisions on the responsibilities of “persons responsible” for the placing on the market of cosmetic products on the one hand, and the “retailers” involved in the distribution chain on the other hand. In practice, these new provisions result, however, in hardly any changes because pharmacies, as well as all other companies involved in the distribution chain of cosmetic products, were responsible in accordance with the EC Cosmetics Directive (as well as the German Food and Feed Code and the German Cosmetics Ordinance) in their respective sphere of responsibility for compliance with the statutory provisions. In terms of content, the new Regulation referred to in the above-mentioned article has only one novelty according to which the retailers have to check prior to the dispensing of cosmetic products whether a possibly labelled date of minimum durability has expired or not.

Another misleading statement is that the “name and address of the responsible person of the manufacturer” has to be labelled on the package. The “responsible person” within the meaning of the Cosmetics Regulation is not an actual person who is employed by a company distributing a cosmetic product. The “responsible person” is rather a “legal entity”, ie the company itself which takes over responsibility for compliance with the basic provisions under cosmetics law through the indication of its company name and address on the package in a visible manner.

In view of the duties of notification of “side effects”, which also concern the trade when they come to its knowledge, it needs to be taken into account that these obligations exist only in the event of “serious undesirable effects”, “which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death”. Such cases are, of course, extremely rare for cosmetic products. In case of doubt, it always makes sense for the pharmacy which is informed by its customers about problems at the application of cosmetic products to inform the “responsible person” mentioned on the package. With the latter’s help the question of duty of notification of the competent authority can also be checked, if necessary.

As opposed to the impression given by the above-mentioned article, there is only a need for changes concerning the labelling in respect of the deadline 11 July 2013 for an extremely low number of cosmetic products. The statutory provisions in accordance with which only certain labelling elements (such as warnings) must be written in German remains unchanged, whereas eg the list of ingredients is marked in accordance with the uniform European “INCI” nomenclature.

What is new here, is above all the obligation to identify nanomaterials in the INCI list by adding "(nano)". The analytics of nanoparticles in cosmetic finished products is, however, still a major challenge. Whether it can be met will only be known from the public authority's point of view once nanomaterials have been defined in a precise and binding manner. According to IKW, it would anyway be fully disproportionate if there were a destruction of values of products which are completely safe for consumers on the shelves due to this Regulation in summer 2013. It is only established in that respect that by the cut-off date in July, there will be no German implementation provision which would, more particularly, specify a penalty catalogue for infringements of the provisions of the EC Cosmetics Regulation. So far not even a draft is available.

Comprehensive support at the interpretation of these provisions is provided by the Colipa Guideline on "Responsibilities within the Supply Chain" and on the "Labelling of Cosmetic Products" which are published in a German translation by IKW on its website www.schoenheitspflege.org in the section "Themen" under "Recht: Infos für Hersteller" in a German translation.

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