New regulations will affect the relationship between manufacturers and distributors of cosmetic products

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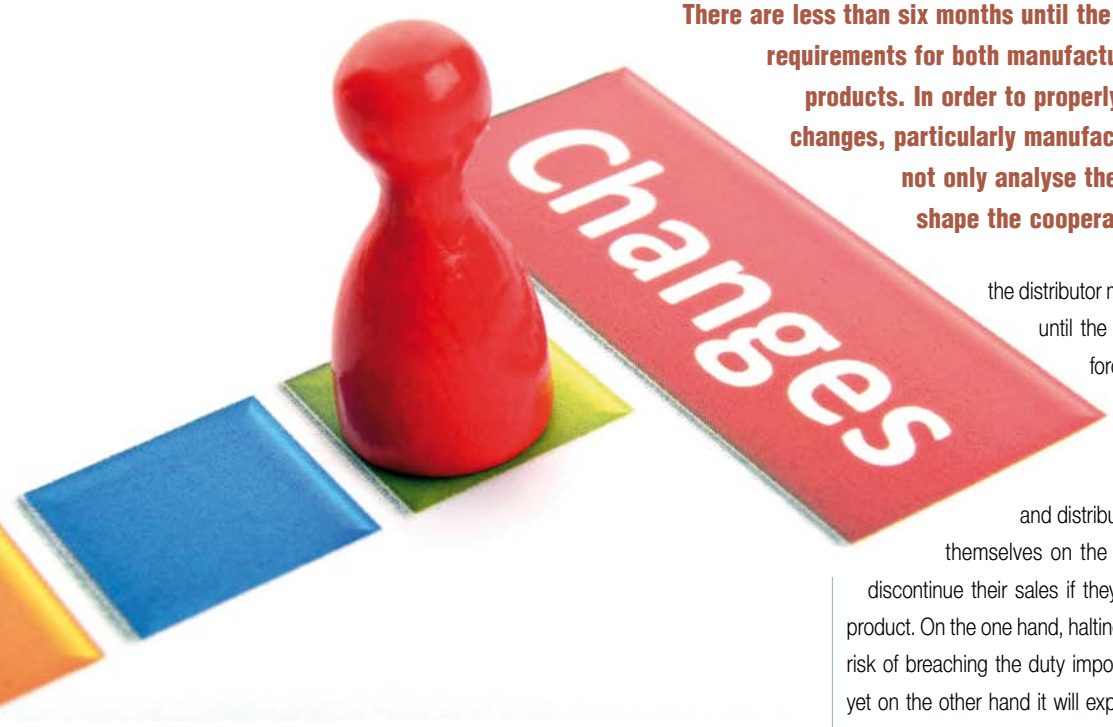

There are less than six months until the introduction of several new legal requirements for both manufacturers and distributors of cosmetic products. In order to properly prepare their businesses for the changes, particularly manufacturers of cosmetic products must not only analyse their operations but also adequately shape the cooperation with their business partners.

Early morning on 11 July 2013 manufacturers and distributors of cosmetic products will wake up to a new legal reality. The scale of changes is reflected in an increased volume of the regulations. Compared to the current Act on Cosmetics, the new regulation (without annexes) will contain 100% provisions more. The new regulations will not only define the current duties in more detail, but also impose a number of new requirements. The purpose of this article is to present exemplified regulations that significantly affect the relationship between manufacturers and distributors, and to identify solutions to enhance legal safety of the conducted activity.

Halting product distribution

One of the main purposes of the new regulation is to ensure a high level of human health protection. Thus, both the manufacturer/responsible person1 and the distributor must pay attention whether the cosmetic products they offer fulfil the requirements. If the products are found not to comply with the regulations, the distributor must among other things halt the distribution until the products comply with the requirements in force. Such a situation may occur for instance if the packaging indicates incorrect details of the responsible person.

As a result of the duties of manufacturers and distributors being so shaped, distributors may find themselves on the horns of a dilemma whether they should discontinue their sales if they have doubts as to legal compliance of a product. On the one hand, halting the distribution will allow them to avoid the risk of breaching the duty imposed under Regulation (EC) No 1223/2009, yet on the other hand it will expose them to direct financial losses in case of unjustified actions. A decision to halt the distribution will obviously impact the business of the manufacturer. The described problem may prove to be important especially in terms of the relationship between businesses operating in different countries (for example, a French manufacturer selling cosmetic products to a Polish distributor). The practice of the administration authorities in different Member States may differ considerably. The labelling in the Member State of the manufacturer may be regarded by local authorities as correct while in the Member State of the registered office of the distributor it would be questioned, at least initially, which entails additional doubts and risks.

The above issues lead to a conclusion that the existing agreements in the manufacturer – distributor relationship require a detailed analysis or need additional provisions to regulate steps to be taken in case of doubts as to compliance of products with regulations. Consideration should be particularly made of:

- the manner of clarifying doubts whether the cosmetic products being the subject-matter of the agreement fulfil the requirements;

[1] It is worth noting that, in general, for cosmetic products manufactured within the Community (and not exported or imported back to the Community), the responsible person will implicitly be the manufacturer established within the Community unless it designates, by written mandate, another legal person or individual to act as the responsible person. Therefore, all comments on the manufacturer will further on apply to a situation where the manufacturer is concurrently the person responsible for its cosmetic products.

- the arrangements concerning remedy measures to be taken (for example, guidelines defining the acceptable level of interference in product labelling by the distributor); and
- the contractual penalties if the distribution is halted without sound reason.

Serious undesirable effects

Yet another area of changes are the duties relating to all signals about adverse reaction to cosmetic products. The requirements concerning the notification of serious undesirable effects apply to both distributors and manufacturers. Serious undesirable effects must be reported by these entities to competent administration authorities. The scope of information that must mandatorily be reported has been defined broadly since it includes not only information which is known to the entity but also information which may reasonably be expected to be known to the said entity. Such wording leaves a lot of discretion in evaluating whether a given entity fulfilled its duties.

The above problem may easily have relevance in the manufacturer – distributor relationship. Naturally, these two entities exchange a lot of trading information, including information relating to product opinions. This may also include information about events qualified as serious undesirable effects, for example the distributor being notified by a customer about the occurrence of undesirable effects after the application of the product. The source of potential problems may be incorrect communication, for example the distributor sending a communication to the e-mail address of the manufacturer's employee who has been on a long parental leave. There are doubts whether in such a situation the manufacturer could have reasonably been expected to know and thus report a serious undesirable effect? The decision of the public administration authority is difficult to foresee. Measures may however be indicated to mitigate legal risk. For example, one of the solutions would be to draw up relevant clauses to agreements concluded with distributors to provide clearly how to communicate information that may concern serious undesirable effects and which will concurrently obligate the other party to the agreement to act strictly in accordance with the accepted procedure. Once such actions have been taken, it will be much easier to substantiate before the competent authorities that in the analysed situation the entity did fulfil its duties and it could have not been expected to know about the notification of serious undesirable effects.

Personal data protection

The issue concerning the duty to report severe undesirable effects is closely related to yet another area of legal regulations which will become increasingly important for the cosmetic products sector. Information about side effects of cosmetic products communicated by customers will often not be qualified as serious undesirable effects. However, such information will be very often related to the health condition and will contain customer data, such as for instance name and surname, address, e-mail address. This means that in order to process these data, personal data protection requirements will have to be fulfilled. These requirements are very restrictive since often they will concern the so-called sensitive personal data (relating among other things to the health condition). It should be emphasized that the requirements for this type of data are not identical with the requirements when gathering ordinary personal data (for example when filling in consumer questionnaires or marketing forms). It is important to be ready in advance to receive such personal data, by knowing applicable legal requirements and establishing relevant company operating procedures.

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In the manufacturer-distributor contractual relationship, an issue that is also worth noting is the exchange of personal data, particularly sensitive data, which will allow avoiding situations when the processing of information would expose both the disclosing party and the recipient to legal liability. This is particularly important in terms of the sanctions which may be imposed in Poland for breach of personal data protection regulations since the Act on Personal Data Protection sets forth restrictive penalties, including deprivation of liberty.

Sanctions in Poland

Notwithstanding the sanctions under the personal data protection regulations, all parties interested in the cosmetics sector are waiting for the identification of sanctions for breach of Regulation (EC) No 1223/2009. The interest in this matter is understandable, particularly considering the lack of clarity as to interpretation of the duties imposed under new regulations. Apart from the generally described powers of the administration authorities, for instance powers to order withdrawal of a given product from the market, Member States are obligated to establish appropriate sanctions. However, as at the end of January 2013, according to the information from the Office of the Chief Sanitary Inspector Office, work is currently only at an early stage in the legislative process. This means that it is difficult to define precisely at present what sanctions will be established and when they are going to be adopted in Poland.

Summary

In order to fulfil new requirements and meet business targets at the same time, it will be necessary not only to implement changes in one's own company but also to optimally shape cooperation with business partners. In practice, this means that existing procedures will have to be reviewed or new procedures will have to be established. The existing and future agreements with business partners should also be analysed. There are less than six months to take relevant action.

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Analyses and recommendations for entrepreneurs regarding the new legal norms for cosmetics can also be found at http://blog.dzp.pl/pharma.