

# The assignation of responsibility

Continuing our series on what to know when breaking into the EU cosmetic market, **Tadej Feregotto** examines the concept of the EU Responsible Person.



**T**he EU regulation 1223/2009 that came into force in 2013 established the notion of a Responsible Person (RP) for cosmetic products placed on the EU market.

Only cosmetic products that have an RP can be placed on the EU market. Furthermore, there can only be one RP per product for the whole of the EU and their name and address have to appear on the product label.

## Tasks

The primary task of the RP is to ensure compliance of the cosmetic product placed on the market with the EU cosmetics regulation. More specifically, the RP has to ensure compliance of the product with no less than 16 different articles from the regulation. Among these, the RP has to ensure that the product is produced according to the relevant GMP (Good Manufacturing Practices) standard; that the safety assessment has been carried out; that the PIF (Product Information File) for the product is compiled and is compliant with the regulation; that no animal testing has been performed; and they must also ensure compliance with the articles on sampling and analysis and restricted substances.

In addition, the RP has to perform the notification to the CPNP (Cosmetic Products Notification Portal); ensure that the product labels are according to the regulation and that the claims made are substantiated; provide access to the information for the public (if necessary); and communicate any undesirable or serious undesirable effects to the competent authorities.

## Contact point

The RP acts as the contact point for any EU competent authorities (usually different ministries of health) and has to keep the PIF file at the address specified on the labels. In case of any non-conformity, the RP has to take appropriate measures, including product recall from the market or taking any corrective action to bring the product into conformity. On request of the competent authorities, the RP has to cooperate with them to eliminate any risk posed by the cosmetic product.

According to the regulation, the RP can be any legal or natural person who is based within the EU. If the manufacturer is from the EU, they usually act as the RP themselves. Cosmetics manufacturers from outside of the EU can't act as the RP themselves, unless they also have a branch in the EU. They can either appoint their importer or a distributor as the RP, which is not recommended, since the RP has to keep the product information file and all the product secrets with it; or they can appoint a third person or a company (such as CE.way) to act as the RP. This person or company must accept this role in writing. **PB**

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