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Communication

The Regulation of Personalized Cosmetics in the EU

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Abstract: Personalized or customized cosmetics are increasing in popularity. While compliance with the EU Cosmetics Regulation 1223/2009 is mandatory, there are no clear guidelines to ensure their compliance. While cosmetic products are subject to numerous regulations, permitting their sale within the European Single Market, this article focusses on the requirements of the Cosmetics Regulation 1223/2009. Certain provisions of the Regulation are considered and possible solutions proposed to enable the safe use of personalized cosmetics placed on the market.

Keywords: cosmetic; compliance; regulatory

1. Introduction

It is a widely established trend that consumers like to personalize their cosmetic products. They want to choose the ingredients in the product according to their skin or hair characteristics with the idea of having unique products that are more effective than off-the-shelf products.

The legal framework for cosmetics in the European Union (EU) is Regulation 1223/2009 (the Regulation) [1]. While the Regulation does not explicitly mention or address personalized products, if the definition of cosmetic is met (a product intended to be placed in contact with the external parts of the human body with the intention of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours), then the product must comply with the Regulation.

This poses several challenges to retailers and/or manufacturers. These include ensuring good manufacturing practice (including the identification of manufacturing site or sites) and assessing the safety of a product that has a variable composition.

2. How are Personalized Cosmetics Manufactured?

Personalized cosmetic products can be produced in many ways. One of the most common is by classical manufacturing facilities. The customer completes an online questionnaire choosing their preferred properties; the product is then manufactured and shipped to the home.

Another very popular method is in retail stores that offer the possibility of blending the product on-site at the point of purchase.

Domestic blending devices are also available on the market. These devices mix the contents of several cartridges containing a base cream and cosmetic active ingredients in the proportion determined to be optimal for the customer according to their skin characteristics. The final formula and mixing concentrations are designed before the device and cartridges are sent to the customer, so the customer receives a cosmetic kit.

Finally, personalization can be achieved by adding active ingredients or boosters to regularly used cosmetic products (e.g., a few drops of Vitamin C added to a regular moisturising cream).

3. How to Achieve Regulatory Compliance?

As the Regulation 1223/2009 states, "for each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations" set out in the Regulation. Personalized cosmetic products must comply with several Articles in the Regulation, as below. Not all Articles of the Regulation are scrutinized in this article.

3.1. Article 8 of the Cosmetics Regulation: Good Manufacturing Practice

Cosmetic manufacturing facilities must work according to good manufacturing practice (GMP). This ought not to present a challenge to products formulated or manufactured in regular manufacturing facilities (i.e., personalized products that are purchased online).

However, the challenge is significant when preparing the cosmetic product *in situ* (i.e., at the retailer's store). If a device is used, the device becomes the "manufacturing facility" and should thus comply with good manufacturing practices. This means the device should be regularly calibrated and standardized in order to ensure that volumes dispensed are accurate and consistent. Devices should also be kept in a good hygienic condition and people using the device should be adequately trained to ensure proper use and maintenance.

If no device is being used, but a person is preparing the product at the store, efforts should be directed towards ensuring that person is properly trained, dispensing materials are calibrated and the environment is clean.

If the device is used at home, a high level of automation is expected, but GMP compliance is still expected (again, the device becomes the manufacturing facility). The device should be designed to ensure accuracy and hygiene when manipulated by the consumer at home. Additionally, clear and accurate directions for use should be provided to the consumer to ensure the manufacturing process results in a safe cosmetic product.

3.2. Article 10 of the Cosmetics Regulation: Safety Assessment

A safety assessment must be performed prior to placing a cosmetic product on the market, that is, before the customer takes the product home or the product is received at home.

If the customized cosmetic product is ordered online and shipped home, the timeframe is manageable, as the product's composition is well known before the final product reaches the consumer and the safety assessment can be prepared in advance.

A bigger challenge exists if the exact product composition is not known in advance, i.e., if the product is designed and blended at the retail store. In this case, Responsible Persons should be able to foresee all possible combinations of ingredients their cosmetic products can have and prepare a safety assessment for each combination, so than any possible product they place on the market is covered. Using concentration ranges for the safety assessment is a possibility, but this approach becomes unfeasible if variable concentrations are possible for more than one ingredient, as ingredient interactions become challenging to predict. Alternatively, a good IT tool to perform the safety assessment *in situ* might be the solution, but some limitations exist, e.g., the time needed to complete the assessment and the need of a safety assessor to sign the document. Nevertheless, a safety issue may arise with this type of product (blended at the retailer's store): Microbiological quality of the product will most probably not be checked, due to practical reasons, and it is therefore questionable if a safety assessor will consider a product is safe if these data are lacking.

When a device is used at home, the final product composition after mixing the contents of the several cartridges will be known. As already mentioned above, this can be considered a cosmetic kit and therefore a safety assessment can be performed before the product reaches the consumer.

Finally, when actives or boosters are used, important safety issues may arise. Actives or boosters should have their own safety assessment (as they represent individual products) before they are placed on the market, but an additional assessment is needed for the product resulting from the combination

of the active or booster with the regular cosmetic product (which we can call the "base"). If the base and booster are manufactured by the same brand, then the properties of the resulting combination can be anticipated, and the safety assessment can be performed in advance. However, if the base is manufactured by another brand, such an approach is limited. Therefore, a safety assessment is unlikely to be performed for such a combination, and the resulting product is non-compliant (and more importantly, may have associated safety issues). Thus, if actives or boosters are to be marketed, they should be prescribed for their use only with bases manufactured by the same brand, unless those brands co-operate. As a confirmation, in July 2017, the ANSM (the French National Agency for the Safety of Medicines and Health Products) published a warning letter [2] regarding the placing on the market of this type of product, highlighting the need to perform an appropriate safety assessment of the resulting mixture.

3.3. Article 12 of the Cosmetics Regulation: Sampling and Analysis

Assuming sampling and analysis of the cosmetic product after manufacturing is performed "in a reliable and reproducible manner" as required by the Regulation, the challenge is space and capacity limitations if a sample of each manufactured batch must be kept.

In regular manufacturing facilities as well as with products blended at the retail store, numerous small batches will be produced instead of one single big batch: each manufacture for every single customer will be a different batch. If a sample of each batch must be kept then the question is, is there enough storage room? This might be easier to solve for big manufacturing facilities, but not so straightforward for a retail store.

If a domestic device is used, batches of the individual components to be mixed will be sampled and stored by the manufacturer at their facilities, which should be possible as bigger batches of each cartridge can be produced. The same applies to actives or boosters. In these two cases, no sampling will be performed for the finished product (the one resulting from the mixture of the different components): As the product is used immediately after mixing, there is no product left for storage that could have any stability issues.

3.4. Article 13 of the Cosmetics Regulation: CPNP Notification

As for the safety assessment, a notification, via the Cosmetic Product Notification Portal (CPNP), must be submitted prior to placing the cosmetic product on the market.

If all ingredient combinations can be predicted or are known, then product notifications can be prepared in advance. This is straightforward for products purchased online and for products prepared at the retail store if all possible ingredient combinations are known in advance; the decision in the latter case is whether to notify exact ingredient combinations (which means several different notifications) or to notify ingredient ranges (which would allow a single notification to be performed covering several products).

For products blended at home, if we consider them as a kit, then notification is achievable in advance.

For actives or boosters, they can be notified as single components; notification of the finished product (after mixing with the base) will only be possible if products from the same brand are used or if brands co-operate and disclose ingredients.

Nevertheless, the possibility of customizing product labels might turn notification into a bigger challenge than expected. As for the PIF (Product Information File), if labels are the same for equal compositions, only a single notification will be needed for a given product. But if product labels are also customized, then different labels represent different products, even for the same formula. Therefore, separate notifications will be needed. This applies to different ways of manufacturing personalized cosmetics.

3.5. Article 19 of the Cosmetics Regulation: Labelling

According to the Regulation, cosmetic products must include the following items in the product label: Responsible Person details, country of origin (if outside the EU), nominal content, date of minimum durability or Period After Opening (PAO), precautions and directions for use, batch number, function of the product and list of ingredients.

This should pose no problems for products manufactured at regular facilities, as the timeframe allows for an appropriate label design.

For products blended at the retail store, labelling must be done *in situ*, which means assigning a batch number, an expiry date and personalizing directions for use and warnings, if necessary, at the moment of purchase. Ingredients must also be correctly listed, according to the product's composition. Achieving this could be facilitated by an IT tool.

Finally, for products blended with a domestic device and for products resulting from the mix of an active or booster with a base cream, no product labelling will be necessary for the finished product, as only ready-to-use amounts are produced and thus there is no need to package the final mixture.

3.6. Article 23 of the Cosmetics Regulation: Communication of Serious Undesirable Effects

As defined in the Regulation, a serious undesirable effect is an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product resulting in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death

In the event of a serious undesirable effect the affected consumer will most probably contact the Responsible Person or the sale point where the cosmetic product was purchased, who must then notify the effect to the competent authority. If standard operating procedures should be in place to deal with these issues.

The challenge for actives or boosters that have been mixed with a base from a different brand, is that it is difficult to determine what is responsible for the adverse effect: is it the active or booster or the base cream?

3.7. Other Articles of the Cosmetics Regulation

The Responsible Person must also ensure compliance with some additional Articles in the Regulation, which are mentioned below. They have not been reviewed in-depth in this article, as compliance is more straightforward (can be planned in advance) and poses no major challenges.

Article 3: A cosmetic product shall be safe for human health taking into account presentation, labelling and instructions for use.

Articles 14 to 17: No banned ingredients or ingredients above restricted levels shall be used when formulating a cosmetic product.

Article 18: Products must comply with the animal testing ban.

Article 20: Claims used in cosmetic product shall be supported by the appropriate evidence and shall be compliant with Regulation 655/2013 on cosmetic claims [3].

Articles 21 and 24: Information on the product's composition and existing data on (serious) undesirable effects shall be made publicly accessible.

4. Conclusions

Fulfilling the legal obligations for personalized products can be challenging, but with the correct strategy, compliance is achievable for most situations. Of all the possibilities to place a personalized cosmetic product on the market (online purchase with manufacture at regular facilities; blending on-site at the retail store; blending with a domestic device; mixing actives or boosters with a base cosmetic), not all easily ensure compliance.

A new, updated guideline, that incorporates the unique challenges that personalized cosmetics pose, should enable consistent best practice for the Single Market. At the very least the guidance should identify all possible methods of manufacture and supply and tackle each scenario with reference to aspects of safety to the consumer giving manufacturers a clear and practical pathway to ensure compliance.

In the absence, yet, of such a guideline, only online purchase and the use of domestic devices appear to satisfy the aforementioned provisions of the Regulation. These methods allow control over product composition and the timely performance of safety assessment and product notification. On the contrary, on-site manufacturing (at the retail store) poses higher compliance and safety challenges. In addition, the use of actives or boosters, unless mixed with the base which is from the same or a co-operating brand (and thus the composition is disclosed), is unlikely to be compliant.

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