Cosmetic Products Packaged in Vials/Ampoules/Syringes: An Information Sharing Paper

Introduction

From the 31st Meeting of ASEAN Cosmetic Scientific Body (ACSB) in Muntinlupa City, Philippines on 13 November 2019, an issue was raised regarding the regulation of cosmetic products that are packaged in vials or ampoules (Vials/Ampoules). A Technical Working Group (TWG) consisting of Thailand, Malaysia, Indonesia and ACA was established to develop the guideline by considering the nature of the cosmetic products for National Regulatory Authorities (NRAs) of ASEAN Member States (AMS).

Objective

This document is intended to be used as an information sharing paper for the NRAs and shares the outcome of the information gathered by the Technical Working Group on Cosmetic Products Packaged in Vials/Ampoules. Its purpose is to share the finding from a survey what the AMS currently practice with regard to the regulation of Cosmetic Products Packaged in Vials/Ampoules/Syringes but also to provide recommendations to mitigate misuse of such products. This document shall not constitute a guideline or reference on regulating cosmetic products packaged in vials/ampoules/ syringes AMS. Nothing in this document shall restrict the NRA from instituting additional regulatory mechanisms to ensure the proper implementation of the ACD in the local context.

Based on the Post Market Surveillance (PMS) activity, it was found that products packed in vial/ampoule/syringes are usually preservative-free and therefore are packaged in this manner so as to maintain stability, protect from contamination and humidity as well as the oxidative effects of air. Parenterally administered products are not classified as cosmetic product.

A survey of cosmetic products packaged in vials and ampoules

A survey was conducted by emailing a questionnaire to the AMS and industry, in two phases. First, TWG responded to the questionnaire between March-August 2020. Second, the AMS responded to the questionnaire between October 2020-January 2021. The questionnaire requested for current information regarding cosmetic products packaged in vials and ampoules, including product categorization, number of imported cosmetic products that are packaged in vials or ampoules, current measures, pre- and post-marketing measures, procedures upon arrival at the custom, and clarification on the definition of cosmetics product.

Results and Discussion

The results of the questionnaire survey are shown in Appendix 1.

Cosmetic products in vials or ampoules which are packed in the sterile product-like packaging are considered as high-risk cosmetic products by respondents including Brunei Darussalam, Lao PDR, Indonesia, Malaysia, and Thailand.

Pre-Marketing Measures

With regard to the current notification and labelling requirement of cosmetic products in vials or ampoules, some AMS countries request product information, while others request primary and secondary labeling and packaging information. The survey indicated that the practices are not consistent across AMS.

Post-Marketing Measures

The member countries screen the information provided on the label. From this label verification exercise it was found that the products were mostly for topical or external application on skin or hair. In certain countries, most products are sold/supplied through beauty salons, aesthetic clinics or online. In addition, very brief information was found on company's website, and most will require potential customer to contact the company for product detail or offered service. The actual application method can only be confirmed when complaints are received from consumers or via direct information from the product vendor. It is a great challenge for the authority to verify the actual product use. Upon finding that the notified products are delivered through parenteral approach the product notification is cancelled and the product removed from the market. Product Information File (PIF) audits are also carried out, if necessary. At the customs, the procedures are similar to the process for other cosmetic products. The custom agents in some countries may inspect the product labeling, primary & secondary packaging, or all the necessary documents in accordance with the product notification. Further enquiry is initiated as needed.

Safety evaluation for both cosmetic ingredients and finished product must be done (ACD Article 3) to ensure that a particular product is safe within the predefined scope of cosmetic use. The product should not be used for parenteral administration. As stated in the ASEAN Guidelines for Safety Evaluation of Cosmetic Product, the selection of adequate packaging is important to maintain the quality of the product.

The rationale to justify the use of vials and ampoules are as follows:

1) conservation of product stability, 2) enable formula innovations, 3) reduce the risk of contamination due to the single use format, 4) maintains the integrity, hygiene and therefore quality of the product, 5) ensure use of right amount of product by consumers, 6) better formula-packaging compatibility, 7) connote innovation, novelty or premium, 8) facilitate inventory control, 9) offer convenience to the consumers, and 10) sensible trial or sampling format.

Conclusion

From the questionnaire survey, the results showed that there are regulatory practices to ensure consumers safety of the cosmetics packaged in Vials/Ampoules/Syringes.

Clear and detailed directions or usage instructions and warnings/symbols such as “For External Use Only”, “For Professional Use”, and active post- marketing surveillance to ensure proper usage and prevent misuse and misrepresentation, should be considered. Use instructions, particularly for products that will be used by consumers at home without professional supervision, should be adequately provided.

With regard to pre-marketing measures, requests of submission of label artwork or full picture of the cosmetic products total packaging, only if necessary, may assist in the clarification of product use directions. This will also allow regulators to have an overall assessment whether the product presented is a cosmetic or not.

The post-marketing may include carefully reviewing of such packaging (such as glass vials with (rubber) stoppers, ampoules, syringe). The applicant should be asked to provide clear information that product complies with the definition of cosmetics. Additional safety information to educate consumers may assist to avoid unintentional misuse.

The post-marketing measures may include requiring relevant technical documents or relevant SOP to ensure proper use of these products. More effective enforcement of post-market surveillance for intentional misrepresentation may assist in the proper usage. The availability of the Product Information File (PIF) for audit could assist in assessing proper usage requirement. Other additional technical information from the manufacturer/importer could also illustrate the need of the products to be packaged products in vial, ampoule, and/or pre-filled syringe-like as well as to indicate that the product is categorized as cosmetic.

Appendix

1. Information regarding the cosmetic products that are packaged in vials and ampoules.
2. Summary from questionnaire response.