Notice

Regulatory Guideline of Cosmetics Vigilance

Year 2022

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Introduction

What is cosmetic vigilance?

It can be defined as a collection, evaluation and monitoring of spontaneous reports of undesirable events (including serious undesirable events (SUE)) observed during or after normal or reasonably foreseeable use of a cosmetic product. Spontaneous reporting gives meaningful indication on reporting rates, which are useful indicators to identify and describe possible signals.

Each company must have a set of valid procedures to enable it to respond appropriately to all the reports of undesirable effects covering their recording and assessment and understanding their nature and future prevention. For companies, this plays an important role in the post-marketing surveillance of cosmetic products and their performance in the marketplace.

Egyptian Pharmaceutical Vigilance Center (EPVC)

The Egyptian Pharmaceutical Vigilance Center (General administration for pharmaceutical vigilance) has been established in December 2009 in line with the global trend to strengthen the rules governing pharmacovigilance.

It is the national center in Egypt responsible for monitoring the safety of pharmaceutical products, medical devices and cosmetics throughout its life cycle. It also represents the regulatory body for pharmaceutical companies for subjects related to the field of pharmaceutical vigilance.

Preface

The main purpose of Market Surveillance is to maintain the protection of health of cosmetics users by monitoring the occurrence and reducing the likelihood of reoccurrence of Undesirable Effects (UE). Following these guidelines will allow responsible entities and distributors to demonstrate compliance with the legal requirements and provide the public and the Egyptian Drug Authority with confidence on the credibility and accuracy of the data supplied, whilst at the same time protecting the privacy of the healthcare professional and their relationship with the individual consumer.

Scope

Compliance with the Egyptian regulatory guidelines for cosmetics requires the identification of the possible sources of information on undesirable effects and

serious undesirable effects. The Egyptian Drug Authority shall be informed immediately with the serious undesirable events that occur within Egypt upon receipt within a maximum of twenty days. Other sources of information may include studies published, international scientific articles or Egyptian media.

The company owning the cosmetic product must keep reports of serious undesirable events which are believed to be caused by the cosmetic product and revealed during post-marketing or other surveys, which are commissioned by the manufacturer, brand owner, or requested by Egyptian Drug Authority, provided that these reports shall be compiled into a Cosmetics Product Safety Report (CPSR)

The company owning the cosmetic product must also report any serious undesirable events discovered through these resources immediately upon being aware of them within maximum twenty days if these undesirable events took place in Egypt.

Management of the undesirable effects

The company owning the cosmetic product should ensure that an appropriate management system of suspected undesirable effect reports is in place, in order to ensure responsibility and accountability for its cosmetic products and that appropriate action can be taken, when necessary. These actions include informing the Egyptian Drug Authority immediately upon receipt within a maximum of twenty days from the date of being aware of it. Accordingly, Each Product owner (Cosmetic products company) should specify the name of one person to be in contact with the general administration for pharmaceutical Vigilance (EPVC), and provide his/her contact details.

Responsibilities of the company owning the cosmetic product:

- Record all contacts in relation to undesirable events
- Determine which undesirable events are “genuine” undesirable events
- Document, investigate, validate and evaluate cases that fulfill the criteria to be classified as undesirable effects in accordance with the Regulation
- Classifying these documented reports in terms of causal relationship.
- Identify the cases that fulfill the criteria to be classified as "serious" and report them to the Egyptian Drug Authority.

- Store the documentation of each report.
- Evaluate this information in terms of frequency, medical significance and causes.
- Ensure that healthcare professionals' and/or consumers' privacy protection is maintained.
- Include updated and substantiated relevant information into the Cosmetic Product Safety Report.
- Be in position to answer questions addressed by the EDA and/or the public under the requirements of the Regulation.

Monitoring of undesirable effects

The company owning the cosmetic product is responsible for enrolling the individual cases of serious, undesirable effects in the Cosmetics Product Safety Report, provided that the safety reports shall be available, at the level of product classes, product categories or at individual product level. This can facilitate data analysis actions and the identification of trends or signals. Similarly, separate analysis and evaluation of Undesirable Effects medically validated from with non-medically validated cases should be considered.

Cosmetics Product Safety Report

The Cosmetic Product Safety Report (CPSR) requires the inclusion of: "All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data." This requirement affects all UEs and SUEs reported to the Product owner, except if the causality assessment between the product and the SUE/UE is 'excluded'. If there is a disagreement between the Product owner and the EDA on the outcome of a causality assessment, this should be mentioned. Different levels of causality assessment should be detailed separately in the Cosmetic Product Safety Report. This report shall be submitted upon request by the Egyptian Drug Authority.

This regulatory guideline for companies owning cosmetics has been developed to

clarify the most important responsibilities and requirements for pharmaceutical vigilance in Egypt, in line with the international guidelines in this field.

For full details, definitions and forms to be used, please refer to the English version EDA Cosmetovigilance Guidelines 2022.