الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidelines on Reporting Undesirable Effects, Recalls & Manufacturing Errors of Cosmetics

Version 1.0

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Saudi Food & Drug Authority

Drug Sector

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Please visit SFDA's website for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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1. INTRODUCTION

Cosmetic product's undesirable effects as a result of normal or reasonably foreseeable use according to cosmetic product's label are rare and are typically mild in nature and completely reversible without medical intervention. Therefore, manufacturers, importers and marketers of cosmetic products in the Kingdom of Saudi Arabia shall have procedures in place to allow it to respond appropriately to any reports of undesirable effects as well as manufacturing errors and recalls according to **Article No. 10 of Saudi Cosmetics Law**.

The reports and notifications of cosmetic product's undesirable effects are used as a useful indicator of reporting rates and identification and description of potential signals, which contributes to protecting consumers' health and reducing the likelihood of recurrence. This is important for companies in terms of post-marketing surveillance of cosmetic products and their market performance.

Therefore, Saudi Food & Drug Authority (SFDA) proposes this guideline for reporting undesirable effects to SFDA to enable companies to demonstrate compliance with legal requirements and give the public and authority's confidence in the credibility and accuracy of the data provided.

2. SCOPE

All serious undesirable effects of cosmetics occurred inside the Kingdom of Saudi Arabia, which are known to the notifier or which may be expected to be known to him must be reported to the Saudi Food & Drug Authority (SFDA) within the timeframe indicated in section 4.2 and the information on these cases should be kept available.

Cases of manufacturing errors should be reported if they are a root cause identified to a serious undesirable effect.

Product recall for products marketed with similar formula inside the Kingdom of Saudi Arabia.

3 DEFINITIONS

3.1 Cosmetic Product:

Any substance or preparation intended to be placed in contact with the external parts of human body (epidermis, hair, nails, lips, teeth, external genital organs or with the mucous membranes of the oral cavity) with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

3.2 Notifier:

The person/legal entity who place the product in the Saudi market (manufacturer, importer, or distributer)

3.3 Undesirable Effect (UE)

'Undesirable effect' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product. Undesirable Effects include, but are not limited to, irritating or allergic reactions that might affect the skin, eyes, or mouth.
This definition excludes undesirable effects induced by product misuse and abuse.

3.4 Serious Undesirable Effects (SUE)

In very rare cases, an undesirable effect could be serious. undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death.

The term serious is not synonymous with severe. Severe used to describe the intensity (severity) of the effect as in mild, moderate or severe. In case of doubts, the seriousness of the undesirable effects should be confirmed by a medical doctor.

4 REPORTING OF UNDESIRABLE EFFECTS

The Notifier should report to the Saudi Food & Drug Authority (SFDA) when an undesirable effect occurs, regardless of the source of the report (consumer, healthcare professional, etc.).

4.1 What should be reported?

I. Serious undesirable effects

II. Manufacturing errors identified as a cause for undesirable effect.

III. Product recall should be reported to SFDA in the following situations:

- Affected batches marketed inside KSA
- Affected batches in other countries for product marketed in KSA with similar formula

4.2 Time frame

Serious undesirable effects, manufacturing errors and product recall must be reported as soon as possible, as follow:

Type	Maximum Time Frame to Report
Product recall	10 calendar days
Serious undesirable effects or manufacturing errors	20 calendar days

4.3 How to report

The Saudi vigilance system should be used to report undesirable effects, manufacturing errors and recalls.

The procedure is as follows:

- Getting into Saudi Vigilance System
- Choose drug & cosmetics → Organizations & Company
- Fill up the mandatory fields
  - Company name
  - Full name
  - Email address
  - Mobile number
  - Product name
  - Description of undesirable effect.
  - Seriousness
  - Current Patient Status
- Fill out as many of the optional fields as you can
  - Product information
  - Product user info.
  - Side effect info.
- Submit the report

Alternatively, by filling up the cosmetic undesirable effect reporting form (available on The Saudi vigilance system website) and upload it via Saudi Vigilance System or send it via cosmetics email cosmetic@sfda.gov.sa

5 Appendix: Saudi Vigilance Webpage

https://ade.sfda.gov.sa/