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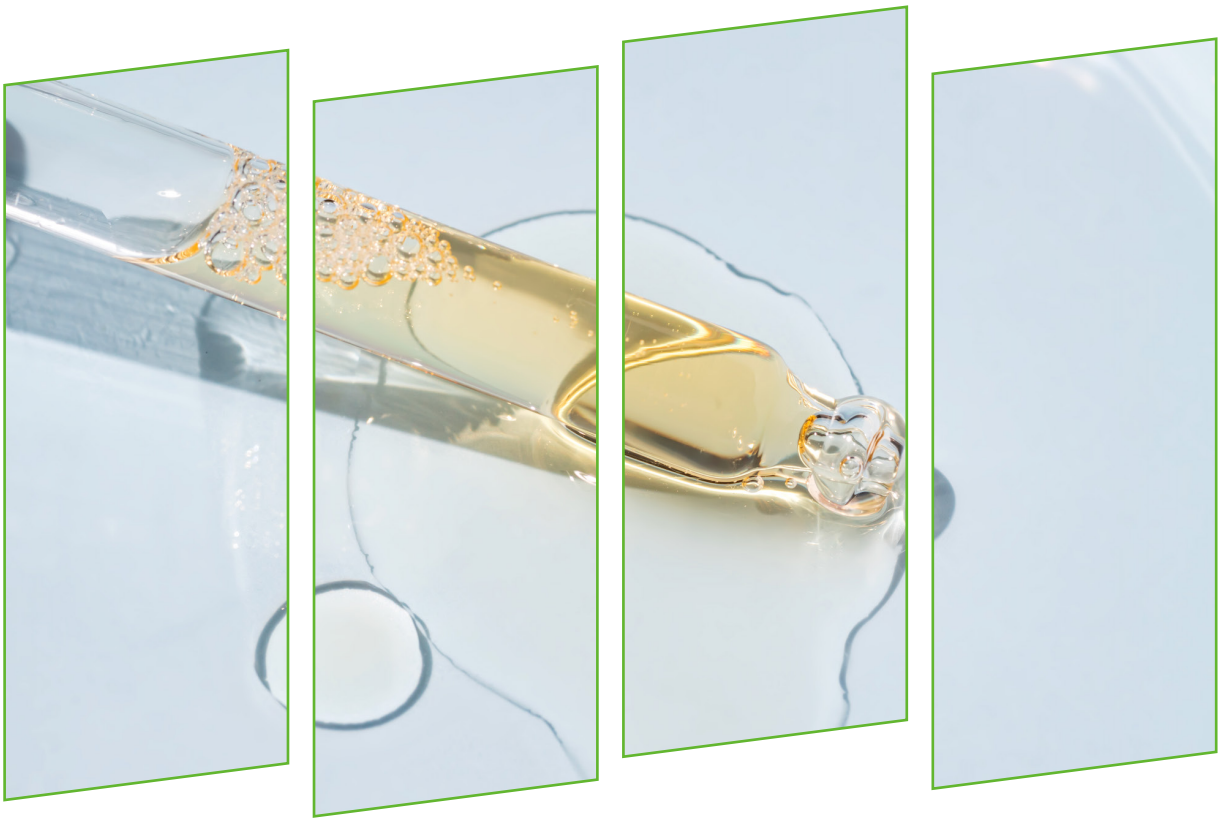

Guidelines for Collection and Reporting of Cosmetic Adverse Reactions by Cosmetic Registrants and Notifiers (Trial)

化妆品注册人、备案人收集和报告化妆品不良反应指南（试行）

Center for Drug Reevaluation and National
Center for ADR Monitoring of China

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Translated by ChemLinked

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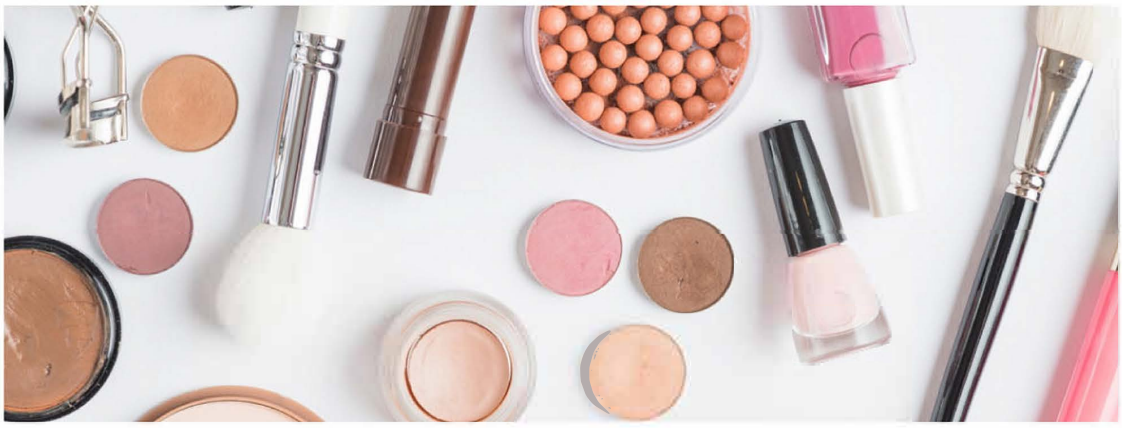

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Guidelines for Collection and Reporting of Cosmetic Adverse Reactions by Cosmetic Registrants and Notifiers (Trial)

In order to standardize and guide the collection and reporting of cosmetic adverse reactions by cosmetic registrants and notifiers (hereinafter referred to as the "registrants and notifiers"), this *Guidelines* is hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations* (*CSAR*), *Supervision and Administration Measures on Cosmetic Production and Operation*, and *Administration Measures on Cosmetic Adverse Reaction Monitoring*, and other relevant regulations.

This *Guidelines* is applicable to guiding registrants and notifiers to collect and report cosmetic adverse reactions within the territory of the People's Republic of China.

Registrants and notifiers shall establish a cosmetic adverse reaction monitoring and evaluation system, be equipped with departments and personnel suitable for their products, and carry out cosmetic adverse reaction monitoring in accordance with regulatory requirements. They shall assign a person in charge of quality and safety to assist the legal representative in assuming the responsibility of managing cosmetic adverse reaction monitoring. They shall also keep confidential the personal privacy and other information of consumers that they are aware of during cosmetic adverse reaction monitoring. Overseas registrants and notifiers shall establish an assistance mechanism with Chinese domestic responsible persons to actively collect, report, analyze, evaluate, investigate and handle adverse reactions, ensuring compliance with the obligations stipulated in the *Administration Measures on Cosmetic Adverse Reaction Monitoring*.

1 Collection of Cosmetic Adverse Reactions

Registrants and notifiers shall establish effective information collection channels with regard to consumers, entrusted manufacturers, cosmetic operators, medical institutions, *etc.*, and actively collect adverse reactions of their marketed cosmetics.

They shall not interfere with the spontaneous reporting behavior of reporters for any reason

or means.

1.1 Consumer Channel

Registrants and notifiers shall disclose their contact number, email address, and other contact information to the public through product labels, official websites, and other means that are convenient for consumers to know. They shall inform consumers of their channels for collecting cosmetic adverse reactions and ensure that their contact information is effective and the information collection channels are unobstructed. If there is a change in the collection channels for cosmetic adverse reactions, registrants and notifiers shall make updates in a timely manner through product labels, official websites, *etc.*

1.2 Entrusted Manufacturer Channel

Registrants and notifiers shall actively collect information on cosmetic adverse reactions from entrusted manufacturers and ensure smooth collection channels. Registrants and notifiers, and entrusted manufacturers are encouraged to sign a written agreement to specify the requirements for entrusted manufacturers to inform the registrants and notifiers of cosmetic adverse reactions, and clarify the requirements for information collection and transfer.

1.3 Cosmetic Operator Channel

Registrants and notifiers shall actively collect information on cosmetic adverse reactions from cosmetic operators and ensure smooth collection channels.

1.4 Other Channels

Registrants and notifiers are encouraged to use official websites, social media, e-commerce platforms, *etc.* to collect information on cosmetic adverse reactions. For example, they may establish a dedicated channel for collecting cosmetic adverse reactions on official websites and provide guidance on the content of cosmetic adverse reaction information collected.

They are encouraged to collect information on cosmetic adverse reactions discovered

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化妆品注册人、备案人
收集和报告化妆品不良反应指南（试行）

为规范和指导化妆品注册人、备案人（以下简称注册人、备案人）开展化妆品不良反应收集和报告相关工作，依据《化妆品监督管理条例》《化妆品生产经营监督管理办法》《化妆品不良反应监测管理办法》等有关规定，制定本指南。

本指南适用于指导注册人、备案人在中华人民共和国境内开展化妆品不良反应收集和报告工作。

注册人、备案人应当建立化妆品不良反应监测和评价体系，配备与其产品相适应的机构和人员，依照法规要求开展化妆品不良反应监测工作。注册人、备案人设置的质量安全负责人应当协助法定代表人承担化妆品不良反应监测管理职责。注册人、备案人在化妆品不良反应监测工作中知悉的消费者个人隐私等信息应当予以保密。境外注册人、备案人应当与境内责任人建立不良反应主动收集、报告、分析评价和调查处理的协助机制，确保履行《化妆品不良反应监测管理办法》规定的义务。

1 化妆品不良反应的收集

注册人、备案人应当建立面向消费者、受托生产企业、化妆品经营者、医疗机构等的有效信息收集渠道，主动收集其上市销售化妆品的不良反应。

注册人、备案人不得以任何理由或者手段干涉报告者的自发报告行为。

1.1 消费者渠道

注册人、备案人应当通过产品标签、官方网站等方便消费者获知的方式向社会公布电话、电子邮箱等联系方式，将收集化妆品不良反应的途径告知消费者，并确保联系方式有效及信息收集渠道畅通。如化妆品不良反应收集途径发生变更，应当及时通过产品标签、官方网站等进行更新。

1.2 受托生产企业渠道

注册人、备案人应当主动收集来自受托生产企业的化妆品不良反应信息，并确保收集渠道畅通。鼓励注册人、备案人和受托生产企业通过书面协议约定受托生产企业向注册人、备案人告知化妆品不良反应，明确信息收集和传递的要求。

1.3 化妆品经营者渠道

注册人、备案人应当主动收集来自化妆品经营者的化妆品不良反应信息，并确保收集渠道畅通。

1.4 其他途径

鼓励注册人、备案人利用官方网站、社交媒体、电子商务平台等收集化妆品不良反应信息，如在官方网站建立收集化妆品不良反应的专门途径，提供化妆品不良反应信息收集内容指导。

鼓励注册人、备案人通过文献检索方式收集发现的化妆品不良反应信息。鼓励注册人、备案人制定文献检索规范或者程序，如对检索频率、时间范围、文献来源、文献类型、检索策略等进行规定。

2 化妆品不良反应的记录与传递

为确保报告化妆品不良反应的内容真实、完整、准确，注册人、备案人应当对化妆品不良反应相关信息形成原始记录，并在汇总原始记录的基础上，建立化妆品不良反应监测记录。

2.1 记录

对各种途径收集的化妆品不良反应信息，注册人、备案人均应当有原始记录。原始记录包括电话记录、电子邮件或者截图等。

2.2 传递

注册人、备案人应当保证化妆品不良反应信息在传递过程中保持真实性、完整性和准确性，不得删减、遗漏。未收集到的信息及对原始记录的改动均应当备注说明。

鼓励注册人、备案人明确化妆品不良反应信息的传递时限，以确保化妆品不良反应报告符合时限要求。注册人、备案人可以通过组织培训等方式，使企业不良反应监测相关人员掌握信息传递要求。

3 化妆品不良反应报告的确认

注册人、备案人应当对收集的化妆品不良反应进行确认。需要确认的内容主要包括：是否符合报告原则、是否为有效报告等。经确认无需向监测机构提交的化妆品不良反应，应当在监测记录中说明未提交的原因，并保存监测记录。

3.1 报告原则

化妆品不良反应报告遵循可疑即报的原则，怀疑与使用化妆品有关的人体损害，均

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