

GLOSSARY OF TERMS

Name of Country: _____

Product Group: Pharmaceuticals/ Cosmetic Products/ Traditional Medicine and Health Supplement Products (note: please indicate the product group for this glossary and provide the appropriate inputs relevant to the indicated product group)

1. **Adverse Drug Reaction (ADR) ***

Adverse Reaction– ASEAN Harmonised Cosmetic Regulatory Scheme Definition For Cosmetic Product

Any genuine harmful or unintended event reasonably attributable to the normal or foreseeable use of a given cosmetic product.

2. **Adverse Event (AE) *** (of a healthcare-related product)

3. **Complementary Medicines ***

Chinese Proprietary Medicines *

Traditional Medicines *

Health Supplements *

4. **Defect *** (of a healthcare-related product)

5. **Level of Confidentiality** (this explains the level of confidentiality that is used in the PMA Form used in the reporting)

6. **Recall Classification *** (e.g. Class 1 & 2 recalls of healthcare-related product)

7. **Recall Level *** (e.g. consumer, retail, wholesale etc)

8. **Withdrawal ***

Note:

This template is intended as a guide for each ASEAN Member Country to draft their respective country-specific glossary. The country-specific glossary will be helpful for the understanding of terminologies and definitions by other Member countries when reading the PMA Form.

* To list the legal definitions, terms, terminologies, process or procedures that are commonly used in the Member Country. The Member Country can add or include new items to the glossary template if the country-specific items are not were found in the template.