LIST OF UPDATES FOR

GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA-SECOND EDITION

(AUGUST 2022 UPDATES)

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This guideline contains 7 main sections, 25 appendices. The main sections are:

• Section 1: General Overview
• Section 2: Cosmetic Notification
• Section 3: Regulatory Requirements for Cosmetic Product
• Section 4: Post Market Surveillance
• Section 5: Regulatory Action
• Section 6: Notification Withdrawal
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	Annex 1, Part 11 — List of Equivalent Cosmetic GMP Guidelines (Moved to Annex I, Part 12) Annex 1, Part 12 — Guideline For Product Information File (PIF) (Moved to Annex I, Part 13) Annex 1, Part 13 — A Guide Manual For Adverse Event Reporting (Moved to Annex I, Part 15) Annex 1, Part 15 — Guideline for Sunscreen Product (Moved to Annex I, Part 9(i)) Annex 1, Part 16 — -	Guideline for Cosmetic Good Manufacturing Practice (GMP) List of Equivalent Cosmetic GMP Guidelines Guideline For Product Information File (PIF) A Guide Manual For Adverse Event Reporting Guidance for Industry – Reporting and Recall of Cosmetic Product
Glossary	Manufacturer The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.	Amended: Manufacturer The manufacturing process includes the complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.
Section 2: Cosmetic Notification	-	2.11 Certificate of Free Sale (Moved from Section 8)
Section 3: Regulatory Requirements for Cosmetics	3.3 Cosmetic Ingredients iii) Marketing of cosmetic product(s) containing the following shall be allowed: • Substances and other ingredients listed in Annex III, Part 2 which are used within the limits and stated the conditions laid down and conforms to the dates as stated in column (g) of Annex III, Part 2.	3.3 Cosmetic Ingredients (Deleted content in 3.3 (iii))

	• Colouring agents listed in Annex IV, Part 2 which are used within the limits and under the conditions laid down, until the admission dates given in that Annex. • Preservatives listed in Annex VI, part 2 used within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product. • UV filters listed in Annex VII, part 2 used within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. - -	3.4 Labelling Requirement (Moved 'Halal' from section 9) 3.5 Cosmetic Claims Inserted: For specific guidance regarding sunscreen products/claims, please refer to Annex 1 part 9 (i) Guideline for Sunscreen Product. For specific guidance regarding hand sanitizers, please refer to Annex 1 part 9 (ii) Guideline for Hand Sanitizer Product. For specific guidance regarding antibacterial hygiene wash products/claims, please refer to

		Annex 1 part 9 (iii) Guideline for Antibacterial Hygiene Wash Products.
	3.7 Good Manufacturing Practice (GMP) For details, please refer to Annex I, part 10: Guideline for Cosmetic Good Manufacturing Practice and Annex I, part 11: List of Equivalent Cosmetic GMP Guidelines. Local manufacturer is subjected to periodical inspection by GMP auditors from the NPRA to ensure continuous compliance. For foreign manufacturer, documentation to prove GMP compliance is to be made available upon request by the NPRA.	3.7 Good Manufacturing Practice (GMP) Amended: For details, please refer to Annex I, part 11: Guideline for Cosmetic Good Manufacturing Practice (GMP) and Annex I, part 12: List of Equivalent Cosmetic GMP Guidelines. A new local manufacturer/ new production line shall be inspected by NPRA prior to cosmetics notification. The manufacturer needs to ensure that the layout of the manufacturing facility is designed and planned according to GMP principles. Please refer to the Frequently Asked Questions (FAQs) related to GMP inspection, which is available in NPRA website. Following from that, all local manufacturers are subjected to periodical regulatory GMP inspection to ensure continuous compliance. For foreign manufacturers, documentation to prove GMP compliance is to be made available upon request by the NPRA. Document/declaration of compliance to cosmetic GMP (or equivalent) must be issued/endorsed by authorised body/agency at country of manufacturer.
	3.9 Product Recall (Moved to Section 5.3)	

	3.10 Reporting of Adverse Event (Moved to Section 4.4)	
Section 4: Post Market Surveillance		4.3 Product Complaint (Inserted new requirement for Product Complaint) 4.4 Reporting of Adverse Event (Moved from Section 3.10) 4.5 Notification of Product Quality Issues (Inserted new requirement for Notification of Product Quality Issues)
Section 5: Notification Exemption		5.3 Product Recall (Moved from Section 3.9) (Inserted Application Process)
Section 8: Certificate of Free Sale	(Moved to Section 2.11)	-
Section 9: Halal	(Moved to Section 3.4)	-
INFORMATION IN THE ANNEXES		
Annex I, Part 1	Illustrative List of Cosmetic Products By Categories	Illustrative List of Cosmetic Products By Categories Added new categories: - Sunscreen products - Hand sanitizers - Essential oil for skin/hair/nail Inserted Note: i. This is not an exhaustive list and will be reviewed when necessary. Amended the list under Important Note: 3. Remove in bracket (leave on product applied on genital part)

		Added new list under Important Note: 4. Products for injection/micro needling 5. Products for oral ingestion 6. Products for the treatment of diseases 7. Pain relief products 8. Sleep aid products 9. Surface disinfectants 10. Body disinfectants/sanitizers 11. Insect repellents 12. Products for animal/pet care 13. Massage oils for therapeutic purposes 14. Essential oil for therapeutic purpose/diffuser use only 15. Products for purpose of systemic detoxification
Annex I, Part 2	Non-Permissible Product Name For Cosmetic Product	Non-Permissible Product Name For Cosmetic Product (Updated example of Non-Permissible Product Name For Cosmetic Product) Inserted new category of Non-Permissible Product Name with example: - Prohibited use of banned substances as part of product name, example are Cannabis, Hemp, Oestrogens, Progesterone
Annex I, Part 3	Charges for Quest Membership	Charges for Quest Membership (Updated Charges for Quest Membership)
Annex I, Part 4	Guide Manual For Quest3 Online Submission	Manual For Quest3+ Online Submission For Cosmetic Notification

		(Updated Manual For Quest3+ Online Submission)
Annex I, Part 5	List of Types of Changes For Notified Product	List of Types of Changes For Notified Product Moved Type 1 changes, no.2 to Notes: 1. For change of company name and/or address without change of distribution rights, Please contact Center of Regulatory Coordination & Strategic Planning
Annex I, Part 7	Cosmetic Labelling Requirements	Cosmetic Labelling Requirements Added information under Objective: - They are required to be labelled in accordance with the Regulations before they can be sold or supplied in Malaysia and to make claims that will not mislead the consumer about the product's contents, quality or safety. Added requirement under 3.1i): - Definition of "Professional use" and "Professional" - Products packaged in vial or ampoule must be labelled 'for external use only' (Deleted 3.1j) Valid contact number of the CNH) Added list under Appendix A: 4. Any other approved standard references. 5. Botanicals and extract of botanicals should be identified by its genus and species.
Annex I, Part 8	Cosmetic Claims Guideline	Guideline for Cosmetic Claims

		(Added examples of unacceptable and acceptable claim for cosmetic products under no.3.) (Added claims under 3a(iii) Safety Claim and 3a(iv) Quantitative Claims)
Annex I, Part 9	Guideline for Cosmetic Advertisement (Moved to Annex I, Part 10)	List of Guideline for Products with specific requirements (Added New Guideline)
Annex I, Part 9 (i)	-	Guideline for Sunscreen Product (Moved from Annex I, Part 15) (Added example under no.4 Note: For example: SPF 130 can ONLY claim as SPF 50+) (Added information at no.5 on SPF value testing)
Annex I, Part 9 (ii)	-	Guideline for Hand Sanitizer Products (Added New guideline)
Annex I, Part 9 (iii)	-	Guideline for Antibacterial Hygiene Products (Added New guideline)
Annex I, Part 10	Guideline for Cosmetic Good Manufacturing Practice (Moved to Annex I, Part 11)	Guideline for Cosmetic Advertisement (Moved from Annex I, Part 9) Added information under no.6 Testimonial: - Advertisement with a testimonial is suggested to include this statement: - 'The effects of the product may vary among individuals'
Annex I, Part 11	List of Equivalent Cosmetic GMP Guidelines Moved to Annex I, Part 12	Guideline for Cosmetic Good Manufacturing Practice (GMP) (Moved from Annex I, Part 10)
Annex I, Part 12	Guideline for Product Information File (PIF)	List of Equivalent Cosmetic GMP Guidelines

	(Moved to Annex I, Part 13)	(Moved from Annex I, Part 11)
Annex I, Part 13	A Guide Manual for Adverse Event Reporting (Moved to Annex I, Part 15)	Guideline for Product Information File (PIF) (Moved from Annex I, Part 12)
Annex I, Part 15	Guideline for Sunscreen Product (Moved to Annex I, Part 9(i))	Guide Manual for Adverse Event Reporting (Moved from Annex I, Part 13)
Annex I, Part 16	-	Guidance for Industry – Reporting and Recall of Cosmetic Product (Added New guideline)