Overview of Cosmetic Products Regulation in Singapore

Cosmetics Control Unit
Complementary Health Products Branch
Medicinal Products Pre-market Cluster
Health Products Regulation Group
Health Sciences Authority
5 Nov 2020

Outline

- Introduction to Health Sciences Authority
- Overview of the ASEAN Cosmetic Directive
- Regulation of cosmetic products in Singapore

INTRODUCTION TO HSA

VISION

To be the leading innovative authority protecting and advancing national health and safety

MISSION

- To wisely regulate health products
- To serve the administration of justice
- To secure the nation's blood supply
- To safeguard public health

Applied Sciences Group | Blood Services Group | Health Products Regulation Group | Corporate Services Group

Roles and Functions

Clinical Trials Review
Product Evaluation & Registration
Audit & Licensing
Vigilance & Compliance
Enforcement
Tobacco Regulation

Forensic Medicine
Forensic Science
Illicit Drugs & Toxicology
Pharmaceutical Testing
Chemical Metrology

Blood Banking & Transfusion Services
Haemovigilance

Health Products Regulation Group (HPRG)

Ensures that drugs, innovative therapeutics, medical devices and health-related products in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy

OVERVIEW OF
THE ASEAN COSMETIC DIRECTIVE

Background on ASEAN Cosmetic Directive

Jul 1998

ASEAN Consultative Committee for Standards and Quality (ACCSQ) Cosmetic Product Working Group (CPWG) formed to harmonise conformity assessment and technical regulations for cosmetic products on request by ASEAN's cosmetics industry

1996

Regulation of cosmetics in Singapore begins with product licensing, importer and manufacturer licensing for higher risk products. Labelling requirements for all cosmetics

Sept 2003

Signing of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) Agreement by ASEAN ministers

Jan 2008

Full implementation of ASEAN Cosmetic Directive (ACD) in Singapore

Documents under the ACD

- Definition and examples of cosmetic products
- Lists of prohibited, restricted and permitted ingredients (colouring agents, preservatives and UV filters)
- Labelling requirements
- ASEAN Guidelines on Good Manufacturing Practice for Cosmetic Products
- Guidelines for the safety assessment of a cosmetic product
- Guidelines for Product Information File
- Guide manual for industry for adverse events reporting
- Guidelines on Limits on Contaminants

REGULATION OF COSMETIC PRODUCTS IN SINGAPORE

Regulatory Principles for Cosmetic Products in Singapore

Cosmetic products are consumer products with low intrinsic risk but the potential extrinsic risk may be high (e.g. adulterated products).

Adoption of a light touch regulatory approach based on prescribed standards (e.g. ingredient lists, labelling) for product safety with onus placed on the dealers

Complemented by post-market surveillance and enforcement measures and consumer advisory & education

Legislative Controls of Cosmetic Products in Singapore

- Cosmetic Products are regulated under Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007 which is under the Health Products Act
- The Regulations provides the following:
  - Legal definition of person responsible and cosmetic products
  - Requirement for notification
  - Ingredients control
  - Labelling requirements
  - Advertising controls
  - Records keeping pertaining to supply
  - Adverse effect and product defect reporting

What is a Cosmetic Product?

Legal Definition:

"Cosmetic product" means any **substance or preparation** that is intended by its manufacturer to be **placed in contact** with the various **external parts of the human body** or with the **teeth or the mucous membranes of the oral cavity**, with a view exclusively or mainly to –

(a) cleaning them;

(b) perfuming them;

(c) changing their appearance;

(d) correcting body odours;

(e) protecting them; or

(f) keeping them in good condition.

Cosmetic Products Notification

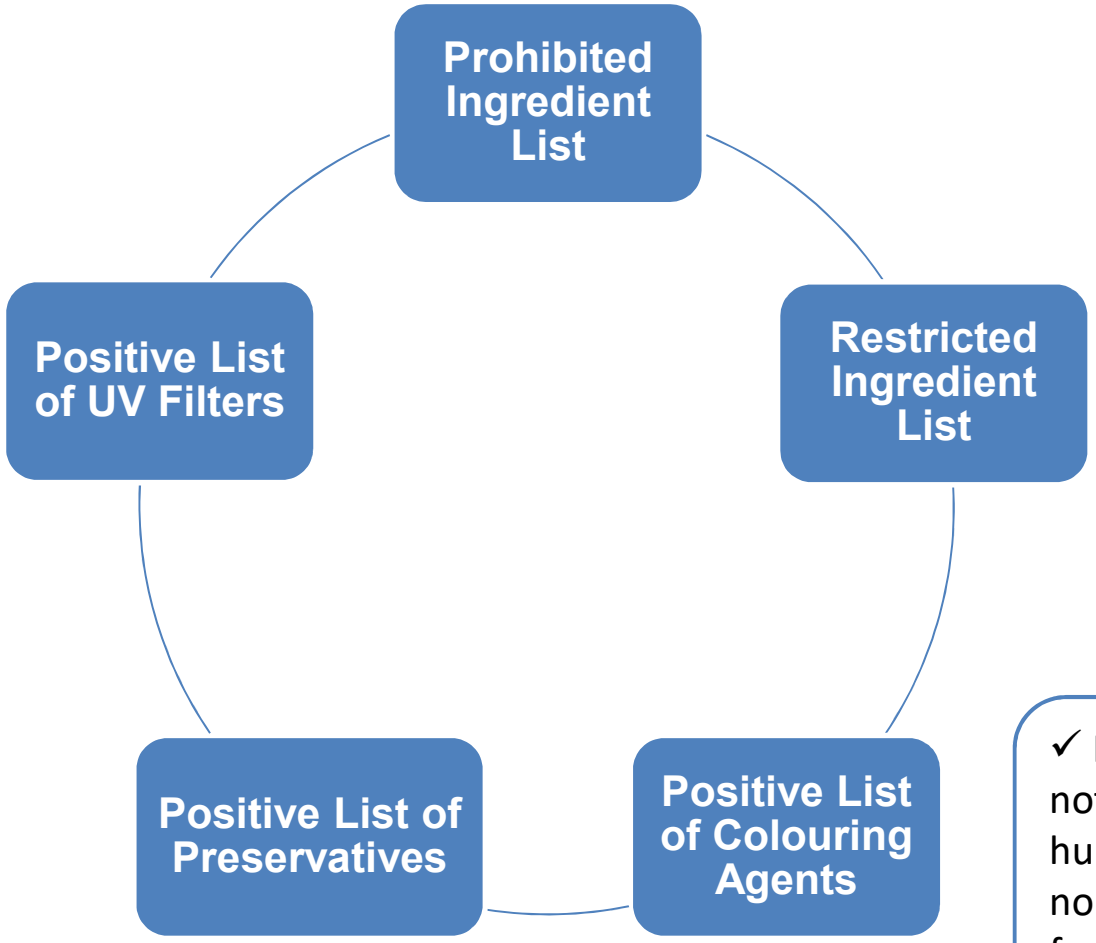
- Person responsible for placing the cosmetic product in the market shall *notify* HSA prior to supply
- Re-notification is required every 12 months
- Importers and manufacturers are primarily the person responsible to notify HSA they are instrumental in causing the cosmetic product to be available for sale in Singapore

Information required during the submission of product notification via PRISM:

- ✓ Particulars of local company responsible for placing the cosmetic product in the market and the person representing the company
- ✓ Particulars of product (e.g. brand name, product name, etc)
- ✓ Particulars of manufacturer

Note: The information required for product notification is needed for product traceability. The person responsible is required to submit safety and technical information to HSA upon request.

Cosmetic Ingredient Listings



✓ Ingredients should not cause damage to human health under normal or reasonably foreseeable conditions

Duties of Importer and Manufacturer of Health Products

- Records of import, manufacture or supply should be kept
  - Information or document regarding health product should be produced to HSA when requested
- Product defects and adverse effects (AE) arising from use of product has to be reported to HSA and HSA may:
  - Require the company to investigate into the cause of defect or AE and report to HSA
  - Require the company to issue to certain persons or the general public a statement informing them of defect or AE
  - Require the company to recall the health product and to immediately stop the manufacture, import, supply, use or administration of the health product;
  - Prohibit the use or administration of a health product and may require the company to address the AE caused
  - Require the company to adopt any measures as requested by HSA

Duties of Importer and Manufacturer of Health Products

- When the safety or quality of a health product is in question, HSA may need to verify the product safety and quality and inform the company that:
  - The product may be subjected to evaluation
  - The company has to submit evidence of safety and quality to HSA upon request
- Inform HSA concerning a recall of health product
  - HSA may require the company to issue a statement to inform the public of the recall

Labelling Requirements

Batch number:

This is an important reference when providing feedback to the manufacturer/importer/distributor or regulatory authority regarding the product.

Brand name and **product name of the cosmetic product:**

To identify the cosmetic product

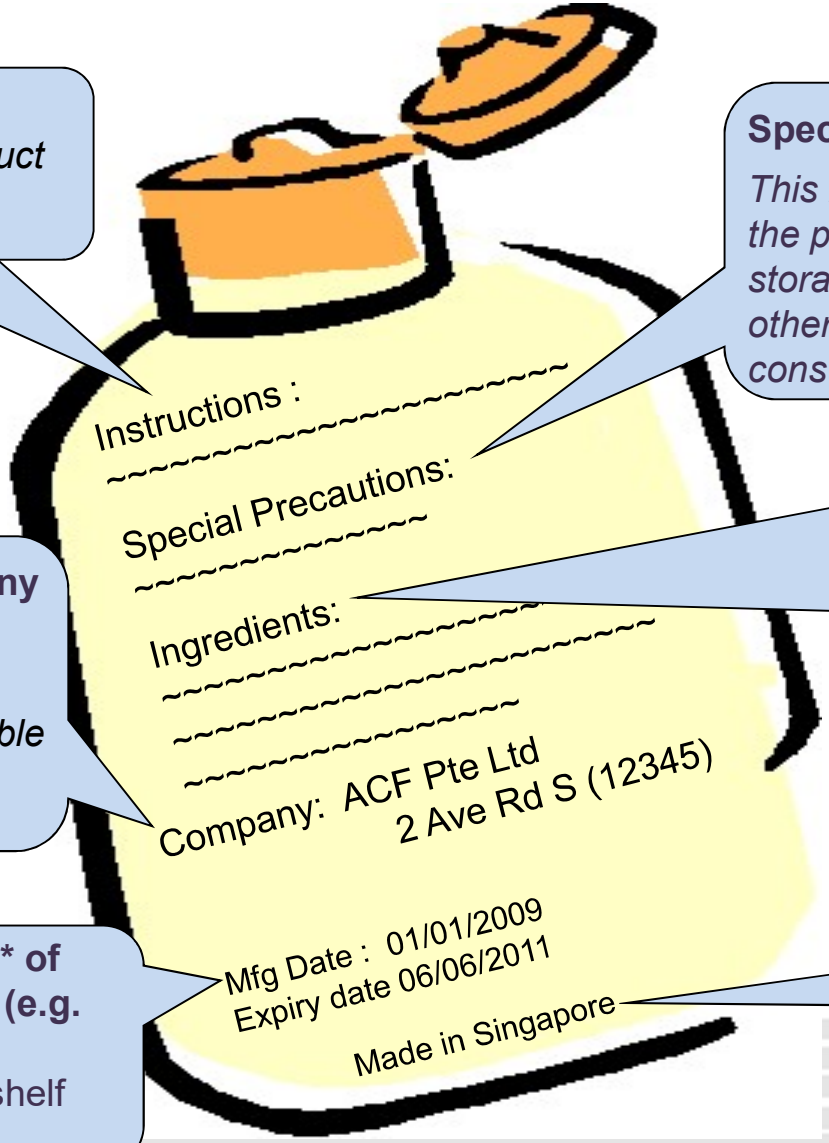
Product content

(in weight or volume)

Labelling Requirements

Instruction of use
(unless it is clear from product name/presentation)

Special Precautions:
This is to advise the consumer on the proper use, warnings or storage of the product and any other important information the consumer has to take note of.



Full Ingredient List:
Since a common risk of cosmetic use is sensitivity to cosmetic ingredients, this will inform consumers of the contents of the product in case the consumer is allergic to any particular ingredient.

Name and address of company responsible for placing the product in the market:
To identify the person responsible for placing the product on the market

Manufacturing/expiry date* of the product in clear terms (e.g. month/year)*
Expiry date is mandatory if shelf life is < 30 months

Country of manufacture must be stated

Labelling Requirements

- In addition, the product labels of cosmetic products shall not contain:
  - Claims, directly or indirectly, that the product is promoted or endorsed by HSA
  - Claims that are likely to create erroneous impression regarding the formulation, composition, safety and quality of the product

Advertising

- A supplier shall not advertise any product as a health product if the product is not a health product
- Advertisements of health products shall not be false or misleading by falsely describing the product or giving false information on the product
- Advertisements of cosmetic products shall not contain:
  - Claims or implied claims of therapeutic purpose or benefit
  - Claims that are likely to create erroneous impression regarding the formulation, composition, safety and quality of the product

Record Keeping

- Records of supply must be kept and produced when requested by HSA
- The records referred to includes:
  - Name and notification number of cosmetic product that was supplied
  - Date on which the cosmetic product was supplied
  - Name and address of the person to whom the cosmetic was supplied
  - Quantity supplied
  - Identification number or mark of the cosmetic product supplied
- Records has to be retained for at least 2 years after the product was supplied

Adverse Effect and Product Defect Reporting

The company responsible for placing the product on the market shall report to HSA any adverse effect or product defect:

a. If the adverse effect has caused death or is life-threatening or the product defect may cause death or may be life-threatening:
   i. inform HSA of the event or occurrence no later than 7 days after first becoming aware of the event or occurrence; and
   ii. submit a detailed report on the event or occurrence to HSA within 8 days after the initial report made; or

b. If the adverse effect has resulted or product defect may result in any person being hospitalised or may cause any persistent or significant disability or incapacity in any person, submit a detailed report on the event or occurrence to HSA no later than 15 days after first becoming aware of the event or occurrence.

Adverse Effect and Product Defect Reporting

- Arising from AE or product defect reported, HSA may:
  - Require the company to investigate into the cause of defect or AE and report to HSA
  - Require the company to issue to certain persons or the general public a statement informing them of defect or AE
  - Require the company to recall the health product and to immediately stop the manufacture, import, supply, use or administration of the health product;
  - Prohibit the use or administration of a health product and may require the company to address the AE caused
  - Require the company to adopt any measures as requested by HSA

- When the safety or quality of a health product is in question, HSA may need to verify the product safety and quality and inform the company that:
  - The product may be subjected to evaluation
  - The company has to submit evidence of safety and quality to HSA upon request

Visit our webpage for more information

- For more detailed information on cosmetic products regulations in Singapore, please visit our website at: www.hsa.gov.sg/cosmetic

THANK YOU