Global Best Regulatory Principles for the Personal Care Industry

George Bouboulis

Personal Care Products Council

Committed to Safety, Quality & Innovation

Discussion topics

- Introduction
- Global regulatory best practices for cosmetics
- Key Principles
- Benefits of “best practice” approach
- Counterfeits
- Next steps

About the Personal Care Products Council

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- **Founded 1894**- One of Washington's most well-established trade associations
- More than **600 member companies**
- Manufacturers & distributors, suppliers of ingredients, raw materials, packaging, and other services
- **Majority small companies**

Council Mission & Goals

Promote Sound Science

Build consumer awareness and trust

By creating a productive business and regulatory environment, enable members to develop and sell safe, quality and innovative products that help consumers live better, healthier lives and to enhance the reputation of the industry.

Advocacy on legislative matters

Assure Global market Access

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Sector characteristics defining regulatory frameworks

- Long history of safety; **low risk products**
  - **Cosmetics should not be regulated like drugs**
- **Fast moving goods**, driven by fashion and innovation
- Global industry necessitates that regulatory frameworks align with **global best regulatory practices**

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Principles for Best Regulatory Practices for Cosmetics

- The framework should be unified and streamlined, using one definition for cosmetics
- Products placed on the market must be safe, based on a safety assessment
- Responsibility for safety and compliance is with the entity who places on the market
- Authorities main responsibility is in market control
- No pre-market registration of products, but simple notification to facilitate in-market control
- No differentiation between domestic and imported products

Benefits of global best regulatory practices

- Better **consumer safety**
  - Companies must take responsibility for safety assurance
  - Better address non conformant; unsafe and counterfeit products on the market
- **Business enabling environment**
  - Framework facilitates exports
  - In-country cost effective system to market products
- **More efficient use of Authorities' limited resources**

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Roles and Responsibilities

- **Entity placing on the market (manufacturer, trademark owner, or importer) is responsible for product safety**
  - Legally responsible for the safety of the products
  - Legally responsible to comply with the local regulations
  - Main contact for the consumers
  - Can work with third parties, but cannot transfer his legal responsibility

- **Authorities are responsible for developing and enforcing regulations**
  - Establish a risk based regulation that applies to all cosmetic products
  - Establish a notification portal
  - Perform in market control

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How do manufacturers assure safe products?

- Follow good manufacturing practices (**GMP**s)
- Effectuate **safety assessments** on all products placed on the market
- **Report serious adverse events** to the Authorities

Good Manufacturing Practices (GMP)

- GMPs describe the manufacturing conditions and management activities involved in the different stage of the production, from the purchase of the raw materials to the dispatch of the packaged end-products.

- **GMPs should be self certified by cosmetic manufacturers**

- By self certifying GMP manufacturers ensure that products are:
  - Consistently manufactured
  - Of appropriate quality for intended use
  - Fit for their purpose

- The choice of GMP is voluntary; however **ISO GMP 22716** is highly relevant

Safety Assessments

- The manufacturer should **submit every product** prior to its placing on the market **to a comprehensive assessment of its safety for human health**

- Cosmetic product safety can usually be assessed by examining the relevant toxicological endpoints of their ingredients, and the likely local and systemic consumer exposure to the product.

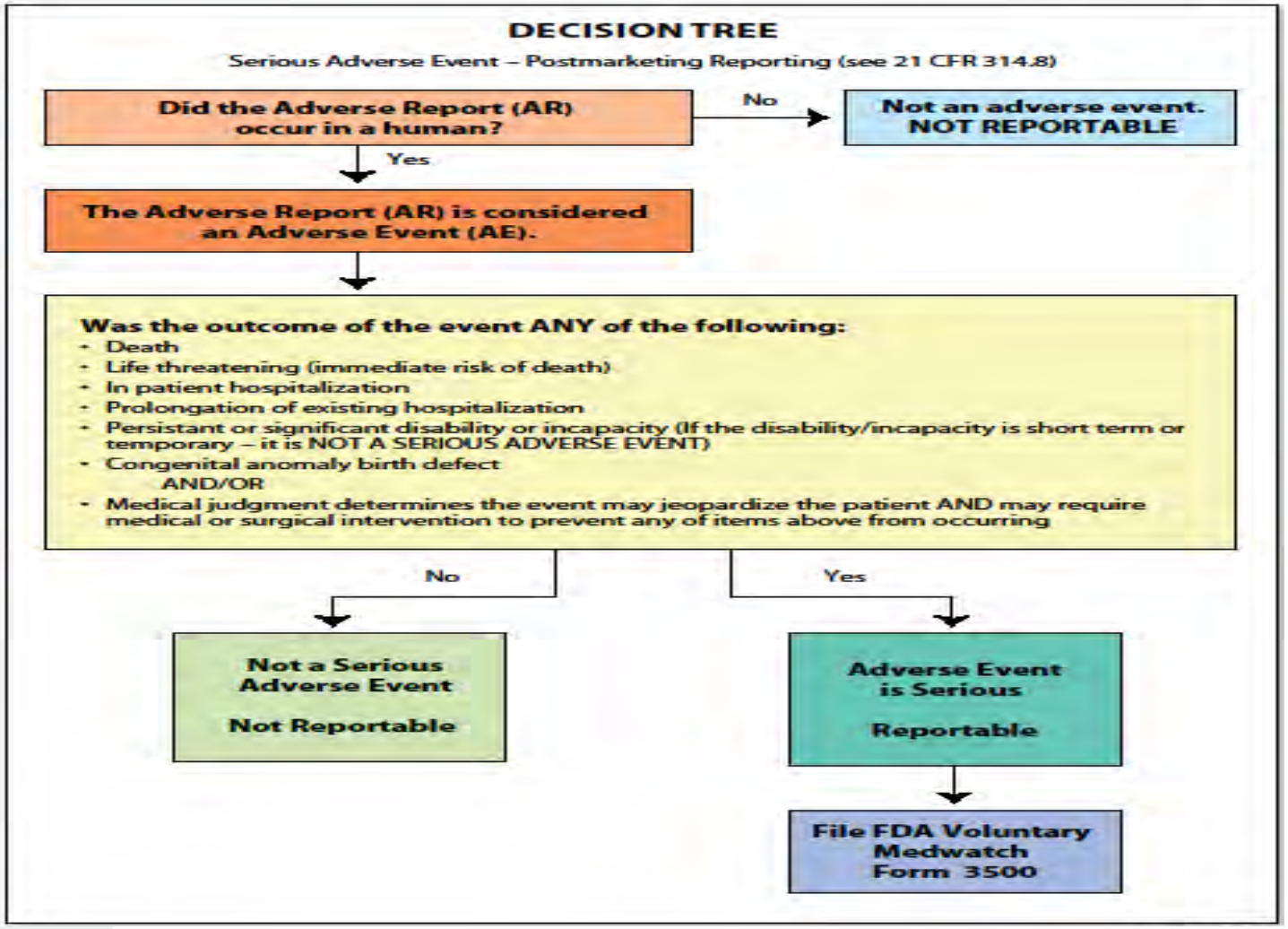
- Safety Assessment information should be made **available to the Authorities upon request**

Reporting of Adverse Events

- Serious and unexpected adverse events are **extremely rare for cosmetic products**
- Companies must alert the competent Authorities of serious and unexpected adverse event
- In the US "Serious" and "Unexpected" are defined as follows:
  - **Serious:** Death; life-threatening; inpatient hospitalization; persistent or significant disability/ incapacity; congenital anomaly/ birth defect
  - **Unexpected:** Not previously observed (i.e. not listed in current labeling including frequency)
- The World Health Organization defines a serious averse event as:

  Any untoward medical occurrence that at any dose:
  - Results in death
  - Life threatening
  - Requires inpatient hospitalization or prolongation of existing hospitalization
  - Results in persistent of significant disability or incapacity

Serious Adverse Event – Post marketing Reporting Example



Authorities' role and responsibilities

- Establish the regulatory framework
- Require companies to provide the necessary information via a simple notification portal
- Perform in-market control

Notification

- Market placement should be allowed **without any pre approval**; instead companies should complete a notification
- Notifications allow easy access to product information and information regarding the entity responsible for the placing on the market for the Authorities
- Notifications reduce the timeframe for placing on the market
- Notifications are **not a pre-registrations;** need to be seen in the context of an in-market control system

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Notification functions

- Allow the authority to monitor market entry
- Allow the authority to ask questions to the entity placing a product on the market
- At an in-market level, the notification assists the work of the inspector by providing the necessary information to:
  - **Identify the product** in the market
  - **Identify the entity placing the product on the market**– so that they can follow up with questions
  - Assure that the product is **backed up by a full set of safety and quality documentation**

In Market Control; Principles

- **In-market control is a surveillance process/mechanism that allows health/competent authorities to ensure safety and compliance of all commercialized products in the market**
  - Cosmetic product is **placed on the market without any pre-control** from the local authority.
  - Local Authorities perform **random inspections**
  - Samples from the shelves are checked for compliance with labelling and may be sent to analytical laboratories;
  - **Inspection frequency is ideally related to the performance and the risk**:

In Market Control; in Practice

- Upon request, product information should be made available to the Authorities
  - When needed
  - Within reasonable time (48-72hrs)
- Product information enables Authorities to control:
  - Regulatory ‘design’ compliance
  - Manufacturing
  - Efficacy
  - Safety of the products
- What is usually inspected?
  - Notification
  - Labeling
  - Chemical and Microbiology tests

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Our understanding of the regulatory framework in CDI

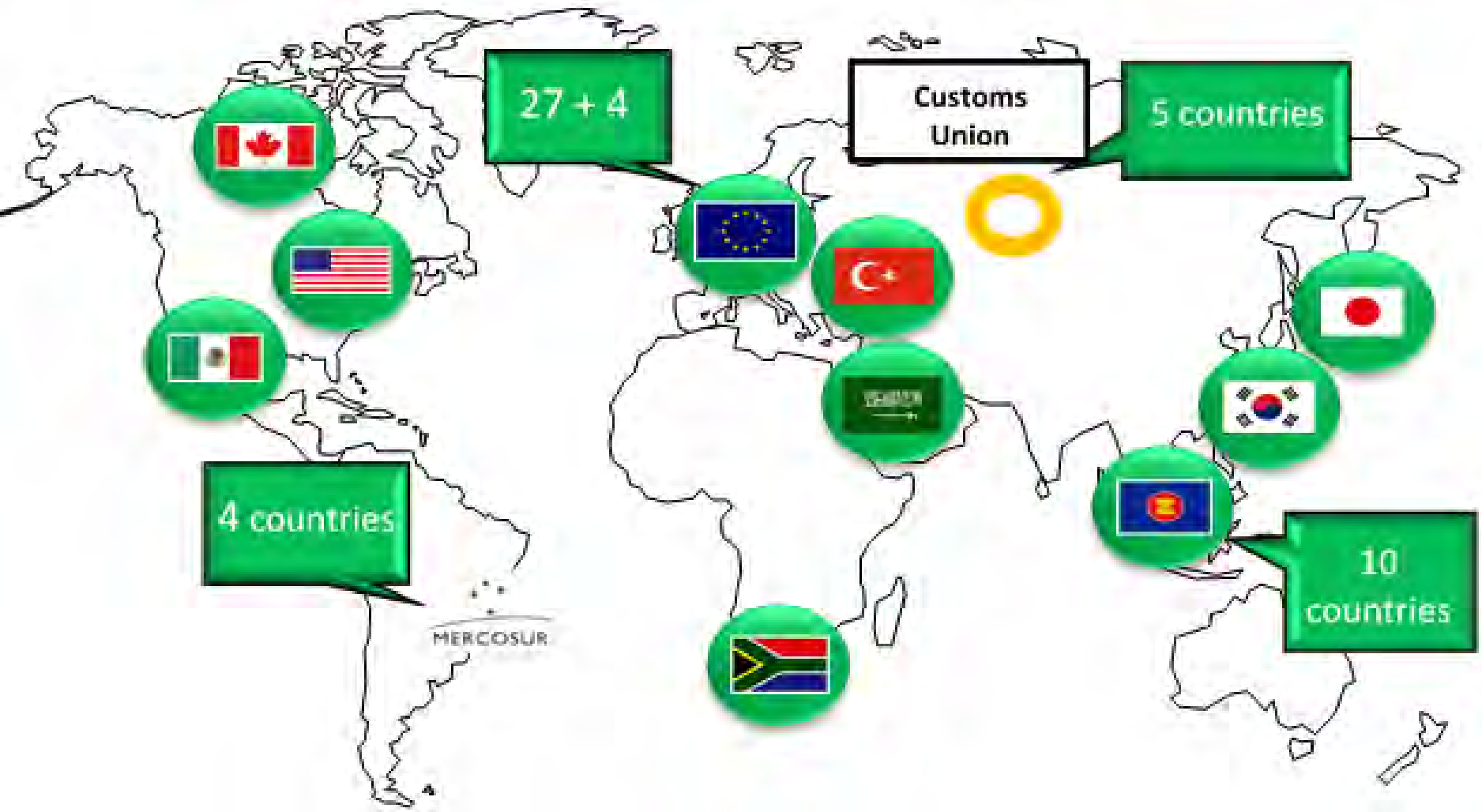
- Pre market approval and registration
- Labeling requirements (Art 20)
- Ingredient lists (Art 7; Art 13)
- Possible inspections of manufacturing and storage conditions for ingredients and finished products

Comparing CDI regulation with global best practices

- ✓ Definition aligned with global best practices
- ✓ Regulation applies to all products under the definition
- ✓ Inspections for manufacturing and storage conditions of ingredients and finished products
- ✓ Annex lists of disallowed ingredients and positive lists for colorants and preservatives

- ➢ Pre market registration:
  - Does not ensure a high level of consumer safety
  - Does not promote a business enabling environment
  - Is an inefficient use of limited Authorities' resources
- Opportunity for alignment with best practices on the roles and responsibilities of actors

Countries with frameworks based on best regulatory principles



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Global Experience with regulatory reform

- Reform is feasible; limited resources necessitate a gradual approach
- Costs can be limited
- The global cosmetics industry is a willing partner for regulators

Countries currently undertaking regulatory reform

- **South Africa** transitioning from a mainly standards based approach in the self regulated framework to a regulation that is based on international regulations while maintaining international standards as best practice

- **Kingdom of Saudi Arabia** transitioning from pre market approval and certificates of conformity to in market control

- **Egypt** currently deliberating a cosmetic reform based on best regulatory principles

Counterfeits

- Global issue
- Regulators and industry share concern
  - Pose potential safety hazards
  - Infringes intellectual property
  - Loss of brand equity and revenue
- Experience internationally shows that standards and pre market approval are not effective in addressing counterfeits
- Should be addressed by law enforcement and/or customs

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Industry & Government Cooperation

- Cooperation between regulators and industry to better identify counterfeit products
- In market control
- Technical testing
- Improve traceability to trace and track counterfeit products on the market

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Thank you!

- What would cooperation with the cosmetics industry look like for you?
- What areas are you most interested in?

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