Update on China Cosmetic Regulatory & Potential Impacts

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Outlines

• 1. China cosmetic regulatory scheme
• 2. Regulatory requirement on imported cosmetics
• 3. Update on regulatory environment
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2. Regulatory requirement on imported cosmetics
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Basic figures on China

**Population**
1.34 Billion (China mainland), around 2.6 times than that of EU (0.51 Billion)

**Land area**
9.6 million square kilometers, over twice than EU area (4.4 million km²)

**Economics**
Nominal GDP, 9.3 trillion USD, equating to 54% of EU (17.4 trillion USD), 2nd largest by country
The ‘facts’ behind figures

**Demography**

1.34 Billion People (2010)

- 665.6 million (urban inhabitants), 49.68%
- 674.1 million (rural inhabitants), 50.32%

Household size: 3.10

- 221 million households
- 401.5 million households
- 225 million households

Personal disposable income:
- 26,955 RMB (2013, urban)
- 8,896 RMB (2013, rural)
The ‘facts’ behind figures

**Actual household disposable incomes**

**Typical Chinese family (3+2+2)**

The Chinese tradition of ‘saving money for their kids’ will define the disposable income per household as, $26,955 \times 5 = 134,775$ RMB ($15,555$ EUR in urban)

In 2010, Euromonitor announced the number of households with disposable income of between 5,000 USD to 15,000 USD stood at 153 million.

The point is the figure is still increased, with prediction of average 38,000 RMB in 2020.
The ‘facts’ behind figures

**Cosmetic Market Size**

China statistics agency released the retail sales of cosmetics is 162.5 billion RMB (18.75 billion EUR) in 2013.

L’Oreal China announced the 2013 revenue is 13.28 billion RMB (1.54 billion EUR) in 2013.

In 2010, total vehicle sales – including buses, trucks and the small commercial vans – rose 46.2 per cent to 13.6m units, this allowed China to coast past the US and become the leading global auto market.
China cosmetic regulatory scheme

5 Must-Know, key points of the regulatory scheme in China

1. Pre-market approval

All the imported cosmetic products and domestically manufactured special use products are subject to pre-market review by CFDA.

This pre-market review scheme was established in 1990 through the implementation of the umbrella law, the Regulation of Hygienic Supervision over Cosmetic Products.

2. Responsible Agent

All foreign exporters should assign a local responsible agent to submit the pre-market application dossier and hold the market permit.
3. Positive & Negative List

CFDA regulates the cosmetic ingredients in the following way:

**Cosmetic Hygienic standards**: presents the list of prohibited & restricted ingredients, preservatives, colorants, dyes and UV filters.

**Inventory of Existing Cosmetic Ingredients in China (IECIC)**: the list of allowable ingredients to be used, and the determinant for new ingredients.

4. Chinese INCI name

The ingredients must be present with Chinese INCI name, and the Chinese over-label is required for all imported cosmetic products.
5. Special and ordinary cosmetics

**Cosmetics Definition**
Article 2 of China’s cosmetic regulation defines cosmetic product as industrially produced chemical product subject to daily use, which are intended to be placed in contact with any external parts of human body (skin, hair system, nails, lips and oral cavity) by spreading, rubbing, spraying, sprinkling etc., with the purpose of cleansing, correcting body odors, protecting, maintain function or changing their appearance.

**Cosmetic type**
Cosmetic products are divided into special cosmetics and ordinary use for the purpose of safety and regulatory management

**Special cosmetics**
Refers to the products with special function, including hair growth products, hair dye, products for waving or straightening hair, hair removal products, beauty breast products, products for body fitness (e.g., slimming cream), deodorants, products for anti-spot or UV protection

**Ordinary cosmetics**
Any products other than special cosmetics, that comply with the cosmetic definition
## China cosmetic regulatory scheme

### Other information on the regulatory scheme

**Authorities involved and their obligations**

<table>
<thead>
<tr>
<th>Authority Name</th>
<th>Responsible for</th>
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<tbody>
<tr>
<td>China Food and Drug Administration (CFDA)</td>
<td>1. Pre-market approval&lt;br&gt;2. In-market surveillance (quality + safety)&lt;br&gt;3. Safety management</td>
</tr>
<tr>
<td>General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)</td>
<td>1. Importation inspection&lt;br&gt;2. Counterfeit products inspection</td>
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<td>State Administration for Industry &amp; Commerce (SAIC)</td>
<td>1. Cosmetic advertising&lt;br&gt;2. Trade mark registration&lt;br&gt;3. Commercial activities management (e.g., consumer complaints)</td>
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Regulatory requirement on imported cosmetics

1. Pre-Market Approval

> All the imported cosmetic products must be approved by CFDA prior to marketing in China

> Exporters should assign one local responsible agent for the pre-market application. The responsible agent can be your importer, subsidiary, or a third party. Be aware of CBI protection!

> Re-formulation or change on the manufacturing process will trigger the new product pre-market application, please contact with your responsible agent for any product change to assure compliance
Regulatory requirement on imported cosmetics

2. Ingredients

> CFDA implements the “positive + negative list” policy to regulate the ingredients, and it will be necessary to check the formulation to make sure all the ingredients are permissible.

> The current “positive + negative” list is set out within the Hygienic Standards of Cosmetics (2007), covering the prohibited substances (1286), restricted substances (73), preservatives (56), UV filters (28) and colorants (156).

> Substances firstly used in cosmetics in China will be regarded as new ingredients, and subject to the safety assessment prior to its application. The Inventory of Existing Cosmetic Ingredients in China (IECIC) is the reference to check the status of new or existing cosmetic substances.

> Some ingredients should comply with the official quality specifications issued by CFDA, such as the content of Di-ethylene glycol which should be less than 0.1% in glycerin ingredient.
Regulatory requirement on imported cosmetics

3. Labelling

> The label on imported cosmetics will be subject to pre-market review by CFDA

> Two options to label the imported cosmetics, newly design the label for China market, or use the original package with Chinese over-label

> Mandatory contents on Chinese label include the product name, address of producer, country of origin, ingredients (Chinese INCI), date of production and durability, and necessary use instruction or precautions

> China has no specific labelling on nanomaterials and allergic fragrance right now.
Regulatory requirement on imported cosmetics

4. Claim

> CFDA established the specific rule on the wording, and some claims should not be present on the package, such as the medical effects.

> Some claims on imported products, such as “hypoallergenic”, “dermatologist tested” or “100% natural”, would be challenged and required to provide proof information by CFDA.

> The claim on the characteristics or effects of the products will be applicable, and no effect supporting document of ordinary cosmetics is required for review, such as anti-aging or whitening skincare.
Regulatory requirement on imported cosmetics

5. Safety

> Industry should substantiate the safety of the products in accordance with the Hygienic Standards for Cosmetic Products

> The safety criteria is product-type dependent, which is set out within Hygienic Standards for different product category, e.g., 1000 CFU/g for skincare and 500 CFU/g for baby products

> There is no requirement on the safety assessment report, and the primary way for safety substantiation is testing, including chemical, microbiological, toxicological (animal testing), and clinical tests.

> Safety assessment on the residual or trace contaminants with toxic concern, officially called risk-concern substance, is required, such as dioxane in the shampoo formulation
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Update on regulatory environment

Key Events

2013-12-26, CFDA released the revised measures on notification of made-in-China non-special use cosmetics, which will be effective in 2014-6-30

- Centralization of on-line notification for domestically manufactured cosmetic products
- Reclassification of whitening products as special use cosmetics
- Alleviating the burden on animal testing for made-in-China non-special use cosmetics

2014-4-11, CFDA unify the authority on cosmetic manufacturing license from AQSIQ

- Combining the two manufacturing license (CFDA + AQSIQ)

2014-6-30, CFDA issued the revised Inventory of Existing Cosmetic Ingredient in China (2014 IECIC)

- Including 8,783 entries and functioning as the determinant of new or existing ingredient
Update on regulatory environment

**Key Events**

2014-11-8, CFDA published the draft version of Cosmetic Management Regulation for public consultation, the umbrella law on cosmetics in China and Legislative Affairs Office initiated the 2nd round of public consultation in 2015-7-20, after which the draft will be subject to the final review of the Standing Committee of State Council which is chaired by the Primer Minister.

2015-2-4, CFDA issued the new draft version of Cosmetic Safety & Technical Standard for public consultation and which will be effective in 2016-12-31.

2015-11-10 CFDA issued the draft guidance on safety assessment of cosmetics for public consultation for the first time in its administrative history.
Update on regulatory environment

Comparison on the basic structure

Cosmetic Hygienic Management Regulation (CHMR, 1990)

Chapter 1 General Principle (4 articles)
Chapter 2 Hygienic Management on Manufacturing (8 articles)
Chapter 3 Hygienic Management on Distribution (4 articles)
Chapter 4 Responsibility of Hygienic Authority (7 articles)
Chapter 5 Penalties (9 articles)
Chapter 6 Supplementary Provision (3 articles)

Total Articles: 34

Cosmetic Management Regulation (CMR Draft, 2014)

Chapter 1 General Principle (8 articles)
**Chapter 2 Ingredients & Finished Products (13 articles)**
Chapter 3 Manufacturing & Distribution (17 articles)
Chapter 4 Labeling and Advertising (8 articles)
**Chapter 5 Market Surveillance (11 articles)**
Chapter 6 Penalties (13 articles)
Chapter 7 Supplementary Provision (8 articles)

Total Article: 86
Update on regulatory environment

Significant Changes on CMR Draft 2014

Scope of Cosmetic Products

*Article 3* Definition of Cosmetic Products

- The application area of teeth and oral mucous membrane is specified, which means that toothpaste could be regarded as a cosmetic in the future

New Cosmetic Ingredients

*Article 9* List of Regulated Ingredient (Positive and Negative list, IECIC and approved NCIs)

*Article 10* New Cosmetic Ingredient Registration

*Article 83* Definition on New Cosmetic Ingredient

- The new cosmetic ingredient registration system will remain, CFDA will adjust the review principles based on the ingredient category and set up a 4-year investigative period for IECIC inclusion
Update on regulatory environment

**Same Playground for Ordinary Cosmetics**

**Article 11** Cosmetic products will be classified as special use and ordinary use, and CFDA will issue and adjust the list of special use cosmetics.

**Article 12** Ordinary cosmetics are subject to the notification in the provisional level FDA, and special one should be registered in CFDA, who have the authority to hand down the review authority to provisional FDA.

- The current pre-market application for imported ordinary cosmetics will be removed, instead of the notification carried out by the local responsible agent within the provisional level, being treated same as the made-in-China ordinary one.

**Import Inspection and Custom Clearance**

**Article 38** Importation Management, CFDA will be responsible for the import inspection, instead of CIQ, and the importer can apply for the Custom clearance based on the permit from local FDA where the Custom is located.

- CFDA will unify the management on cosmetic in the future, such as combining the manufacturing license, in-market surveillance and import inspection.
More Regulatory Requirements on Imported Cosmetics

**Article 19** The oversea supplier should appoint the China local agent to be responsible for the registration/notification and product safety

**Article 32** Traceability, the distributor must keep the product traceable

**Article 37** Withdraw and Recall, distributor should stop marketing, report to CFDA for adverse effects and recall the sold products under the cooperation with the producers

**Article 39**, ‘sticking’ label will not be allowed, which means the Chinese sticker for imported products would be prohibited.

**Article 55** Adverse Effect Monitoring, it is intended to set up the related monitoring system to cover the supplier, clinical and social resources

**Article 57** Oversea Inspection, CFDA can investigate the foreign supplier on site

- The responsibility on safety for imported cosmetics is firstly specified, and the local responsible agent should shoulder it, which is quite the same as the ‘responsible person’ concept
- Safety Assessor is specified within Article 20, who can be the in-house staff or third party
- Pre-market burdens will be replaced by the post-market compliance, such as the adverse effect monitoring, product traceability, and labeling re-design for China market
## Update on regulatory environment

### Comparison on Cosmetic Safety & Technical Standard

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<tr>
<td><strong>1) Heave Metal</strong>&lt;br&gt;Limit: 40 mg/kg</td>
<td><strong>1) Heave Metal</strong>&lt;br&gt;Limit: 10 mg/kg</td>
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<td><strong>2) Prohibited Ingredients</strong>&lt;br&gt;1,288 entries</td>
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<td><strong>3) Preservatives</strong>&lt;br&gt;56 entries</td>
<td><strong>3) Preservatives</strong>&lt;br&gt;51 entries, ban on some parabens (isopropyl-, isobutyl- and benzyl-), and exclude Chloroacetamide, Methenamine, Methyldibromo glutaronitrile, Quaternium-15 and Sodium iodate</td>
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<tr>
<td><strong>4) UV Filters</strong>&lt;br&gt;28 entries</td>
<td><strong>4) UV Filters</strong>&lt;br&gt;27 (exclude PABA)</td>
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<td><strong>5) Colorants</strong>&lt;br&gt;156 entries</td>
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<td><strong>6) Hair Dye</strong>&lt;br&gt;93 entries</td>
<td><strong>6) Hair Dye</strong>&lt;br&gt;73 entries</td>
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Useful Links

Updates on China cosmetic regulation
www.chemlinked.com,

Guidance in a nutshell – Ebook 18
Your gateway to China cosmetic regulation
all freely download on Chemlinked.com

Communication -
Dedicated discussion group in LinkedIn
China Cosmetic Regulation and Safety Evaluation

<table>
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<tr>
<th>Title</th>
<th>Ebook 18: China Cosmetics Guidance in a Nutshell</th>
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<td>Code</td>
<td>Ebook18</td>
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<tr>
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<tr>
<td>Author</td>
<td>Mr. Tommy Kong (REACH24H)</td>
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<tr>
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Thank you for your attention!

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