

CHAPTER 17 COSMETICS

OVERVIEW

The Cosmetics Sector Committee represents the voice of EuroCham business members engaged in importing, manufacturing and trading cosmetic products in Vietnam. Recently, the Cosmetics Sector Committee has been actively collaborating with management authorities to address challenges in business operations and propose policy changes to foster the growth of the Vietnamese cosmetics industry, increase its competitiveness in the region, and meet diverse trends and needs of the market.

At the conference on “The Current Situation and the Orientation of Cosmetic Management” held on 16 June 2023 in Hue City, the Drug Administration of Vietnam - Ministry of Health announced a plan to promulgate a Decree on cosmetic management to complete the legal framework for the cosmetics manufacturing and trading industry in Vietnam. The Cosmetics Sector Committee shares the same vision as the regulatory authority and aims to maintain our cooperating in drafting the Decree. We believe that the relevant authorities concentrate resources and strengthen post-market surveillance in cosmetic management; additionally streamline administrative procedures and reduce pre-market surveillance requirements to create favorable conditions and provide a robust impetus for the growth of businesses and the Vietnamese cosmetics industry.

Regarding antiseptic products, in 2023, the Health Environment Management Agency - Ministry of Health drafted a Decree amending Decree 91.¹ We acknowledge the open-mindedness of the management authority in considering businesses’ comments during the drafting process. However, there are still some issues that require further attention in order to promote the development potential of this product group.

I. SIMPLIFY ADMINISTRATIVE PROCEDURES IN COSMETIC MANAGEMENT - FOCUS ON STRENGTHENING POST-MARKET SURVEILLANCE

Relevant authorities: Drug Administration of Vietnam (DAV) & Department of Legal Affairs - Ministry of Health, Agency of Grassroots Culture - Ministry of Culture, Sports and Tourism

1. Removal of cosmetic advertising pre-approval procedures

Issue description

The plan to remove cosmetic advertising pre-approval procedures and change the cosmetic advertising management method from pre-market to post-market surveillance has received support from the cosmetics management authority since 2019.² The Drug Administration of Vietnam has also expressed its support by suggesting the abolition of the procedure for approving cosmetic advertisement content and coordinating with relevant authorities (Department of Legal Affairs - Ministry of Health, Agency of Grassroots Culture - Ministry of Culture, Sports and Tourism) to amend the document upon receiving their requests.³ The Prime Minister also promulgated Decision 1661,⁴ setting out a roadmap to completely remove this procedure in the period 2022-2025.

However, businesses are concerned that the revision of applicable regulations, which have been issued since 2019, has not yet been initiated.

¹ Decree 91/2016/ND-CP dated 1 July 2016 on management of insecticidal and germicidal chemicals and preparations for household and medical use (Decree 91).

² Official Dispatch 21305/QLD-MP dated 19 December 2019 of the Drug Administration of Vietnam.

³ Official Dispatch 9153/QLD-MP dated 16 September 2022 of the Drug Administration of Vietnam.

⁴ Decision 1661/QĐ-TTg dated 4 October 2021 on approving the plan to reduce and simplify regulations related to business activities under the management of the Ministry of Health.

Potential gains/concerns for Vietnam

Without changes in the regulations, businesses continue to be impacted by the requirement for pre-approval of cosmetic advertising. This pre-approval process does not hold much significance in terms of management compared to the actual advertising inspection of advertising, but it significantly hampers the progress of introducing products to the market and reaching consumers.

It is known that the Ministry of Culture, Sports and Tourism plans to revise Decree 181⁵ and eliminate the requirement for pre-approval of cosmetic advertising once the amendment to the 2012 Advertising Law is completed.⁶ However, such requirement is not specified in the 2012 Advertising Law and is only set out in Decree 181. Thus, the content of cosmetic advertising pre-approval requirement can be removed immediately regardless of the revision of the Advertising Law. The roadmap to amending the Law usually takes several years. We recommend that the roadmap to remove advertising pre-approval procedures proposed by the Prime Minister should not be dependent on the revision of the Law.

The Drug Administration of Vietnam has included the content of reducing administrative procedures for cosmetic advertising in the program for developing the Decree on cosmetic management. We appreciate this proposal and hope to receive support from the Agency for Foundation Culture to accelerate the revision of advertising regulations in the coming time, ensuring consistency with the content in the Decree on cosmetic management.

Recommendations

- The Agency for Foundation Culture removes the requirement for cosmetic advertising pre-approval in Decree 181 at the earliest opportunity.
- The content of reducing administrative procedures for cosmetic advertising should be incorporated in the Decree on cosmetic management.

2. Removal of requirement for a Certificate of Free Sale

 Relevant authorities: Drug Administration of Vietnam (DAV) - Ministry of Health (MOH)

Issue description

Currently, the Certificate of Free Sale (CFS) is required by the Ministry of Health as a mandatory document for the notification of imported cosmetics products. We acknowledge that CFS does not contribute to ensuring the quality of cosmetic management but is rather an unnecessary administrative requirement that can be removed.

In reality, many cosmetics with CFS are not available in the country of issuance and CFS are issued by industry associations rather than management authorities in many countries. The CFS requirement has been removed for cosmetics produced in CPTPP countries since 2020; furthermore, starting from 2021, for cosmetics imported from ASEAN countries, the template for notification of cosmetic products can be used instead of CFS. Implementation to date has been smooth and has not caused consumer safety issues or regulatory difficulties. Imported products can still be traded safely when enterprises comply with the standards on factory and product safety and cosmetics can be managed in post-audit form. This proves that CFS is an unnecessary administrative requirement that can be abolished as it discriminates against EU imported products.

Potential gains/concerns for Vietnam

In the dialogues in 2019 and 2020 between EuroCham and the Office of Government, the representative of the Ministry of Health announced that after removing the CFS requirement for cosmetics produced in Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) countries, the Ministry of Health will work with relevant ministries and authorities to consider options for other areas, including the EU. At EuroCham's 2023 Whitebook launching ceremony, the Drug Administration of Vietnam shared that the Ministry of Health will study management requirements and, if appropriate, remove the CFS requirement for imported cosmetic products. The

⁵ Decree 181/2013/ND-CP dated 14 November 2013 of the Government detailing the implementation of some articles of the Advertising Law

⁶ Advertising Law 16/2012/QH13 dated 21 June 2012 promulgated by the National Assembly (2012 Advertising Law)

business community anticipates that the removal of CFS requirement for imported cosmetics will be included in the Decree on cosmetic management in the near future.

Particularly for cosmetics imported from EU countries, Vietnam has signed the Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme which has been developed according to the Regulation (EC) 1223/2009 of the EU on cosmetic products. Considering that CFS is no longer required for ASEAN Member States, it is reasonable to remove the CFS requirement for cosmetics imported from the EU. The EVFTA requires imported products from the EU not to be discriminated against other imported products and prohibits unjustified or unnecessary obstacles to trade.

Recommendation

- The content on removing CFS requirement for all imported cosmetics, especially those imported from the EU, should be included in the Decree on cosmetic management.
- No alternative should be required when the CFS requirement is abolished.

II. STRENGTHEN THE APPLICATION OF INFORMATION TECHNOLOGY AND E-GOVERNMENT IN COSMETIC MANAGEMENT

1. Nationwide cosmetic online management

Relevant authorities: Departments of Health (DOHs), People's Committees of provinces and cities; Drug Administration of Vietnam (DAV) - Ministry of Health (MOH)

Issue description

The process of notifying imported cosmetics to the DAV could be implemented online on the National Single Window linked to the customs system. However, due to occasional failures of the system, the application submission and receipt of notification numbers take a lot more time than the three-day period stated in the regulation,⁷ even up to several months, which has caused significant inconvenience for businesses.

In most local DOHs, the process of receiving applications for notification of domestically produced cosmetics still relies on hard copy documents. While some DOHs have online systems, they still require hard-copy dossiers along with the online applications. Each DOH also has its own system which varies in the level of accepting online applications and is not consistent with the imported cosmetics management system.

In addition, Circular 06 has some wording that can be interpreted as a requirement to submit hard-copy documents: "original or copy", "02 copies of cosmetic product announcement sheet"; "video disc, audio disc, soft file with 03 scenarios". Some DOHs refer to these terms to justify their refusal to accept online applications without hard copies

Potential gains/concerns for Vietnam

The DAV and businesses have recently encountered numerous challenges as a result of failures in the imported cosmetics notification system. In addition, the DOHs' reliance on hard-copy dossiers is not aligned with e-Government development. The submission period is prolonged due to objective factors and the reception of dossiers by post.

In addition, information on management of imported cosmetics and domestically produced cosmetics is not synchronized on one system. DAV does not have a centralized database for nationwide cosmetics management. When a regulatory authority needs to access information about the number of products, both imported and domestically manufactured, from each enterprise, the number of products notified in each province or city, or the use of a chemical in an ingredient formula, etc., they must submit a written data request to each DOH and await the reports from the respective DOHs.

⁷ Circular 06/2011/TT-BYT dated 25 January 2011 of the Ministry of Health regulating the cosmetic management (Circular 06)

Recommendations

- To synchronously solve the problems, we propose the MOH develop online software to receive cosmetic notification dossiers nationwide. This system will consistently apply level 4 public services to both imported cosmetics (notified to the DAV) and domestically produced cosmetics (notified to the DOH). By doing so, we not only address the challenges faced by businesses but also facilitates efficient and transparent dossiers processing. Businesses in every province and city can apply the same online notification process and each province or city does not need to develop its own software. This system will serve as a comprehensive nationwide cosmetics industry database, allowing management authorities to easily access information and support post-market surveillance efforts.
- Revise the provisions on cosmetic notification process in the Decree on cosmetic management and remove any words that could be interpreted as requiring of hard-copy applications in Circular 06.
- When planning to upgrade the software, management authorities should notify businesses in advance of the expected time so that businesses can actively plan their upgrade accordingly.
- Propose all provincial DOH to apply a full online approval procedure for Cosmetic Notification and Cosmetic Advertising without requiring hard copy dossier submission.

2. Allow electronic labeling of some mandatory information on cosmetic labels

Relevant authorities: Drug Administration of Vietnam - Ministry of Health, Directorate for Standards, Metrology and Quality - Ministry of Science and Technology

Issue description

According to Circular 18⁸, electronic labeling has been implemented for some mandatory labeling information on product labels. However, Circular 18 does not apply to cosmetic products.

Potential gains/concerns for Vietnam

Because of their specific nature, cosmetic products are often small in size. Therefore, obtaining permission for electronic labeling will be of great significance in minimizing the label area to meet all legal requirements of labeling information or will reduce the number of labels that must be discarded or reprinted in case of minor changes in label content, thereby improving flexibility in production.

In terms of regulations, according to Circular 06 on cosmetic management and the Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme, there are nine mandatory information items that must appear on cosmetic labels. In case the primary container does not have enough space for all these nine information items, the product name and production batch number are required while other information may be shown on the secondary label. Among the information that can be placed on secondary labels, businesses propose allowing electronic labeling for the following information:

- Ingredients according to international nomenclature: Ingredient names according to international nomenclature are unfamiliar to most consumers. This content mainly facilitates management authorities and supermarkets in checking circulating goods and comparing with the ingredients listed in the template for notification of cosmetic products. Consumers and regulatory agencies with specialized knowledge can easily access this information electronically.
- Usage instructions: Cosmetics used by most consumers are common products in daily life such as shampoo, shower gel, toothpaste, hand soap, etc. and usually have no special instructions for use.
- Origin: Products' primary labels contain the name and address of the company in charge of product marketing - the entity responsible for quality and products in Vietnam. In terms of origin (place of manufacture), cosmetic

⁸ Circular 18/2022/TT-BKHCN dated 30 December 2022 of the Ministry of Science and Technology detailing a number of mandatory contents to be electronically displayed on labels of some groups of goods

businesses often have many factories in many countries producing with the same formula and following the same quality standards. Information of product origin should be presented in electronic form so that businesses do not discard the labels when they relocate any factory, thereby reducing waste discharged into the environment.

According to the discussion of the Cosmetics Sector Committee with representatives of the Drug Administration of Vietnam at the 2023 Whitebook launching event, this proposal has been acknowledged by management authorities to consider including in relevant regulations for cosmetic products.

Recommendations

- The Drug Administration of Vietnam incorporates electronic labeling into cosmetic labeling regulations in the Decree on cosmetic management.
- The Directorate for Standards, Metrology and Quality includes cosmetic products in the scope of application of electronic labeling in the updates of Circular 18.

III. DEVELOP A COMPETITIVE AND FAIR COSMETIC MARKET FOR CONSUMER SAFETY

Relevant authorities: Drug Administration of Vietnam (DAV) - Ministry of Health, Vietnam E-commerce and Digital Economy Agency & Vietnam Competition Commission - Ministry of Industry and Trade

Issue description

Currently, cosmetics produced, imported, and traded by individuals or private stores are widely sold, particularly on e-commerce platforms. Any individuals, regardless of being a brand owners, product manufacturers, or authorized distributors, can effortlessly sell cosmetic products without needing to comply with cosmetic notification regulations, register for advertising, pay taxes, or register for doing business, etc. when selling on e-commerce platforms. Because of these advantages, individual sellers can offer prices lower than the market prices to attract customers.

Potential gains/concerns for Vietnam

This situation has led to unfair competition in the business environment, significantly affected registered businesses, brand owners, and genuine distributors as well as resulted in tax losses for the Government. In addition, because the origin of cosmetic products sold by these individuals often cannot be clearly verified, consumers are at a high risk of purchasing fake and low-quality goods.

The available information on existing e-commerce platforms lacks clarity, making it difficult for consumers to differentiate between the legitimacy and safety of products sold in official stores and those sold in unofficial stores. Besides, the suggestion of products sold by unofficial stores may confuse consumers who are specially seeking for product information in an official store.

Recommendations

- The Ministry of Industry and Trade updates regulations related to e-commerce management and completes e-commerce management legal framework to upgrade the management level in line with the current development of e-commerce.
- The Ministry of Industry and Trade strengthens management on e-commerce platforms, especially for unofficial stores to build a fairer and healthier business environment.
- The Drug Administration of Vietnam and Departments of Health put more resources and focus on post-market surveillance of cosmetics traded on electronic platforms.

IV. STREAMLINE THE PROCESS OF REGISTRATION OF SKIN ANTISEPTICS WITH SIMPLE FORMULATION

Relevant authorities: Health Environment Management Agency (VIHEMA) - Ministry of Health

Issue description

Many skin antiseptic products, such as hand sanitizers, have simple formulation and are widely used in daily life with high safety level, which ensure people's health and hygiene. In Vietnam, the process of registering these products is the same as insecticidal products, which is complicated, depends on hard-copy dossiers, and usually lasts 4 to 6 months, even up to 12 months, much more complicated than other countries in the region and around the world.

Potential gains/concerns for Vietnam

EuroCham appreciates the purposes of the Ministry of Health's amendment to Decree 91, which are to suit management practices and facilitate production and business activities of enterprises. We acknowledge that VIHEMA agreed to allow submitting experiment test from the beginning for hand sanitizer containing safe active substances (ethanol and isopropanol) and accepting experiment tests from foreign qualified laboratory for imported antibacterial product. However, the latest revision only applies to minor of household skin antiseptics and does not cover for majority of skin antiseptic with simple formulation used widely in daily circumstances. The registration procedure have not yet been streamlined significantly.

Recommendations

We request that the MOH develop a separate notification for skin antiseptics with common formulas and active ingredients similar to other Asean countries (Singapore, Thailand, Philippine, Malaysia...) and reduce unnecessary document requirement. This group's safety risk is completely different from that of insecticides, so management requirements should be adjusted to accommodate businesses's and consumers' needs.

For these products, test results of overseas-qualified laboratories should be accepted for both import and locally manufactured antiseptic products. The guidance regulation on experiment procedures for antiseptic should also be revised and updated.

ACKNOWLEDGEMENT

EuroCham Cosmetics Sector Committee