
Indian government steps in to regulate cosmetic imports

Next time you enter a store to buy your favorite perfume, and the salesman tells you that it is an 'imported' brand and will soon become 'out of stock', believe him. However, this will not happen because of poor inventory management by the store. It is because of the introduction of new regulations which have come into effect from April this year as a result of which the 'unregulated' imports of cosmetics in India have completely stopped. The new rules introduced by the Ministry of Health & Family Welfare and administered by Drug Controller General of India, now require a compulsory registration certificate for importing cosmetics in India.

The Indian Government has implemented new rules (from April 1st, 2013) to regulate the import of cosmetics. The rules to amend the existing **Drugs and Cosmetics Rules, 1945**, were first published (as draft rules) way back in February 2007. Subsequently after few amendments these were finalized as 'Drugs and Cosmetics (4th Amendment) Rules, 2010' on 19th May, 2010. Amidst concerns raised by many importers on the *timely* grant of registration certificates, the Government did defer the implementation. However, these rules were finally brought into effect on 1st April, 2013.

The Indian Cosmetic Industry:

According to a research report "Indian Cosmetic Sector Analysis (2009-2012)", published by Research and Markets, Indian cosmetics industry has emerged as having immense growth potential. The report notes that the cosmetics industry has registered sales worth Rs. 422.3 Billion (approx. US\$ 9.3 Billion) in 2010. It further observes that this rise is attributed to the ever-growing purchasing power and rising fashion consciousness and beauty concerns of the Indian population. And of course Indian urban population's brand/s fetish appears to be never satiated giving rise to increasing import of cosmetic products.

The 'new rules':

All cosmetic products that are imported for sale in India now need to be registered with the **Central Drugs Standard Control Organization** (CDSCO) which has been appointed as the licensing authority for the purpose of these rules.

This new 'registration' requirement is primarily to regulate indiscriminate import of beauty and personal care products by traders with no accountability for contents and no mechanism to fix responsibility in case a consumer is not satisfied with the quality. In many cases, because of the lack of regulations on imported cosmetics, these were found to contain hazardous materials. Thus, new regulation is an attempt to check the sale of sub-standard cosmetic products and also to harmonize import requirements with those for products manufactured in India.

Which products are covered?

All cosmetic products which are 'imported' for 'sales and distribution in India' are covered. The Indian Food and Drugs Cosmetics Act provide a broad definition of cosmetics:

"any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic."

Some NEW 'definitions':

Some of the new definitions introduced under the aforementioned Rules are as follows: -

- i. **"a Manufacturer is the 'Brand/trade name owner'"** and not the 'actual manufacturer; and

- ii. **A 'Brand' is a category/class of products** as opposed to being just the trade name /brand. *For example, the 'Brand' will include all brands of lipsticks imported by the applicant and not just a particular 'brand name' of Lipstick. Further, for each product class, a separate application needs to be filed. For example, shampoo and conditioner belong to different classes even though these may have a common 'brand name'. A single application may be made for registration of more than one brand of cosmetics (including its different variants and pack sizes) by the same manufacturer.*

Registration Procedure:

The trade mark owner, who has no manufacturing unit in India but intends to sell his goods by way of import through their appointed importers/distributors/marketers in India, is now required to obtain registration certificate to continue with their marketing activities in India.

For this purpose an application for registration on Form-42, along with all requisite documents needs to be submitted to Drugs Controller General (I), CDSCO, FDA office in New Delhi.

Information required from the Manufacturer/authorized applicant:

The new rules are an attempt to identify the source of ingredients used in the cosmetic product, its place of manufacture, claimed benefits and most importantly, its safety standards for human use. Hence, the rules have mandated a compulsory registration which requires submission of an application accompanied by documents which provide such information.

Documents required and fees:

An application for the issue of a Registration Certificate for cosmetics intended to be imported into India need to be made on a specified form, i.e. **Form 42** either by:

- a. *the manufacturer himself or*
- b. *by his authorised agent or*

c. *importer in India or*

d. *by the subsidiary in India authorized by the manufacturer*

Further, the documents to be provided along with the application include:

- a) A request letter by the applicant on the letterhead of the importer or the authorized agent applying for the registration duly stamped and signed by the authorized person.
- b) Form 42 - This requires details such as the location of the actual manufacturing sites of the products. A single application can cover many brands (read Trademarks/brand names), many variants; many pack sizes and different manufacturing units corresponding to the products applied.
- c) Proof of payment of requisite fee: Original treasury challan indicating the payment of registration fee of **USD 250** or its equivalent in Indian rupees for each 'brand' of cosmetic product.
- d) Power of Attorney (if the application is being submitted by an authorized agent of the manufacturer. This document needs to be notarized and apostilled or legalized by the Indian embassy in that country)
- e) Schedule D III (details of the cosmetic products to be imported including the chemical and safety data)
- f) Original or a copy of the Label and art works thereof (this will contain the details of the actual manufacturer and in cases where the manufacturer is not the brand name owner, the label will at least state, 'manufactured in XYZ country')
- g) Free Sale Certificate (FSC)/Marketing Authorization
- h) Manufacturing License (and attested English translation if not in English), if any: If there are multiple manufacturers for a single product, all manufacturers need to provide these documents
- i) Product specifications and testing protocols: details of ingredients used, quality data etc.
- j) List of countries where Market Authorization or import permission or registration has been granted
- k) Package inserts, if any (copies of any leaflets, product specification data that goes inside the packaging has to be provided. No specific requirement has been listed, it is suggested to provide information about the potential side effects/allergic reactions and other safety concerns and remedies available)
- l) Copies of the information about the brands, products and manufacturer

Time lines for processing of applications:

The time period for issuance of the registration certificate has been indicated to be within six months from the date of submission of the application form and the required documents (especially details required with schedule D III). The feedback suggests that the department is processing and granting the registration certificates within 2-3 months of application being filed.

The 'registration certificate' and validity:

The duration of a registration certificate (which is provided with certain conditions imposed and is given in a specified format- Form 43) is valid for a period of three years from the date of its issuance.

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