

Pharma industry raises concerns over new Schedule M's impact on cosmetic manufacturing

The Federation of Pharma Enterprises (FoPE) that represents medium and small-scale enterprises has written to the health ministry citing that setting up a new plant exclusively for cosmetic manufacturing is financially not viable.



New Delhi: The pharmaceutical industry has raised concerns regarding the government's newly notified schedule M that proposes a blanket ban on manufacture of any other article or product apart from

drugs in the units licensed for drug production.

The Federation of Pharma Enterprises (FoPE) that represents medium and small-scale enterprises has written to the health ministry citing that setting up a new plant exclusively for cosmetic manufacturing is financially not viable. It sought that such units be permitted to manufacture cosmetics in the area dedicated for making topical products such as external preparations such as creams and lotions.

According to FoPE's representation, the requirement as specified in the revised Schedule M has caused difficulties to members which are medium scale and small-scale pharmaceutical entrepreneurs having well-equipped facilities with good manufacturing practices.

An exception was provided from the requirement that no manufacturing activity shall be undertaken therein except in respect of units licensed prior to 2001. In view of the aforesaid exception, units licensed prior to 2001 were allowed to manufacture allied items such as nutraceuticals and ayurvedic medicines in the same plant. They were also allowed to manufacture cosmetic products in the section meant for topical products i.e. external preparations.

"However, some of them licensed prior to 2011 are engaged in the manufacture of cosmetics in the external products section. Now, in view of revised Schedule M, they will have to set up a new plant exclusively for cosmetic manufacturing which is financially not viable," it said.

They also noted that entrepreneurs from 1988 till 2024 had no difficulties or issues about quality for either drug or cosmetics products as necessary precautions including line clearance and preventing cross contamination were taken by the concerned licensees.

Against this background, FoPE has urged the government to allow the medium scale and small-scale manufacturers to make cosmetic products in the section designated for manufacturing of topical product i.e. external preparations such as creams and ointments.

FoPE has asked the government to consider their request as cosmetic products are mostly in the form of creams, suspensions, lotions that are like topical products such as creams, and ointments. It also said that like topical products, cosmetic products are also used externally, mostly for aesthetic purposes.

"Thus, there is a strong logical justification for allowing cosmetic product in Section dedicated for manufacture of external preparation as by allowing it the cosmetic will be manufactured in much more stringent good manufacturing practices requirement as compared to those specified in Seventh Schedule of the Cosmetics Rules, 2020," the letter to the health secretary said.

News Source:

<https://health.economictimes.indiatimes.com/news/pharma/pharma-industry/pharma-industry-raises-concerns-over-new-schedule-ms-impact-on-cosmetic-manufacturing/110780526>