Industry seeks more support for domestic manufacturing of bulk drugs

The much anticipated guidelines for the four schemes to promote indigenous manufacturing of bulk drugs, active pharmaceutical ingredients (APIs) and medical devices have been released by Government of India on July 27, 2020. These schemes provide grant-in aid, production linked incentives and other financial benefits for setting up bulk drug parks and medical devices parks. These schemes also promote indigenous manufacturing of key starting materials (KSMs) which are used as inputs for manufacturing APIs.

India is self-reliant in 700 APIs used for manufacturing formulation drugs. However, it is critically dependent on imports for 53 other APIs that are used in manufacturing finished drugs. The guidelines issued for these four schemes encourage domestic production of these 53 APIs. The guidelines contain a list of 41 products to enable domestic production of these 53 bulk drugs. Also, the guidelines incentivize local manufacturing of medical devices, for which India is dependent on imports to meet 86% its requirement.

Under these schemes, government offers financial incentives for companies or special purpose vehicles (SPVs) that set up manufacturing units for these identified products. Micro, small and medium enterprises (MSMEs) that supply chemical ingredients to bulk drug manufacturers can also benefit from these schemes by forming partnership or joint ventures with their corporate buyers.

The financial incentives given under these schemes are expected to offset the manufacturing cost disadvantage that Indian companies suffer vis a vis Chinese manufacturers. According to industry estimates, this manufacturing disadvantage is estimated to be around 23%. Chinese companies are able to produce bulk drugs at low cost because of their large scale production capacity and economies of scale.

While the domestic pharmaceutical industry welcomes these schemes, they feel that the incentives under these schemes are not sufficient to compensate for the manufacturing cost disadvantage suffered by Indian companies. Therefore, the domestic industry wants the government to amend the guidelines by including the following suggestions.

1. The incentives announced by the government are subject to annual ceilings. According to the industry, this cap on incentives will prevent manufacturers from setting up large scale production facilities to reap economies of scale. Therefore, the industry wants the government to reconsider the ceiling mentioned in the guidelines.

2. The guidelines contain a list of 41 products used for producing bulk drugs. The industry wants the government to expand this list of chemical products covered under this

scheme to include all intermediates used in the production of Active Pharmaceutical Ingredients (APIs).

3. Bulk drug manufacturing facilities release effluent waste, which are harmful to the environment, unless discharged with proper treatment. Therefore, the industry wants government to encourage technology partnership between manufacturers and academic or research institutions for eco-friendly treatment of effluents generated from the manufacturing process.

4. Interest rates in India are higher than those in the global market. To reduce cost of domestic manufacturing, banks should offer loans for projects under these schemes at interest rates prevalent in global markets.

Industry players expect that the above recommendations, if included in the guidelines, will make these schemes attractive for local and foreign investors.

Notifications

Press Information Bureau, Government of India

Schemes for Bulk Drug Parks and Medical Devices Parks

https://pib.gov.in/PressReleasePage.aspx?PRID=1641517

Single window clearance for approvals to be set up soon

https://pib.gov.in/PressReleasePage.aspx?PRID=1641556

Daily Bulletin on COVID 19

https://pib.gov.in/PressReleasePage.aspx?PRID=1641580

CBIC

Fixation of tariff value for edible oil, brass scrap

https://www.cbic.gov.in/resources//htdocs-cbec/customs/cs-act/notifications/notfns-2020/cs-nt2020/csnt62-2020.pdf

Amendment in customs notifications

https://www.cbic.gov.in/resources//htdocs-cbec/customs/cs-act/notifications/notfns-2020/cs-nt2020/csnt61-2020.pdf

RBI

Speech by RBI Governor

https://www.rbi.org.in/Scripts/BS_SpeechesView.aspx?Id=1098