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PART III

Other Notifications, Orders, etc.

GOVERNMENT OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS
AND COORDINATION
(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 2nd March, 2022

No. F. 1-2/2022-CEO-DRAP.—In pursuance of the Federal Cabinet's decision in Case No. 79/05/2022 dated 15th February 2022, the Drug Regulatory Authority of Pakistan is pleased to notify the 'Promotion and Growth of Active Pharmaceutical Ingredient (API) Industry in Pakistan Policy', as follows: -

Introduction

Advanced and efficient technologies are needed for Active Pharmaceutical Ingredients (APIs) production to gain a competitive edge. Pakistan's API industry is in its initial phases and requires policies that promote its expansion. Currently, 23 pharmaceutical manufacturers possess the license to manufacture API out of which 05 have the license for the basic manufacturing 39

(419)

Price: Rs. 6.00

[7430(2021)/Ex. Gaz.]

APIs are currently licensed for production by way of basic manufacturing whereas 117 APIs are licensed for production by way of semi-basic. These firms produce approximately 15% of API while the remaining 85% is being imported. Among locally produced bulk drug substances (APIs), national demand of 16 APIs is met and the most of national leading brands are using the afore-mentioned local APIs in their products.

Global API market is currently over 180 billion USD and projected over 250 billion by 2024. Owing to its great potential and attaining self-reliance, it is desirable to invest in this sector. However, Investors shy away from setting up manufacturing plants due to complex nature of manufacturing processes, substantial cost of R&D involved, readily available APIs from international market and lack of incentivization.

There are numerous raw materials in the form of chemicals, starting materials and intermediates that are required for API manufacturing. The synthesis process of APIs might need multi-step complex chemistry utilizing a range of processing technologies and therefore, specialized equipment.

Due to its lucrative nature, many countries are investing in promotion and growth of their API industry. For this purpose, Governments of China, India, and Bangladesh have taken the lead to incentivize this industry for boosting its potential. For creating self-reliance in the country by encouraging manufacture of pharmaceutical raw materials by way of basic/ semi-basic manufacture, following short and long-term incentives to the existing and prospective industry are proposed:

A. Short-Term Incentives to API manufacturers

1. Reduction is suggested in custom duty on those starting & intermediate materials, chemicals, and machinery items by Tariff Policy Board for five years which are used in basic & semi-basic manufacturing but are not locally manufactured, and do not fall under current list of items having zero percent custom duty. Initially, a list of specific items will be referred by DRAP. However, due to dynamic nature of this list, DRAP may consider addition or deletion after approval of its Central Licensing Board (CLB) as and when needed.
2. Any reduction in the import prices (dumping prices), of the materials manufactured in Pakistan, by the foreign suppliers should immediately be supported through levy of Anti-dumping Duty. The M/o NHS, R&C/ DRAP, after fulfilment of criteria of availability and quality, will forward the specific items to Tariff Policy Board for imposition of regulatory duty as and when it deems appropriate.

3. API manufacturers can avail financing facilities already available under 'Export Finance Scheme (EFS)' and 'Long-Term Finance Scheme (LTFF)' provided by State Bank of Pakistan.
4. Allowing API manufactures to retain export earnings to the tune of 15 % of FOB value of their export's proceeds same as already allowed by Ministry of Finance for pharmaceutical sector.
5. The tariff structure of APIs will be reviewed by the Tariff Policy Board, on the recommendation of Ministry of National Health Services, Regulations and Coordination, as and when the production starts, on case-to-case basis.
6. DRAP will establish a cell for guidance to applicants/ investors, and to coordinate with relevant ministries on timely completion of requisites for issuance of licenses and registrations applied to it on a fast-track basis.
7. Establishing linkages between academia and basic /semi-basic API manufacturers for funding of related research projects from Higher Education Commission (HEC)/ Pakistan Science Foundation/ DRAP CRF/ International Donor Agencies.

B. Long-Term Incentives to API manufactures

1. Establishment of API Mega Parks with all the required facilities including but not limited to common wastage and effluent treatment plants, power houses, distillation plants and environmental control.
2. Ministry of Industries & Production shall develop a policy to incentivize Naphta Cracking Plant for promoting basic chemical and pharmaceutical industry.

MUHAMMAD IQBAL,
Deputy Secretary (Admin-I).