MITTELSTAND GLOBAL
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Supported by:
Federal Ministry for Economic Affairs and Energy
on the basis of a decision by the German Bundestag

PharmaUpdate India
2021/1

Having established itself as a key pharmaceutical market in South Asia, India is already a host to many multinationals drugmakers. Economic expansion, a growing middle class, and political reforms are forces contributing to this development. At the same time, the Indian pharmaceutical market is subject to relatively frequent and short-term regulatory interventions and new business models are evolving. The export initiative for the German healthcare industry, HEALTH MADE IN GERMANY, set up *PharmaUpdate India* to ensure German companies are able to respond rapidly to changes in import, licensing, and marketing regulations. The English-language newsletter will appear regularly and provide the latest information on the most important new regulations for the pharmaceutical market in India.

***PharmaUpdate India* is a service provided by HEALTH MADE IN GERMANY, the export initiative for the German healthcare industry, set up by the German Federal Ministry for Economic Affairs and Energy (BMW).**

1. Government extends validity of existing import licences for drugs

The Ministry of Health and Family Welfare (MoH&FW) has issued a notification specifying the validity of import licence which are about to expire and where drug companies wish to renew the licences. The Government received representations and feedback from pharmaceutical industry stakeholders in India to consider providing extension on the validity of import licences to ease the import of drugs and pharmaceutical products amid the disrupted supply chain ecosystem. As per the latest notification, the Health Ministry under section 26B of the Drugs and Cosmetics Act, 1940 directed that if an existing valid drug import licence holder applies for a fresh import licence before the expiry of the existing licence, the existing import licence will remain valid until the application is processed. This extension on import licence will remain valid until 25th May 2021.

Relevance for German exporters and manufacturers: *COVID-19 induced delays resulted in lag of processing applications for several pharma products. The authorities aim to ensure that the supply of drugs do not get affected and the drugs must remain available to the public despite procedural challenges given the backlog of applications. Foreign drug manufacturers and suppliers can expect easing out of efforts while exporting products to the Indian market as the authorities have initiated handling the backlog of import licence renewals.*

Link:

www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjcyMQ==

2. Deadline permitting import of drugs with less than 60% shelf life revised

In April 2020, the Central Drugs Standard Control Organisation (CDSCO) had eased restrictions to allow the import and sale of drugs, vaccines, and biological products with less than 60% residual shelf life. Prior to this notification, import of drugs with less than 60% shelf life were not permitted into the country. Due to the ongoing COVID-19 pandemic and uncertainty around shipments, the CDSCO has decided to further revise the deadline till 30th April 2021 to allow the import of such drugs with residual shelf life less than 60%. According to the Drugs and Cosmetics Rules 1945, the licencing authority shall not allow the import of a drug with less than 60% residual shelf life as on the date of import. However, in exceptional cases, the import of drugs with a lesser shelf life can be permitted.

Relevance for German exporters and manufacturers: *The Ministry of Health and Family Welfare (MoHFW) has instructed authorities to undertake measures to maintain uninterrupted supply of drugs in the domestic market. German pharmaceutical exporters and manufacturers can continue to market their drugs with residual shelf life less than 60% on the date of import to India as a result of the updated import policy. The CDSCO's second extension to permit the import of drugs is aimed to provide support to foreign pharmaceutical exporters and suppliers facing challenges in shipping drugs.*

Link:
www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc3OA==

3. Govt notifies exemption for reference standards imports for specific applications

The Import and Registration Division of the Central Drugs Standard Control Organisation (CDSCO) has published a clarification on the import of reference standards. The applicability of regulations on reference standards substances based on the application and their intended use to be stated at the time of import. Based on the CDSCO and Central Drugs Testing Laboratory consultation, the regulator classifies reference standards as 'susbtances of known purity which are intended to be used exclusively for a specified analytical calibrating or referencing and not to be used as drugs'. The authorities stated that reference standards / reagents / impurity standards which are not intended for use as drugs for treatment or diagnosis in either humans or animals can be imported without being subjected to the provisions of importing drugs. Furthermore, the notification underlines the requirement to explicitly label or state the reference standards substances.

Relevance for German exporters and manufacturers**:** *German manufacturers and exporters of substances considered as reference standards / impurity standards / general chemicals can now export their products without undergoing the scrutiny of other pharmaceutical products given the substances are exported exclusively for the purpose of examination, test or analysis. As the latest notification specifies substances which may be classified under reference standards and the applicability of regulations on such products, details on the import provisions of reference standards substances based on intended application is expected to provide greater clarity to the suppliers.*

Link:
www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjcyNg==

4. CDSCO extends validity of self-attested documents for import of cosmetics

The Government had simplified the procedure to submit applications for import and registration of cosmetics and drugs in April 2020 as a response to COVID-19. The Central Drugs Standard Control Organisation (CDSCO) has extended the validity of self-attested documents submitted by drug companies to relax the procedure to submit applications for import and registration of cosmetics in India. The notification is a revised extension of the CDSCO's August 2020 order. Following the relaxation in attestation process, the authorities allowed the submission of self-attested documents with an undertaking to complete the attestation process later. Importers are not required to immediately submit notarised, apostilled and embassy attested regulatory documents such as power of attorney, manufacturing licence, GMP and COPP certificates as per the Drugs and Cosmetics Act, 1940 and can submit regulatory documents after the normalisation of the pandemic situation or within four months.

Relevance for German exporters and manufacturers: *In a major boost to strengthen ease of doing business during the pandemic era, the revised extension on the submission of self-attested documents for import registration will simplify and reinforce the government's commitment to facilitate foreign cosmetics and drugs companies to export to India. The Government's decision to extend the validity of self-attested documents will prevent any unnecessary delays in the import of drugs and cosmetics in the country as notarised documents, which usually take time to be furnished, are exempted from submission in the immediate import registration applications.*

Link:
www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc3OQ==

5. NPPA extends the ceiling price of Heparin injections

The Ministry of Health and Family Welfare (MoH&FW) has recommended Heparin, a critical blood-thinning drug, for the treatment of severe COVID-19 patients. In June 2020, the National Pharmaceutical Pricing Authority (NPPA), the apex drug price regulator in the country, had raised the ceiling prices of Heparin injections by 50% until 31st December 2020 following the recommendations of the MoH&FW committee constituted to monitor trade trends of formulations and raw materials. The hiked ceiling price is now applicable till 31st March 2021. The NPPA considered the increase in prices of APIs and raw material used in Heparin manufacturing as the reference to raise the price of Heparin. The NPPA had set the ceiling price of 1,000 International Units per millilitre (IU/ml) of Heparin injection at Euro 0.3 per ml and 5,000 IU/ml of injection at Euro 0.7 per ml.

Relevance for German exporters and manufacturers: *Due to the shortage of Heparin injection in the Indian market, the price regulator authority decided to increase the ceiling price of raw materials to mitigate the increasing API import cost from China and ensure commercial viability of domestic drug manufacturers. Additionally, the Health Ministry has listed Heparin among essential drugs to ensure supply. To address the shortfall of Heparin supply, German manufacturers and exporters of Heparin injections can supply the blood-thinner to India and take advantage of the continuity of increased ceiling price.*

Link: www.nppaindia.nic.in/wp-content/uploads/2020/12/4_E_Heparin.pdf

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