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Analysts expect India to be among the global top ten pharmaceutical markets by 2020. 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. Govt extends deadline for submitting notarized documents for cosmetics import, registration

The Drugs Controller General of India (DCGI) has extended the deadline for submitting notarized or apostilled regulatory documents to import and register cosmetics by four months. According to the recent notification, the applicant may submit applications for import and registration as per the provisions specified under the Drugs and Cosmetics Act, 1940. The list of regulatory documents comprises the power of attorney, QMS certificate, free sale certificate and manufacturing license with legal signatures. The applicant must self-attest the application submitted to the authorities. Along with the self-attested application, the applicant must also present an undertaking to elucidate the submission of notarized documents with legal signatures after the normalization of the pandemic or within four months, whichever is earlier. The decision was taken after the DCGI, Central Drugs Standards Control Organization (CDSCO), received representation from the industry expressing difficulties in submitting notarized documents for import.

Relevance for German exporters and manufacturers: *As per the notice issued by the DCGI, importers will now be required to submit a self-attested application to the concerned authorities before importing cosmetics in India. The importer must ensure that the self-attested application is accompanied by an undertaking, highlighting the submission of notarized documents within the aforementioned stipulated time frame. Furthermore, if the application is found satisfactory by the authorities, the import registration may be issued for the same.*

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

2. Pharma firms revise prices, import duty of Remdesivir to make it accessible

Drug companies manufacturing Remdesivir injections have voluntarily curtailed the injection prices, with the potency of 100mg/vial, to meet the rapidly growing demand in the country. The revision in prices was recorded after the National Pharmaceutical Pricing Authority (NPPA) intervened to ensure an uninterrupted drug supply at affordable rates. Pharmaceutical manufacturers such as Cadila Healthcare, Cipla and Dr Reddy's have significantly reduced the prices of their respective brands to make them more affordable. The prices have been reduced in the range of USD 13.63-36.81. Furthermore, the Finance Ministry has exempted basic customs duties on import of Remdesivir injections, active pharmaceuticals ingredients (APIs), and Beta Cyclodextrin used in manufacturing Remedsivir until the end of October 2021. The consumption of the anti-viral drug has proven to be highly effective in treating COVID-19 patients.

Relevance for German exporters and manufacturers: As the number of COVID-19 infected patients have grown exponentially, the country has cited a shortage of Remdesivir injections. Local manufacturers are unable to arrest the current demand-supply gap. As India looks to procure Remdesivir from different countries to treat COVID-19 patients, German firms can explore an export opportunity for corresponding injection and ingredients in the Indian market. The exemption on basic customs duty will further facilitate them to supply the drug at a low price. Additionally, the expedited custom clearance process for COVID-19 related pharmaceutical products will further ease the process.

Link:www.business-standard.com/article/economy-policy/easing-of-essential-goods-imports-to-help-fight-covid-19-pandemic-121050300063_1.html

3. Customs to clear all imports of COVID-19 vaccines; allow restricted use in emergency

The Indian Customs authorities have decided to clear all imports of COVID-19 vaccines at an expedited turnaround time. The Central Board of Indirect Taxes (CBIT) and Customs authorities are setting up measures to handle the clearance of the consignments on main cargo ports, i.e. ports in Chennai, New Delhi, Bengaluru and Mumbai. The approvals are applicable on all vaccines with no minimum value limit. The Government provides other relaxations, such as authorizing the restricted use of vaccines in emergencies, to curb the rapid spread of the virus. The vaccines that are approved by the regulators in the USA, the UK, the

EU, Japan or those enlisted by the World Health Organization (WHO) can be used for emergency purposes. Furthermore, a detailed list of standard operating procedures (SOPs) has been outlined to ensure that the consignment is cleared as soon as it arrives at the port.

Relevance for German exporters and manufacturers**:** *The rising number of COVID-19 infected patients has compelled the authorities to introduce measures and relaxations to manage the spread of the virus in the country. The limited capacity of domestic manufacturers to manufacture vaccines has also contributed to the recent series of decisions taken by the authorities. German firms manufacturing vaccines can export EU-approved vaccines to India at an expedited pace. Furthermore, German firms must comply with the conditions highlighted in the notice issued by CDSCO while supplying the vaccines to India to avoid any repercussions.*

Link:www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0Mw==

4. Import of drugs with residual shelf life of less than 60% allowed: CDSCO

The CDSCO has allowed the supply and sale of drugs with a residual shelf life of less than 60% until 31st October 2021. The decision was taken in response to the concerns raised by importers expressing delayed clearances at port offices because of the disruption caused by freight movement. Since the pandemic outbreak, importers have consistently witnessed a delay in the approval and delivery of imported drugs in the market. The CDSCO has authorized the import and circulation of drugs with less than 60% shelf life on the condition that the importer must submit an undertaking that the drug will be consumed before the expiration date on the product. In certain exceptional cases, the authority may grant import permission, for reasons recorded in writing, to drugs with a lesser shelf life than otherwise specified but before its expiry date.

Relevance for German exporters and manufacturers: *The CDSCO ensures that no imported drug is circulated in the Indian market unless it complies with the prescribed strength, quality and purity. The recent extension allowed by the CDSCO will enable foreign firms to supply drugs with less than 60% residual life. The firms must adhere to prescribed quality and standard set by the authorities. Moreover, the importers of such drugs must submit a written undertaking assuring the consumption of the drug before expiration to avoid any legal consequences.*

Link:www.medicaldialogues.in/news/industry/pharma/cdsco-allows-import-of-drugs-with-residual-shelf-life-less-than-60-percent-till-october-31-2021-76780

5. Industry seeks 20% price increment on all non-scheduled drugs

Indian pharmaceutical companies have urged the NPPA and the Department of Pharmaceuticals (DoP) to allow a 20% price increment on all non-scheduled drugs and permit a revision in the drugs sold below the authorized ceiling prices. The manufacturers underscored that they looked to manage the high input material cost and transportation cost with the proposed increment. Since 2020, the cost of procuring intermediates has become exorbitant, consequently affecting the business viability of the manufacturers. For instance, the price of para aminophenol (PAP), a key intermediate for producing paracetamol, has doubled. Similarly, the cost of propylene glycol, a drug solubilizer, has increased four times. With Asian countries being the biggest supplier of these materials to India, the expensive procurement has made it unviable for manufacturers to produce affordable medicines. Moreover, a rise in the cost of packaging materials such as PVC blister foils has seen a 40% increment in price.

Relevance for German exporters and manufacturers: *Asian countries have been active suppliers of materials, including intermediates, active substances, and packaging materials to India. The increasing cost of procuring inputs from these countries to manufacture medicines such as paracetamol and vitamins has rendered the ability of domestic manufacturers to supply affordable drugs and maintain commercial viability. Furthermore, the authorities' ban on importing raw materials required to manufacture packaging material has further contributed to the rising cost. These changes in price from neighbouring countries have opened up a window for international firms to supply drugs and packaging materials to Indian manufacturers.*

Link: www.pharmabiz.com/NewsDetails.aspx?aid=137775&sid=1

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Bei Fragen zu diesem Newsletter werden Sie sich bitte an die
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