MITTELSTAND GLOBAL
HEALTH MADE IN GERMANY

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

PharmaUpdate India
2021/3

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. Govt mandates reporting of adverse events in clinical trials through online submission

The Central Drugs Standard Control Organization (CDSCO) has directed all stakeholders involved in clinical trials (CT) for online submission of serious adverse event (SAE) reports through SUGAM portal (www.cdscoonline.gov.in). According to the Drugs Controller General of India, online reporting of SAE in CT will be effective from March 14, 2021 and "from this date physical / offline files of SAE reports may not be accepted for processing". However, follow up reports of the already submitted SAE reports shall continue to be submitted in offline mode. SUGAM is an e-Governance system to facilitate multiple functions performed by CDSCO under the Drugs and Cosmetics (D&C) Act, 1940. The software system is an online portal where applicants can apply for NOCs, licenses, registration certificates, and approvals. Applicants can also apply online on SUGAM Portal for permission to import or to conduct CT.

Relevance for German exporters and manufacturers: *To process applications and generate permissions online for stakeholders, with drugs which require to conduct clinical trials for the Indian market, the move equips CDSCO officials with a swift mechanism. The development of software for online submission of SAE reports is complete, and availing this facility by foreign drug manufacturers and suppliers would result in effective time management and optimized transaction cost. The online portal is expected to bring down the timelines for granting*

BPI Bundesverband der Pharmazeutischen Industrie e.V.
.B.A.H Bundesverband der Arzneimittel-Hersteller e.V.
vfa. Die forschenden Pharma-Unternehmen

permissions or approvals for applications by nearly three times as it also contains process-based guidance to the applicants on the SUGAM portal.

Link:
www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njk5NA==

2. IPC releases guidance document for drafting and formatting monographs

The Indian Pharmacopoeia Commission (IPC) has released the Guidance Document for Drafting and Formatting of Monographs for Indian Pharmacopoeia (IP) to guide the stakeholders involved in the Indian pharmaceutical industry including drug manufacturers/ marketers, laboratories, and academicians for drafting drug monographs prior to inclusion in the IP. The aim is to provide guidance for drafting clear unambiguous texts, with similar requirements presented in the same way in each monograph. In the guidance document, the Commission has emphasised to elaborate IP monographs under the categories of active pharmaceutical ingredients (APIs), dosage forms, herbal products and pharmaceutics. IP is a compilation of official standards for drugs manufactured or marketed in India. A monograph states the quality or test parameters, the acceptance criteria and details of the tests that are to be performed to determine compliance with the criteria.

Relevance for German exporters and manufacturers: *Pharmacopoeial monograph provides a reliable basis for making an independent and objective assessment to the quality of a pharmaceutical substance. Foreign drug companies looking to explore the Indian pharmaceutical market are advised to familiarise themselves with the IP guidance document. As IP standards are statutory, it is important that the contents of monographs are unambiguous; acceptance criteria are clearly spelt out; and methods of evaluation provide all the details for carrying out the tests and assays, including the equipment, reagents and other ancillary materials that are to be used.*

Link:
www.ipc.gov.in/images/Guidance_Document_for_Drafting_and_Formatting_of_Monographs_for_Indian_Pharmacopoeia.pdf

3. NPPA directs pharma companies to submit online application for retail price fixation

The National Pharmaceutical Pricing Authority (NPPA) has completed the implementation process required to submit online application in Form-I for retail price fixation of new drugs. According to the NPPA, from April 1, 2021 no application in Form-I for retail price fixation of new drugs shall be accepted in physical form. NPPA has stipulated that the applicant companies need to submit the application with all requisite documents via email at pricing-nppa@gov.in. NPPA had published a proposal in August 2020 to develop an online system for disposing and monitoring of applications filed under various provisions of Drug Prices Control Order, 2013 (DPCO, 2013) towards ease of doing business. NPPA had also stipulated pharma companies to submit Form-II related to quarterly return in respect of production/import and sale of National List of Essential Medicines (NLEM) Drugs and Form-V related to price list.

Relevance for German exporters and manufacturers**:** *For streamlining the procedure and processing of Form-I for application for the pricing of new drugs in a time bound manner, the apex price regulator has moved to online mechanism. NPPA has stipulated timelines for online disposal of applications in different categories including in Form I, which is related to new drug prices and the given timeline is within 60 days. For foreign drug exporting companies looking to introduce new drugs in the Indian market, the notification is relevant as it would help them manage compliance in a contactless and automated process.*

Link: www.nppaindia.nic.in/wp-content/uploads/2021/02/Form-I-OM.pdf

4. Health Ministry regulates registration of BA labs with amendment to NDCT Rules

The Ministry of Health and Family Welfare (MoH&FW) has issued draft notification on New Drugs and Clinical Trials (NDCT) Amendment Rules, 2021 for inclusion of provisions related to registration of standalone Bio-analytical (BA) laboratories. As per the draft rules, these rules may be called the New NDCT Amendment Rules, 2021 and come into force on the date of their publication in the Official Gazette on February 05, 2021. The notification proposes to amend the NDCT Rules, 2019 to include the provision of registration of stand-alone Bio-analytical laboratories by inserting the word 'analytical part' in the definition as follows – "BA and BE study centre means a centre created or established to undertake BA study or BE study

of a drug for either clinical part or 'analytical part' or for both clinical and 'analytical part' of such study".

Relevance for German exporters and manufacturers: *The NDCT 2019 and the amended rules specify the conditions under which data from a local clinical trial may not be required to be submitted along with the application for permission to import a new drug for sale or distribution. These rules also specify regulations for testing and laboratory ecosystem to strengthen the approval infrastructure, which will help in providing early access to Indian patients to drugs already approved in the specified countries, thereby facilitating entry of foreign drug manufacturers for their drugs proposed to be marketed or manufactured in India.*

Link:
www.cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njk1NQ==

5. Indian and British Pharmacopeia Commissions sign MoU on pharmacopeial standards

The Indian Pharmacopoeia Commission (IPC) has signed a Memorandum of Understanding (MoU) with the British Pharmacopoeia Commission (BPC) for knowledge sharing on pharmacopoeial standards. Through this MoU, both institutions will recognize the importance of developing close cooperation and exchange of information in the field of regulation of medicines with special reference to pharmacopoeial standards in accordance with the respective laws and regulations. This will also ensure both organizations to explore opportunities for technical cooperation in areas of mutual benefit in the development of monographs and future technologies. The areas of co-operation will cover the development of standards for active pharmaceutical ingredients as well as finished products. The IPC is an autonomous institution under the Ministry of Health and Family Welfare (MoH&FW). Indian Pharmacopeia (IP) prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of humans and animals.

Relevance for German exporters and manufacturers: *IPC publishes official documents for improving quality of medicines by way of adding new monographs and updating existing*

monographs in the form of Indian Pharmacopoeia (IP). The agreement of IPC with a foreign commission bears significant relevance as there is a need for regular updation of IP to meet essential requirements for harmonisation of analytical methods in IP with those accepted internationally. It will also help adopt harmonizing standards, exchanging information on quality of medicines and sharing technical expertise on the development of monographs and test methods.

Link: www.ipc.gov.in/images/News_Collaboration_with_BP_19.02.2021.pdf

Alle Informationen im vorliegenden Newsletter wurden mit größtmöglicher Sorgfalt recherchiert. Wir bemühen uns, Ihnen diese Informationen möglichst aktuell, inhal

tlich richtig und vollständig anzubieten. Dennoch ist das Auftreten von Fehlern nicht vollkommen auszuschließen. Soweit dies gesetzlich zulässig ist, können wir daher keine Haftung für die Richtigkeit und Vollständigkeit übernehmen, es sei denn, die Unrichtigkeit oder Unvollständigkeit beruht auf vorsätzlichem oder grobem Verschulden. Darüber hinaus enthält der Newsletter Kommentierungen und Handlungsempfehlungen allgemeiner Art, die auf persönlichen Erfahrungen beruhen. Diese Kommentierungen und Handlungsempfehlungen stellen keine Rechts- oder Unternehmensberatung dar und können diese im Einzelfall nicht ersetzen.

Bei Fragen zu diesem Newsletter werden Sie sich bitte an die
Exportinitiative Gesundheitswirtschaft:

pharma@health-made-in-germany.com
030.20 00 99 – 0

Weiterführende Informationen zum umfassenden Unterstützungsangebot finden Sie auf
www.exportinitiative-gesundheitswirtschaft.de

Die in diesem Newsletter enthaltenen Informationen wurden recherchiert durch:
T&A Consulting, 122001 Gurgaon, Indien