NEWSLETTER

PharmaUpdate Indien

Mit uns am Puls der Gesundheitswirtschaft

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The pharmaceutical landscape in India is undergoing significant regulatory changes, with proposals from the Drugs Technical Advisory Board (DTAB) for improved labelling standards for excipients and the Ministry of Commerce unveiling the Patent (Amendment) Rules, 2024. Additionally, the National Pharmaceutical Pricing Authority (NPPA) has revised ceiling prices for over 800 scheduled drug formulations, impacting essential medicines and reflecting ongoing challenges in the industry. For German exporters and manufacturers, these developments signal the importance of adapting to evolving standards to ensure compliance and navigate the complexities of the Indian pharmaceutical market effectively.

1. DTAB proposes labelling standards for excipients

The Drugs Technical Advisory Board (DTAB) has proposed a recommendation to India's drug regulator (Central Drugs Standard Control Organisation) regarding excipient labelling in medicines. This initiative aims to address the growing concern over inadequate information about excipients, particularly among individuals with allergies or sensitivities. This recommendation was prompted by a surge in complaints from individuals experiencing allergic reactions to certain excipients, such as parabens commonly used as preservatives. The lack of clear indications of excipient composition on medicine packaging, especially in retail medical shops, posed challenges for individuals seeking allergen-free medications, particularly for conditions like hypertension. To tackle these issues, the DTAB proposed exploring alternative methods such as incorporating excipient details in package inserts or using QR codes. Collaborating with the Drug Consultative Committee (DCC), the recommendation suggests initially focusing on capturing excipient information through QR codes for the top 300 brands.

Relevance for German exporters and manufacturers: *The recommendation proposed by the DTAB underscores the necessity for the manufacturers to align their products with evolving labelling standards. By addressing the growing concerns over inadequate information about excipients, particularly among individuals with allergies or sensitivities, the recommendation demonstrates the importance of enhancing transparency and facilitating informed consumer*

choices. German manufacturers have an opportunity to showcase their commitment to safety and quality by adhering to these enhanced labeling requirements, thereby bolstering consumer trust in their products. Furthermore, the emphasis on exploring alternative methods such as QR codes or package inserts presents an avenue to showcase technological innovation and adaptability.

Link:https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/Minutes%20with%20approval%20letter%20of%2090%20DTAB.pdf

2. Ministry of Commerce unveils Patent Amendment Rules, 2024

The Union Ministry of Commerce and Industry has introduced the Patent (Amendment) Rules, 2024, aiming to streamline pre-grant opposition procedures and simplify patent management. Notable changes include a refined process for disposing of representations and fixing fees for pre-grant oppositions, aimed at curbing fraudulent activities while encouraging genuine oppositions. Additionally, the time limit for furnishing foreign application details has been reduced from six months to three months from the issuance of the first examination report. Frequency of filing statements of patent working has been decreased to once every three financial years, with provision for condoning delays of up to three months. Furthermore, the rules provide flexibility through simplified provisions for extending time limits and condoning delays. In response to technological advancements, the time limit for filing examination requests has been reduced to 31 months from the priority or filing date, whichever is earlier.

Relevance for German exporters and manufacturers: *The amendments aim to streamline pre-grant opposition procedures and simplify patent management, fostering a more conducive environment for innovation and intellectual property protection. The reduction in time limits for furnishing foreign application details and filing examination requests aligns with the fast-paced nature, enabling German stakeholders to expedite patent processes efficiently. Additionally, the provision for condoning delays in filing statements of patent working allows flexibility in compliance, ensuring smoother operations for German companies. Overall, these amendments facilitate a more efficient patent system, providing German stakeholders with greater clarity and expedited processes in the protection and management of their intellectual property assets.*

Link:https://ipindia.gov.in/writereaddata/Portal/IPORule/1_83_1_Patent_Amendment_Rule_2024_Gazette_Copy.pdf

3. NPPA revises the ceiling price of over 800 scheduled formulations

Starting April 1,2024 there has been a marginal hike in the cost of antibiotics and painkillers due to the National Pharmaceutical Pricing Authority's (NPPA) latest notification allowing a minimal 0.00551% price increase for selected medicines. While consumers may find this hike minimal, pharmaceutical companies attribute it to rising raw material costs and stricter price controls. The Department of Pharmaceuticals has issued revised ceiling prices for 923 scheduled drug formulations and retail prices for 65 formulations, effective from April 1, 2024. This routine exercise is based on the annual change in the wholesale price index (WPI), which

stood at (+) 0.00551% for the calendar year 2023. This follows previous price hikes of 12% in 2021 and 10% in 2022. The adjusted prices will impact over 800 drugs, including paracetamol, azithromycin, vitamins, minerals, COVID-19 drugs, and steroids listed under the National List of Essential Medicines (NLEM).

Relevance for German exporters and manufacturers**:** *Currently India has approximately 400 molecules and 960 formulations covered under the National List of Essential Medicines (NLEM). This hike, attributed to NPPA's recent notification allowing a 0.00551% increase for select medicines, reflects ongoing challenges in the pharmaceutical industry, including rising raw material costs and stricter price controls. The Department of Pharmaceuticals' issuance of revised ceiling and retail prices, based on the annual change in the wholesale price index, impacts over 800 drugs, including essential ones like paracetamol, azithromycin, and vitamins. The German manufactures and exporters of the scheduled drugs and medicines must adhere to the revised prices.*

Link: https://www.nppaindia.nic.in/wp-content/uploads/2024/03/253444.pdf

4. Push for unified drug regulatory authority gains momentum

India is on the brink of a significant transformation in pharmaceutical landscape with the proposed establishment of the Indian Drug Regulatory Authority (IDRA), replacing the Central Drugs Standard Control Organization (CDSCO) and introducing the Indian Drug Regulatory Services (IDRS) cadre. This evolution aims to harmonize existing frameworks, address challenges like counterfeit drugs and regulatory inconsistencies across states and streamline licensing processes under a unified authority. The envisioned IDRA, reminiscent of global regulatory bodies such as the United States Food and Drugs Administration (USFDA) or European Medicines Agency (EMA), promises enhanced operational efficiency and global recognition. However, ensuring regulatory coherence amidst decentralization and managing operational challenges demands meticulous planning and stakeholder consultation. For German manufacturers and exporters, this evolution signals potential for streamlined operations and compliance with uniform standards, aligning with India's vision of "One Nation, One Market" and promoting collaboration on international regulatory best practices.

Relevance for German exporters and manufacturers**:** *For German manufacturers and exporters of drugs and medicines, India's proposed establishment of the Indian Drug Regulatory Authority (IDRA) is highly pertinent. The transition from CDSCO to IDRA signifies a move towards harmonized regulations and streamlined processes, potentially reducing bureaucratic hurdles, and ensuring compliance with uniform standards. This development aligns with India's vision of "One Nation, One Market," facilitating easier market access and operations for German companies. Furthermore, collaboration on international regulatory best practices promises enhanced trade opportunities and global recognition, underscoring the relevance of this for German pharmaceutical businesses seeking expansion in India's market.*

Link: https://thehealthmaster.com/2024/03/15/the-proposal-for-a-unified-drug-regulatory-authority-in-india/

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