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In '22, industry saw several regulatory changes

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The rules and regulations governing health in India are distinctive because of the country's healthcare requirements. The goal of succeeding Indian administrations has been to significantly reduce out-of-pocket spending on healthcare and medications because there is no large insurance or reimbursement system. Since 2014, drug costs and access to affordable healthcare have been a central theme in general and state elections. The need for accessible healthcare and the excessive attention paid to medicine and device costs have taken up more space in politics and the media.

The present administration is now putting forth significant legal and regulatory changes in addition to expanding the scope of price control for pharmaceuticals and devices that have been classified as drugs (stents, orthopaedic knee implants). To make India a market dominated by generic products, public pharmacies that dispense generic medications have been established, along with the policy and regulatory initiatives outlined in this article.

In terms of volume and value, the Indian pharmaceutical sector is the 10th largest in the world. By 2020, it is projected to have a turnover of Rs 3.53 trillion (US$55 billion), growing at a compound annual growth rate (CAGR) of 15.92 per cent. By incremental growth, India is probably in the top three pharmaceutical markets and ranks sixth in market size. However, because the market is primarily generic, the nation's rules and regulations- including intellectual property, drug regulation, drug pricing, prescriptions, etc.; are designed to support and control a generic market. It will be pushed farther in this direction by measures in the works.

In the pharmaceutical industry, there has been a lot of regulatory activity in the first half of 2022. Numerous regulatory changes have been made in this industry to simplify regulation, including creating a new Indian pharmacopoeia, notifications regarding over-the-counter medications, the display of package sale prices and so on.

Indian Pharmacopoeia Book Updates

To complement the current Indian Pharmacopoeia ("IP"), the book of standards under the 1940 Drugs and Cosmetics Act ("D&C Act''), the Indian Pharmacopoeia Commission has produced the Indian Pharmacopeia 2022 (''IP 2022"). IP 2022 is anticipated to go into effect on December 1, 2022. With 92 new monographs, 21 vitamins, minerals, amino acids, fatty acids, 27 active pharmaceutical ingredients, 2 herbal products, 3 biotechnology-derived products, 4 human vaccines and immunosera, 33 dosage forms, and 2 blood and blood-related products, IP 2022 is the most comprehensive publication to date.

The IP 2022 also includes 12 general chapters on:

(a) a microbiological assessment of the Burkholderia Cepacia complex in non-sterile products
(b) an approach to alternative microbiological methods
(c) the design and development of a biological assay and its validation
(d) subvisible particulate matter in therapeutic protein injections
(e) an assessment of calcium pantothenate
(f) Raman spectrometry
(g) uniformity of dosage
(j) vaccine adjuvants
(k) elemental impurities
(l) impurities containing nitrosamine

Additionally, the IP 2022 adds general specifications for phytopharmaceuticals and therapeutic monoclonal antibodies for human use. The Indian Pharmacopoeia's guidelines must be followed for all medications created and sold in India. If the IP criteria are not followed, the medicine may not be of Standard Quality and may be subject to D&C Act penalties.

Pricing Amendments

India has had some price regulations since the 1970s. All medications on the National List of Essential Medicines (NLEM) are covered by the Drug Price Control Order (DPCO), which was established under the Essential Commodities Act of 1955. There are currently 3,762 medications in NLEM 2015 and a few patented medicines. The National Pharmaceutical Pricing Authority (NPPA) is responsible for setting prices.

Pharmaceutical price regulations, frequently arbitrary and unpredictable, have done business in India complicated for the industry. Price reductions that are irrational and excessively drastic have been a de facto trade barrier for do-

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22 medical devices have been notified

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ing business in India. The Indian Government has recently extended the reach of such arbitrary price limitations, previously only applicable to medications, to cover medical devices. These regulations are far stricter and illogical than those that apply to drugs.

Currently, 22 medical devices in India have been notified as pharmaceuticals; four are already subject to price controls, while the NPPA monitors the remaining 18 for possible price control.

The draft National Pharmaceutical Policy 2017 (the NPP) discusses a more comprehensive range of price regulations. It suggests that price caps should apply to all dosage sizes and strengths of medications included in the NLEM. Additionally, a policy for pricing patented medicines is being discussed by an inter-ministerial committee, as is a method of price negotiation that could be used for pricing patented drugs and medical devices before their marketing approval in India.

Since 2016, the price of oxygen has been regulated. A new lower ceiling price (a "revised price cap") was announced in the notification dated September 25, 2020, due to the product's increased demand during the Covid-19 pandemic. The NPPA subsequently extended the amended price cap through notices dated March 25, 2021, and September 23, 2021. In the public's best interest, the current notice further extends the application of the amended price cap.

"DPCO," or the Drugs (Prices Control) Order of 2013, according to India's principal medication price control rule, the Government may set drug ceiling prices for a length of time that it deems appropriate, regardless of the wholesale price index, in light of extraordinary circumstances in the interest of the public. Under this clause, the updated price cap has been put into effect.

API Labelling D&C Rules Changed to Include the QR Code

To add a new labelling requirement for active pharmaceutical ingredients ("API") or bulk pharmaceuticals made or imported in India, the MoHFW has published the Drugs (Amendment) Rules, 2022 ("Amendment Rules"). On January 1, 2023, the Amendment Rules will go into effect.

According to the Amendment Rules, an API made in India or imported must include a Quick Response code (or "QR Code") on the packaging label to hold data or information that may be read by software programs and aid product tracking and tracing. The stored information connected to the QR code must have the minimum required information, including the API's name, unique product identification code, brand name, batch number, batch size, the manufacturing date of expiry and so on.

It was suggested that a different committee be set up to make recommendations for ways to stop the exploitation of the current policy

The QR Code labelsling requirement is anticipated to enhance medication tracking and tracing and will compile all information about pharmaceuticals in one location for simple access by individuals. It is expected to support the manufacturing process of medications by assisting drug manufacturers in conducting quality checks and helping the supply chain ensure security and integrity in the proper API storage.

CDSCO permits drug imports with less than 60% residual shelf life.

On May 6, 2022, the CDSCO issued a circular extending the applicability of previously published circulars, which allowed for the import of medications having a residual shelf life of less than 60%. Until October 31, 2022, or until future instructions from the CDSCO, whichever comes first, is the length of the prolongation.

The circular was released in light of the industry's comments and to guarantee the country's ongoing access to and supply of medications in the face of the Covid-19 epidemic. A medicine with a residual shelf life of less than 60% as of the import date is prohibited by Rule 31 of the D&C Rules. The CDSCO may, however, under exceptional circumstances, permit the import of any medication with a shorter shelf life before its expiration.

The Drug Technical Advisory Board ("DTAB") recommended that emergency and life-saving drugs for Covid-19 and conditions of similar public health importance should only be marketed, sold, and distributed after approval of the clinical trial results. This recommendation formed the basis for the notification that was released on November 8, 2021.

One Company, One Brand, One Molecule Regulation

The Drug Consultative Committee's 50th meeting, which took place on November 4, 2016, was the first to address the issue of the sale of the same medication under various brand names and at different costs. Multiple brands of the same medicines sold at various price points and made by the same business have drawn criticism.

It was suggested that a different committee be set up to make recommendations for ways to stop the exploitation of the current policy on medicine manufacturing by third parties, in which several other businesses promote a single company's product. Multiple brand names are to be restricted, and the one manufacturer, one salt, one brand name, and one price principle is to be put into practice, according to the present text of the NPP. The draft NPP also suggests banning third-party manufacturing by businesses to create brand variations of the same product.

To conclude, In the first half of 2022, the pharmaceutical industry saw several regulatory changes, including introducing new package labelling regulations, displaying a QR code in API labelling, easing restrictions on medicine imports, and others. The pharmaceutical industry is actively regulated, and although we have yet to see the developments implemented, the sector is constantly evolving.

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