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2022 seeks holistic revamping of pharma regulations

03 January 2022 | Views | By Upendra N Sharma, Partner, J Sagar Associates, Gurugram

With the increasing relevance of the pharmaceutical industry, worldwide, as well as domestically, developments in regulation and policy pertaining to the industry are being keenly watched. We explore the expectations of a few opportunities and challenges that are projected for this industry in the coming year.

India's pharmaceutical industry is one of the largest in the world, as it currently ranks at No. 3 worldwide for pharmaceutical production by volume and No. 14 by value. Notably, India is also stated to be the largest provider of generic drugs globally, which majorly attributes to the status that the country commands as the "Pharmacy of the World". Currently, the Indian pharmaceutical sector contributes to 1.72 per cent of the country's Gross Domestic Product (GDP).

Greater Focus on Domestic Production

In the backdrop of the pandemic highlighting the need for a robust Indian manufacturing base of pharmaceutical products, and finding its roots in the current government's "Atmanirbhar Bharat" and "Make-in-India" policies, the pharmaceutical industry (among others) has been a focus of multiple schemes relating to domestic production-linked incentives (PLI Schemes). PLI Schemes primarily focus on making the Indian pharmaceutical industry self-reliant and to reduce dependency on other countries for pharmaceutical manufacturing.

The first PLI Scheme, announced on July 21, 2020, focused on the promotion of domestic manufacturing of Key Starting Materials (KSMs) or Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs) and was initiated with a financial outlay of Rs 6,940 crore. This was followed by a more extensive and broader PLI Scheme, announced on March 3, 2021, with a total sanctioned amount of Rs 15,000 crore, under which 55 of 278 applicants were recently selected by the government.

It is imperative for the Indian pharmaceutical industry to grow adequately, particularly in view of the pandemic situation in India and the impending threat of disruption due to the new Omicron variant of the virus. This suggests that the policy push towards consolidating India's domestic pharmaceutical industry is likely to continue, and 2022 may bring in further grants in the form of additional PLI Scheme(s) or similar initiatives for the pharmaceutical industry.

This was further highlighted by Prime Minister Modi's statements at the recent Global Innovation Summit, stating that India's healthcare sector has been called the 'pharmacy of the world', and that the focus on developing indigenous manufacturing abilities should continue, including for key ingredients for vaccines and medicines. This may be seen as an opportunity especially for Indian players and should be duly capitalised upon in the coming year.

Collaborations between Indian and Foreign Players

The government's continuing, and potentially growing focus on incentivising domestic manufacturing by the pharmaceutical industry would not only benefit Indian players but would also provide an opportunity to foreign pharmaceutical players to collaborate with Indian companies.

The potential lies in collaboration between foreign players with established Indian manufacturers, as well as the various healthcare startups in India, by way of joint ventures, investments, technology transfer agreements, among others.

India has historically seen various successful collaborations between domestic and foreign players, such as Bayer-Cadila, Pfizer-Biocon, AstraZeneca-Torrent Pharma, among various others. The coming year may, similarly, bring with it opportunities and avenues for collaborations between Indian and foreign partners, in all shapes, sizes, and forms. These ventures should aid domestic players in terms of receiving foreign investment and/or technology and know-how, while also potentially allowing foreign players to capitalise on the government's efforts to promote the domestic industry.

New Drugs, Cosmetics, and Medical Devices Bill

One of the most significant regulatory changes to the Indian regulatory landscape expected relating to the pharmaceutical industry is an overhaul and revamp of the current legal framework. The Government of India has recently constituted an eight-member panel, chaired by Dr V G Somani, Drugs Controller General of India, to frame a new draft law for drugs, cosmetics, and medical devices (New D&C Law).

The current legal framework pertaining to drugs, cosmetics, and medical devices is centred around the Drugs and Cosmetics Act, 1940 and various rules and regulations thereunder, including in relation to medical devices.

The existing framework has often been criticised as being an aging and complex set of rules and regulations, with multiple piecemeal amendments made over time to keep up with developments in the pharmaceutical industry. There is thus a need for a holistic revamp to tackle the same, and to focus on more nuanced issues within the law.

In view of the same, the New D&C Law is expected to play a significant role in revamping the regulatory framework relating to the pharmaceutical industry. Certain key aspects that the New D&C Law should ideally incorporate are, among others:

(i) Streamlining and Restructuring the Regulatory Structure: The New D&C Law should aim to simplify and streamline the regulations around the pharmaceutical industry, putting an end to the piecemeal manner in which various aspects are currently governed and regulated. This may also include revamping the various functionaries established under the law, and clearly defining their roles in ensuring that uniformity in regulation and enforcement is achieved across the country, to the greatest extent possible.

(ii) Medical Devices: In view of the growing relevance of medical devices within the pharmaceutical industry and the functioning of any robust medical system, a key aspect to tackle the regulatory framework for medical devices, which are currently regulated as 'drugs' within the existing legal framework. The New D&C Law should have a separate and holistic framework for the regulation of medical devices, and should ideally not be linked fully to the regulation of drugs, given the

significant differences between drugs and medical devices.

(iii) Online Pharmacies: While there are many online pharmacy websites in India, the current framework does not duly address the various aspects of such websites and portals. The New D&C Law should aim to provide for a specific framework around online pharmacies as well, taking into account the nuances and differences between online pharmacies and brick and mortar pharmacies (which the current regulations primarily focus to govern).

The New D&C Law, once submitted by the panel and which may potentially come into force in the course of 2022, may provide for a significant collection of opportunities and challenges for the pharmaceutical industry, depending on how effective it is at meeting the expectations of the industry participants.

Road ahead

The year almost gone by has been quite challenging and tumultuous for the Indian market in general, including especially the pharmaceutical industry, which faced its fair share of challenges. The industry, with the support of the Government, has made many efforts and taken various steps to tackle the challenges previously faced.

In this backdrop, 2022 should come with its own set of opportunities and challenges for the Indian pharmaceutical industry, which are likely to be focused largely on the Government's concerted efforts to promote and consolidate the domestic pharmaceutical industry. Further, the New D&C Law (if enacted in 2022) may have its own collection of regulatory opportunities and challenges for the industry.

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