India: Legislative Changes For Medical Devices

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In its Cabinet Note in December, 2014, the Government of India proposed significant amendments to the Consolidated Foreign Direct Investment Policy, 2014 ("FDI Policy") with respect to India's medical device industry. With the release of Press Note No.2 (2015 Series) dated January 6, 2015 ("Press Note 2"), the Department of Industrial Policy and Promotion (DIPP) addresses the need for a separate FDI framework for medical devices that is independent of regulations governing the pharmaceutical industry.

Devices vis-à-vis Drugs

Although medical devices are inherently different in nature and function from pharmaceuticals, both were being treated at par under previous FDI policies. Ambiguities in the previous FDI Policy arose primarily because the Ministry of Health and Family Welfare, Government of India, has notified certain medical devices and other medical products as 'drugs' under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 ("Act") – their import, manufacture, distribution and sale are accordingly regulated by the Act and Drugs and Cosmetics Rules, 1945, as there exists no separate legislation for regulating medical devices in India. Medical devices other than those notified do not require any registration, license, permission or No-Objection Certificate for their import, manufacture, distribution and sale[1].

On the other hand, pharmaceuticals and medical devices are treated as distinct industrial activities under the National Industrial Classification (NIC) 2008 - the industrial classification system for economic activities in India. The sector codes for 'Manufacture of pharmaceuticals, medicinal, chemical, and botanical products' and 'Manufacture of medical and dental instruments and supplies' are 2100 and 3250 respectively, wherein medical devices fall under 'medical and dental instruments and supplies'. As the previous FDI Policy was silent on the norms for medical devices, notified medical devices being 'drugs' were treated as a sub-set of pharmaceuticals by virtue of the deeming legal fiction and medical devices (whether notified or non-notified) were subjected to FDI regulations that were in place for the pharmaceutical sector.

DIPP recently linked sectors and activities in the FDI Policy to their corresponding codes under NIC–2008, with the objective of easing processes for foreign investors. Through Press Note 1 (2015 Series) dated January 5, 2015, NIC-2008 codes for the pharmaceutical sector have been incorporated in the FDI Policy whereas provision of relevant codes for medical devices is currently awaited.

Carve-out

Under the previous and extant FDI Policy, 2014, up to 100% FDI is permitted in the pharmaceutical sector under the Automatic route for greenfield projects and under the Government route (i.e. with prior approval of Foreign Investment Promotion Board) for brownfield projects, subject to sector-specific conditions. An important condition relates to the prohibition of non-compete clauses in merger and acquisition agreements. By virtue of Press Note 1 (2014 Series) dated January 8, 2014, foreign pharmaceutical companies were forbidden from imposing non-compete clauses that restrict the target Indian entity from entering the same line of business in the domestic market. In an effort to increase competition and access to low-cost drugs in the domestic market, non-compete clauses are now permitted only under 'special circumstances' and with prior approval of FIPB. As the previous FDI Policy clubbed pharmaceuticals with medical devices, this ban became applicable to both industries.

A year later, DIPP has now carved out separate regulations for the medical device industry vide Press Note 2. With effect from January 21, 2015, up to 100% FDI under the Automatic route shall be permissible for both greenfield and brownfield projects – however, FDI has been restricted to manufacturing of medical devices in order to promote domestic production. Given that India imports nearly 70% of medical devices used in the country as per industry estimates, the sectoral conditions for pharmaceuticals have not been made applicable to manufacturing of medical devices. As a result, foreign investors may now acquire up to 100% stake in existing manufacturing units under the Automatic route, as well as validly impose non-compete clauses on domestic targets without having to seek prior permission from FIPB. However, the Association of Indian Medical Device Industry (an umbrella association of Indian manufacturers of medical devices) has criticized the move as potentially endangering domestic manufacturers and has called for a blanket ban on 100% FDI in brownfield projects[2].

Regulatory Overhaul

Simultaneous to these changes to the FDI regime for medical devices, the Department of Health and Family Welfare has proposed a regulatory overhaul for the medical devices industry, to be introduced as the Drugs and Cosmetics (Amendment) Bill, 2015 ("Bill") in the upcoming Budget Session of Parliament.

The Bill inter-alia proposes a separate Chapter IIA for regulating import, manufacture, sale and distribution of notified medical devices including penal provisions for contravention – thereby removing medical devices from the purview of 'drugs'. Essential aspects including classification, standards, manufacturing, testing, distribution, labelling, packaging, essential requirements for quality, safety and performance, adverse events, post-marketing surveillance, exemptions, conditions of licenses, etc. shall be as prescribed.

In comparison to the current definition of 'medical devices' in Press Note 2 (which is subject to a corresponding amendment to the Act), the Bill proposes a broader definition[3] for 'medical devices' as including a wide range of instruments, whether used alone or in combination, for the purposes specified therein.. To avoid any ambiguities, both definitions require to be aligned. The absence of a clear description of 'manufacturing' activities in the context of medical devices is a glaring omission in the present Act. Though Press Note 2 has not specified the scope of activities that qualify as 'manufacturing' of medical devices, the Bill[4] reveals the legislature's intention as including any process for designing, making, assembling, configuring, finishing, packing, sterilizing, labelling, refurbishing, or adapting of medical devices with a view to sell, stock or distribute or market them but as not including assembling or adapting by registered medical practitioner, a device already approved for use for an individual patient.

Other salient features of the Bill include separate definitions for 'investigational new medical device' (i.e. new device which is an object of clinical investigation or research or development involving one or more human participants to determine its safety and the effectiveness) as well as 'new medical device' (i.e. a device which has not been approved by the Central Licensing Authority), and the establishment of a new Medical Devices Technical Advisory Board whose role would be to advise the Central and State Governments on matters pertaining to medical devices.

A series of measures have also been recently introduced by the Central Drug Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India to regulate the quality, safety and efficacy of medical devices, especially as it declared 2015 as the 'Year for streamlining regulatory procedures without compromising patient safety'. The comprehensive draft rules proposed by CDSCO in December, 2014 on good manufacturing practices and requirements of premises, plant and equipment for medical devices, in-vitro diagnostic kits and reagents, seeking to replace Schedule M-III of the existing Rules, is a welcome step. Even procedures for clinical trials of medical devices have been made similar to the stringent provisions applicable to clinical trials of drugs/vaccines[5]. As FDI in manufacturing sector for medical devices is expected to increase, standardization of best practices is the need of the hour.

Footnotes

1 Order dated July 9, 2014 by Central Drug Standard Control Organization, Government of India.

2 http://articles.economictimes.indiatimes.com/2014-12-29/news/57494921_1_cent-fdi-100-fdi-blanket-ban

3 Section 3(v), Drugs and Cosmetics (Amendment) Bill, 2015

4 Section 3(t)(iii), Drugs and Cosmetics (Amendment) Bill, 2015

5 Order dated July 3, 2014 by Central Drug Standard Control Organization, Government of India.

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