INTRODUCTION OF SEPARATE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

By Sunil Tyagi and Anu Chowdhry

In the Indo-U.S. Joint Statement released for the January 2015 visit of the U.S. President to India, bilateral collaboration in medical devices, pharmaceuticals, biotechnology and health-related information technology occupies prime position. Other healthcare agendas in the Joint Statement include completion of a Memorandum of Understanding among the Indian Ministry of Health & Family Welfare, the Indian Department of Biotechnology, the Indian Council of Medical Research, the All India Institute of Medical Sciences, the U.S National Institute of Health and National Cancer Institute and the upcoming completion of an Environmental Health, Occupational Health and Injury Prevention as well as a Control MoU between the U.S. Centerss for Disease Control and Prevention and the Indian Council for Medical Research.

India's total revenue potential for electronic medical devices is estimated at $ 6.4 billion for 2020. In an Executive Briefing in June, 2010, the United States International Trade Commission (USITC) noted that India's market for orthopaedic devices alone is expected to touch $600 million by 2015, attributable to an increasing elderly population that is projected to reach nearly 200 million by 2025. Healthcare companies in the U.S. have begun to tap into this market by forming strategic alliances with Indian entities. For instance in October 2013, Minneapolis-based Medtronic, the world's largest maker of heart rhythm devices, announced its entry in the kidney dialysis business in collaboration with India's Apollo Hospitals Enterprise Limited, and dedicated an investment of $24 million towards research, development and manufacturing in India. GE Healthcare (healthcare division of American conglomerate General Electric) has set up three manufacturing plants in the State of Karnataka, invested $500 million towards R&D in these facilities and has plans to introduce low-cost portable ultrasound machines in India. Predominant factors attracting such large-scale investment include focus on health insurance coverage and preventive care, rising demand for better medical infrastructure and specialized facilities, as well as growth of medical tourism. Despite the favorable outlook for India's medical device industry and the U.S. being considered a world leader in medical device innovation, foreign investors are yet to leverage these opportunities – a key reason being that although previous Foreign Direct Investment (FDI) policies permitted FDI in medical devices, separate norms for the sector had not been explicitly provided for.

Under the National Industrial Classification (NIC) 2008 (the industrial classification system for economic activities in India), pharmaceuticals and medical devices have been categorized as distinct industrial activities. 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, where medical devices fall under "medical and dental instruments and supplies." Despite this distinct categorization and vast differences in nature and function between these two classes of goods, medical devices and pharmaceuticals were being treated as the same under the previous FDI regulations. A main reason was the Ministry of Health and Family Welfare, Government of India had classified 14 categories of medical devices as "drugs" under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 (''Act''). As there is no separate legislation for regulating medical devices in India, their import, manufacture, distribution and sale is currently regulated under this

Act read with the Drugs and Cosmetics Rules, 1945. (Non-notified [i.e. not specifically listed or categorized by the government] medical devices do not require registration, license, permission or No-Objection Certificates for import, manufacture, distribution and sale. This was clarified in an Order dated July 9, 2014 by Central Drug Standard Control Organization, Government of India). Notified medical devices were listed as being "drugs" and were hence considered a sub-set of pharmaceuticals by virtue of this legal fiction. In the absence of explicit FDI norms, medical devices (whether notified or non-notified) were subject to regulations that were in place for pharmaceuticals.

Shortly after the Government of India proposed amendments to the Consolidated Foreign Direct Investment Policy, 2014 ("FDI Policy") in its Cabinet Note in December, 2014, the Department of Industrial Policy and Promotion (DIPP) released Press Note No.2 (2015 Series) on January 6, 2015 (''Press Note 2''), thereby addressing the domestic industry's long-standing need of an FDI framework for medical devices which is independent of that governing pharmaceuticals. With effect from January 21, 2015, up to 100% FDI under the Automatic route is permissible in the medical device industry for both greenfield and brownfield projects. FDI in this sector has been restricted to manufacturing activities to boost local production, given that nearly 75% of the domestic market is presently dominated by imported medical devices.

For the pharmaceutical industry, the present FDI Policy continues to permit up to 100% FDI under the Automatic route in greenfield projects and under the Government route (i.e. with prior approval of Foreign Investment Promotion Board) in brownfield projects, subject to sector-specific conditions. An important sector-specific condition for pharmaceuticals - brought into effect by Press Note 1 (2014 Series) dated January 8, 2014 - prohibits foreign companies from imposing non-compete clauses on Indian entities. To increase competition and access to low-cost drugs in the domestic market, non-compete clauses are permitted to be imposed only under "special circumstances" and with prior approval of FIPB. As pharmaceuticals and medical devices, which were clubbed together under the previous FDI Policy, the ban on non-compete clauses applied to both industries. Press Note 2 has altered the investment landscape by stipulating that sectoral conditions applicable to pharmaceuticals shall not be 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. The American Chamber of Commerce has hailed the recent amendments to India's FDI Policy as conducive for American multinational corporations to undertake the manufacture of medical devices.

DIPP has sought to further ease the doing of business in India by linking sectors and activities in the FDI Policy to their corresponding codes under NIC–2008. Though NIC-2008 codes for the pharmaceutical sector have been incorporated in the FDI Policy through Press Note 1 (2015 Series) dated January 5, 2015, codes for medical devices are yet to be incorporated but likely to be soon included in the upcoming Consolidated FDI Policy of April, 2015.

The U.S. medical device trade association "AdvaMed" had stressed the need for separate legislative provisions for medical devices for sustaining long-term innovation and investment. The Medical Devices Regulation Bill, 2006 was an attempt in this direction but had been shelved. In parallel to the amendments in the FDI regime, the Department of Health and Family Welfare has now proposed a regulatory overhaul for medical devices, to be introduced as the Drugs and Cosmetics (Amendment) Bill, 2015 ("Bill") in the upcoming Budget Session of Parliament. The Bill proposes a separate Chapter IIA for regulating import, manufacture, sale and distribution of notified medical devices including penal provisions for contravention – thereby delineating legislative provisions on medical devices from 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 definition of medical devices contained in Press Note 2 (which is subject to a corresponding amendment to the Act),

Section 3(v) of the Bill proposes a broader definition as including a wide range of instruments, whether used alone or in combination, for the purposes specified therein. To bring clarity as to what constitutes a medical device, both these 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, Section 3(t)(iii) of the Bill 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. This proposed definition excludes the assembling or adapting of a medical device (already approved for use for an individual patient) by registered medical practitioners from the purview of "manufacturing." 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.

A series of other welcome measures have been 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." Regulations governing clinical trials in healthcare had long been a grey area for India. As per CDSCO's Order dated July 3, 2014, clinical trial procedures for medical devices shall be similar to the stringent provisions applicable to clinical trials of drugs/vaccines. The Drugs and Cosmetics (Fourth Amendment) Rules, notified in September, 2014, prescribe exhaustive labelling requirements and a five-year shelf-life rule for medical devices. The Rules also permit an extension of shelf-life subject to provision of satisfactory evidence justifying such extension. In December, 2014, CDSCO proposed comprehensive draft rules on good manufacturing practices and requirements of premises, plant and equipment for medical devices, in-vitro diagnostic kits and reagents, aimed at replacing Schedule M-III of the existing Rules. As FDI in manufacturing of medical devices is expected to increase, standardization of best practices is the need of the hour.

Incentives have also been provided under the direct tax regime to encourage scientific research and development (R&D), especially for businesses engaged in manufacturing activities. In May 2014, the Department of Scientific & Industrial Research (DSIR), Ministry of Science and Technology, issued new guidelines for approval of in-house R&D centers under Section 35(2AB) of the Income-Tax Act, 1961. Under this Section, where a company engaged in the business of bio-technology or in any business of manufacture or production of any defined article incurs any expenditure on scientific research on in-house R&D facilities approved by the prescribed authority (DSIR), it is allowed a deduction of a sum equal to two times the expenditure so incurred. This 200% deduction benefit is available subject to fulfilment of specific conditions and the assessee entering into an agreement with DSIR for co-operation in R&D. Nevertheless, it seems that the industry feels more fiscal incentives are required to position India as a global manufacturing hub for medical devices and generate cash flows for R&D. In this respect, the Federation of Indian Chambers of Commerce and Industry (FICCI) has proposed that the weighted deduction benefit be increased to 250% of approved expenditure incurred towards R&D for indigenous medical technology, and that manufacturers of indigenous medical devices be completely exempted from levy of Minimum Alternate Tax (MAT). Under Section 115(JB) of the IT Act, if the tax payable by any company (including a foreign company taxable in India) is less than 18.5% of its book profits, it is currently required to pay MAT which would be deemed as 18.5% of its book profits.

Indian industry has largely been biased towards importing finished medical devices due to these being chargeable with lesser import duty in many cases, as compared to import duty leviable on certain raw materials required for manufacturing medical devices. For example, importing titanium sheet/rod used for manufacturing implantable pacemakers attracts total import duty of 22.853% but importing the finished pacemaker itself attracts import duty of 12.034%. To address this imbalance, FICCI has called for no excise duty on medical devices that are manufactured in India (where imported raw material content is limited up to 50% of complete equipment cost) and no customs duty on raw materials imported by manufacturers of medical devices (where imported raw material content is limited up to 50% of complete equipment cost). Although the existing duty structure requires rationalization, relying on tariff barriers alone to promote local manufacturing may delay the entry of advanced medical technology and prove counter-productive for attracting foreign investment. Exempting or minimizing the service tax burden (currently levied at the rate of 12.36% on gross basis) for maintenance services with respect to medical devices has also been suggested by the industry. A recent news report summarized India's strengths in the medical device industry as having ''the right minds to produce low-cost gadgets, highly qualified doctors for advice, an ideal market that has a demand for these products and the capability to manufacture these products here.'' Though multinationals already produce medical devices in India, these legislative measures will create a favorable investment climate and make manufacturing a profitable enterprise.

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