



**Testimony of TwoFour Insight Group, LLC
Before the U.S. International Trade Commission
Investigation No. 332-550
Trade and Investment Policies in India, 2014–2015
May 5, 2015**

Dear Commissioners:

Thank you for the opportunity to present before you this morning. It is a pleasure and a privilege to be here today.

Before I begin, I would like to provide as context just a few words about TwoFour Insight, LLC. We are a relatively new organization that started operations 18 months ago. Our primary focus is on the trade between the United States and India, particularly in the life sciences sector—pharmaceuticals, biotechnology and medical devices. We offer a range of services, including market research and advisory services to life sciences companies interested in the U.S. and Indian market. As a result, we actively monitor the daily changes taking place in the regulatory and commercial space in both India and the United States. One of our offerings is a subscription service that identifies and analyzes on a daily basis changes initiated by the Indian government that have a direct impact on the life sciences sector in India, including intellectual property decisions, pricing policies, product approvals, clinical trial application reviews, amongst other areas.

Today, we have been asked to present on the changes that have taken place under Prime Minister Modi’s leadership and the overall environment for life sciences companies in India.

At a high level, I would say that there is much that is promising since the Prime Minister Modi has come into power. We have seen a remarkable change in tempo and tone from the Indian government under his leadership. This comes primarily in the form of an openness and willingness by the government to engage on difficult topics, such as intellectual property rights (IPR), which was not always the case. However, to judge by the specific steps taken by officials in terms of policies and regulations under Prime Minister that impact the sector, there is less to cheer. Improvement in some areas such as relaxation of foreign direct investment (FDI) in the medical device sector is being countered by policies such as broadening price controls of health products. There are many similar examples. However, what I would like to do today is provide a sampling of

the changes that have we seen take place under the leadership of the new government and discuss their potential impact on the life sciences sector.

Pharmaceuticals

First, I would like to begin with the pharmaceutical/biotechnology sector that has seen a significant number of new developments and changes that have taken effect since Prime Minister Modi took office in late May 2014. Some of the key areas that I will highlight today, include, the overall drug/device regulatory system, clinical research and pricing of products.

Drug Regulation

In order to understand the drug regulatory system in India, it is important to briefly review the various types of pharmaceutical products that are available in the Indian market.

- First, similar to the United States, there are so-called “new drugs” or patented drugs that are approved for the first time in India and typically have no competition day one in the market. Notably, the definition of “new drug” is not defined in the Drugs & Cosmetics Act, but rather in the Drugs & Cosmetics Rules, which essentially defines new drugs as drugs that have been in the market for at least four (4) years or are listed in the Indian Pharmacopeia (IP).
- Second, the Indian market also has a small segment of unbranded generic drugs, which are akin to what we refer to in the United States as “generic” drugs. These are typically low cost versions of the original approved drug in India that are sold without a trade name.
- Third, you can find the largest category of drug products that are referred to as “branded-generic” drugs. These drugs are marketed with a trade name and are directly marketed to physicians and other healthcare providers. Note that there are no provisions in the Drugs & Cosmetics Act or Rules that govern designating a trade name for a product. This is solely an intellectual property rights (IPR) exercise with no involvement by the drug regulator in approving the name.
- Finally, not all drugs require a prescription in India before they can be dispensed to a patient. Instead, drugs that are referenced in certain schedules such as Schedule H and H1 require a prescription and limit dispensing to a licensed pharmacist.

Only drugs deemed as “new” or imported drugs need to be approved at the Central Government level. All other drug products can be approved at the State level with minimum coordination with the Central Drugs Standard Control Organization by State

Licensing Authorities. Because the drug regulator at both the central or state level do not publish approval information, there is a considerable lack of transparency in the approval of drug products, including the company receiving the approval, the latest approved labeling for the drug, or when a product is *anticipated* to be approved or the status of the approval of any drug (e.g., Tentative Approval). The latter is key if you are the marketer of a “new drug” and do not anticipate immediate competition only to find out that a state regulator has approved a branded or unbranded generic version of your drug. Because of this highly uncertain and fragmented system, physicians and patients tend to favor branded-generics from reputed companies to ensure quality and consistency.

For several years there have been failed attempts to centralize the drug regulatory system in India, including attempts at passing comprehensive legislation to do so. To date, Prime Minister Modi’s government has not re-introduced legislation, however, amendments to the Drugs & Cosmetics Act, 1940 have been proposed by the Health Ministry that would at least bring fixed dose combination products under sole purview of CDSCO. In addition, in an effort to increase transparency, the drug regulator has commenced offering pre-market submission meetings with drug applicants to discuss an applicant’s upcoming filing and established weekly “open” meetings to allow any applicant to come in to discuss pending applications, etc. Overall, the regulation and approval of drugs remains a challenge in India, especially as it relates to lack of transparency of drug product approvals by company, use of trade names and lack of harmonization of standards across the country. The latter is particularly challenging especially in light of the reported number of substandard drugs throughout the country.

Clinical Research

By way of background, in early 2012, public interest litigation (PIL) was filed by a health advocacy group, Swasthya Adhikar Manch, Indore & Anr., in the Supreme Court of India alleging malpractice by the Government of India in the process and administration of clinical research in India . The Supreme Court case remains open despite pleas by industry to Prime Minister Modi, soon after his arrival in office, to resolve the case so that sector can move on. Even though the case remains open, CDSCO and the Drug Controller General of India (DCGI) have systematically implemented a number of changes discussed during the court proceedings that have been outlined in various court Orders. Some of these changes include:

- Three part test to evaluate New Chemical Entities and Global Clinical Trials
 - Risk versus Benefit
 - Innovation *vis a vis* existing therapeutic options
 - Unmet Need

- Three part committee review process for applications
 - Subject Expert Committee
 - Technical Committee
 - Apex Committee
- Registration of Ethics Committees
- Compensation for patients injured during a clinical trial
- Audio-visual informed consent

Overall, the changes, including the new committee structure, appears to be working and applicants continue to receive approval and most importantly the moratorium on approvals that plagued the industry a few years ago has been lifted. However, the compensation requirements for both serious adverse events and non-serious adverse events along with a proposed audio-visual informed consent have the potential to be troublesome for industry.

Pharmaceutical Price Controls

After several years of negotiations with industry, the Government of India issued the Drug Price Control Order, 2013, (DPCO 2013) which replaced the Drug Price Control Order, 1995 (DPCO 1995). The two major changes implemented by the DPCO 2013 are the “market based” methodology for calculating ceiling prices and the inclusion of National List of Essential Medicines (NLEM) under price control. While the implementation remains a work-in-progress in many ways, as there are limitations in the pricing information that is available to the government along with which company is producing which product, the Government of India appears committed to utilizing the DPCO 2013 to control pricing in the market.

For example, within days of Prime Minister Modi taking office, on May 29, 2014, the National Pharmaceutical Pricing Authority (NPPA), which is responsible for implementing the DPCO 2013, issued “internal guidelines” under Paragraph 19 of the DPCO 2013 to bring certain non-scheduled drugs under price control. Many in the industry were caught off-guard with these guidelines. On July 10, 2014 the NPPA brought 108 formulations of 50 HIV/AIDS, diabetes and cardiovascular drugs under price control under this provision. Consequently, several trade associations representing both the multinational and larger domestic pharmaceutical companies challenged NPPA in court to try and stop these orders based on lack of “extraordinary circumstances”, which is required to be demonstrated under paragraph 19 of the DPCO 2013. This had a chilling effect on the industry in light of the limited transparency and consultation on exercise of Paragraph 19. In September 2014, under pressure from the Solicitor General and others, the NPPA rescinded the internal guidelines, however the court case remains ongoing.

Also, despite the withdrawal of these guidelines, the Prime Minister Modi-led government has continued to insist that the July 10 orders would remain in effect. In addition, the NPPA has announced the implementation of a consumer complaint system that would allow patients to directly inform the government of concerns of products being labeled or sold above their set ceiling prices. Note that even if a drug is not “scheduled”, there is a limitation on companies to raise the price of their drug in any given year.

Medical Devices

As has been well documented in the past, the regulation of medical devices in India is limited to 14 categories of medical devices. In July 2014, soon after Prime Minister Modi came into office, the DCGI issued an Office Order clarifying that only the 14 medical devices notified in the 2010 Order require licenses, registration, etc. This certainly provided some optimism for industry in that the government may finally take steps to officially recognize medical devices as being different than drugs. Even though this has not translated into a separate regulatory regime per se, in late 2014, Prime Minister Modi’s Union Cabinet proposed the removal of medical devices from the Foreign Direct Investment (FDI) policy governing pharmaceuticals. The announcement also contains a distinct definition of medical devices that would require the Drugs & Cosmetics Act to be amended. Once amended, the natural next step would be to create a separate regulatory regime for medical devices that is either modeled after the United States Food and Drug Administration (USFDA) or a Western Europe type of system with reliance upon third parties for certain devices. Any regime that India chooses to implement requires considerable caution in light of the limited technical resources available.

Foreign Direct Investment:

But, first, late last December 2014, the Union Cabinet approved a change in the Consolidated FDI Circular 2014 relating to medical devices. The Cabinet took the decision to carve-out medical devices from the FDI policy governing pharmaceuticals. Since medical devices are defined in the Drugs & Cosmetics Act, 1940, as amended, as a subset of pharmaceuticals, all policies governing pharmaceuticals also apply to medical devices with certain limitations. One such example was the FDI policy for pharmaceuticals, which was restricted a few years ago when the concerns about multinational companies acquiring domestic pharmaceutical companies reached a peak. In the new policy, multinationals were prohibited from acquiring existing “brownfield” facilities without prior government approval and potential conditions such as not imposing non-compete agreements and/or mandating the continued production of certain drugs. These provisions automatically applied to medical device companies. The carve-

out of medical devices from the FDI Circular went into effect in January 21, 2015 with the issuance of Press Note No. 2 (2015 Series).

By way of this Press Note, 100% automatic route is permitted for FDI in the medical devices sector. This note also included the same definition of medical devices that is included in the 2014 Union Cabinet Note. In theory, the carve out of medical devices from pharmaceuticals is in itself a small victory for the relatively small medical device sector in India, holding out hope that perhaps now foreign investment would start flowing. It also signaled an intention to create a separate definition of medical devices, which would require rewriting the Drugs & Cosmetics Act. However, this change in the FDI policy will likely not make a measurable impact on inbound investment in this sector for a number of reasons.

The restrictions imposed on FDI in the pharmaceutical sector were only introduced in November 2011. Even though we have not looked at the FDI inflow in the medical device sector from November 2011 to January 2015 and compared it to the pre-November 2011 period when there were no restrictions on FDI in pharmaceuticals, we feel confident in saying the FDI policy has not been the determinative reason for the lack of FDI in the medical device sector in India. Instead, the decision to make an investment in the sector is determined by the size of the potential market, regulatory hurdles and reimbursement opportunities.

Medical Device Regulation

As noted previously, medical devices are currently regulated as “drugs”, meaning that there are no separate set of rules and regulations for medical devices. Furthermore, only fourteen (14) categories of medical devices are “notified” meaning subject to any regulation. Over the years, the global medical device industry has repeatedly called for separate regulations for medical devices and as of the beginning of this year, it looked like 2015 would be their year. In January, the Health Ministry released a draft amendment to the Drugs & Cosmetics Act, which would create a separate definition of medical devices that would inevitably require a separate set of regulations for medical devices. However, so far, this new bill has not been introduced in the Budget Session of Parliament, which ends in three days (May 8, 2015).

If the bill is introduced or passed in another creative way, the immediate challenge facing the country and industry will be the type of regulatory scheme that the country will implement for regulating medical devices. If India chooses to implement a highly-centralized USFDA-type of regulatory system, significant resources and training will be required, which is not budgeted under the current Health Ministry Budget that was



introduced during this on-going Budget Session. Implementation of a new regulatory scheme in a constrained resource environment will also likely cause significant backlog of approvals, shortages, as well as potential supply disruptions, not to mention a higher cost for patients. Alternatively, if India decides to implement a decentralized European-type of regulatory scheme, there will still be resource constraints and the same issues could arise, but perhaps the pain may be shorter lived than if they attempted to implement a USFDA type of system.

While the debate continues on for medical devices, the DCGI has released several guidance documents over the past year that at least acknowledges that medical devices are not the same as pharmaceuticals. For example, on September 25, 2014, the Drugs & Cosmetics (4th Amendment), Rules 2014 were issued. These amendments made fundamental changes to the regulatory framework for medical devices, including the introduction of a definition of competent staff for medical device manufacturing along with testing and labeling requirements, shelf life, exemptions for custom made devices, and adoption of certain standards. However, while the regulators (Ministry of Health & Family Welfare) were providing positive signals to the medical device industry, the pricing authority, the National Pharmaceutical Pricing Authority (NPPA) did not signal any different treatment for medical devices that are subject to price control as it sent a reminder notice to medical device companies to submit pricing information that is required under the DPCO 2013.

Pricing

During 2014 and 2015, the NPPA, the Parliamentary Standing Committee that oversees the Ministry of Chemicals & Fertilizers, its Department of Pharmaceuticals, as well as State Drug Controllers, continued to express concerns about pricing of medical devices in India. The concerns resulted in the NPPA issuing several notices to medical device trade associations reminding them of their obligations to provide pricing information for the 14 notified medical devices and cautioning against raising the prices beyond the DPCO 2013 allowance. If ever there is a separate definition of medical devices that is introduced, this may be bittersweet victory for the industry, as it will open up calls for bringing “all” or at least “essential” medical devices under some type of price control. However, this may also provide an opportunity to negotiate a separate methodology for calculating pricing for medical devices that takes into account the different distribution channel for medical devices as compared to pharmaceuticals.

Overall, we see a lot of optimism in India for the life sciences industry. In particular, I would like to applaud the Indian government for its attempts at greater transparency and its nascent efforts to harmonize its regulatory standards with other countries. However, in



order to fully realize its potential and in order to better serve the country's patients with high quality and affordable products, there are several remaining areas, some of which I have noted today, that need to be monitored by the international community and ultimately addressed by the Indian government.

Thank you very much for the opportunity to speak with you today and I welcome any questions you might have for me.