In August this year, the government had introduced the Insurance Laws (Amendment) Bill, 2008, which proposes to raise the cap on foreign direct investment (FDI) in insurance joint ventures from 26% to 49%. However, with the Congress and other Opposition parties resisting the move, the Bill was referred to a Parliamentary select committee for further scrutiny. The chances of Parliament approving the proposed Bill now, in the ongoing winter session, finally appears to be a possibility. The approval to the insurance Bill, apart from providing a fresh stimulus for foreign investments, will also indicate that there is a possibility of political parties coming to a consensus on certain economic reforms.

The government also initiated the process to simplify and streamline the country’s archaic laws. The Law Commission led by AP Shah suggested the repeal of 72 obsolete statutes immediately in its first interim report. The government also wants to push key labour reforms aimed at creating millions of jobs and making India a manufacturing hub. It introduced the Factories (Amendment) Bill, 2014, and the Apprentices (Amendment) Bill, 2014, in the Lok Sabha seeking to revamp archaic labour laws. The factories Bill and the apprentices Bill seek to amend laws that came into force in 1948 and 1961, respectively. Once passed, they are expected to make it easier to do business in India, with provisions to allow flexibility in both hiring and working hours of workers.

One of the latest and much anticipated change that the government has initiated is the opening up of FDI in medical devices. As per a draft Cabinet note that was circulated in early November by the ministry of commerce and industry for inter-ministerial comments, the government is looking at relaxing the policy for the cash-starved medical devices sector to attract more investments and boost domestic manufacturing.

This is a positive move and will help bring down the cost of capital and increase the flow of funds, thereby bringing down the costs of such medical devices. This will be a big boost for this sector. Interestingly, Ficci, in one of its reports, has estimated that the medical devices and equipment industry, valued at $2.5 billion, contributes only 6% of India’s $40 billion healthcare sector. Moreover, it is growing at a faster annual rate of 15% than 10-12% growth seen in the healthcare sector in its entirety.

As per DIPP, it considers all medical devices to fall under the pharmaceutical category and they accordingly are subjected to FDI limits and other conditions, such as the mandatory government approvals. Further, as per the current FDI policy, in the pharmaceutical sector while FDI is permitted through automatic route in the case of greenfield investment (new venture), government approval is required in the case of brownfield (existing companies).

Unfortunately, the term ‘pharmaceutical’ has neither been defined in the FDI policy nor has been clarified by the regulatory authorities.

Accordingly, the definition of ‘drugs’ under the Drugs and Cosmetics Act, 1940, is typically used as an aid to interpretation of the term ‘pharmaceutical’ as used in the FDI policy. As far as medical devices are concerned, the definition of ‘drugs’, as set out in the drugs Act, is used in reference.
Even the Central Drug Standards Control Organisation, in one of its office orders of 2014, set out a list of 14 medical devices and clarified that only such medical devices should be considered ‘drugs’ under the drugs Act. However, FIPB thinks otherwise. Accordingly, investment in a company that manufactures medical devices (whether or not such medical devices are classified as drugs under the drugs Act) comes under the ambit of government route.

In addition, a common practice in the pharma industry is to get a third-party manufacturer to manufacture drugs on a contract basis. In such cases, while the raw material, specifications, etc, are provided by the principal, it is the contract manufacturer who undertakes the actual manufacture of the drugs. A common question that one encounters is that whether the principal would be considered as carrying on a ‘manufacturing activity’ or would the principal be considered as carrying on a ‘trading activity’ (whether wholesale or retail, single-brand or multi-brand)? The reason why this question becomes important is because as far as the pharma sector is concerned, manufacturing and trading activities would be very differently regulated in terms of the FDI policy and clarity on this aspect will certainly assist the investor class.

The above would also bring greater clarity and boost the manufacturing activities in the medical devices sector—a clear shot in the arm for Modi’s ‘Make in India’ initiative designed to transform India into a global manufacturing hub.

Victory march rolls on an emphatic victory for the BJP in Haryana and its emergence as the single-largest party with a big score in Maharashtra gives the PM a tremendous boost to pursue economic reforms swiftly. The much awaited GST, speeding up of the stalled projects, reduction in subsidies, MGNREGA recast, supply-side response to inflation, implementation of ‘Make in India’, bank capitalisation, and solving NPA issues are all areas that need immediate attention in order to get investor confidence back on track.

Let the action begin!