REVISED FDI POLICY IN PHARMA

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Cabinet Committee on Economic Affairs had decided in November 2013 and conveyed its decision to the Department of Industrial Policy and Promotion ("DIPP") regarding the changes in the FDI policy in pharmaceutical sector. The announcements to continue with the same FDI limits were taken earlier this year. The current position is that 100% FDI is allowed in both Greenfield (new) Brownfield (existing) segments and the investments under the Brownfield is subject to approval by the Foreign Investment Promotion Board ("FIPB"). However, DIPP has said that a "non-compete clause" will not be allowed except in special cases and that too with the prior approval of FIPB.

PSA view – Though Health and Commerce Ministry had suggested to lower the FDI cap but Cabinet Committee decided not to do that but in order to give some respite to the local players they have suggested the "non-compete clause" deletion. Now the sellers will not have to agree regarding not competing with the buyers and in launching of similar products in the same or relevant markets. This can allow the local players to start afresh in the same segment, in the same market and hire its old employees from the entity it has just sold.

Supreme Court guides the government on DPCO and Clinical Trials

A bench headed by Justice G S Singhvi said that the central government is being guided by market-driven forces and the current DPCO would encourage profiteering of medicine brands prescribed by doctors. The court was hearing a PIL filed by NGO, All India Drug Action Network, which contended that market based pricing is never used for any price regulatory purposes and under the new policy simple average ceiling prices are in many cases higher than the market leader price.

In another PIL filed by an NGO, Swasthya Adhikar Manch in February 2012, Supreme Court got all geared up to guide the central government for ensuring a proper mechanism on clinical trials. A bench headed by Justice R.M. Lodha made observations on the conducting of clinical trials.

PSA view – These observations by the Supreme Court suggests the apathy of the government and government agencies in firstly providing for a regulatory mechanism and secondly, wherever there is a mechanism, to enforce strictly such a mechanism to bring about the desired result for which the mechanism was set up. A lot needs to be done to ensure safe and cost effective essential drugs to the common citizen and to ensure that clinical trials are conducted by the rule book in India and subjects are appropriately taken care of or compensated.

Clinical trials in India: new statistics, new regulations

Ever since the clinical trials have come under the scanner of the Supreme Court of India ("SC") following its order on January 3, 2013, the regulatory agencies, the Drug Controller General of India ("DCGI") and the CDSCO have intensified the monitoring of the clinical trials and the government had also set up Apex Committee and Technical Committee to supervise the clinical trials. In the last few years, they have issued notices in 235 cases and inspected 577 clinical trial sites. Increased proactive steps and new guidelines have resulted in a sharp decline in the number of clinical trial approvals. Till the end of August this year, the DCGI has given permission to only 162 clinical trial applications.

The government had also constituted 12 New Drugs Advisory Committees ("NDACs"). The NDACs met 78 times and evaluated 1,122 applications for approval of clinical trials, new drugs and fixed dose combinations. Among these applications, 331 were related to approval of Global Clinical Trial ("GCT"), which included clinical trials of new chemical entities and NDACs have recommended for approval of 285 applications. For 46 applications, no recommendation have been made. Out of the above 285 applications, DCGI has given approval to conduct clinical trials in 162 cases.

As per the directions by the SC to consider the views of all the states, a meeting of the Chief Secretaries, Health Secretaries of the State Governments and the Administrators of the Union Territories was convened by the Union Health Ministry. With a view to further streamlining clinical trials and minimizing the irregularities in the sector, some states have suggested restricting the trials only to the government-run hospitals in the country.

Keen on improving the current scenario, government has proposed a new Drugs and Cosmetic (Amendment) Bill, 2013, now under the scrutiny of the Parliamentary panel. The idea is to have a separate chapter on clinical trials and put all the existing guidelines and instructions from the DCGI under the framework of law. It has comprehensive provisions to monitor the trials and also deciding compensations to the victims. Further, an expert panel has been appointed under Prof Ranjit Roy Chaudhury, which recommended several changes including creation of a Central Accreditation Council to oversee the accreditation of institutes, clinical investigators and institute ethics committees for clinical trials in the country. It also suggested that trials should be carried out only at centers which have accreditation.

PSA view – India needs a robust system for conducting clinical trials and to ensure that trials are conducted in a scientific and ethical manner and in compliance to the regulatory provisions. There have been allegations that the approvals to the clinical trials are coming hard and slow after the SC order thereby impacting the overall performance of the clinical trials sector. This sector has great potential to grow but the slew of legislations and guidelines has already stopped several CROs to suspend trials here. As the government is aware of the implications from investments perspectives, it has started taking proactive measures to streamline the sector and gain back the confidence of the foreign players in the market, while also keeping the concerns and safety of subjects involved in the overall process.

Ministry issues formula to determine quantum of compensation in deaths occurring during clinical trials

The proposed formula will prove to be a great aid in computing the quantum of compensation in the cases of SAEs of deaths occurring during clinical trials. The criteria on which it is based includes the age of the subject and the risk factor depending on the seriousness and severity of the disease, presence of co-

morbidity and duration of disease of the subject at the time of enrolment in the clinical trial. As per the new formula, the compensation amount will vary from Rs. 4 lakhs – Rs. 73.60 lakhs depending on the age of the deceased and the risk factor. However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs would be given. The expert committee has also said that the trials can only be carried out in accredited centers and the principal investigator and ethics committee of the institute where the trial is being done, should also be accredited. During the deliberations, the expert committee felt that the criteria used to determine the quantum of compensation should not be discriminative in nature due to socio-economic conditions like income and education, and it should not discriminate gender/sex. The criteria should not be such which may have minimal impact but may create large variability and the formula should be such that the inter group variability of compensation value so arrived at, has little scope of discretion, thus avoid possible bias.

PSA view – It is an appreciable development that the formula has finally been created and introduced in public domain. It would be good to see that at implementation stage the formula is applied without any bias and no discrimination is caused owing to factors such as income, sex, gender etc. Secondly, the payment of compensation should be done in a timely manner, otherwise this practice of creating the formula will be rendered futile.

Department of Health Research signs MoU with NIHCE

The MoU between Department of Health Research and National Institute for Health and Care Excellence, UK ("NIHCE") provides the framework for strategic and technical cooperation between the two countries with an aim to (i) bring modern health technology to people by encouraging innovations; (ii) translate these innovations into products/processes by facilitating evaluation; (iii) introduce the aforesaid innovations into public health service. The two countries will also exchange institutional expertise and experience on clinical trial guidelines, quality standards, application of health technology assessment and implementation of the decisions of the assessment into clinical policy and practice. They will also explore the opportunities for collaborative research projects in clinical policy and practice.

PSA view – This is a good collaborative step towards healthcare policy making and facilitating innovations. This strategic and technical collaboration will benefit the Indian healthcare system to a greater extent.

DoP's constant efforts to fix patent drugs' prices

Even after facing utter failure in fixing the prices of patented drugs in the country DoP is back in action, this time with an inter-ministerial committee of joint secretaries of different ministries to look into the issues and suggest ways and means to fix the prices of patented drugs. The inter-ministerial committee has been constituted in light of the diverse opinion of different stakeholders received on DoP's earlier report on patented drugs. In its past report on the issue, DoP committee had recommended a formula on price negotiation of patented drugs, linking it to the per capita income in the country and had also suggested that the price of patented drugs should be frozen before the drugs are marketed.

PSA view – A patient's interest can be protected in a better manner if the rates of drugs is well regulated. Recently MCI had also asked the doctors to prescribe drugs with generic names so as to minimize usage of drugs of very high end brands. It is praiseworthy that DoP has not left the matter in lurch and is doing constant efforts to fix the prices of patented drugs. Once the move is successful, it is surely going to benefit

the customers who sometimes end up spending more than their spending capacity on drugs alone. Secondly, once the rates are regulated, the drugs makers will not be able to exploit the market with their patented drugs.

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