DOP FOR SETTING UP VC FUND FOR R&D IN PHARMACEUTICALS

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The government would initially allocate Rs.500 crore between all the pharma funds to be set up under this project. Each fund would then be expected to invest (i) at least Rs.150 crore or more and (ii) 4 times of investment sought from the government. The project sets out the manner in which fund will be established and managed, the roles of key stakeholders and estimated event schedules and timelines.

The government would act as an investor whose contribution would be managed by the fund manager in terms of the contribution agreement between them and the trustee. The funds will be provided as a financing solution for high-risk, potentially high-reward projects that, due to the lack of substantial tangible assets, expected years of negative earnings, and uncertain prospects, are unable to raise funding from more traditional sources like banks or capital markets. Like pharma R&D, where the fund would promote entrepreneurship and support the development of a self-sustaining environment.

PSA view – This is a strategic move to involve direct participation of patients in the PvPI as patient awareness is the key to the success of the PvPI program and their reporting will provide hands on information about adverse events. The IPC and Central Drug Standard Control Organization (“CDSCO”) plans to provide training and technical support to the stakeholders and the guidance document will be an important tool for conducting pharmacovigilance activities.

Animal friendly move of health ministry

The Union health ministry has banned the import of cosmetics tested on animals. The ban comes in the form of Rule 135-B that states, “Prohibition of import of cosmetics tested on animals. – No cosmetic that has been tested on animals after the commencement of Drugs and Cosmetics (Fifth Amendment) Rules, 2014 shall be imported in to the country.” The ban will be effective from November 13, 2014. Appreciable enough that, by banning the import of cosmetics tested on animals, India has become the first cruelty-free cosmetics zone in South Asia. In fact, recently, Indian government had banned animal testing of cosmetic products within the country.

PSA view – The move is quite praise worthy but the cosmetic manufacturers are going to have a tough time with this. The historic ban on the import of newly animal-tested cosmetics highlights government’s anti-cruelty policy. Cosmetic formulae are many a times non-vegetarian and can be very reactive. It would not be easy to have subjects to conduct clinical trials for this. Manufacturers may resort to falsely labeling their products indicating that they are not animal tested. It would be interesting to see the implementation of the ban.

Pharmaceutical companies must register on online database now

The NPPA in collaboration with the National Informatics Centre has developed IPDBMS to set-up a comprehensive in-house market database in respect of price fixation system for both scheduled and non-scheduled formulations.

In this regard, all drug manufacturers i.e., any person who manufacturers, imports and markets drugs for distribution or sale in country have a legal obligation to register themselves and disseminate details "which include inputting of company details, details of production/procurement sources and product list", etc., on or before October 30, 2014, after which the data inputting facility shall be made available to all registered users for online submission. Thus, the pharmaceutical companies are mandated to carry out the online filing of returns in Form II, Form III and Form V under the Drugs (Prices Control) Order, 2013 (the DPCO). Non-compliance will attract penalties and punishment under the Essential Commodities Act, 2005.

PSA view – This is a commendable step by NPPA considering the significance of a robust mechanism which acts as self-contained guide on market-based data on drugs. IPDBMS is launched to fulfill the objectives of DPCO, 2013 necessitating the government to come out with an appropriate mechanism for obtaining market based data in due course of time. This mechanism will assist the authorities to monitor and regulate the price fixation and price revision system in respect to scheduled drugs and non-scheduled formulations and control the availability and production of scheduled formulations.

Stricter Regulatory Scrutiny on Medical Device Industry

The recent amendments to the Drugs and Cosmetics Rules, 1945 is a wake-up call for the players in medical device industry as the new law prescribes a stern regulatory framework in respect of labelling requirements and standard control requirements to be fulfilled by the manufacturers and exporters of medical devices. As per Gazette notification GSR 690 (E) dated September 25, 2014, the Union health ministry has notified the following changes in the Drugs and Cosmetics Rules, 1945 pertaining to the medical device industry:

(a) Rule 109 A is amended to make labelling of medical devices mandatory in India. It is now necessary that the label should carry the proper name of the medical device, the intended number of use, substances used in the device and such other details necessary for the user to identify the device, its use and name of the manufacturer;

(b) Rule 109 B specifies certain exemptions to labelling requirements for medical devices exported from India i.e., firstly, if the consignee does not require the device to be labeled with the name and address of the manufacturer, then it should bear a code number and the code should contain the name of the State or Union Territory, in abbreviation, followed by the word "Device and "manufacturing license number", as approved by the licensing authority and secondly, if the consignee does not require the device to be labeled with the code number, then the label should bear the special code number requested by the consignee and approved by the licensing authority.

(c) Rule 109 C prescribes that the shelf life of the medical devices shall not exceed sixty months from the date of manufacture. However, the period may be extended, if satisfactory evidence is produced by the manufacturer to justify such an extension.

(d) Schedule R-1 is amended and Union ministry has listed the standard requirements for all medical devices i.e., if there is no standard laid down by Bureau of Indian Standards for the medical device, then it should conform to the International Standards, like International Organization for Standardization, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. In case national or international standards are not available, the device shall conform to the manufacturer's validated standards.

PSA view – The present amendment to the Drugs and Cosmetics Rules, 1945 is a step in the right direction as the regulatory framework for the medical device industry is more stringent than before. Further, the attempt to formulate a definite industry standard is a welcome step.

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