45 UPCOMING PRICING REGIME DAYS TO COMPLY TO

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The government may give drug companies just 45 days to comply with the upcoming pricing regime that promises cheaper essential medicines, making it mandatory for companies to conform to revised rates irrespective of the date of manufacture. The intent is to cater to the consumer's interest by not allowing the manufacturers to sell the previous batches at non-revised price. The industry officials, on the other hand, have criticised this step claiming that the directive could lead to chaos and even shortage of essential drugs in the short term. As per them, the task of recalling batches "from every nook and corner" is a logistic nightmare which could lead to losses on account of price-cut, labelling and additional freight movement. Factoring this, the government intends to allow pharma companies to send a supplementary price list of revised prices that the retailers will have to display in their premises.

PSA view – The pharma companies had ample time to implement the price policy which was notified on December 7, 2012 and thus avert the possibility of these potential losses. The time line at present is speculative and the pharma companies could be given an extension for implementation. However, regardless of whether an extension is granted, the companies should make changes to the drug price as this is a reality which is to be implemented sooner rather than later.

Government to introduce ART Bill in next session of Parliament

The Union Health Ministry is formulating the ART Bill to be presented in the next session of the parliament. The ART Bill aims to provide a national framework for regulating and supervising the mushrooming business of infertility clinics and surrogacy in India. Many technologies relating to fertility require enormous technical expertise and infrastructure and, hence, the government is looking to regulate the same. The ART Bill has been drafted with the assistance of the Indian Council of Medical Research and has gone through almost 4 years of government and public discussions. The ART Bill looks to establish strict parameters for the establishment of an infertility clinic and also, defines the minimum requirement regarding staff in an infertility clinic and minimal physical requirements for a clinic.

PSA view – The step taken by the government to introduce the ART Bill is in the right direction. However, the ART Bill still has certain lacunae. For example, the ART Bill legalizes surrogacy without really describing the rights of surrogates. The Health Ministry should provide a strong legislation which covers all aspects relating to assisted birth and surrogacy.

Ayush Department issues GCP guidelines

With a view to facilitate researchers and institutions in adopting standards for good clinical practices for conducting clinical trials in ASU medicine, the Ayush Department has issued GCP Guidelines. These Guidelines are addressed to investigators and all interested parties involved at various stages of conducting clinical trials and provide guidance for designing, conducting, auditing, reporting, documenting and terminating studies related to new ASU drugs on humans. This 114 page Guidelines is a step to encourage clinical trials in alternative medicines and maintain the sanctity and clinical efficacy.

PSA view – The announcement of the Guidelines is well timed, especially in view of the focus on scientific validation of ASU cures which are meant for voluntary use, not linked with any provisions of Drugs & Cosmetics Act, 1940, and the rules thereunder. The Guidelines shall prove significant in validating the fact that ASU drugs have minimal side effects by providing for a means of validation of safety and efficacy using scientific and evidence-based methodologies. These are needed for universal acceptability, gaining confidence of practitioners in ASU medicines and cures.

WHO approved Indian vaccine standards

Earlier this month, the vaccine industry received a much desired relief when the WHO team of international experts from eight countries approved India's vaccine regulatory system for maintaining international standards. The team had conducted comprehensive tests in December 2012 and found that the Indian body – National Regulatory Authority of India and its affiliated institutions meet the WHO standards and the efficacy indicators for a functional vaccine regulatory system.

PSA view – This approval shall open new vistas for easy export of vaccines produced in India. Currently, the Indian vaccine industry is MINR 190,000 strong and is expected to grow further as it is a major vaccine producer that has 12 major vaccine manufacturing facilities. India currently exports 16 prequalified vaccines through United Nations agencies and this number is all set to increase now.

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