GOOD DISTRIBUTION PRACTICES FOR BIOLOGICAL PRODUCTS

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The CDSCO has issued the Draft for biological products with the objective to assist in ensuring the quality and identity of biological products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices. The Draft shall be applicable to all persons and outlets involved in any aspect of the storage and distribution of biological products, including the manufacturers, wholesalers, suppliers, distributors, government institutions, international procurement organization, donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers. All parties involved in the distribution of biological products shall have the responsibility to ensure that the quality of biological products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent. Even the government, custom agencies, law enforcement agencies, regulatory authorities shall ensure the quality and safety of biological products and prevent the exposure of patients to spurious biological products. An agreement must be executed with all agencies involved in the storage, transportation and distribution.

PSA view – Distribution is an indispensable part of the integrated supply-chain of biological products. As several parties are responsible for the handling, storage and distribution of products, it becomes crucial to have adequate controls over the entire chain of distribution. Adherence to the Draft would be necessary to maintain the original quality of biological products and remove the risks of adulteration, contamination, cross-contamination, spurious and unsuitable storage conditions.

Industry association pleads to have 140 drugs notified by the DGCI

The industry association, comprising primarily of small and medium sized manufacturers has approached the DGCI for notification of 140 drugs that have been labeled as “not irrational” by the expert panel headed by the DGCI himself. This request has been made due to the inordinate delay by the DGCI to announce and notify the state licensing agencies of the 140 fixed dose combination drugs which have been declared as “not irrational’ by the expert panel far back in April this year. In the absence of such notification to the state licensing agencies, manufacturers have no option but to approach the DCGI directly.

PSA view – The expert panel formed by the DGCI due to the controversy stirred up by the former DGCI in 2007 who had originally cancelled the licenses for approximately 270 fixed dose combinations on account of being “irrational.” Now, with 140 drugs being declared “not irrational” by the expert panel, while the industry

sighs a breath of relief, its full effect will only be felt once these combinations are notified to the state licensing agencies. It remains to be seen how long the DGCI takes to notify its finding of the fixed dose combination, now that the issue has been partially resolved, and whether any other concerns will be raised by the DGCI or the industry on the drugs that were actually declared to be irrational.

Drug pricing policy to be finalized next week?

After the Supreme Court's directive to the Central Government on regulating prices of essential medicines, the panel of ministers tasked with the mandate to finalize the country's drug pricing policy is expected to meet on September 27 to finalize a pricing policy.

The pharmaceutical industry is largely in favor of the pharmaceutical department's October 2011 proposal that retail prices be fixed using the "average of brands" method. As per this method the drugs will be priced after taking the average of the top three selling brands in that particular segment. This policy has been opposed by the health ministry and various NGOs who have suggested options like using the market-based mechanism to arrive at a final price for a particular brand, which factors in the cost of production of the medicine while determining the price.

PSA view – It has been over a year and still no headway has been made on introducing a pricing policy. Even though the Supreme Court has given the government an ultimatum of two weeks to finalize the pricing policy, failing which an interim order will be passed, it is widely expected the panel of ministers will not be able to finalize a policy in such a short time.

A pricing policy is the need of the hour as pricing of 348 essential drugs is dependent on this. However, at the same time a balanced policy is also the need of the hour because along with making drugs available at an affordable price, the pricing guidelines should not be detrimental to the drugs industry. Though the panel of ministers is expected to meet on September 27, only time will tell whether they will be able to finalize a policy on that date.

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