Pharma & Healthcare Update

April 08, 2015

PHARMA ALERTS

- NPPA revamps pricing information for scheduled drugs
- DCGI issues draft accreditation standards for ethics committees, investigators and clinical trial sites
- Draft guidelines issued for search and examination of patent applications

NPPA REVAMPS PRICING INFORMATION FOR SCHEDULED DRUGS

After considering stakeholder feedback, the National Pharmaceutical Pricing Authority (NPPA) has decided not to go ahead with an initial proposal to implement a ceiling price per unit on the label of a drug product. Expressed concerns included labels already being over-congested and that consumer confusion could result from the maximum retail price and ceiling price both being mentioned on the same label. The NPPA accepted that its proposal was not solving the problem of a lack of consumer awareness of the ceiling price under the Drugs (Price Control) Order, 2013 (DPCO 2013). As an alternate option, the NPPA, again based on extensive discussions with stakeholders, has proposed that the invoice issued by the retailer to the consumer should specify if the medicine is scheduled or non-scheduled under DPCO 2013. If the drug is a scheduled drug, the receipt must also specify the current notified ceiling price per unit.

The NPPA believes that this move will strike a balance between ease of implementation on the one hand, and consumer awareness and education on the other hand, and will also help in the effective implementation of the DPCO 2013.

DCGI ISSUES DRAFT ACCREDITATION STANDARDS FOR ETHICS COMMITTEES, INVESTIGATORS AND CLINICAL TRIAL SITES

The Drugs Controller General of India (DCGI), on 3 March 2015, issued the Draft Accreditation Standards (along with the application format) for accreditation of ethics committees, investigators and clinical trial sites. The standards were prepared by the Quality Council of India (QCI). The policies and procedures for the accreditation of ethics committees cover aspects such as:

- Composition and procedures for new induction and resignation of members.
- Frequency of committee meetings.
- Receipt, review and decision making of proposals, reporting and analyses.
- Opining on issues related to non-compliances, protocol violation, complaints by participants and other stakeholders.
- Compensation in clinical trials.

The QCI has also prescribed policies and procedures concerning investigator roles, responsibilities and qualifications. An investigator is required to follow certain procedures, including those relating to informed consent, safety reporting and management, investigational product, clinical trial documentation, and records retention.

The policies and procedures for clinical trial sites cover aspects such as a clinical trial subject protection policy, a transparent mechanism for enrolments, reporting of adverse and serious adverse events, research pharmacy, conflicts of interest disclosure policy and protocol compliance issues.

The draft policies and procedures seek to aid streamlining of the entire clinical trial process. The DCGI is inviting comments on these drafts within 30 days of their publication.

DRAFT GUIDELINES ISSUED FOR SEARCH AND EXAMINATION OF PATENT APPLICATIONS

The Controller General of Patents, Designs and Trademarks (CGPDTM) has issued draft guidelines for the search and examination of patent applications including in connection with medical products. These guidelines provide guidance for examiners for conducting a search for novelty and inventive step prior art and also a search strategy that can be adopted by the examiners. The guidelines seek to bring uniformity and consistency in patent examination and also provide illustrative examples to assist the examiners. This includes providing examples of pharmaceutical and biotech patent applications, showing how examination of these applications should be conducted.

The CGPDTM has made it clear that the guidelines will not be legally binding. In case of a conflict between the guidelines and the Patent Act and Rules, the latter would prevail. Stakeholders were invited to provide comments until 25 March 2015.

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