IPC LAUNCHED AER REPORTING FORM AND GUIDANCE DOCUMENT

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The AER reporting form was launched during a national level conference that was held in Delhi to sensitize the patients about the ADRs and the immense importance in participating in Pharmacovigilance Program of India ("PvPI") program directly. This form will be available on pilot basis in 150 ADR centres and will help in understanding whether patients are comfortable with the form for reporting of ADRs in future. The IPC, which acts as the national coordination centre ("NCC") for the program plans to pan it across on an active manner for better success of this initiative. The current version of consumer reporting form is available in English version; however NCC has already started converting the same into Hindi and several regional languages. In addition, based on the recommendations of WHO-NRA assessment, the IPC released a guidance document during the 47th Drug Consultative Committee meeting in Delhi which will act as a point of reference to ensure best practices with respect to ADRs, to help streamline the process in a uniform manner.

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.

MBBS & MD students can't practice profession without first serving rural areas

The DME in Telangana and Andhra Pradesh has withheld the certificates of recently passed out MBBS and MD students for want of fulfilling their pledge to compulsorily serve in the rural areas. To ensure compliance with this mandate, the State Governments have even got a bond signed for an amount of Rs.20 lakh from the students. The students rebelled against this move and approached the High Court which ordered the DME to release certificates of students who have got super specialty seats in various colleges. However, this move has put the other graduates in a lurch.

According to rural services guidelines, the MD students have to complete one year of rural service but many students have bagged seats in reputed colleges for super-specialty courses. However, junior doctors say the Directorate of Medical Education is asking them to complete rural service first and then go for super specialty. Medical students had approached the High Court, which directed the government to release certificates of those.

PSA view – The state government's mandate to serve rural areas is indeed good. However, the government must appreciate that students of medicine already invest a lot of time in completing their course. It would be

better to send practicing doctors, who are comparatively in a better financial position, to serve in the rural areas. State should also consider providing good infrastructure in rural areas; poor infrastructure and equally poor salaries are one of the main reasons which deter doctors from serving rural areas. It won't be surprising to see other states replicate the same move.

Wrong labeling under Schedule H1 causing confusion to chemists

Off late many incidents of mislabeling of certain drugs as Schedule H1 has caused utter confusion amidst pharmacists across the country and they have urged the regulatory body clear the confusion. Schedule H1, which was included in the Drugs & Cosmetics Act ("DCA") after amending the Act in 2013, came into effect from March 1, 2014, consists of a list of only 46 drugs. However, experts point out that there are more products in the market that are being sold under this category than necessary. This they feel needs to be investigated to find out the possibility of any swindling in this matter. Pharmacists who are doing manual billing are under a legal mandate to keep separate bill books or separate series of bill numbers, so that they can produce the records immediately when asked by the drug control officials. With such a long list of medicines it becomes tedious and cumbersome issue for many to keep a record of the drugs, especially when they are well aware that they do not fall under the category.

PSA view – Schedule H1 drugs require a prescription by registered medical practitioner. Mislabeling may desist the consumers to buy over the counter products such as body lotions etc. This may lead to lot of revenue loss to the pharma industry and in some cases where the products cross expiry dates, the losses will be irreparable. The issue must be plugged at the earliest possible.

Some crucial developments

(a) The US Food and Drug Administration ("US FDA") has issued a draft guidance for the pharma and biotechnology industry to provide regulatory submissions in electronic format to create a new age of simplification in submissions and adoption of paper-less procedures. Now, the companies will have to adopt the electronic-common technical document specifications. The US FDA has indicated that it would take 24 months for this document to be finalized and implemented. Submissions that are not presented electronically in the format specified will not be accepted, unless exempted from the electronic submission requirement.

(b) The Indian Council of Medical Research ("ICMR") proposes to collaborate with private companies for further development and commercialization of a large number of indigenous healthcare technologies that it develops to develop affordable technologies for healthcare. The ICMR has already developed technologies which include diagnostic assays/reagents/devices for diabetes mellitus, cervical cancer and thalassemia; vaccines for hepatitis E; infectious diseases for tuberculosis, leptospirosis, hepatitis E, rotavirus diarrhoea, food borne pathogens, Kalazar, Malaria, Filaria, etc.

(c) The Indian Patent Controller has released the revised "draft guidelines for examination of patent applications in the field of pharmaceuticals." This draft will help the examiners and the controllers of the patent office in achieving uniform standards of patent examination and grant of patents. These guidelines are supplementary to the "Manual of Patent Office Practice and Procedure", "Guidelines For Examination of Biotechnology Applications" and the "Guidelines For Processing of Patent Applications Relating to Traditional Knowledge and Biological Material". In case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules will prevail.

(d) In a complaint filed by Arora Medical Hall, a wholesale trade of medicines in Ferozepur, Punjab through its partner Rajesh Arora under section 19(1) (a) of the Competition Act, 2002 ("CA 2002"), the Competition Commission of India ("CCI") has imposed a penalty of Rs.1.41 cr on Chemists and Druggists Association, Ferozepur ("CDAF"), Punjab alleging contravention of sections 3 and 4 of the CA 2002. Arora Medical Hall has alleged that CDAF has made it mandatory for any chemist or druggist, who wishes to take distributorship for medicines of a company in Ferozepur, to take a No Objection Certificate and Letter of Credit from it by making a payment of Rs. 2100 per company. It further states that it objected to the said rule in 2010, because of which it was expelled from the primary membership of CDAF. The CCI has directed CDAF to cease and desist from indulging in such anti competitive practices which have been found to be anti competitive in terms of the provisions of section 3 of the CA 2002.

(e) To ensure protection of rights and safety of trial subjects and authenticity of the data generated, the CDSCO will soon launch an IT-enabled system for online submission of various information on clinical trials. The CDSCO will keep track of all information in the system with the unique identification number ("UIN"). Once the UIN is granted to a sponsor/applicant, they need to share the same with investigators and the ECs, so that they can maintain the database on day to day basis. All the sponsors/CROs, investigators and ethics committees are required to put the information in a common repository related to a particular CT which is updated by the stakeholders on day to day basis.

(f) The government recently announced that EEPC India will henceforth handle the export related issues and promotional activities of the medical device and pharma machinery sector industry. EEPC deals with export promotion of engineering goods, projects and services from India. Earlier the Council used to handle exports of only those medical devices notified as drugs under the DCA, whereas it is understood that now EEPC will be handling exports of all the medical devices.

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