Drug Information Bulletin

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Content

Editorial

Government of India created a mandate of Pharmacovigilance system for reporting ADR to licensing authority by every manufacturer or market authorization holder. They are require to have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drugs manufactured or marketed by the applicant in the country. The entire exercise should be managed by a Medical officer or trained Pharmacist. They are also require to submit Periodic Safety Update Reports (PSURs) as per the regulation.

Pharmacovigilance Programme of India (PvPI), working since 2010 is now a matured one having strong infrastructure and manpower. Presently more than 250 AMCs are working successfully and generating a good number of ICSRs. On the basis of data collected through this system, PvPI contributed several data to the WHO-UMC collaborating centre. They have also provided several alert notices to the stake holders and made several recommendations to the CDSCO. CDSCO has already instructed Marketing Authorization Holders (MAH) to comply the same and also made suitable amendment of Drugs and Cosmetics Act & Rules.

Now the Indian regulatory agencies are taking action on the basis of data generated in our country instead of depending entirely on the data generated in other countries. Now MAH are require to submit PSUR data as per the provision of the Drug & Cosmetic Rules.

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IMPORTANT NOTIFICATION

The draft *Diploma in Pharmacy Exit Examination Regulations (DPEE), 2018* (DPEE) has been put on the PCI website inviting comments from stakeholders by December 31, 2018.

All stake holders may offer their comments by 31.12.2018

PCI comes out with Draft Diploma In Pharmacy Exit Examination Regulations

The Pharmacy Council of India (PCI) has come out with a draft *Diploma in Pharmacy Exit Examination Regulations (DPEE), 2018* to ensure that only competent D.Pharm pass outs having a better understanding of the subject and requisite professional skills get registered with the State Pharmacy Council.

The draft DPEE has been put on the PCI website inviting comments from stakeholders by December 31, 2018.

After passing Diploma in Pharmacy (D.Pharm) course in any of the PCI approved colleges, students will have to appear for the exit exam. They can go for registration after clearing the exam.

As per the draft, the exit examinations will be conducted by an authority to be established or designated by the PCI as the Prescribed Authority.

The candidates may appear for the exit examination conducted twice every year or as frequently as may be required as per the schedule of examination announced by the Prescribed Authority.

The date of examination and the examination centre will be allotted to the candidate by the Prescribed Authority based on the availability of the examination centres.

The exit exam shall have three papers of multiple choice questions in Pharmaceutics, Pharmacology, Pharmacognosy, Pharmaceutical Chemistry, Biochemistry, Hospital and Clinical Pharmacy, Pharmaceutical jurisprudence and Drug Store Management. The language of the examination shall be English. The test for each paper shall be of three hours' duration.

A candidate shall be declared as having passed only if he obtains a minimum of 50% marks in each paper separately. A candidate shall have to pass all the three papers in the same attempt.

However, there shall be no restriction on the number of attempts to appear in the examination. A certificate of eligibility for enrollment and practice shall be issued to the successful candidate which will be presented before the State Pharmacy Council for registration as a pharmacist.

In other words, after having passed the exit exam, a candidate shall be entitled to registration as a pharmacist.

For details:

U.S.-EU Partnership on GMP Inspections adds five countries

The FDA has agreed to recognize drug and active pharmaceutical ingredient GMP inspections carried out by authorities in Belgium, Denmark, Finland, Latvia and Estonia, updating the 1998 mutual recognition agreement between the U.S. and the European Union.

Recognition of the five additional EU member states means that 20 of the EU's 28 member states can be relied upon to conduct inspections equivalent to those of the FDA. The European Medicines Agency (EMA) says plans are "on track" for the agreement to be operational in all EU member states by July 15, 2019.

The mutual recognition agreement, which was overhauled in March 2017, aims to cut the cost of duplicate inspections so agencies can shift resources to facilities in China, India and other countries that manufacture drugs and APIs for sale in the U.S. and EU.

Source: https://www.fdanews.com

Scholar Rock's SRK-015 an Orphan Drug in Europe for spinal muscular atrophy

The European Medicines Agency's Committee for Orphan Medicinal Products has adopted a positive opinion backing Orphan Drug status for SRK-015 (human anti-promyostatin monoclonal antibody) for the treatment of spinal muscular atrophy (SMA).
Among the benefits of Orphan Drug status in Europe is a 10-year period of market exclusivity for the indication, if approved.
The FDA designated SRK-015 an Orphan Drug for the indication in March.
Source: https://seekingalpha.com

FDA issues warning on severe adverse effect of Enasidenib in AML

The FDA has issued a warning for patients with acute myeloid leukemia taking Celgene's Idhifa, or enasidenib, to watch for symptoms of differentiation syndrome, a life-threatening adverse effect that can manifest between 10 days and five months after beginning the medication. Physicians are advised to inform patients of symptoms when starting the medication and to implement aggressive management to reduce the risk of serious illness and death.
Source: Medscape

NICE recommends BMS' skin cancer recurrence drug for NHS use

The National Institute for Health and Care Excellence recommended Bristol-Myers Squibb's Opdivo, or nivolumab, for National Health Service funding to prevent early stage skin cancer from recurring after surgery. The drug was previously rejected by the cost regulator for this indication because it was not considered to be cost effective.
Source: PharmaTimes

Delhi HC quashes centre's ban on Oxytocin drug production

The Delhi High Court on Friday set aside a Central Government order restraining private companies from manufacturing and selling oxytocin drug.
A Bench of Justices S. Ravindra Bhat and A.K. Chawla observed that the order was "unreasonable and arbitrary" and did not seem to be based on any scientific study.
The court also observed that oxytocin was an essential life saving drug.
The court heard the pleas of Mylan Laboratories' subsidiary BGP Products Operations GmbH, Neon Laboratories and the All India Drug Action Network (AIDAN), an NGO, challenging the government decision.
Earlier this year, the government had restricted the manufacture of oxytocin formulations for domestic use to public sector only. The State-run Karnataka Antibiotics and Pharmaceuticals Ltd (KAPL) was solely allowed to produce the drug for domestic use.
The decision taken under Section 26A of the Drugs and Cosmetics Act, 1940 is aimed at checking the misuse of oxytocin, a reproductive hormone found in mammals that increases the contraction of the uterus during labour and stimulates ejection of milk into the ducts of the breasts.

***Citation**: BGP Products Operations GMBH and Anr. vs UOI, Delhi High Court, WP (C) 6084/2018, CM Appl 23517/2018, D/d 14.12.2018*

Hospitals get Tax Notices for Implants

The tax department is scrutinising applicability of Goods and Services tax (GST) specifically on medical implants like stents and knee replacements in a move that is likely affect the cost of surgery for Indian patients. In last few days, taxmen have issued preliminary notices to several hospitals across India seeking details.
According to the notices, financial details of medicines and implants supplied to IPD (hospital inpatient care) were sought from the hospitals. The tax notices also demanded

"copies of invoices of implants purchased by the hospital and corresponding bill of supply" from the hospitals.

Tax experts point out that as per the GST framework and some of the later clarifications by the government; medical services were out of the purview of the tax. Some said the taxman is going on a "fishing expedition" that could lead to hospitals dragging the government to court in the coming days.

"If GST is applied on medicines and implants used on patients instead of a composite tax rate, then this may result in a huge impact and hospitals will have to challenge this in courts.

The GST framework has be en quite clear around this aspect and tax can't be levied on something like stents or knee implants separately," said Abhishek A Rastogi, partner, Khaitan & Co. Several hospitals across India have been issued these notices. It is expected that more hospitals are under the scrutiny and would receive the notices in the coming weeks.

Tax experts say that as per a recent Authority of Advance Ruling (AAR) ruling, medicines and implants are exempted from GST for IPD patients. "The exemption given to healthcare services is broad enough to cover a variety of ailments/treatment and even extends to the transportation of the patient.

A recent AAR ruling has clarified that even medicines provided to patients would be exempt and only medicines sold to out-patients would attract GST," said MS Mani, partner, Deloitte India. As per the current regulation there is no GST on any healthcare services including surgeries except cosmetic ones.

However, if the hospitals were to pay GST on implants — say stents — they may pass on the cost to the customer. However, that quantum of the cost passed on to the customer would depend on the operating model of the hospital among several other things. What typically happens in case of a medical operation is that the doctor quotes a total price, which includes the cost of an implant. The patient pays that.

The tax department is scrutinising whether an implant — like a stent used in angioplasty — should be separately taxed when it is supplied to the customer by the hospital.

The tax department's notices sought details from the hospitals from July, 2017. The notices also wanted access to details of revenues of laboratories run by the hospitals.

Source ET Health World

Pics of NPW celebration: