Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

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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 huge 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. Being a stake holder Indian Pharmaceutical Association (IPA) is trying its best to support the programme in several ways to ensure safe medicine to the general mass.

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USP-NF has updated monographs of the following drugs with effect from April 1, 2018

- Doxycyline Tablets
- Oxybutynin Chloride Extended-Release Tablets
- Ritonavir Capsules
- Trazadone Hydrochloride

USP-NF has updated monographs of the following drugs with effect from May 1, 2018

- Amoxicillin Capsules
- Amoxicillin Tablets
- Aprepitant Capsules
- Atorvastatin Calcium Tablets
- Bumetanide Tablets
- Doxycycline Capsules
- Epoetin
- Lamotrigine Extended-Release Tablets
- Levetiracetam Extended-Release Tablets
- Nevirapine Extended-Release Tablets
- Ziprasidone Capsules

Direct-acting antivirals (DAAs) Possible effects on blood glucose control when used in patients with type 2 diabetes

Medsafe investigated the association of direct-acting antivirals (DAAs) and effects on blood glucose control when used in patients with type 2 diabetes. During the medicines monitoring period (13 March 2017 to 31 December 2017), no cases of abnormal glucose levels were reported to the CARM. Effects of the use of DAAs on blood glucose control, when used in patients with type 2 diabetes, could not be confirmed. The balance of benefits and risks of harm for DAAs remains positive and no further action is required at this time. Medsafe will re-investigate this concern should more information become available.

Reference: Safety Information, Medsafe, 31 January 2018 (www.medsafe.govt.nz/) No.2, 2017: Possible effects on blood glucose control when used in patients with type 2 diabetes: added to the medicine monitoring scheme in New Zealand)

Retinoids Updated measures for pregnancy prevention and potential risk of neuropsychiatric disorders Europe.

EMA's PRAC has completed a review of retinoid medicines and has recommended that pregnancy prevention measures need to be updated. In addition, prescribing information for oral retinoids should be updated to include a warning on the possibility of neuropsychiatric disorders. Oral retinoids are used to treat various forms of severe acne, severe hand eczema that does not respond to treatment with corticosteroids, severe forms of psoriasis and other skin conditions, and certain types of cancer. Retinoids applied to theskin are used to treat various skin conditions including mild to moderate acne. The review confirmed that oral retinoids can harm the unborn child and must not be used during pregnancy. Data on neuropsychiatric adverse events was not sufficient to assess the risk with retinoid use. However, considering that patients with severe skin conditions may be more vulnerable to neuropsychiatric disorders due to the nature of the disease, the prescribing information for oral retinoids will be updated to include a warning about this possible risk.

Reference: EMA, 23 March 2018 (www.ema.europa.eu)

MoH comes out with suspected ADR form and Medicine Side-Effect reporting form for intensive ADR monitoring

In its bid to take proactive action for reporting adverse drug reactions (ADRs) towards focused Pharmacovigilance (PV) for approved drugs in the country, the Union health ministry has come out with suspected ADR form for healthcare professionals and medicines side-effect reporting form for consumers besides a toll free helpline number in the interest of patient safety.

This comes at a time when the health ministry has also tasked 250 ADR Monitoring Centres (AMCs) existing in the country to establish clinical evidence between the drug and the adverse drug reaction through a robust system of causality assessment.

Central Drugs Standard Control Organisation (CDSCO) in collaboration with Indian Pharmacopoeia Commission (IPC) had in the past also started auditing healthcare institutions through assessment on aspects like SOPs and causality assessment in order to review the functioning of AMCs in the country.

The exercise was meant to generate awareness in medical institutions to put in place effective surveillance system for detection of ADRs. IPC under the union health ministry is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).

CDSCO under the Union health ministry had initiated a nation-wide PvPI in July 2010. PvPI leads with 0.82 points as per quality completeness score of Individual Case Safety Reports (ICSR) as against the global average of 0.55 accounted on a quarterly basis for a total of 150 countries including India which contribute to the global PvP database.

ICSR as part of ADRs are reported from all over the country to NCC-PvPI, which also work in collaboration with the global ADR monitoring centre (WHO-UMC), Sweden to contribute in the global ADRs data base.

To strengthen ADR monitoring, IPC had come out with draft guidelines focused on targeted drugs and events as a part of Intensive adverse drug reaction monitoring exercise under PvPI so that action could be taken on specific drugs involving adverse reactions.

The health ministry had in the past mandated based on the ADR monitoring protocol effective implementation of the projects related to Intensive adverse drug reaction monitoring with help from competent institutions in the country.

Based on the learnings of these projects, government will be equipped in taking regulatory decisions in a timely manner. The exercise has been initiated keeping in view the fact that data from spontaneous reporting of ADRs have generally been mis-spelt.

“Inference can be drawn from the diabetic drug Pioglitazone which was suspended and then revoked due to lack of India specific data in the country for adverse reactions leading to conditions like bladder cancer,” concludes a senior IPC official.

Source: Pharmabiz

India to oppose planned patents rule

An effort by the World Intellectual Property Organisation (WIPO) to bring in a new rule that would allow countries to delegate the functions of their patents office to another country or international organisation has set alarm bells ringing among many developing countries and activists working on access to medicines. They fear such a rule could result in smaller countries in particular being coerced to delegate these functions to countries or organisations that would push for more stringent intellectual property protection and easier patenting, which could affect access to medicines and India's pharma exports to them.

The WIPO secretariat, which is responsible for administering the patent cooperation treaty (PCT), an international agreement of more than 150 countries including India, will bring this proposal at the 11th session of the PCT working group to take place from June 18 to 22 at the WIPO headquarters in Geneva. Public health activists have urged the Indian delegation to resist the move.

"This rule has been floated for some time. But India has been opposed to the harmonization of patentability criteria and any attempt to do so will be opposed by our mission there. We can harmonize certain issues like being part of PCT, but patentability criteria is a country's sovereign right. Any decision on that can only be done by modifying TRIPS and not decided by few countries," said Rajiv Aggarwal, joint secretary in the Department of Industrial Policy and Promotion.

The proposed rule states once the patent office functions have been delegated, the delegated office would "assume all rights and obligations in respect of the 'delegating' country"

The UN Secretary-General's High Level Panel on Access to Medicines had recommended that multilateral organizations like WIPO should strengthen the capacity of national and regional patent examiners to apply criteria that are sensitive to public health concerns. However, this proposal could weaken national patent examination capacities.

Unlike India, which has set a very high bar for a patent to be granted, countries like the US grant patents even for new dosage forms of medicines and new drug delivery systems. Hence, functions being delegated to a country like the US would

effectively mean the application of the same criteria in the country contracting out its patent office.
Source: The Times of India

India pitches for WTO talks on checking theft of traditional knowledge

India today pitched for reviving negotiations at World Trade Organization on issues related to prevention of theft of traditional knowledge such as Ayurveda and naturopathy.
It is organising an international conference on Trade-Related Aspects of Intellectual Property Rights (TRIPs) - Convention on Biological Diversity (CBD) linkage in Geneva on June 7 and 8, to re-energise talks on the subject, Joint Secretary in the Department of Commerce Sudhanshu Pandey told reporters here.
The conference, he said, will witness participation from various countries such as Brazil, China, Indonesia, Peru, Philippines and New Zealand.
Traditional knowledge, a kind of intellectual property, is something which is passed on from generation to generation within a community. It often forms part of a people's cultural and spiritual identity. In India it includes areas like Ayurveda, Yoga and naturopathy.
Pandey said this is an important issue and the WTO members should deliberate upon this matter.

"TRIPS-CBD Linkage is important for India and other developing countries because it seeks to address bio-piracy. It has been a long standing demand that patents should not be granted for existing traditional knowledge and associated genetic resources," he added.
The issue assumes significance as India wants an effective legal international regime to stop misappropriation and reckless patenting of traditional knowledge like healing properties of neem and turmeric.
Several multi-national companies in the pharma sector already have patents for manufactured products which use key properties of traditional knowledge. Many more patent applications are awaiting approvals in different countries.

The CBD is a multilateral agreement on sustainable development and fair and equitable sharing of benefits arising out of the utilization of genetic resource.
Preventing theft would help in giving global protection against patenting or commercial exploitation of traditional knowledge base of developing countries like India.
Developing countries, including India, have time and again asked and floated proposals in the WTO for incorporating a new provision in the TRIPS (trade related aspects of intellectual property rights) agreement of the global trade body.
Under the provision, the developing countries have asked for mandatory disclosure of source or origin of the biological resource, evidence of prior informed consent and benefit sharing from patent applicants before granting any patent to a company.
According to a report, domestic trade of Ayush industry in India is about USD 1.2 billion. The world trade in herbal products are at USD 120 billion and is expected to touch around USD 7 trillion by 2050.

Forthcoming Event:

Annual General Meeting of IPA Bengal Branch

Date: 22nd July 2018

Venue: Auditorium, IPA Bengal Branch, 22 B Panchanontola Road, Kolkata-700029

Time: 6.00 pm