Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

&

Regulatory Affairs Division (RAD), IPA

Volume: 13 ***Number: 06*** ***16th June 2019***

Content

Editorial

Govt. of India notified more than one year back directing all Pharmacy, Chemist and Druggist dispensing anti-tubercular medicines, shall notify respective tuberculosis patients along with details of medicines to local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known; or their designated District Tuberculosis Officers.

Pharmacy, Chemist and Druggist, failing to notify may attract the provisions of sections 269 and 270 of the Indian Penal Code (45 of 1860), as the case may be, which are reproduced below: "269. Negligent act likely to spread infection of disease dangerous to life. - Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both. 270. Malignant act likely to spread infection of disease dangerous to life. - Whoever malignantly does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both." This is an appropriate step to ensure proper tuberculosis diagnosis and its management in patients and their contacts and to reduce tuberculosis transmission and further to address the problems of emergence and spread of Drug Resistant-Tuberculosis, it is essential to collect complete information of all tuberculosis patients.

This direction is also applicable for Medical Practitioners and Medical Laboratories as notified vide F.No. Z-28015/2/2012-TB dtd. 16th March 2018 (available at: http://www.cdsco.nic.in/writereaddata/management%20in%20patients.pdf).

This is a golden opportunity for the pharmacists engaged in community pharmacy to establish them as one of the important health care provider. But unfortunately reporting is very meager from all quarter which making the effort of TB free India by 2025.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

New Drug:

Remogliflozin etabonate bulk and Remogliflozin etabonate film coated tablets 100 mg has been approved by C.D.S.C.O indicated in adults aged 18 years and older with type 2diabetes mellitus to improve glycemic control as:-

- Monotherapy when diet and exercise alone do not provide adequate glycemic control.
- Add on therapy with metformin, together with diet and exercise, when these do not provide adequate glycemic control.

Glenmark has marketed this tablet in India having price of Rs. 12.50 per tablet.

Govt. wants to define E-Prescription format to regulate online Sale of medicines

The new government is looking to plug loopholes in doctors issuing e-prescriptions as part of its efforts to regulate the online sale of medicines in India.

An e-prescription or e-Rx is one that is sent electronically by a doctor to a patient. It is generally considered error-free and legible, unlike the handwritten prescriptions where chances of errors or modifications are high.

In India, however, e-pharmacy apps allow users to merely upload a snapshot of a prescription as opposed to the electronic version. This practice has raised questions on the authenticity of prescriptions being sent to e-pharmacy outlets through mobile apps.

The issue was discussed at a high-profile meeting on 10 June, chaired by secretaries and joint secretaries from the Ministry of Health, Department of Pharmaceuticals along with the top officials of the Niti Aayog, the Drug Controller General of India and drug commissioners.

"In a takeaway from the meeting, we may define the format of the prescriptions that could be used for placing orders at e-pharmacies," said a senior official from the Ministry of Health who was a part of the meeting.

"Various stakeholders have found this to be a grey area. The chemist associations, such as the AIOCD, have found various prescriptions to be fake, tampered or modified or repeated prescriptions," he said.

"It is a serious concern which, if not regulated, could be exploited at e-pharmacies."

The plan

The government is planning to define 'e-prescription' under the draft of the e-pharmacy regulations.

Online pharmacies currently do not fall under the ambit of any existing law and are temporarily working on the principles of their brick-and-mortar counterparts. The Central Drugs Standard Control Organisation (CDSCO), the national regulatory body for medicines, is working on finalising the draft rules that were released by the health ministry in September 2018.

"We will understand the present laws in the developed countries and their format of designing online prescriptions," the official quoted above said. "The final policy could incorporate the definition of e-Rx."

E-prescriptions have proved beneficial for patient safety across the world. According to the United States health department, e-prescriptions, adopted in 2003 under the Medicare Modernization Act (MMA), have reduced medication errors in the country.

In Europe, the use of electronic prescription is counted among the strategic steps to improve health care. Countries such as Norway, Sweden, Belgium, Italy, England, Scotland and Denmark also use e-prescriptions on a regular basis.

Regulating Narcotic medicines

The government is also working on the list of drugs that cannot be sold online. While the government plans to bar narcotic drugs and psychotropic substances, the medical bodies, including the India Medical Association, chemist associations and the Gujarat Pharmacy Council, have asked it to extend the list.

In the meeting, the government has deliberated on barring the other hazardous categories including the Schedule H and Schedule H1 drugs.

"We are considering to regulate the list of drugs that could be sold online," the official said. "However, it is a critical subject and discussions are going on."

Source: THEPRINT

Fecal Transplants may transmit deadly Drug-Resistant Infections: FDA Warns

The US Food and Drug Administration (FDA) is alerting healthcare providers and patients that fecal microbiota for transplant (FMT) may transmit multidrug-resistant organisms, leading to serious or life-threatening infections.In a safety communication, the FDA said two immunocompromised adults who received FMT developed invasive bacterial infections caused by extended-spectrum beta-lactamase (ESBL)–producing Escherichia coli.
For details: https://www.emedinexus.com/post/12378

Knowledge Portal: New resource for finding evidence on policies for innovation and access to medicines

The Knowledge Network for Innovation and Access to Medicines launched today a new online tool providing open-access information, research and analysis on policies relating to pharmaceutical innovation and access.
The Knowledge Portal, available at https://www.knowledgeportalIA.org
aims to make existing knowledge more widely-available and easily accessible to researchers, advocates, practitioners and policymakers to improve policies for innovation and globally-equitable access to medicines.
It is a project of the Global Health Centre at the Graduate Institute of International and Development Studies in Geneva, supported by a grant of the Open Society Foundations.
The Knowledge Portal brings four main resources: research syntheses, data sources, list of research gaps and webinars. The resources are divided into three interrelated themes: Pricing, Intellectual Property and Innovation, and cover a range of related topics.

The research syntheses https://www.knowledgeportalia.org/>
provide a concise, comprehensive overview of the current state of research on a specific topic, covering the main studies in the academic literature, with efforts to cover the grey literature as well.

Currently, the Portal offers syntheses of the state of research on 17 topics, such as tiered pricing, competition law, shortages and public funding of R&D, with further topics in progress. The research syntheses are living documents; they will undergo open peer review and be periodically updated to incorporate feedback and new research.
In addition to the research syntheses, the Knowledge Portal has a section on data sources <https://www.knowledgeportalia.org/overview-of-data-sources>,
a compilation of open-access data sources to find further information related to innovation and access to medicines issues. Data sources include information on medicines prices, pharmaceutical company policies, patent information, R&D costs & funding, and clinical trials, among topics.

Another resource provided is a synthesized list of research gaps <https://www.knowledgeportalia.org/research-gaps>
identified in the current knowledge database.
The 'Research Gaps' list was drawn from a combination of data sources gathered in 2018-19: literature reviews synthesizing the existing knowledge base, in-person research meetings, and expert opinion.

Under each topic are links to further information on the website on relevant literature and/or data sources; however, these resources only partially address the research gaps. The list may be of use to researchers, students, research funders and others who can help to fill the gaps.

Finally, the Portal announces upcoming webinars <https://www.knowledgeportalia.org/webinars>
presented by leading medicines policy researchers in the series organized by the Knowledge Network, and houses recordings of previous webinars. The webinars aim to make recent, policy-relevant research more accessible to a global public audience, and to bring questions from communities of policy & practice to researchers.
The Knowledge Portal is intended to be a collaborative tool. Comments and information about additional research and data sources, as well as suggestions for the webinar series, are

welcome at
globalhealthresearch@graduateinstitute.ch.

Marcela Vieira
Project Coordinator
Knowledge Network for Innovation and Access to Medicines
Global Health Centre, Research
Graduate Institute of International and Development Studies
marcela.vieira@graduateinstitute.ch
Source: E-drug

Ayush Ministry identifying to deliver Traditional Medicinal Services at Grass-Root level

The Ayush Ministry is in the process of identifying 12,500 health and wellness centres across the country to deliver traditional medicinal services at grass-root level with special focus on preventive health care keeping in view the rising instances of chronic lifestyle diseases, official sources have said. The Central government aims at strengthening its flagship health insurance scheme Ayushman Bharat by integrating traditional medicine therapy with allopathy at the primary health centres to check rising non-communicable diseases such as diabetes and obesity.
It is stressing on seamless integration of two pillars of Ayushman Bharat -- Health and Wellness Centres (HWCs) and Pradhan Mantri Jan Arogya Yojana (PMJAY) --- to achieve the "health for all" target.

According to official sources, the need for appointing AYUSH doctors has been increasingly felt at the Primary Health Centres level, particularly following the success of a pilot project launched in 2016 in three districts - Bhilwara (Rajasthan), Surendranagar (Gujarat) and Gaya (Bihar) -- ayurvedic medicines, dietary regimen and yoga classes are being used to treat non-communicable diseases.

The Council of Scientific and Industrial Research (CSIR) has, for instance, developed anti-diabetic ayurvedic drug BGR 34, which has proved a milestone in curing diabetic disease, an official said, adding it's a scientifically developed drug produced by completing various medical tests and is proving very beneficial in controlling diabetes.
Source: ET HEALTH WORLD

FDA committees discuss possible restrictions for high-dose opioids

The FDA's Anesthetic and Analgesia Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee started a two-day meeting to seek input from patients and health care experts on the clinical value and potential risks of higher opioid doses. The agency will use the feedback to determine whether higher opioid doses should be restricted or pulled from the market.
Ref.: Becker's Hospital Review

TB Alliance's tuberculosis drug recommended by FDA panel

In a 14-4 vote, the FDA's Antimicrobial Drugs Advisory Committee backed the safety and efficacy of TB Alliance's pretomanid, in combination with bedaquiline and linezolid, for the treatment of adult patients with extensively drug-resistant and multidrug-resistant tuberculosis.
Ref.: MedPage Today