Editorial

Greetings from Drug Information Bulletin!

It is feared that some clauses in the draft Patents (Amendment) Rules, 2023 released on 22nd August 2023 will affect important public health safeguards against patent ever greening and unmerited monopolies. Health care experts, intellectual property experts, civil society organizations and health care stakeholders raised concern that the proposed rules will hurt the effort of the process to ensure access to affordable medicines, diagnostics, and vaccines for patients in India and other developing countries. They apprehended that people’s rights to file pre-grant opposition to patents will be jeopardized by the new provisions like Exorbitant Charges for filing pre-grant opposition, which was free of charges in the earlier version of the Patent Rules 2006. This proposed amendment is also extended excessive authority to the Controller to determine the maintainability of the representation, which may have been misused. Another apprehension is departure from the existing rule of transparency. The fact is that under Section 8 of the existing Patents Act, patent applicants must periodically disclose foreign patent applications and related developments on their legal status, ensuring transparency, but the proposed rule requirement is onetime disclosure.

They proposed this amended rules to streamline the activity of the patent office and expedite the process, but it is feared that health care would be affected if it is accepted in present form. Therefore health care experts and civil citizens requested the govt. to reconsider their proposal for the sake of public health. The draft Patent (amendment) rules 2023 is available at https://egazette.gov.in/WriteReadData/2023/248296.pdf

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New Drug: Plecanatide Tablets

Plecanatide tablets (TRULANCE), for oral use
Initial U.S. Approval: 2017

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
• TRULANCE is contraindicated in patients less than 6 years of age; in young juvenile mice, plecanatide caused death due to dehydration.
• Avoid use of TRULANCE in patients 6 years to less than 18 years of age.
• The safety and effectiveness of TRULANCE have not been established in patients less than 18 years of age.

INDICATIONS AND USAGE: TRULANCE is a guanylate cyclase-C agonist indicated in adults for treatment of chronic idiopathic constipation (CIC).

DOSAGE AND ADMINISTRATION: The recommended adult dosage of TRULANCE is 3 mg taken orally once daily.
Administration Instructions: • Take with or without food. • Swallow tablets whole. • For patients who have difficulty swallowing tablets whole or those with a nasogastric or gastric feeding tube.

DOSAGE FORMS AND STRENGTHS: Tablets: 3 mg

CONTRAINDICATIONS: • Patients less than 6 years of age due to the risk of serious dehydration.
- Patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS: Diarrhea: Patients may experience severe diarrhea. If severe diarrhea occurs, suspend dosing and rehydrate the patient. ADVERSE REACTIONS: Most common adverse reaction (≥2%) is diarrhea.

Ref. USFDA

Status in India: Plecanatide Bulk Drug & Plecanatide Tablets 3mg indicated for 1.) Chronic idiopathic constipation (CIC) 2.) Irritable bowel syndrome with constipation (IBS-C) approved by CDSCO on 08.06.2023.

Source: CDSCO

UK unveils pharmacies plan to ease NHS pressure

Britain's pharmacists will soon be able to prescribe drugs that were previously only authorized by doctors, under government plans to ease pressure on the state-run National Health Service.

Prime Minister Rishi Sunak, whose Conservative party was battered in local polls last week over the worsening cost-of-living crisis, wants to ease pressure on doctors' surgeries and slash NHS waiting lists before a general election expected next year.

The NHS however remains plagued by strikes as health workers protest over wages that have failed to keep pace with rampant inflation, despite their vital role during the COVID pandemic and beyond.

Under the new plans, treatments for seven common conditions including earache and sore throats will be available without seeing a doctor.

"One of my five priorities is cutting waiting lists. And today's announcement is getting on with that," Sunak, whose mother was a pharmacist, said on a visit to his home city of Southampton.

"When it comes to pharmacies, what we are doing is providing them with extra money so that people can go to their pharmacy and get medicines for common ailments," he added.

The government hopes the measure will be introduced this winter.

NHS chief executive Amanda Pritchard wrote in the Daily Mail that the overall package to deal with doctor waiting times "will help us to free up millions of appointments for those who need them most."

The state-funded healthcare system recently suffered its biggest day of strike action since it was founded in 1948, with staff complaining of dwindling pay, overwork caused by a lockdown backlog and difficulty in replacing departing colleagues.

Ref.: AFP

India has identified three health priorities under G20

India identified three major health priorities that aim to strengthen the global health infrastructure, deliver health and provide universal health coverage.

The first is digital health – the future of health.

It focuses on consolidating the existing digital health initiatives and fostering equity in healthcare by amplifying efforts to incorporate tools such as telemedicine and artificial intelligence.

The second health priority for this year’s G20 Leader’s Summit is focusing on preparing for the health crisis – antimicrobial resistance, which has been dubbed as a silent pandemic by experts.

The third priority is to prioritize strengthening health emergency preparedness and response with a focus on antimicrobial resistance and One Health Framework, which recognizes the interconnection between people, animals and plants and their shared environment to withstand future shocks. Not just from infectious diseases but all types of health hazards.

Ref. ANI

Amlodipine Potential risk of Hyperkalaemia

The Saudi Food & Drug Authority (SFDA) has released a safety signal concerning amlodipine and risk of hyperkalaemia. Amlodipine is an antihypertensive drug belonging to the group of drugs called dihydropyridine calcium channel blockers. Hyperkalemia is defined as a serum or plasma potassium level above the upper limits of normal. In 2023, the SFDA has detected a signal of Amlodipine and hyperkalaemia and reviewed all the evidence available on the association between them. The SFDA found one local case and 225 international cases in VigiBase (the WHO global database of ICSRs) and applied WHO-UMC
causality assessment criteria on thirty cases with highest completeness score. It resulted in two probable cases, sixteen possible cases, six unlikely case and six cases not assessable. Data mining of this drug/ADR has been estimated using Information component (IC= 1) which revealed a positive statistical association. Furthermore, a case report was found in the literature that support the association. The SFDA’s investigation concluded that the current available evidence from causality assessment of the reported cases and literature might support a relationship between Amlodipine and hyperkalaemia. This signal needs further investigation to confirm the risk, and health-care professionals should be aware of this potential adverse reaction.


Nitrofurantoin Risks of pulmonary and hepatic adverse drug reactions United Kingdom

The MHRA has reminded healthcare professionals that prescribing nitrofurantoin should be alert to the risks of pulmonary and hepatic adverse drug reactions and advise patients to be vigilant for the signs and symptoms in need of further investigation. Nitrofurantoin is a broadspectrum antibacterial agent, which has been available since the 1950s. It is indicated in adults, children and infants over three months old for the treatment and prophylaxis of acute or recurrent uncomplicated urinary tract infections (UTIs) and acute or recurrent uncomplicated pyelitis. The potential for acute pulmonary damage with nitrofurantoin is welldocumented in the product information. The MHRA has advised health-care professionals as follows:

• patients and caregivers to be vigilant for new or worsening respiratory symptoms while taking nitrofurantoin and promptly investigate any symptoms that may indicate a pulmonary adverse reaction.
• immediately discontinue nitrofurantoin on the occurrence of new or worsening symptoms indicative of pulmonary damage.
• be vigilant for symptoms and signs of liver dysfunction in patients taking nitrofurantoin for any duration, but particularly with longterm use, and monitor patients periodically for signs of hepatitis and for changes in biochemical tests that would indicate hepatitis or liver injury.
• use caution when prescribing nitrofurantoin in patients with pulmonary disease or hepatic dysfunction, which may mask the signs and symptoms of adverse reactions.

Reference: Drug Safety Update, MHRA, 26 April 2023 (link to the source within www.gov.uk/mhra)