Greetings from Drug Information Bulletin!

A recent study reveals that change in Government policies and amendment of Drug Rules in India have given opportunities for improving access to medicines and vaccines. The newly introduced New Drugs and Clinical trial Rules have provisions to market drugs and vaccines without local clinical trials if, the new drug is approved and marketed in countries specified by the Central Licencing Authority (CLA) and if no major unexpected serious adverse events have been reported; and the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the CLA. Thereafter CDSCO has published a guideline in this matter and the process of approving new vaccines becomes easier. This guidelines stated that no local clinical trials are required if a vaccine for Covid-19 already approved by USFDA, MHRA, PDMA Japan and listed by WHO for emergency use for Covid-19. These two steps helps quick approval for emergency use of vaccines already approved by USFDA, MHRA, PDMA Japan and WHO listed Covid-19 vaccines. Using these provisions Covid -19 vaccines developed by Moderna in US already got approval for import by an Indian company and hope that some more vaccines will be available in India in future using these provisions. These proactive regulatory steps helped Indian manufacturers to develop Covid-19 vaccines in a record time and made it available in global market. These provisions also facilitated Covid -19 vaccines developed and marketed in developed market available in India.

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Adverse Drug Reactions (ADRs) alert as released by the PvPI on 29th March 2023

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Suspected Drugs</th>
<th>Indications</th>
<th>Adverse Drug Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Metoprolol</td>
<td>For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.</td>
<td>Hyponatraemia</td>
</tr>
<tr>
<td>2.</td>
<td>Nebivolol</td>
<td>For the treatment of essential hypertension</td>
<td>Hyperkalaemia</td>
</tr>
<tr>
<td>3.</td>
<td>Olmesartan</td>
<td>Use as an Anti-hypertensive</td>
<td>Muscle Spasm</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td>Taste Disorder</td>
</tr>
<tr>
<td>5.</td>
<td>Sulfasalazine</td>
<td>Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn’s diseases.</td>
<td>Visual Impairment</td>
</tr>
</tbody>
</table>

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in), through Android Mobile App “ADR PvPI” and PvPI Helpline No. 1800-180-3024.

Source: PvPI

Manufacturing of Class C & D non notified medical devices will be under licenses w.e.f. 01.10.2023
Roll-out of the world’s first malaria vaccine

John Bawa, who leads vaccine implementation in Africa at the global non-profit organization PATH in Accra, has been working for more than a decade on the first vaccine against malaria. And he has become used to hearing the same question: “Where is your vaccine?” So, last year, when the World Health Organization (WHO) recommended the use of the vaccine, known as RTS,S and marketed as Mosquirix, in children living in countries hardest hit by the disease, “it was a great relief for us”, he says. “Now I have my vaccine.”

The WHO’s recommendation was a historic milestone. RTS,S took 30 years to develop, and is not only the first malaria vaccine, but also the first vaccine for any parasitic disease. Although the efficacy of the shot is modest — about 50% in the first year — it is expected to save tens of thousands of lives each year. One study estimated that, if the vaccine were rolled out in countries with the highest burden of malaria, it could prevent 5.3 million cases and 24,000 deaths in young children each year. But reaping that benefit will take time. So far, more than one million children have received one or more doses of the vaccine in a pilot study in Ghana, Kenya and Malawi. That’s just a fraction of the 25 million children in more than 30 countries who need it. It could be years before many of those countries get their first doses.

Specialists estimate that demand will be 80 million to 100 million doses per year. The vaccine’s manufacturer GlaxoSmithKline (GSK), a pharmaceutical company based in Brentford, UK, has promised to deliver 18 million doses over the next 3 years. For the people who have watched this vaccine hit roadblock after roadblock during its long period of development, the supply problems come as a disappointment.

But Dyann Wirth, a malaria researcher at the Harvard T.H. Chan School of Public Health in Boston, Massachusetts, is trying to look on the bright side. Having some vaccine is much better than having none. RTS,S approval “changed the conversation about whether vaccines were feasible for malaria”, she says. And that will pave the way for better vaccines.

Source: Outlook

Tranexamic acid injection Risk of medication errors resulting in inadvertent intrathecal injection

WHO is alerting healthcare professionals about the risk of administration errors that can potentially occur with tranexamic acid (TXA) injection. There have been reports of TXA being mistaken for obstetric spinal anaesthesia used for caesarean deliveries resulting in inadvertent intrathecal administration. In TXA administered intrathecally, potent neurotoxin and neurological sequelae are manifested, with refractory seizures and 50% mortality. The profound toxicity of TXA administered intrathecally was described in 1980. A 2019 review identified 21 reported cases of inadvertent intrathecal injection of TXA since 1988, of which 20 were life-threatening and 10 fatal. Sixteen were reported between 2009 and 2018. WHO recommends early use of intravenous TXA within 3 hours of birth in addition to standard care for women with clinically diagnosed postpartum haemorrhage (PPH) following vaginal births or caesarean section. TXA should be administered at a fixed dose of 1g in 10 ml (100 mg/ml) IV at 1 ml per minute, with a second dose of 1g IV if bleeding continues after 30 minutes. TXA is frequently stored in close proximity with other medicines, including injectable local anesthetics indicated for spinal analgesia (e.g., for caesarean section). The presentation of some of the local anesthetics is similar to the TXA presentation (transparent ampoule containing transparent solution), which can erroneously be administered instead of the intended intrathecal anesthetic resulting in serious undesirable adverse effects. Recently, obstetricians from several countries have reported inadvertent intrathecal TXA administration and related serious neurological injuries. TXA is a lifesaving medicine; however, this potential clinical risk should be considered and addressed by all operating theatre staff. Reviewing of existing operating theatre drug handling practices are required in order to decrease this risk, such as storage of TXA away from the anaesthetic drug trolley, preferably outside the theatre.
Vitamin B6 (pyridoxine): Risk of peripheral neuropathy

The TGA has strengthened labelling requirements for products containing daily doses of 10mg of vitamin B6 (pyridoxine) to include a warning about peripheral neuropathy. Previously, products containing daily doses over 50mg were required to carry the warning. The maximum permitted daily dose of vitamin B6 in products has also been reduced from 200 mg to 100 mg for adults, with lower daily dose limits in place for children depending on their age. Vitamin B6 is present in many multivitamin and mineral supplements. Peripheral neuropathy is a known adverse reaction of vitamin B6, where delayed diagnosis and continued exposure can lead to its progression. Up to 5 August 2022, the TGA had received 32 adverse event reports with sufficient information to establish a possible causal association between peripheral neuropathy and products containing vitamin B6. The TGA found that peripheral neuropathy can occur at doses less than 50 mg, and when people are taking multiple products containing vitamin B6. The risk appears to vary between individuals, with no minimum dose, duration of use or specific patient risk factors identified. Health-care professionals should consider vitamin B6 toxicity in patients presenting with symptoms of peripheral neuropathy. A review of the patient’s vitamin B6 intake is recommended paying close attention to potential sources such as multivitamins, magnesium and zinc products, particularly when taken in combination.

Newer antidiabetic medicines used with insulin and/or sulfonylureas Risk of hypoglycaemia

The Medsafe has alerted health-care professionals on the risk of hypoglycaemia associated with newer antidiabetic medicines (glucagon-like peptide 1 (GLP1) receptor agonists, sodiumglucose co-transporter 2 (SGLT-2) inhibitors or dipeptidyl peptidase-4 (DPP-4) inhibitors) used concomitantly with insulin and/or sulfonylureas. Newer antidiabetic medicines are not typically associated with hypoglycaemia when used as monotherapy, although two cases have been reported domestically. Health-care professionals should monitor for and discuss the risks of hypoglycaemia when prescribing medicines to treat type 2 diabetes mellitus. Patients on concomitant therapy may require a lower dose of insulin or the sulfonylurea to prevent episodes of hypoglycaemia.

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