Greetings from Drug Information Bulletin!

Access to essential medicines is an important concern throughout the world, especially in the developing and under developed countries. India is not an exception and it varies from state to state, despite India being the third largest producer of medicines and is exporting to more than 250 countries. Out-of-pocket (OOP) expenditure for health care and medicines account for about 70 percent of expenses of households in India and also in developed countries, due to spiraling medicine costs. This is also causing about 63 million populations to sink below poverty line, and this vicious cycle is not allowing them to surface again. In fact increased spending on health is putting its fangs on the budgets of families, forcing them to cut down on nutrition, and tragically even on medicines, leading to a grave socio-economically compromised system and a burden of sick individuals. Health care experts have identified a plethora of complex factors behind this scenario. One major reason for this situation is irrational use of medicines. So promoting concept of Rational Use of Medicines (RUM) could be an effective strategy. Three effective tools of implementing RUM are-Essential medicines list (EML), Standard Treatment Guidelines (STG), and Drug Formulary. The last tool is a concise book containing dose, dosage form, indication, contraindication, adverse drug reaction for ready reference for the prescriber and pharmacist. Every healthcare set up should have its own formulary so that authentic information is available to the prescribers and the pharmacists, but unfortunately all health care facility does not have such a book. Indian Pharmacopoeia Commission (IPC) has released 6th edition of the National Pharmacopoeia of India (NFI) recently may be referred by all healthcare stake holders for detailed information of drugs, but very unfortunately it is not promoted for the purpose it made.
<table>
<thead>
<tr>
<th>S.No</th>
<th>Issue Date</th>
<th>Suspected drugs</th>
<th>Indication</th>
<th>Adverse Reactions</th>
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<td>11</td>
<td>28th July 2021</td>
<td>Etoricoxib</td>
<td>For the treatment of pain, swelling &amp; inflammatory conditions due to arthritis.</td>
<td>Acute Generalized Exanthematous Pustulosis (AGEP)</td>
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<tr>
<td>12</td>
<td>28th July 2021</td>
<td>Torsemide</td>
<td>For the treatment of oedema associated with congestive heart failure &amp; hypertension</td>
<td>DRESS Syndrome</td>
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</table>
| 13   | 28th July 2021    | Quetiapine & Valproic Acid Interaction | Quetiapine:  
• For the management of the manifestation of psychotic disorders (schizophrenia).  
For the additional indication "acute manic episode associated with bipolar disorder".  
Valproic Acid:  
• As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure.  
• As monotherapy or adjunctive therapy in the treatment of patients with complex partial seizure and manic episodes associated with bipolar disorder. | Neuropsychiatric Adverse Events  
(Depressed level of consciousness/Coma & Disorientation) |
| 14   | 31st August 2021  | Sofosbuvir                       | In combination with other medicinal products for the treatment of chronic hepatitis C in adults. | Stevens-Johnson Syndrome                               |
| 15   | 30th September, 2021 | Dimethyl Fumerate | For Relapsing remitting multiple sclerosis | Alopecia                                               |
| 16   | 30th September, 2021 | Cefazolin                        | Cephalosporin antibiotic-indicated in the treatment of serious infections due to susceptible organisms – respiratory tract infections, urinary tract infections, skin & skin structure infection, biliary tract infections, septicemia | Acute Generalised Exanthematous Pustulosis             |
| 17   | 30th November, 2021 | Diclofenac                       | For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful postoperative pain following dental surgery, migraine attack and postoperative inflammation in patients who have undergone cataract operation. | Skin hyperpigmentation                                 |
| 18   | 28th December, 2021 | Remdesivir                       | Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19 operative inflammation in patients who have undergone cataract operation. | Sinus Bradicardia                                      |

** It has been observed from the above list that adverse effects are more associated with the drugs which are not in the Essential Medicines List (EML) of India in comparison to the drugs which are included in the Essential Medicines List (EML) of India.
Setback to Pharma Companies: Freebies to Doctors are Illegal: Finance Bill, 2022

Section 37 of the Act provides for allowability of revenue and non-personal expenditure (other than those failing under sections 30 to 36) laid out or expended wholly and exclusively for the purposes of business or profession. Explanation 1 of sub-section (1) of section 37 of the Act provides that if any expenditure incurred by an assessee for any purpose which is an offence or which is prohibited by law shall not be deemed to have been incurred for the purpose of business or profession and no deduction or allowance shall be made in respect of such expenditure.

However, it is seen that certain taxpayers are claiming deductions on expenditure incurred in offering certain benefits or perquisite to a person which are not intended to be allowed under this section, like meeting his expenditure related to travel, hospitality, conference etc. In these cases acceptance of such benefit or perquisite by such person is in violation of a law or rule or regulation or guidelines, as the case may be, governing the conduct of such person.

CBDT, vide circular No. 5/2012 dated 1.8.2012, noted that the Indian Medical Council in exercise of its statutory powers amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (the regulations) on 10.12.2009 imposing a prohibition on the medical practitioner and their professional associations from taking any Gift, Travel facility, Hospitality, Cash or monetary grant from the pharmaceutical and allied health sector Industries. Accordingly, CBDT clarified that the claim of any expense incurred in providing above mentioned or similar benefits in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible under section sub-section (1) of section 37 of Act being an expense prohibited by the law. Delhi High Court decision which was relied upon by ITAT in some decisions was in completely different context as discussed by ITAT Mumbai in their judgment in the case of Macleods Pharmaceuticals. These ITAT decisions allowing such expenditure are clearly not in line with the intention of the legislation.

Further, some taxpayers are seen to be claiming deduction on expenses incurred for a purpose which is an offence under foreign law or for compounding of an offence for violation of foreign law, claiming that provisions of Explanation 1 to subsection (1) of section 37 of the Act applies only to offences which are prohibited by the domestic law of the country. In some case this view has also been accepted by the tribunal. These judgments are also against the intention of the legislation as the legislation does not say that the Explanation 1 applies only to the violation of domestic law.

In order to make the intention of the legislation clear and to make it free from any misinterpretation, it is proposed to insert another Explanation to sub-section (1) of section 37 to further clarify that the expression “expenditure incurred by an assessee for any purpose which is an offence or which is prohibited by law”, under Explanation 1, shall include and shall be deemed to have always included the expenditure incurred by an assessee, —

i. for any purpose which is an offence under, or which is prohibited by, any law for the time being in force, in India or outside India; or

ii. to provide any benefit or perquisite, in whatever form, to a person, whether or not carrying on a business or exercising a profession, and acceptance of such benefit or perquisite by such person is in violation of any law or rule or regulation or guidelines, as the case may be, for the time being in force, governing the conduct of such person; or

iii. to compound an offence under any law for the time being in force, in India or outside India.

9. This amendment will take effect from 1st April, 2022.

Note: Health activists are happy with this amendment, as they believe that this will help to reduce irrational prescription by a section of prescribers.

10% who died of Omicron were vaccinated: Study
Only 10% deaths were recorded among fully vaccinated people who were hospitalised with Omicron infection, compared with nearly 22% fatalities among the unvaccinated or partially-vaccinated, Indian Council of Medical Research (ICMR) director general Balram Bhargava said on Thursday, citing a study based on data from the national clinical registry of Covid-19, to stress that increase in vaccination has significantly helped reduce deaths during the present surge.

Co-morbidities, however, remained a cause of concern as most people who died due to Covid had at least one associated disease. About 91% of the fully vaccinated people who died of Covid and 83% of the unvaccinated or partially vaccinated who succumbed to the virus attack had at least one comorbidity, the data shows. Overall, around 3%-4% of those infected with Omicron needed hospitalisation, Niti Aayog member health Dr VK Paul said.


COVID-19 Vaccine Update: Zydus Cadila supplies first batch of ZyCoV-D to Centre
Zydus Cadila on 2nd February 2022 said that it has started supplies of its COVID-19 vaccine ZyCoV-D to the government. The company has initiated the supply as per the order placed by the government, the drug firm said in a statement. The pharma major also plans to make it available in the market, it added.

ZyCoV-D is a three-dose vaccine administered intradermally using the painless pharmajet needle-free system on day 0, day 28 and day 56. It is a plasmid DNA vaccine which, when administered, produces the spike protein of the SARS-CoV-2 virus and elicits an immune response mediated by the cellular and humoral arms of the human immune system, which play a vital role in protection from disease as well as viral clearance, claimed the company.

Zydus Cadila in its data submitted to the Central Drugs Standard Control Organisation had said that the vaccine showed an efficacy of 66.6 percent against symptomatic COVID-19 infection. It was later granted emergency use authorisation for the age group of 12 years and above in August but had thus far not been included in India’s COVID immunisation drive.

The vaccine is now being priced at Rs 265 per dose and while the applicator is being offered at Rs 93 per dose, excluding GST.

Congratulations Dr. Krishna Ella and Smt. Suchitra Ella*
(Duo)- Padma Bhushan 2022

Congratulations Dr. Cyrus Poonawalla- Padma Bhusan 2022

DISCLAIMER:
The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.