



# Drug Information Bulletin

*Drug Information Centre (DIC)*

*Indian Pharmaceutical Association*

*Bengal Branch*

Tele fax: 033 24612776, [E-mail: ipabengal.dic@gmail.com](mailto:ipabengal.dic@gmail.com)

Web Site: <http://www.ipabengal.org>

Contact: 09830136291

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## *Editorial*



### **Greetings from Drug Information Bulletin!**

Govt. of India directed 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. 16<sup>th</sup> March 2018 (available at: <http://www.cdsc.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 quarters.



**Dr. Subhash C. Mandal**

*Editor*

*E mail: subhash.mandaldr@gmail.com*

*Mob.. 9830136291*

## Inclusion of Oseltamivir and Zanamivir in the Schedule H1

**MINISTRY OF HEALTH AND FAMILY WELFARE**  
**(Department of Health and Family Welfare)**  
**NOTIFICATION**

New Delhi the 5th February, 2024

**G.S.R. 95(E).**— Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Ministry of Health and Family Welfare, Government of India, number G.S.R. 686 (E) dated 25<sup>th</sup> September, 2023 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from the persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And, whereas, copies of the Gazette were made available to the public on 25.09.2023;

And, whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

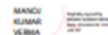
1. (1) These rules may be called the Drugs (Amendment) Rules, 2024.  
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs Rules, 1945, in Schedule H1, after serial number 48 and entries relating thereto, the following serial number and entry shall be inserted, namely:-  
“49. Oseltamivir  
50. Zanamivir”.

[F. No. X.11014/10/2016-DRS]  
RAJIV WADHAWAN, Advisor (Cost).

**Note:** The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 922(E), dated the 28<sup>th</sup> December, 2023.

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### Orchid Pharma gets USFDA approval for Exblifep

Orchid Pharma has received approval by the United States Food and Drug Administration (USFDA) for its novel invention, 'Enmetazobactam'. This development comes in close succession to the recent recommendation for approval by the European Medicines Agency (EMA). Enmetazobactam is the first completely invented-in-India Beta Lactamase Inhibitor.

This USFDA approval paves the way for the introduction of Enmetazobactam in the US, the largest pharma market in the world. The product is expected to be launched within the next couple of quarters in the US market.

This New Drug Approval (NDA) allows the use of Exblifep (Cefepime and Enmetazobactam) as an

injection for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex.

Enmetazobactam was invented in India by Orchid and then out licensed to Allegra Therapeutics for further development.

### Paracetamol study could open door for way to treat liver damage

Scientists have shed new light on how the common painkiller paracetamol causes liver damage. Their findings may offer valuable insights

into poisoning caused by an excess dose, which can be difficult to treat and may prove fatal. The discovery could inform research into therapies to counteract harm caused by the drug, which is the leading cause of acute liver failure in the Western world. Scientists at the University of Edinburgh studied the impact of paracetamol on liver cells in human and mouse tissue, and tests showed that in certain settings paracetamol can damage the liver by harming vital structural connections between adjacent cells in the organ. When these cell wall connections – known as tight junctions – are disrupted, the liver tissue structure is damaged, cells are unable to function properly and they may die. This type of cell damage is known to occur in liver conditions including hepatitis, cirrhosis, and cancer, but until now it was not linked to paracetamol toxicity. Researchers aim now to develop a reliable method of using human liver cells as an alternative to animal testing. They then will seek to examine how varying paracetamol doses and timescales affect toxicity in the liver, and identify potential targets for new drugs. The study, involving researchers from the Universities of Edinburgh and Oslo and the Scottish National Blood Transfusion Service, was published in Scientific Reports. It was supported in part by the Biotechnology and Biological Sciences Research Council and the Chief Scientist Office. Dr Leonard Nelson, of the University of Edinburgh's Hepatology Laboratory and Institute for Bioengineering, who co-led the study, said: "Paracetamol is the world's preferred pain remedy – it is cheap, and considered safe and effective at therapeutic dose. However, drug-induced liver damage remains an important clinical problem and a challenge for developing safer drugs. Our findings reinforce the need for vigilance in paracetamol use, and could help discover how harm caused by its adverse use might be prevented." Ranked among the top universities in the world Co-author Pierre Bagnaninchi, of the University's MRC Centre for Regenerative Medicine, said: "Although liver damage caused by paracetamol toxicity has been the subject of intense study for 40 years, recent developments in biosensor technology are enabling a fuller picture of the biological

mechanisms involved." For further information, please contact: Catriona Kelly, Press & PR Office, 0131 651 4401; [Catriona.Kelly@ed.ac.uk](mailto:Catriona.Kelly@ed.ac.uk)  
Ref. University of Edinburgh

### **Germany legalizes recreational use of cannabis**

Germany on Friday joined the small group of countries and jurisdictions that have legalised cannabis when the Bundestag passed a law allowing individuals and voluntary associations to grow and hold limited quantities of the drug.

The law passed by Chancellor Olaf Scholz's ruling three-party coalition legalises cultivating up to three plants for private consumption and owning up to 25 grams of cannabis.

Larger-scale, but still non-commercial, cannabis production will be allowed for members of so-called cannabis clubs with no more than 500 members, all of whom must be adults. Only club members can consume their product.

Health Minister of Germany-Karl Lauterbach said that they have done it with two goals. First is to crack down on the black market and second is to improve protection of children and young people. Germany becomes the ninth country to legalise recreational use of the drug, which is also legal in some other countries like-Canada, Georgia, Luxembourg, Malta, Mexico, South Africa, Thailand, and Uruguay, plus 24 states and 3 territories and the District of Columbia in US and the Australian Capital Territory in Australia.

Many more countries allow its medical use as a painkiller. Cannabis remains illegal for minors as does consuming it near schools and playgrounds.

Ref. Reuters

### **BCG revaccination study in high-risk adults to begin in 23 States**

Twenty-three States have consented to participate in the BCG revaccination study in adults that will be undertaken in a "programme implementation study mode" to evaluate the effectiveness of the vaccine in reducing TB disease incidence. The study will target some high-risk groups — those older than 50 years, prior TB disease, underweight adults, diabetics, and those who smoke and consume alcohol. The phase-1 of the study will be conducted in Uttar

Pradesh and Madhya Pradesh, says a Delhi-based official.

Ref. The Hindu

### **Gabapentin: Risk of drug dependence and withdrawal symptoms**

1. The HPRA has announced that the product information for gabapentin will be updated to indicate that drug dependence at therapeutic doses and withdrawal symptoms following discontinuation can occur. Gabapentin is indicated for the treatment of neuropathic pain in adults, and as monotherapy or as adjunctive therapy for specific forms of epilepsy. The update has been made following a review of available data by the PRAC of the EMA. Health-care professionals should carefully evaluate an individual patient's risk of misuse, abuse and dependence before prescribing gabapentin. Patients treated with gabapentin should be monitored for these symptoms. If gabapentin use is to be discontinued, it is recommended this should be done gradually over a minimum of one week independent of the indication. In addition, neonatal withdrawal syndrome has been reported in newborns exposed in utero to gabapentin. Coexposure to gabapentin and opioids during pregnancy may increase the risk of neonatal withdrawal syndrome. Newborns should be monitored carefully.
2. Risk of Toxic Epidermal Necrolysis (TEN) The HPRA has announced that the product information for gabapentin will be updated to include the risk of Toxic Epidermal Necrolysis (TEN) under the heading of severe cutaneous adverse reactions (SCARs), where Steven Johnson-Syndrome (SJS) and Drug Rash with Eosinophilia and Systemic Symptoms

(DRESS) are already listed as known adverse reactions. SJS, TEN and DRESS, which can be life-threatening or fatal, have been reported with gabapentin treatment. Health-care professionals should advise patients of the signs and symptoms and closely monitor for skin reactions when starting treatment with gabapentin. If signs and symptoms suggestive of these reactions appear, gabapentin should be withdrawn immediately. If a patient has developed a serious reaction such as SJS, TEN or DRESS, treatment with gabapentin must not be restarted in this patient at any time.

Reference: Drug Safety Newsletter, HPRA, December 2022

### **Itraconazole Risk of hypokalaemia**

The MHLW and PMDA have announced that the product information for itraconazole (oral dosage form and injections) should be revised to include the risk of hypokalemia. Itraconazole is indicated for the treatment of fungal infection. The MHLW and PMDA reviewed three cases of hypokalaemia reported domestically, in which a causal relationship between the drug and event was reasonably possible. The MHLW and PMDA concluded that hypokalaemia should be added as a clinically significant adverse reaction. Health-care professionals are advised to perform blood electrolyte tests periodically irrespective of particular conditions for use (e.g., dosage and period of administration).

Reference: Revision of Precautions, MHLW/PMDA, 12 October 2022 (link to the [source](http://www.pmda.go.jp/english/) within [www.pmda.go.jp/english/](http://www.pmda.go.jp/english/))

#### **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.