# Drug Information Bulletin

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## Editorial

### Greetings from Drug Information Bulletin!

The Lok Sabha passed the Jan Vishwas (Amendment of Provisions) Act, 2022 on 27th July 2023 with an aim of improving ease of doing business attracted criticism from the stakeholders. This bill dealt with amendments of several provisions of 42 laws in force in India including The Drugs and Cosmetics Act 1940 and The Pharmacy Act, 1948. In this bill the sub section (2) of Sec.30 of drugs and Cosmetics Act the words "imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees, or with both", will be substituted by the words "fine which shall not be less than five lakh rupees" and In section 32B, in sub-section (1), after the words and figures "of section 13,", the words, brackets, letters and figures "clause (d) of section 27 and clause (ii) of section 27A," shall be inserted. It appears that “imprisonment” will be replaced by fine only. Similarly Section 26A, section 41 and section 42 of the Pharmacy Act 1948 has been amended through this bill by replacing the “imprisonment” by fine only.

Experts opined that this bill will dilute the penal provisions and encourage violators as they can escape just by paying fine only as per the new bill.


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## Clarification on alternate methods in the Indian Pharmacopoeia

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**F. No.** T.11013/02/2018-AR&D **Date:** 26th February 2021

**NOTICE**

**Subject: Clarification on Alternative Methods in the Indian Pharmacopoeia-regarding**

Indian Pharmacopoeia Commission (IPC) has been receiving many enquiries on the subject of use of alternative methods instead of official methods included in the Indian Pharmacopoeia (IP). General Notices of IP (Volume I, Page 12) have the provision to use alternative methods and the same is reproduced below:

**Alternative Methods**. The tests and assays described are the official methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacturer of substance or product.

**2.** For removal of doubts, it is clarified that the authority competent to authorise manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval.

**3.** All concerned are requested to bring the above clarification to the notice of all authorities under their control.

**(Dr Rajeev Singh Raghuvanshi)**
**Secretary-cum-Scientific Director**

To,

1. The Drugs Controller General (India)
2. CDSCO Zonal Offices
3. All State Drug Controllers
4. Members of the Scientific Body of IPC
5. Members of Sub-Committees of the Scientific Body of IPC
6. Directors of Drugs Testing Laboratories
7. Government Analysts
8. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations

## Initiatives taken by the Government of India for treatment of rare diseases

The Government has launched National Policy for Rare Diseases (NPRD), 2021 in March, 2021 for the treatment of rare disease patients. The salient features of NPRD, 2021 are as under:

- The rare diseases have been identified and categorized into 3 groups namely Group 1, Group 2 and Group 3.

  Group 1: Disorders amenable to one-time curative treatment.

  Group-2: Diseases requiring long term/lifelong treatment having relatively lower cost of treatment and benefit has

been documented in literature and annual or more frequent surveillance is required.
Group 3:- Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy.

- Provision for financial support of up to Rs. 50 lakhs to the patients suffering from any category of the Rare Diseases and for treatment in any of the Centre of Excellence (CoE) mentioned in NPRD-2021, outside the Umbrella Scheme of Rashtriya Arogaya Nidhi.
- In order to receive financial assistance for treatment of rare disease, the patient of the nearby area may approach the nearest Centre of Excellence to get him assessed and avail the benefits.
- Eight (08) Centres of Excellence (CoEs) have been identified for diagnosis, prevention and treatment of rare diseases.
- Five Nidan Kendras have been set up for genetic testing and counselling services.

The NPRD, 2021 has provisions for promotion of research and development for diagnosis and treatment of rare diseases; promotion of local development and manufacture of drugs and creation of conducive environment for indigenous manufacturing of drugs for rare diseases at affordable prices.
Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufacturers selected under the Scheme for domestic manufacturing of various product categories, which also include Orphan drugs.
Department of Revenue, Ministry of Finance vide their Notification No. 46/2021-Customs dated 30.09.2021 gives full waiver of Basic Customs Duty (BCD) and Integrated Goods and Services Tax (IGST) to drugs imported (personal use only) for treatment of Spinal Muscular Atrophy (SMA) rare disease, thereby making the medicines for SMA rare disease more affordable.
In addition, Department of Revenue, Ministry of Finance vide their Notification No. 02/2022-Customs dated 01.02.2022 has given exemption from Basic Customs Duty to drugs or medicines, which are used in the treatment of Rare Diseases when imported by Centres of Excellence (CoEs) as specified in NPRD, 2021 or any person or institution on recommendation of any Centre of Excellence listed in NPRD, 2021, certifying that the person (by name) for whom the drugs or medicines are imported, is suffering from a rare disease (to be specified by name) and requires the drugs or medicines for the treatment of said rare disease.
Source: PIB

**Statins Potential risks of myasthenia gravis and ocular myasthenia**

The PRAC has recommended a change to the product information for statins to include potential risks of myasthenia gravis and ocular myasthenia. Statins are HMG-CoA reductase inhibitors and include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin. In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Treatment with statins should be discontinued in case of aggravation of symptoms. Recurrences when the same or a different statin was (re-) administered have been reported.
Reference: PRAC recommendations on signals, EMA, 6 February 2023 (link to the source within www.ema.europa.eu)

**Pholcodine Prior use of pholcodinecontaining cough and cold remedies and risk of perioperative anaphylactic reactions to neuromuscular blocking agents (NMBAs)**

WHO is alerting healthcare professionals and regulatory authorities of the risk of anaphylactic reactions in people who have taken pholcodine-containing products at least 12 months prior to surgical procedures involving the administration of general anaesthesia with neuromuscular blocking agents (NMBAs). Some regulatory authorities have taken decisions to withdraw pholcodine-containing products from their markets to address this risk. Pholcodine is an opioid medicine and is used in adults and children to treat nonproductive (dry) coughs. Several

preparations are readily available and commonly used as over-the-counter tablets and syrups globally. The European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee reviewed all available evidence including post-marketing safety data, information from third parties such as health-care professionals, and final results of a French multicentre casecontrol study comparing pholcodine exposure within a year before anaesthesia between patients with NMBArelated perioperative anaphylactic reactions.1 The available data showed that the use of pholcodine in the 12 months before general anaesthesia with NMBAs is a risk factor for developing an anaphylactic reaction (a sudden, severe and life threatening allergic reaction) to NMBAs. Based on the lack of effective measures to minimize the risk, the lack of an identified patient population for whom the benefits of pholcodine outweigh its risks, and the seriousness of the safety risk, the European Commission issued a legally binding decision applicable in all EU Member States to withdraw pholcodine containing products.2 As of 29 March 2023, at least three other regulatory authorities had withdrawn prescription and over-the counter preparations containing pholcodine from their markets: the Therapeutic Goods Administration (TGA), Australia, the Medicines and Healthcare products Regulatory Agency (MHRA), the United Kingdom, and the National Pharmaceutical Regulatory Agency (NPRA), Malaysia.3 4 5 Advice to health-care professionals and consumers is provided by the TGA and other authorities as follows: For health-care professionals: • Advise patients to stop taking pholcodine containing medicines and consider appropriate alternatives to treat their symptoms. • Check whether patients scheduled to undergo general anaesthesia with NMBAs have used pholcodine in the previous 12 months and remain aware of the risk of anaphylactic reactions in these patients. For consumers: • Check if any of your overthe-counter cold and flu medicines contain pholcodine. Pholcodine is particularly used in cough lozenge (tablet) or syrup products but can be found in other medicines. If they do, ask your doctor or pharmacist to suggest an alternative treatment. • If you need general anaesthesia and have taken pholcodine in the past 12 months, tell your health professional prior to the procedure. It may help to show this safety alert to your doctor. WHO is issuing this safety alert in view of the wide use of pholcodine-containing products globally and the seriousness of potential anaphylactic reactions. The information was also previously covered by WHO in its Pharmaceuticals Newsletter. Additionally, the WHO has received individual case safety reports (ICSRs) of anaphylactic reactions in VigiBase (the WHO global database of ICSRs) from different countries following the administration of pholcodine and NMBAs.

Reference: Safety alert, WHO, 31 March 2023 (link to the source within www.who.int) (See also WHO Pharmaceuticals Newsletter No.1 2023: Withdrawal of pholcodine medicines from EU market in Europe, No.4, 2022: Pholcodine and Potential risk of developing anaphylactic reactions to NMBA in Europe)

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.