



# Drug Information Bulletin

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*Bengal Branch*

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## *Editorial*

Recent steps of National Pharmaceutical Pricing Authority (NPPA) of capping prices of stents and orthopedic implants is a huge relief to patients and a bold step towards improving access to health care in India. But it is also reported that hospitals are increasing ancillary costs of hospital-stay, to shrewdly recover the margin lost due to decreased stent prices.

Recently the NPPA has also exposed the huge margins charged by corporate hospitals may evoke some regulatory measures to curb this malpractices to protect the health of the people.

In a study it is also revealed that the retail prices of syringes are up to 664% higher than distributors' purchase prices, with needles marked up as high as 356%. Health care activist groups demanded to the government for immediate impose price controls on the devices.

At this juncture, transfer of the Chairman of NPPA raised great apprehension amongst the stake holders and some of them also protested against this move as they feel this will be deterrent to the process of improving access to health care to the Indian population. Hope Government of India will take suitable measure to achieve "Universal Health Care" policy.



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# Drug Safety

## **Antiepileptic drugs Advice on switching between different manufacturers' products.**

The MHRA has reminded healthcare professionals to consider that antiepileptic medicines vary in characteristics which influences the risk of whether switching between different brands may cause adverse effects or loss of seizure control. Antiepileptic medicines can be classified into three main categories. Advice about switching for each category has been given, for example patients taking carbamazepine, (a category one medicine) should be maintained on a specific manufacturer's product. Other advice on considerations that should be taken for patient related factors such as negative perceptions and clinical factors such as seizure frequency, have been highlighted for switching medicines in categories two and three.

Reference: Drug Safety Update, MHRA, Volume 11, issue 4: 4, November 2017 ([www.gov.uk/mhra](http://www.gov.uk/mhra))

## **Chlorhexidine Risk of serious allergic reactions**

The HSA has informed health-care professionals about the outcome of a review on the known risk of allergic reactions, whilst using chlorhexidine-containing products. Chlorhexidine is a broad-spectrum antiseptic which is effective against gram-positive and gram-negative bacteria on the skin and is widely used to reduce the risk of bacterial infections. This review was conducted following safety alerts of serious allergic reactions reported with antiseptic products containing chlorhexidine. Fifteen reports of anaphylactic reactions related to chlorhexidine were identified over a span of 36 years (1981 to 2017). There was no increase in trend of serious allergic reactions to chlorhexidine-containing products observed. At the time of the review, HSA did not identify any significant safety signals regarding serious allergic reactions with the use of chlorhexidine in Singapore. Health-care professionals are advised to inform patients to stop using the product and seek immediate medical attention if they experience symptoms of a serious allergic reaction, such as wheezing, swelling of the face, or severe rashes.

Reference: Product Safety Alerts, HSA, 29 September 2017 (<http://www.hsa.gov.sg/>)

## **Quinine Dose-dependent QTprolonging effects and interactions with other medicines**

The MHRA has reminded healthcare professionals of dose-dependent QT-interval-prolonging effects associated with quinine use. Quinine should be used with caution in patients with QT prolongation risk factors (e.g. pre-existing cardiac disease) or in those with atrioventricular block. Quinine has been used for the treatment of nocturnal leg cramps in the United Kingdom. Quinine is metabolised via hepatic oxidative cytochrome P450 pathways, predominantly by CYP3A4. A review in 2017 identified a pharmacokinetic study reporting that serum levels of phenobarbital or carbamazepine can be raised with concomitant quinine use. Although data appear to be limited, it is advisable to monitor for evidence of toxicity if quinine is used concomitantly with these anticonvulsant medicines.

Reference: Drug Safety Update, MHRA, Volume 11, issue 4: 2, November 2017 ([www.gov.uk/mhra](http://www.gov.uk/mhra))

## **Benzodiazepines and barbiturates Risk of neurodevelopmental disorders: not enough evidence**

Health Canada has carried out a safety review to assess the potential development of neurodevelopmental disorders with the use of benzodiazepines and barbiturates (lorazepam, midazolam, phenobarbital and thiopental) when used in early childhood (up to and including five years of age) or during pregnancy (exposure of the fetus). Benzodiazepines and barbiturates are sedative and anaesthetic medicines and are often required during surgery and medical procedures in children and adults. At the time of the review, Health Canada searched for Canadian and international cases that reported effects of benzodiazepine and barbiturate exposure to fetus in pregnant women or in young children on the development of children's brains. There were a total of 137 Canadian reports and 110 international reports. However, due to multiple factors (e.g. symptoms described in the reports did not meet the definition of

neurodevelopmental disorders) it was not possible to draw conclusions from these reports. Animal studies in pregnant or young animals did not show consistent evidence of negative effects on the development of children's brains with the use of benzodiazepines and barbiturates medicines. Health Canada's review of the available information concluded that there is limited evidence suggesting a link between the use of benzodiazepines and barbiturates and neurodevelopmental disorders.

Reference: Summary Safety Review, Health Canada, 22 December 2017 ([www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)) (See also page -11-)

## National News:

### Syringes, needles have stiff mark-ups in India

India's National Pharmaceutical Pricing Authority reported that retail prices of syringes are up to 664% higher than distributors' purchase prices, with needles marked up as high as 356%. Malini Aisola of the patient group All India Drug Action Network called for the government to immediately impose price controls on the devices.

Ref. : [The Economic Times \(India\)](#)

### Uniform implementation of provisions of Drugs and Cosmetic Act and The Rules throughout Country

In connection to [unstarred question No. 2331](#) regarding measures for uniform implementation of provisions of Drugs and Cosmetic Act and the rules throughout the country through Drug Technical Advisory Board (DTAB) the Minister of State for MoH & FW, Mr Ashwini Kumar Choubey [replied](#) on 09.03.2018 in the Loksabha that Drug Technical Advisory Board (DTAB) in its [77th meeting held on 16.06.2017](#), agreed to various recommendations of Drugs Consultative Committee (DCC) held on 16.06.2017 such as minimum experience for Licensing Authorities, creation of Intelligence cell at each State, deputation of State regulatory officials to the Central regulatory system & vice versa, cadre restructuring in Drugs Controlling Authorities etc., for uniform implementation of the provisions of Drugs and Cosmetic Act, 1940 and Rules, 1945.

The Minister of State (Health and Family Welfare), Sh Ashwini Kumar Choubey stated this in a written reply in the Lok Sabha here today.

Source: Drugs Control

### DAVP barred 51 Newspapers from getting Govt. Ads for two months In Sept, 2017

The nodal agency for central government's advertisements, DAVP, had suspended the empanelment of 51 newspaper in September for two months, most of them for publishing paid news, Parliament was informed today in connection to [Unstarred Question No. 2294 of Dr. P. Venugopal](#).

As many as 37 newspapers were suspended from September 13, 2017 to November 12, 2017 for indulging in paid news, according to a list provided by Minister of State for Information and Broadcasting Rajyavardhan Rathore in the Lok Sabha.

The other reasons for suspension included publishing false news, obscene photograph and 'inaccurate and disrespectful news reports'.

The Directorate of Advertising and Visual Publicity (DAVP) initiative came after the Press Council of India (PCI) censured these newspapers for indulging in paid news or for violation of various norms of journalistic conduct, the minister said.

He said the 51 newspapers were suspended on September 13, 2017, disqualifying them from getting government advertisement for two months from September 13, 2017 to November 12, 2017.

To another [Unstarred Question No. 2290 of Dr. Kirit P. Solanki](#), Rathore said Grievance Against Misleading Advertisements (GAMA), a portal launched by Department of Consumer Affairs (DCA) to handle complaints regarding misleading advertisements, has received 3,302 complaints in 2017.

The portal had received 2,032 complaints against misleading advertisements in 2016 and 641 in 2015.

DCA, a department under Ministry of Consumer Affairs, Food & Public Distribution, has entered into a Memorandum of Understanding (MoU) with Advertising Standards Council of India (ASCI),

a self-regulatory body on advertisement industry, to process the complaints received on GAMA portal.

Source: Brand Equity

## International News:

### Australia allows Densitas to sell breast density software

Medical software company Densitas obtained permission from Australia's Therapeutic Goods Administration to market its DM-Density breast density software in the country. The automated software, which will be offered through the EnvoyAI platform, reads patients' mammograms to identify their breast density category in a few seconds.

Ref.: AuntMinnie

## Forthcoming Events:

Refresher course for registered Pharmacist

**Organized by:** IPA, Bengal Branch

**Supported by:** Pharmacy Council of India

**Schedule:**

17.03.2018: DSP Main Hospital

25.03.2018: CMOH Meeting Hall, Tamluk

30.03.2018: Barasat Dist Hospital

01.04.2018: Suri Sadar Hospital

08.04.2018: Paschim Medinipur MCH Lecture Hall

14.04.2018: IPA Auditorium, Kolkata

21.04.2018: IPA Auditorium, Kolkata

21.04.2018: Purulia

28.04.2018: NBMCH, Siliguri

29.04.2018: Institute of Pharmacy, Jalpaiguri

05.05.2018: Hooghly

05.05.2018: Baruipur

12.05.2018: Malda

19.05.2018: Coochbehar

26.05.2018: Assansol



## Indian Pharmacopoeia Commission,

Ministry of Health & Family Welfare,  
Government of India  
Sector – 23, Raj Nagar, Ghaziabad-201002



## IPC-EDQM Symposium on Drug Standards and Regulatory Updates

**At Mumbai on 26-27<sup>th</sup> April, 2018**

Indian Pharmacopoeia Commission (IPC), Ghaziabad is an autonomous institute under the Ministry of Health and Family Welfare, Government of India, mandated for Drug standard setting in India, has been awarded the Observer Status for participation in the activities of the European Directorate for the Quality of Medicine and Healthcare (EDQM), France.

In order to update and enhance awareness among the stakeholders about the activities / initiatives of the two organizations, vis-a-vis the regulatory aspects, the symposium on Drug Standards and Regulatory Updates is being organized in Mumbai on 26-27 April, 2018.

The symposium shall be the unique opportunity for the stakeholders, which may include professionals from Pharma Industry, API Manufacturers, Associations; Academicians; Individuals and Regulators etc. to hear Key-Speakers from IPC, EDQM and Regulatory Bodies, and attend interactive sessions.

The participation is through registration, the process for which and the programme details may be had from IPC ([www.ipc.gov.in](http://www.ipc.gov.in)) and EDQM ([www.edqm.eu](http://www.edqm.eu)) website. In view of space constraint, the enrolment shall be on first come first serve basis.

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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.