



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

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Editorial

In a recent meeting DTAB approves DCC recommendations for uniform implementation of provisions of D & C Act and Rules throughout the country is a mile stone in the history of Drug Regulatory system of India. In which it is recommended cadre restructuring in the state Drug Control departments to make it uniform for uniform implementation of the Drugs and Cosmetics Act, 1940 and Rules, 1945. It is recommended that Drugs Inspectors will be re-designated as “Drugs Control Officer” with uniform pay scales. It is also recommended that the Central government should issue direction to the State governments to ensure adequate regulatory officials which will be commensurate with the number of sale outlets and manufacturing units located in the respective States considering that there should be one official for every 200 sale outlets and one official for every 50 manufacturing units. There should be provisions for deputation of State regulatory officials to the Central regulatory system and vice versa. The minimum experience for Licensing Authorities (LA) relating to manufacturing and sale of drugs should be raised adequately. It is also recommended that there should be a single Licensing Authority for Manufacturing activity in each state, appointment of a Nodal officer of intelligence Cell for market surveillance and conducting investigation in respect of spurious, adulterated drugs in coordination with CDSCO, guidelines should be developed by CDSCO for uniform implementation, The Medical Device officers to be appointed under the Rules should have B. Pharm/M. Pharm. qualification. Such officer should undergo training in medical device regulation under a training module being developed under joint collaboration between Delhi Pharmaceutical Science and Research University and IPC, Ghaziabad or any other institutions which deems fit for such activity. Uniform nomenclature of CDSCO and state drugs control. Apart from this there are some other important recommendations, which are considered as very much needed for strengthening the Drugs Control mechanism of India. It is expected that the fate of this recommendation will not follow several such recommendations in the past.



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Recently banned Fixed Dose Combinations in India

SL. No.	FDC	Order No. & Date
1	FIXED DOSE COMBINATIONS OF NIMESULIDE + LEVOCETRIZINE	S.O.1851 (E) DATED 08.06.2017
2	FIXED DOSE COMBINATIONS OF OFLOXACIN + ORNIDAZOLE INJECTION	S.O.1852 (E) DATED 08.06.2017
3	FIXED DOSE COMBINATIONS OF GEMIFLOXACIN + AMBROXOL	S.O.1853 (E) DATED 08.06.2017
4	FIXED DOSE COMBINATIONS OF GLUCOSAMINE + IBUPROFEN	S.O.1854 (E) DATED 08.06.2017
5	FIXED DOSE COMBINATIONS OF ETODOLAC + PARACETAMOL	S.O.1855 (E) DATED 08.06.2017

No price change in 78% of actively used drugs post GST: NPPA

Drug pricing regulator NPPA on Friday said prices of around 78 per cent of 'actively used' drugs will remain unaffected after the rollout of the Goods and Services Tax from midnight tonight.

The National Pharmaceutical Pricing Authority (NPPA) has already announced provisional ceiling prices of 761 medicines, including anti-cancer, HIV, diabetes and antibiotics, with a majority being reduced ahead of the GST implementation. These prices will be notified as formal revised ceiling prices immediately after GST notification, NPPA had said in a memorandum earlier this week.

"Prices of approximately 78 per cent of all actively used and traded drugs in the country are going to remain unaffected post GST", NPPA said in a tweet on Friday.

It had earlier indicated that the prices of majority of essential drugs would increase by up to 2.29 per cent when the GST regime kicks in. The government has fixed GST rate of 12 per cent on most of the essential drugs as against the current tax incidence of around 9 per cent.

"I am confident that GST implementation will be by and large smooth and will not cause any major disruption in the availability of drugs in the country," NPPA Chairman Bhupendra Singh had earlier told.

Reference: ET Health World

Fluconazole: Not to use during pregnancy

1. Reminder not to use during pregnancy Ireland.

The HPRA has provided the following advice to health-care professionals: Fluconazole in standard doses and short-term treatments should not be used in pregnancy unless clearly necessary. Fluconazole in high doses and/or in prolonged regimens should not be used during pregnancy except for potentially life threatening infections. Fluconazole is used for treatment and prevention of specified fungal infections in adults and children. Results of an observational study suggests an increased risk of spontaneous abortion in women taking fluconazole during the first trimester of pregnancy. Previous studies have linked high dose and long-term treatment to birth defects. Reference: Drug Safety Newsletter, HPRA, March 2017

2. Caution in use during pregnancy Malaysia. The NPRA is reviewing the possible association between oral fluconazole exposure during pregnancy and the risk of spontaneous abortion and stillbirth. The NPRA advises cautious prescribing of oral fluconazole in pregnancy until this review is completed. Since year 2000 to July 2016, the NPRA has received 149 safety reports with 236 adverse events associated with fluconazole. The highest reported adverse events were maculo-papular rash, increased hepatic enzymes, and pruritus. At the time of this communication, there were no reports

related to spontaneous abortion or stillbirth. The NPRA has provided advice for health-care professionals to prescribe oral fluconazole during pregnancy with caution and to consider alternative treatment options, such as clotrimazole for uncomplicated candidiasis.

Reference: Reaksi Drug Safety News, NPRA, No. 34, March 2017

Testosterone: Risk of arterial thromboembolism/venous thromboembolism

The TGA has reminded health-care professionals that they should only prescribe testosterone if prescribing is in line with the registered indications and Pharmaceutical Benefits Scheme restrictions. The TGA has been monitoring testosterone in relation to the risk of arterial thromboembolism/venous thromboembolism since the publication of a US FDA safety communication in 2014. As part of the review, the TGA sought advice from the Advisory Committee on the Safety of Medicines (ACSOM). During the meeting on 2 September 2016, ACSOM found that there was a weak signal of increased cardiovascular risks with use of testosterone medications in general (but not for specific events). The TGA noted this advice, but given there is only a weak signal, the TGA has decided that it is not necessary to update the Product Information documents for testosterone medicines for the time being.

Reference: Medicines Safety Update, TGA, Vol. 8, No. 2, April-May 2017 (www.tga.gov.au)

Canagliflozin Increased risk of leg and foot amputations

The US Food and Drug Administration (FDA) has requested that the product label for Canagliflozin (Invokana® and Invokamet®) is updated to include the risk of leg and foot amputations. Canagliflozin is a sodium glucose cotransporter-2 (SGLT2) inhibitor and is used with diet and exercise to lower blood sugar in adults with type-2 diabetes. Final results from two clinical trials

- the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants with Type-2 Diabetes Mellitus) - showed that leg and foot amputations occurred twice as often in patients treated with canagliflozin compared to patients treated with placebo.

Reference: Drug Safety Communication, US FDA, 16 May 2017 (www.fda.gov)

Report predicts growth for global orthopedic devices market

A Market Data Forecast report predicts the worldwide market for orthopedic devices will reach \$49.14 billion by 2021 with a 5.12% compound annual growth rate because of an increasing incidence of osteoporosis, an expanding geriatric population and a growing number of sports injuries. Medtronic, DePuy Synthes, Stryker, Smith & Nephew and Zimmer Biomet are among the key market players.

Ref. Becker's Spine Review

DTAB approves DCC recommendations for uniform implementation of provisions of D & C Act and Rules throughout the country

The Drugs Technical Advisory Board (DTAB), the highest decision making body under the Union health ministry on technical matters, in its 77th meeting held on June 16, 2017 has agreed with the recommendations of the Drugs Consultative Committee (DCC) on measures for uniform implementation of provisions of Drugs & Cosmetics Act and Rules throughout the country and for strengthening drug regulatory system in the country.

The major recommendations of the DCC include cadre restructuring in state drugs control departments for uniform implementation of provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945. As per the recommendation, the post of Drugs Inspectors should be re-designated as Drugs Control Officers; the grade pay of Drugs Inspector should be raised to Rs. 5,400 in Pay Band-2; the grade pay of Assistant Drugs Inspector should be raised to Rs. 4,800 in Pay

Band-2; and all the other higher posts should accordingly be re-organized.

As per the DCC recommendation, the Central government should issue direction to the State governments to ensure adequate regulatory officials which will be commensurate with the number of sale outlets and manufacturing units located in the respective States considering that there should be one official for every 200 sale outlets and one official for every 50 manufacturing units. There should be provisions for deputation of State regulatory officials to the Central regulatory system and vice versa. The minimum experience for Licensing Authorities (LA) relating to manufacturing and sale of drugs should be raised adequately.

The DCC had further recommended that the practice of having multiple LA in a State for regulation of manufacture of drugs may be replaced by a single LA with provision for delegation of powers to other regulatory officials. Guidelines, directions as and when issued, should be communicated to the State government and not to the State Drugs Controllers for ensuring effective uniform implementations of such guidelines directions. It was suggested that Drugs Control Authority of each State should create an Intelligence cell with a Nodal Officer for market surveillance and conducting investigation in respect of spurious, adulterated drugs in coordination with CDSCO.

The DCC further recommended that the drugs samples from supply chain of procurement agencies needs focused monitoring for ensuring quality of the drugs. The procurement agencies get their sample tested at approved private drug testing laboratories and obtain test reports in Form

39, which is supposed to be issued by such laboratories only to drug manufacturers who do not have testing facilities. The Drugs and Cosmetics Rules, 1945 should be amended to prescribe a separate Form for issuing test reports by such laboratories for procurement agencies. The committee while appreciating the recently conducted National Drugs Survey, mentioned that a system should be put in place to address issue, if any, relating to the Survey, when brought to the notice of the authority.

Guidelines should be prepared for disposal of expired drugs - a committee comprising Drugs Controllers of Telangana, MP and DOC (I), Hyderabad zone should be constituted in this regard. Weak areas of market identified on the basis of risk analysis and intelligence information shall be kept under active quality surveillance of GAP by conducting special operations. Regulatory officials should not participate in the procurement activities as there may be conflict of interest.

Minutes of all DCC and DTAB meetings held so far should be compiled and uploaded in CDSCO website. The Medical Device officers to be appointed under the Rules should have B. Pharm/M. Pharm. Such officer should undergo training in medical device regulation under a training module being developed under joint collaboration between Delhi Pharmaceutical Science and Research University and IPC, Ghaziabad or any other institutions which deems fit for such activity. Uniform nomenclature on the pattern of earlier proposal of naming CDSCO as Indian Drug Administration. Likewise, in the States whether they may be named as IDA (Name of the State/FDA/name of the institution), the DCC further recommended.

Ref. Pharmabiz

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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.