



Drug Information Bulletin

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Indian Pharmaceutical Association

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Content

- *Editorial*
- *USFDA updates warnings for fluoroquinolones antibiotics on risk of mental health and low blood sugar adverse reactions*
- *Quizartinib extends survival in rare form of leukemia*
- *Devices, Disposables & Consumables May Enter Essential Medicines List*
- *Oxytocin will be available in medical shops till August 32, 2018*
- *Shut Chinese companies hit Indian pharma players*
- *Forthcoming Events*

Editorial

Oxytocin-an essential drug is used widely for inducing labour. But unfortunately it is being misused in several means.

Govt. of India has taken several steps to curb this menace, through a notification vide no. G.S.R. 411(E) dtd. 27th April 2018 mandating that-

- The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.
- The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.
- The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.
- The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.
- The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-
 - to the registered hospitals and clinics in public and private sector directly; or
 - to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.
- The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.

This notification shall come into force on the first day of July 2018.

The effective date was further deferred by 120 days through a notification vide S.O. 3448 (E) dtd. 13th July 2018. Hope these measures will evoke good results



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USFDA updates warnings for fluoroquinolone antibiotics on risks of mental health and low blood sugar adverse reactions

Press Release:

The U.S. Food and Drug Administration today is requiring safety labeling changes for a class of antibiotics called fluoroquinolones to strengthen the warnings about the risks of mental health side effects and serious blood sugar disturbances, and make these warnings more consistent across the labeling for all fluoroquinolones taken by mouth or given by injection.

“The use of fluoroquinolones has a place in the treatment of serious bacterial infections — such as certain types of bacterial pneumonia — where the benefits of these drugs outweigh the risks, and they should remain available as a therapeutic option. The FDA remains committed to keeping the risk information about these products current and comprehensive to ensure that health care providers and patients consider the risks and benefits of fluoroquinolones and make an informed decision about their use,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research.

FDA-approved fluoroquinolones include levofloxacin (Levaquin), ciprofloxacin (Cipro), ciprofloxacin extended-release tablets, moxifloxacin (Avelox), ofloxacin, gemifloxacin (Factive) and delafloxacin (Baxdela). There are more than 60 generic versions. The safety labeling changes the FDA is requiring today were based on a comprehensive review of the FDA’s adverse event reports and case reports published in medical literature.

Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described in the Warnings and Precautions section of the drug labeling, but differed by individual drug. The new class-wide labeling changes will require that the mental health side effects be listed separately from other central nervous system side effects and be consistent across the labeling of the fluoroquinolone class. The mental health side effects to be included in the labeling across all the fluoroquinolones are disturbances in attention, disorientation, agitation, nervousness, memory impairment and delirium.

Additionally, the recent FDA review found instances of hypoglycemic coma where users of fluoroquinolones experienced hypoglycemia. As a result, the Blood Glucose Disturbances subsection of the labeling for all systemic fluoroquinolones will now be required to explicitly reflect the potential risk of coma with hypoglycemia.

Today, the FDA also published a drug safety communication about safety information regarding hypoglycemic coma and mental health side effects with fluoroquinolones.

The FDA first added a Boxed Warning to fluoroquinolones in July 2008 for the increased risk of tendinitis and tendon rupture. In February 2011, the risk of worsening symptoms for those with myasthenia gravis was added to the Boxed Warning. In August 2013, the agency required updates to the labeling to describe the potential for irreversible peripheral neuropathy (serious nerve damage).

In 2016, the FDA enhanced warnings about the association of fluoroquinolones with disabling and potentially permanent side effects involving tendons, muscles, joints, nerves and the central nervous system. Because the risk of these serious side effects generally outweighs the benefits for patients with acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections, the FDA determined that fluoroquinolones should be reserved for use in patients with these conditions who have no alternative treatment options.

The patient Medication Guide that is required to be given to the patient with each fluoroquinolone prescription describes the safety issues associated with these medicines.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

For details:
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm612995.htm>

Quizartinib extends survival in rare form of leukemia

The investigational drug quizartinib was found to extend survival in adults with relapsed acute myeloid leukemia and FLT3 internal tandem duplication compared with salvage chemotherapy in 367 patients, based on data from a Phase III study presented at the European Hematology Association's annual meeting. Median overall survival of those treated with quizartinib was 6.2 months versus 4.7 months for patients treated with standard salvage chemotherapy.

Ref. Specialty Pharmacy Times

Devices, Disposables & Consumables May Enter Essential Medicines List

Recently Indian government has decided to restructure the National List of Essential Medicines (NLEM) with the objective to make it more contemporary, and in line with public health needs. For this purpose, the government will constitute a 'Standing National Committee on Medicines' involving scientists, doctors and experts to "review and revise" the NLEM, and may also include medical devices, disposables and consumables to the list, official sources told TOI. Only cardiac stents from medical devices were included in the NLEM in 2016, following a court order.

The development assumes significance as the National List typically forms the basis of price caps extended on essential medicines by the drug prices regulator, as was done in the last revision. Also, this time round, a standing committee with a three-year term has been constituted and will meet every six months to take stock and may also incorporate changes in the essential list. With medical science evolving each day, there was a need for a committee which can take stock and have a longer tenure, the official added. NLEM was last revised in 2015 by a one-time committee formed by the health ministry. The list was expanded to 384 drugs from the existing 348, after which ceiling prices were fixed by NPPA the following year. In the last exercise, though drugs for critical illnesses like cancer, HIV and diabetes were added, many therapies were still missing.

The present exercise is expected to make the list more relevant and broad-based with inputs taken

from World Health Organisation and Indian Pharmacopoeia, and add drugs included in the national health programmes.

Ref. The Times of India

Oxytocin will be available in medical shops till August 31, 2018

The restrictions on the private production and sale of Oxytocin, which were to come into effect from July 1, has been deferred to August 31, 2018.

The government on June 29 had issued a notification, banning commercial production and sale of Oxytocin from July 1. The drug, used mainly for controlling maternal mortality, to contract uterus and stop bleeding during labour, has been known for its misuse in cattle, especially to enhance milk production in cows.

The medical community had raised objection to the sudden ban of the drug that has to be given to pregnant women during delivery, as per the standard guidelines.

Bengaluru-based Karnataka Antibiotic & Pharmaceutical Limited (KAPL) will produce the drug for the entire country.

A KAPL officer said the production will begin in a week. "The government has deferred the ban for two months, through a gazette notification. At present, it is available for sale in all chemists' shops and will continue till August 31. We've already been getting requests from hospitals from across the country. It has been deferred also to prepare the medical community," said the officer.

The unit, however, has to verify whether the hospital that has raised a request for the drug supply is registered with the government.

"We've to crosscheck if the hospital is a registered one as per the government specifications, as the drug can be handed over to only a registered medical centre. The hospitals must have registration number allotted to them for us to dispatch the drugs. We are not only into production of the drug but into verification process," said the officers.

Source: ETHealthworld

Shut Chinese companies hit indian pharma players

Over the last year, nearly 1.5 lakh factories in China have closed down, of which a quarter will

affect pharmaceuticals. It is feared that most small suppliers will not open again as they would not be able to comply with the tough environmental standards.

The shakeup in Chinese factories in the wake of environmental concerns is sending shivers down the spine of the domestic drug industry, with many fearing there will be supply disruptions and inflationary pressures. The environmental disruption in China has led to a massive increase — as high as 120 per cent — in prices of key raw materials like active pharmaceutical ingredients (APIs).

Costs have increased across therapies — including anti-diabetic, cardiovascular, central nervous system, vitamins and antibiotics — over those prevailing in June 2017. Some of the largest hikes have happened in oncology where prices of key starting material for oncology APIs, like 5-Fluorocytosine and HMDS, have witnessed a jump of 60 per cent and 484 per cent, respectively. Certain others jumped around 20 per cent in 3 years.

Over the last year, nearly 1.5 lakh factories in China have closed down, of which a quarter will affect pharmaceuticals. An estimated 145 API manufacturers have shut shop there. It is feared that most small suppliers will not open again as they would not be able to comply with the tough environmental standards.

For the last several decades, the Indian pharmaceutical industry has been dependent on APIs as well as key intermediates for API manufacturing sourced from China. This was driven by the competitive pricing that Chinese suppliers could offer, based on large scales of manufacture as well as state driven subsidies. A Dr Reddy's executive told TOI, "All these factors have led to a rise in input prices for most manufacturers of APIs. Furthermore, there is high pressure on formulation prices, especially in the US, which is the result of consolidation as well as pressure on healthcare costs. Therefore, API

prices on formulations."

Since several basic chemicals could still be affected, the effects on supply chain are yet to be seen. Many starting materials could be impacted soon, then key raw materials, then APIs in weeks or months.

API manufacturer Uquifa's executive director Saurabh Gurnurkar said, "Price increases of API are happening due to increase in KSM (key starting material) prices, which are the building blocks for the API (active ingredient). This is being driven by supply uncertainties emerging out of China, which is where KSM manufacturers are located. Even in India (another key base for KSMs), there have been instances of units being impacted by pollution concerns, leading to supply issues and thus the impact on product pricing, though clearly to a lesser extent than China."

As KSM manufacturing starts to pick up outside China, increasingly products will be priced according to local economics, and this too impacts KSM costs and spills over to API pricing as well, he added.

For details: ETHealthworld

Forthcoming Events:

- **27th FAPA Congress**
October 24th-27th, 2018
Manila, Philippines
- **57th National Pharmacy Week(NPW)**
18-24th November 2018
Theme: Pharmacists for a Healthy India
- **70th Indian Pharmaceutical Congress (IPC)**
21-23 Dec 2018
Amity University, Noida, NCR Delhi

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