



# Drug Information Bulletin

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## Editorial

Recent order of the Central Govt., suspending manufacture for sale, sale and distribution of Pioglitazone is an eye opener for establishing a robust Pharmacovigilance system in India. Though the order has not mentioned any specific reason for its suspension, it is learnt that the ADR of Pioglitazone (bladder cancer) identified in the developed countries has prompted this move. In the meantime a group of Dialecticians have raised the question about the lack of pharmacovigilance data in India to support the bladder cancer effect of Pioglitazone and they are of the opinion that there is no economically viable alternative of Pioglitazone for Type 2 diabetes treatment. As a result Govt. has taken the suggestion of some experts. Sources say that the Govt. is going to reconsider its decision of suspending manufacturing and distribution of Pioglitazone.

It may be recalled that an initiative was taken in 2004 for setting up of a National Pharmacovigilance system in India under the leadership of CDSCO. Under this programme, two Zonal centers have been established at Mumbai and Delhi. 5 regional centers were established at Kolkata, Mumbai, Nagpur, New Delhi and Pondicherry. 24 peripheral centers at different medical colleges or Pharmacy colleges throughout the country. The purpose of national Pharmacovigilance programme was to encourage the reporting of all suspected adverse reaction to drugs and other medical substances including herbal, traditional or alternative remedies. Unfortunately this programme has not generated expected results.

Thereafter, a new Pharmacovigilance programme has been initiated by CDSCO under Health Ministry with its Coordinating centre at Indian Pharmacopoeia Commission (IPC) in the year of 2010. This system is under progress which needs to be more efficient to generate data so that it can support the decision of Govt. in future to avoid any more controversy.

## Setting up of Central Drug Authority (CDA) through The Drugs and Cosmetics Bill, 2013

The bill proposes to set up a Central Drugs Authority (CDA) to act as an appellate body for central and state drug controllers.

Licences for manufacturing drugs under 17 critical categories will be given only by the Centre and not by states, a new bill has proposed.

The Drugs and Cosmetics Bill, 2013, a comprehensive legislation for the drugs and cosmetics sector, was cleared by the Union Cabinet on 11<sup>th</sup> July, sources said.

The Health Ministry proposes to introduce the bill in Parliament during the Monsoon session.

The proposed bill seeks to replace the Drugs and Cosmetics Act, 1940, which was amended in 2008, and will have a separate chapter on clinical trials and another on medical devices, which lays down specific penal provisions in case of any violation.

The purpose behind the bill is to bring a comprehensive legislation to cover various aspects of drugs and cosmetics, including regulation of clinical trials and medical equipment sector, Health Ministry officials said, adding that it aims to help strengthen the domestic drug manufacturing industry.

The new legislation proposes a separate set of rules for grant of compensation in case of death or injury during clinical trials and contains penal provisions, including fine or imprisonment, for violation of the law.

It also seeks to bring medical devices under the purview of the Act and proposes a separate set of rules for it, as such equipment was considered as 'drugs' under

the existing act and had no provisions to regulate it.

Under the new bill, only the Central Drugs Standard Control Organization will have powers to grant manufacturing licences to 17 critical categories of drugs that includes life-saving drugs, vaccines and DNA products which require specialized manufacturing.

Once the bill becomes a law, state drug controllers will not have powers to grant licences for drugs in these categories.

Manufacturing licences for such drugs have been till now granted by state drug controllers after obtaining no-objection from the central drug controller.

This resulted in grant of manufacturing licences to drug makers by state drug controllers in the garb of 'new drugs' without even conducting clinical trials on Indian population to check the efficacy and safety of the drugs.

The Parliamentary Standing Committee on Health took serious objection to this violation of the law and sought remedial measures. The new bill includes major recommendations of the Parliamentary panel.

The proposed Central Drug Authority would judge the actions taken by the state and central controllers and would be a multi-member authority headed by the Health Secretary.

It would have secretaries of seven related ministries as members, besides nominees from states and experts in the field.

The CDA will have the power to review, suspend or cancel licences granted by the central and state drug licensing authorities.

The proposed bill comes in the wake of recent Supreme Court directions to regulate drugs licensing and that the Health Secretary should be responsible for all drug licencing.

The new bill also seeks to establish a Medical Devices Technical Advisory Board as such equipment will henceforth be regulated under the proposed law.

It also proposes to expand the Drugs Technical Advisory Board and creation of a new cadre of officers for regulation of medical devices on the lines of that for drugs and for defining 'adulterated cosmetics'.

The new bill does not contain amendments in respect of [AYUSH](#) (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy systems) drugs.

The Department of AYUSH will bring a separate proposal for carrying out the provisions relating to AYUSH drugs from the Drugs and Cosmetics Act and enacting a separate law exclusively for regulating these drugs.

Reference: Business Standard

### **More treatments for neglected diseases are being approved**

New drug approvals for neglected diseases increased from 2.6 annually from 2002 to 2008 to five in 2009 to 2012, according to a report from the Tufts Center for the Study of Drug Development. "The trend in approvals is clearly going in the right direction, but annual R&D spending to treat neglected diseases has leveled off at \$3 billion in total, after rising rapidly from 2000 to 2007, which is a cause of concern," said Joshua Cohen, an assistant professor and the study's lead investigator.

Ref.: [American City Business Journals/Boston/Bioflash blog](#)

### **U.S. calls off 40 studies in huge blow to India's R&D**

The NIH, the biggest research funder in the world, has abandoned nearly 40 ongoing clinical trials in India because of the country's unstable regulatory environment, adding that this environment is why sponsors are moving trials to Canada and Malaysia, among other places. "Given the fact that we have the world's highest disease burden, the most impacted by an unstable regulatory environment are patients for many of whom clinical research provided early access to new therapies and is often the only viable treatment option," Quintiles India Managing Director Anil Raghavan said.

Ref.: [BioSpectrum Asia](#)

### **FDA grants antibiotic candidate QIDP status**

Dow Jones Newswires reported Tetrphase Pharmaceuticals Inc. announced on Monday that its antibiotic candidate, eravacycline, has been given qualified-infectious-disease-product status by the Food and Drug Administration. The Watertown, Massachusetts-based biopharmaceutical company said the agency granted the designation for complicated intra-abdominal-infection and urinary-tract-infection indications. Tetrphase plans to move into Phase III clinical trials that were planned for the end of the year. The QDIP status includes incentives such as priority review, and five additional years of market exclusivity, if approved.

### **Five more countries approve Tofacitinib to treat RA**

The AP reports Pfizer Inc. announced Monday that its twice-daily rheumatoid arthritis treatment, Xeljanz (tofacitinib), has been approved in five more countries. The New York City-based pharmaceutical company, which launched the medication

in the US in November, said it has now been cleared for sale in “Russia, Argentina, Kuwait, the United Arab Emirates and Switzerland.” The AP points out that Switzerland is the “only country in Europe” so far, to clear Xeljanz. EU countries, citing rare but serious side effects including an increased risk for cancer, have been reluctant to do so. However, Pfizer has been asking EU regulators to “reconsider their recommendation in April not to approve the drug.”

### **Ministry officials detain Chinese Glaxo executives for bribery**

In a front-page story, the Wall Street Journal reports Chinese officials within the Ministry of Public Security’s economic crime investigation unit announced four Chinese GlaxoSmithKline executives were detained for corruption. They are being accused of using travel agencies as fronts for bribing government officials, hospitals and physicians to sell their medication at increased prices. According to ministry official Gao Feng, a significant part of Glaxo’s strategy “for sales and marketing has been to conspire and encourage the possibility of commercial bribery.” He said that since 2007, Glaxo and travel agencies swapped three billion Chinese yuan, or roughly \$489 million, declining to say how much of that money was used for legitimate business purposes. He also accused the agencies of using sexual bribes to influence senior Glaxo executives.

Another article in the Wall Street Journal quotes Glaxo in a statement saying the company is “concerned and disappointed by these serious allegations of fraudulent behavior and ethical misconduct.” Glaxo agreed to cooperate with Chinese officials, and will stop using travel agencies named in the investigation. It will also review previous travel agency transactions.

In the New York Times reports Chinese authorities accused Glaxo Chinese senior executives Monday of “organizing fictitious

conferences, overbilling for training sessions and in various other ways filing sham expenses for which the cooperating travel agencies would issue bogus receipts.” These false statements allowed the executives to “reimbursed by their company with money they could use for bribes, investigators said, while the travel agencies skimmed off shares of the money for themselves.” The possible punishments or fines for the pharmaceutical giant “are unclear, experts said, but the investigation is almost certain to cause concern among the ranks of major multinational companies operating in China.”

The AP reported that the “four employees being questioned include a vice president and human resources director of Glaxo’s Chinese unit, the Xinhua News Agency said Monday.” The scheme allowed the “employees circumvent GSK’s rules that limited gift-giving to 300 yuan (\$50) per recipient.” Authorities also “questioned the corporate representative of the Shanghai Linjiang International Travel Agency,” citing an anonymous investigator who claims most of the “agency’s business came from laundering money for the bribery scheme.”

### **Forthcoming Events**

## **Health Camp**

### **Dates:**

22<sup>nd</sup> July, 29<sup>th</sup> July, 5<sup>th</sup> August, 12<sup>th</sup> August, 19<sup>th</sup> August, 26<sup>th</sup> August

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