Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

Volume: 07 ***Number: 16*** ***27th July 2013***

Content

Editorial

Safety of the subject in any clinical trial is an important issue in conducting clinical trial. A recent report of a Parliamentary committee also expresses deep concern about the safety of the subjects. It has also been observed that the level of understanding of GCP is low. In order to ensure safety of the subject and streamlining the clinical trial three new Rules like - 122DAB, 122DAC and 122DD have been inserted in the Drugs and Cosmetics Rules during the last six months. Through these three Rules it has made mandatory that before starting any trial permission required to be taken from DCGI, Ethics Committee (EC) require to be registered with DCGI before recruitment of any subject and prescribed the mode and mechanism of compensation of any injury or death during trial. In order to enforce the legislation regarding the clinical trials the CDSCO has been empowered to inspect clinical trial site and to ask any questions to the team involved in any trial. They are also empowered to inspect any documents of EC and to ask any question any members of the IEC. For this purpose CDSCO can take help of the officers of the State Drugs Control. This measure is considered as an effective instrument for protecting the safety and interest of the subject involved in Clinical trial.

Study: Cheaper version of Sitagliptin available in Indian Market

Glenmark has marketed Sitagliptin Phosphate (Zita) and a combination of Sitagliptin Phosphate with Metformin

(Zitamet) at a cheaper rate in comparison to the brand leader Januvia and Janumet. Price in Indian market is mentioned in the table below:

	Brand Name	MRP (Rs.)
1	Januvia (7 tablets)	299
2	Zita (7 tablets)	196
3	Janumet (7 tablets)	299
4	Zitamet (7 tablets)	98

Source: CIMS & Local market

EMEA recommends restriction in use of Metoclopramide and suspended Oral Ketoconazole marketing authorization

The European Medicines Agency's Committee on Medicinal Products for Human Use has recommended changes to the use of metoclopramide containing medicines in the European Union, including restricting the dose and duration of use of the medicine to minimize the known risks of potentially serious neurological side effects. Separately, the CHMP has finalized a review of GLP-1-based diabetes therapies. The agency concluded that presently available data does not confirm recent concerns over an increased risk of pancreatic adverse events with these medicines. In addition, the agency has recommended that the marketing authorizations of oral ketoconazole containing medicines should be suspended. The CHMP concluded that the risk of liver injury is greater than the benefits in treating fungal infections.

GSK China boss replaced in wake of scandal

GlaxoSmithKline has replaced the British head of its Chinese operations, which are in the midst of a cash and sexual bribery scandal. Britain's biggest drug company said Mark Reilly, who left China for London before the police arrested four of his senior subordinates, has been replaced by Herve Gisserot, the company's vice president for Europe. GSK refused to state if Reilly, who has been head of its Chinese operations since 2009, has been replaced over fears he may be arrested if he returns to Shanghai. A GSK spokesman said the company understands there are "no allegations of wrongdoing" against Reilly and said he is "very willing to help the authorities with their investigation."

The U.S. Pharmacopeial (USP) Convention announces revision of eight monographs

* Alfuzosin Hydrochloride Extended-Release Tablets (posted 26-Jul-2013; official 01-Aug-2013)
* Alprazolam Extended-Release Tablets (posted 26-Jul-2013; official 01-Aug-2013)
* Cabergoline (posted 26-Jul-2013; official 01-Aug-2013)
* Cetirizine Hydrochloride Tablets (posted 26-Jul-2013; official 01-Aug-2013)
* Ciprofloxacin Extended-Release Tablets (posted 26-Jul-2013; official 01-Aug-2013)
* Fenofibrate Capsules (posted 26-Jul-2013; official 01-Aug-2013)
* Fenofibrate Tablets (posted 26-Jul-2013; official 01-Aug-2013)
* Hydromorphone Hydrochloride Oral Solution (posted 26-Jul-2013; official 01-Aug-2013)

For details:http://www.usp.org/usp-nf/official-text/revision-bulletins

European patent for Pfizer's Viagra expires - 21st June 2013

Despite extending the patent protection on Viagra **(**sildenafil) in the US until 2020, Pfizer now has to face the effects of

patent expiration in the UK and other countries in Europe.

Pfizer saw global sales of Viagra in 2012 of over $2billion; however half of this came from outside the US. In the UK in 2012, the NHS spent £40.3m on Viagra but they will now turn to generics in order to cut costs.

With over 20 pharmaceutical companies and biotechs ready and waiting to release generic forms of Viagra onto the market, and prices in the UK expected to drop by around 90% - from £10 to less than £1 a pill – Pfizer will have to do whatever they can to maintain sales of the branded drug. So far Pfizer has launched a website to sell Viagra at discounted prices in an attempt to limit the loss of revenue. They may also release their own generic form of Viagra called Sildenafil Pfizer in order to compete with others such as Teva, the largest generic drug company in the world.

Indian state to slash prices of 348 drugs

Tripura becomes the first Indian state, whose government has decided to slash the maximum retail price of 348 essential medicines from August 1 drug-price-india The Tripura government has decided to open a generic medicine counter at the Agartala Government Medical College (AGMC) and banned the hospital from writing the brand names of medicines Related Articles Indian court: HP govt should regulate drug prices Australia temporarily bans 19 synthetic drugs China to expand list of price-controlled drugs China to reduce prices of drugs by up to 20% Singapore: Tripura has become the first Indian state to announce its implementation of the country's health ministry's decision to reduce the maximum retail prices of essential drugs. The Tripura state government has asked the state drug control authority to be vigilant about implementation of this decision to slash the maximum retail price (MRPs) of 348 essential medicines from August 1. Health minister Mr Tapan Chakraborty, said that, "I hope that in time we receive the necessary documents from the Union health ministry so that we can ensure that the price reduction of essential drugs is implemented as per the notification of the national pharmaceutical pricing authority." Further the state government is planning to open a generic medicine counter at the Agartala Government Medical College (AGMC). The hospital has been banned from writing the brand names of the medicines too. The government is in talks with the Rajasthan Generic Medicine Manufacturing Society over supply of adequate number of drugs to Tripura where patients can procure them at a low price.

Ref. Biospectrum

UK considers moving analgesic to restricted drug class

Medscape reports that the UK's Advisory Council on the Misuse of Drugs recently recommended making the analgesic tramadol a "class C drug" because of "concerns about the misuse of tramadol and an increase in the number of deaths" related to use of the medication. The UK "government has accepted the ACMD's recommendation and Crime Prevention Minister Jeremy Browne has launched a public consultation, in conjunction with the Department for Health, on access to tramadol." The department will accept public comments on the pending classification change until Oct. 11.

Six new drugs in clinical development stage: Dr Reddy's

Country's second largest drug maker Dr Reddy's Laboratories has said it is working on six new drugs in different areas, including metabolic disorders and cardiovascular diseases, psoriasis and migraine.

According to a filing with US Securities Exchange Commission, the drug maker said as of March 31, 2013, DRL had 21 active products in the proprietary products pipeline, of which six are in clinical development stage.

"Since repositioning our research activities in the years ended March 31, 2009 and 2010, our proprietary products segment has focused its efforts towards developing drugs to meet key unmet clinical needs. We have built a pipeline of assets that we expect to produce a steady stream of investigational new drugs in the coming years," DRL said.

"As of March 31, 2013, we had 21 active products in our proprietary products pipeline, of which 6 were in clinical development stage," the company stated.

The drugs which are currently in clinical development stage are targeted in the areas of cardiovascular disorders, psoriasis, pain, anti-infective atopic dermatitis/psoriasis and migraine.The new drug research on metabolic disorders/ cardiovascular disorders is in phase-II while the remaining five drugs are in clinical stage, it said.

In FY13, Dr Reddy's invested approximately Rs 767 crore in R&D activities, which accounted for 6.6 per cent of consolidated revenues, against Rs 591 crore in FY12.

This represents a growth of 30 per cent over the previous year, and is mainly attributable to increasing spends on complex molecules and a greater focus on biosimilars and proprietary research, GV Prasad, chairman and CEO DRL, said in the latest annual report.

The clinical trial process can take five to 10 years or more to complete, and there can be no assurance that the data collected will be in compliance with good clinical practice regulations, will demonstrate that the product is safe or effective, or, in the case of a biologic product, pure and potent, or will provide sufficient data to support US Food and Drug Administration approval of the product, DRL said in the SEC filing.

The Indian drug maker also said the US FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk.

Forthcoming Event

Health Camp
At Tarakeswar

Dates:

22nd July, 29th July, 5th August, 12th August 2013

Organizers:

Indian Pharmaceutical Association, Bengal Branch
&
IPA Bengal Pharma and Health Care Trust

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