



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

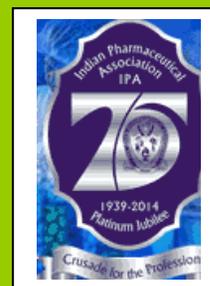
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Regulatory Affairs Division (RAD), IPA



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Editorial

Access to essential medicines is a problem throughout the globe especially in the developing and under developed countries. India is not an exception, where only 35-50 percent of its population has access to essential medicines, though India is the third largest producer of medicines and is exporting to about 170 countries. Experts believe there are several complex reasons behind it. One of them is irrational use of medicines. Prescribing in generic name is considered as one of the important tools for improving rational use of medicines.

In India Central Government, several State Governments and some agencies have instructed the doctors under Govt. sector to prescribe in generic name but unfortunately it has not been strictly implemented.

Though a small fraction of our population is covered by govt. sector health facilities and mostly depends on private health care facilities, it was noticed that recently a few state Governments have taken stringent measures for its implementation. It is expected that it may bring tangible changes in improving the health care system in India.

Dr. Subhash C. Mandal
Editor

Corrections of I.P 2014 has been published by Indian Pharmacopoeia Commission for immediate implementation

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**INDIAN PHARMACOPOEIA COMMISSION
MIN. OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD - 201002**

No. HPC/7035/IP-2014/118-002

Dated 17-10-2014

To,

1. DCG (D) CDSCO, Zonal Offices
2. All State Drug Controllers
3. Members of Scientific Body of the IPC
4. Members of Sub-committee of Scientific Body of the IPC
5. Government Analysts
6. Director of Drug Laboratories
7. IDMA/OPPI/BDMA/FFSAL/Small Scale Industry Associations

ERRATA – 002 for IP 2014

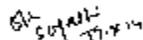
As you are aware that the 7th edition of Indian Pharmacopoeia has become official from 1st April, 2014. Based on scientific inputs, some monographs, appendices needed corrections, accordingly an Errata – 002 is issued containing minor corrections. This is for notice and immediate compliance.

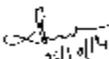
Yours faithfully,


(Dr. G/N. Singh)
Secretary-cum-Scientific Director

Encl:
ERRATA – 002 for IP 2014

CC to: Publication Division to put up on IPC website.


27/10/14


27/10/14

Details are available at www.ipc.gov.in

MCI summons 300 doctors for promoting costly brands of Ahmedabad based Drug Company

The Medical Council of India (MCI) is in the process of scrutinising a complaint revealing names of 300 doctors for illegally promoting

the products of an Ahmedabad based pharma company. According to the complaint, pharma company's brand which are priced 15 per cent to 30 per cent higher than those of well-established companies like Aristo, Alkem, Zydus, Cipla, Ranbaxy, Sun and Cadila are

prescribed by doctors in lieu of gifts or alternative means of bribe.

A group of doctors were circulated a proforma by the MCI to answer questions based on the complaint. Some of the doctors have appeared before MCI's ethics committee and the rest have yet to appear along with their explanations. As per an official, scrutiny is in the preliminary stages and the chargesheet would be made only when the responses from doctors are received. Doctors have been asked to give a response in writing. This, however, may take some time.

The complainant claimed that the firm was adding the cost of bribes to its products, forcing the patient to pay up. The complainant has sought an Income Tax probe since doctors who allegedly accepted these bribes were also found evading income tax rules. It has also been alleged that the doctors were violating basic norms and that the turnover of the pharma company had grown from zero to Rs.400 crore in just five years.

According to the complaint, the Ahmedabad-based pharma company has been paying doctors lakhs of rupees as well as gifting them cars and flats and sponsoring family foreign trips in return for prescribing its medicines even though cheaper alternatives from better known companies are available.

Of the 150 doctors summoned to appear at the last meeting of the ethics committee, 109 appeared. About 135 are left and they have been asked to appear at the next meeting of the committee in December. According to the rules, they have to be given three chances.

The letter asking doctors to appear before the committee states that the concerned doctor should bring his/her ITR, bank statement for the last three years, passport in original, as well as a set of photocopies of the said documents. The letter also states that if the doctor fails to appear on the above said date and time, the ethics committee will proceed for ex parte decision against him/her

on the basis of available records in the council office.

According to the complaint, one of the ways in which the firm would bribe doctors would be by paying lakhs of rupees for running advertisements on a TV installed in their clinics.

Ranbaxy sues FDA over revoking approvals for Nexium, Valcyte copies

(Reuters) - Ranbaxy Laboratories Ltd has sued the U.S. Food and Drug Administration (FDA) for revoking approvals granted to the Indian firm to launch copies of two drugs including AstraZeneca Plc's heartburn pill Nexium, court documents showed.

The FDA told Ranbaxy this month that it believed its decisions to grant the company tentative approvals for copies of Nexium and Roche AG's antiviral Valcyte were "in error", after it found that Ranbaxy's plants at the time were not compliant with the FDA's manufacturing quality standards.

The agency also stripped Ranbaxy of a six-month market exclusivity on the launch of generic Valcyte.

In the suit filed in the District Court for the District of Columbia, Ranbaxy said the FDA's move violated constitutional rights, exceeded the agency's statutory authority, and was "arbitrary, capricious, and otherwise contrary to law."

"FDA has no power to correct an alleged mistake it made six years ago," Ranbaxy said in the court filing dated Nov. 14 and seen by Reuters on Tuesday.

Ranbaxy, which is being acquired by larger local rival Sun Pharmaceutical Industries Ltd for \$3.2 billion, has been hit by a series of regulatory sanctions in the past year due to poor production practices at its India-based plants.

The company, which was expected to hugely benefit from the launch of the generic versions of the two drugs, has said it was working on resolving issues at the [India](#) plants, all of which are banned from exporting to the United States, its largest market.

Sandy Walsh, a spokeswoman for FDA in Washington, said the agency does not comment on pending litigation. Ranbaxy did not immediately respond to a request for comment.

Analysts had expected generic Nexium to contribute about \$150 million to Ranbaxy's revenue in the first six months of market exclusivity, while Valcyte was expected to bring in \$40 million to \$50 million.

After pulling Ranbaxy's tentative approvals, the FDA granted final approval to another

Indian generic drugmaker Dr Reddy's Laboratories Ltd and U.S.-based Endo International Plc to launch copies of Valcyte. Ranbaxy in the lawsuit also requested the court to restrain FDA from approving any other generic versions of Valcyte or Nexium until its six-month exclusive periods on the launch of the drugs has ended.

Ref.

<http://www.reuters.com/article/2014/11/18/u-s-ranbaxy-lab-fda-lawsuit-idUSKCN0J21EH20141118>

IPA's Platinum Jubilee celebration by IPA, Bengal Branch on 15th & 16th November 2013 at Kolkata



From L to R: Ms. Agnimitra Paul, Dr. Subhash C. Mandal, Mr. Kaushik Desai, Prof. Samir K. Brahmachari, Mr. Pankaj R. Patel, Dr. C.M.Ghosh, Dr. Sujan Chakraborty, Mr. Debashis Dutta



From L to R: Ms. Agnimitra Paul, Dr. Subhash C. Mandal, Mr. Kaushik Desai, Prof. Samir K. Brahmachari, Mr. Pankaj R. Patel, Dr. Sujan Chakraborty, Dr.



Prof. Samir K. Brahmachari conferring Acharya P.C. Ray Memorial Award to Mr. Pankaj R. Patel on behalf of IPA, Bengal Branch



Mr. Kaushik Desai inaugurating tabloid bearing messages against Microbial resistance



From L to R: Dr. D.K.Mitra, Dr. G.P.Mohanta, Mr. Kaushik Desai and Dr. P.K.Mukherjee



A section of audience of the workshop entitled "Redefining the Role of Pharmacists in Health Care System" held on 16th Nov.