# Drug Information Bulletin

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**Content**



## *Editorial*

*Recent development in Maharashtra of lodging FIR against some pharmacists, who are misusing their registration, is an eye opener to the entire regulatory system of India. This practice of pharmacists is rampant in India irrespective of state or region affecting the quality of health care.*

*Drugs are being dispensed by a person other than a pharmacist in a retail pharmacy, because of absence of the pharmacists, may leads to dispensing error and lack of adherence. Reasons for absence was mentioned by different quarters are – paucity of pharmacists. This reason is no longer valid as there is no dearth of pharmacist as more than one lakhs of Pharmacists are coming out from more than 1000 Pharmacy institutions every year. Huge number of unemployed pharmacist is ready to take up the job to serve the society in our country. But their expertise is not utilized properly. The policy makers and the regulators require serious thinking to utilize their expertise for the benefit of the health of the people.*

*The main reason is lack of awareness amongst the society about the important role played by the pharmacist in the health care system, retail shop owners are not ready to share a fraction of their profit to pay the pharmacists and mostly lack of seriousness of the regulators. Regulators have their plea like- having no sufficient numbers of officers, external pressure not to implement the law properly etc.*

*Recent developments in the Maharasthra FDA proved that inspite of several impediments it is possible to implement existing regulations to ensure service of the pharmacist for better health care outcome.*

*It is expected that all stake holders will be serious in this issue and ensure pharmaceutical services for better health care to the nation.*

## Maharashtra FDA files FIRs against pharmacists for doing dual employment

In order to deter pharmacists from selling their licenses to illegally run drug stores and taking up employment elsewhere, the Maharashtra Food and Drug Administration (FDA) has filed FIRs against 10 pharmacists in different cases of cheating and impersonation under different sections of CrPC of IPC across Maharashtra.

Three pharmacists from Mumbai, two from Nanded, one from Pinjar, two from Thane and two from Nashik have been booked under section 416 for impersonation, 420 for cheating and 199 for violating the affidavit of oath (false statement made in any declaration which is by law receivable as evidence).

The state FDA has also come across rampant violation of Drugs and Cosmetics (D&C) Act as several chemist shops in the state despite their licenses being canceled were found to be operating and dispensing drugs without any qualified pharmacist. Around 2500 cancellations and 1400 suspensions have been made across Maharashtra over a period of seven months due to absence of pharmacists at drug counters.

Informs Sanjay Kale, joint vigilance commissioner, Maharashtra FDA, "We found that suspensions and cancellations have failed to make any impact as the drug store owners after getting penalised succeed in getting a stay on the matter from the appellate authority and continue with their illegal business."

"This is the outcome of the fact that there is a rising trend of qualified pharmacists selling their licenses to chemist shops and taking up dual employment either as a Medical Representative in a pharma company or as a faculty in an educational institution," he explains.

Inspections done by the state FDA across Maharashtra over a period of seven months reported absence of pharmacists in 95 per cent of shops and in five per cent cases due to other reasons.

Chemist shops across Maharashtra has been facing a massive crackdown by the state drug regulator in the past several months over absence of pharmacists and not maintaining proper billing records.

## Motsoaledi: Big pharma's 'satanic' plot is genocide

Health minister Aaron Motsoaledi is livid about a pharmaceutical company campaign he says will restrict access to crucial drugs.

Health Minister Aaron Motsoaledi has accused a group of multinational pharmaceutical companies active in South Africa of conspiring against the state, the people of South Africa and the populations of developing countries, and of planning what amounts to mass murder.

"I am not using strong words; I am using appropriate words. This is genocide," Motsoaledi told the Mail & Guardian on Thursday, in response to a plan he described as a conspiracy of "satanic magnitude" - a plan he called on all South Africans to fight "to the last drop of their blood".

The plan in question is a nine-page document obtained independently this week by both the M&G and the department of health, blandly titled Campaign to Prevent Damage to

Innovation from the Proposed Draft National IP Policy in South Africa.

But the contents have Motsoaledi spitting fire and nongovernmental organisations (NGOs) deeply concerned, and its disclosure will likely lead to open war between the various parties - a conflict that all sides believe will have inevitable consequences for the long-term health and wealth of a significant fraction of the world's population.

[From South Africa's 'Mail & Guardian', copied as Fair Use]
For details:
http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide

## Medical Technology Assessment Board to be set up to assess medical technologies

The Department of Health Research (DHR) will set up a Medical Technology Assessment Board (MTAB) to evaluate all kinds of existing and new medical technologies, in line with the recommendation of the Planning Commission working group for the current Five Year Plan.

The MTAB will aim to encourage the process and finalize the development of standardized cost effective interventions that will reduce the cost and variations in patient care, expenditure on medical equipment indirectly affecting the cost of patient care, overall cost of medical treatment, reduction in out of pocket expenditure of patients and streamline the medical reimbursement procedures. Sources said the steps have already been taken to set up the Board and put into action at the earliest.

The need to establish such a board was discussed and recommended by 12th Plan Working Group on Health Research. Considering the recommendations, the Government recognized the urgent requirement of Medical Technology Board in India and therefore, has decided to set up MTAB for evaluation and appropriateness and cost effectiveness of the available and new health technologies in the country, sources added.

The government would also hold consultation with stakeholders like technology generators, industry, regulators, economists, user groups and experts knowledgeable about similar models from UK, Canada, Australia, Thailand etc. The MTAB will be a part of the overall regulatory/promotional structure being established in the DHR to accelerate indigenous production of health products/instruments/medical devices that are vital for providing cost effective healthcare.

As part of this initiative, an MoU has just been signed between the DHR and the National Institute of Clinical Excellence (NICE), UK. Follow-up action is being initiated to identify areas for collaboration for exchange of knowledge on procedures used by NICE for regulatory arrangements in UK in the first phase. An Apex Advisory Committee to set up the board has been constituted and started functioning, sources added.

A Parliamentary panel has also called for early action for setting up MTAB which, the panel said, would go a long way in promoting development of indigenous medical technologies. “The MTAB is proposed to be assigned with very critical activities. However, the reply of the Department does not indicate any time-frame within which the MTAB would become functional. A timeline may be

fixed for completing the task," the panel said.

## EU drug approvals rose substantially in 2013

The European Union approved 81 new drugs last year, a 42% increase over the number in 2012, according to data from the European Medicines Agency. The EMA noted that companies that requested and followed the agency's scientific advice had a 90% approval rate compared with 30% for companies that did not. By contrast, the U.S. FDA approved 27 new drugs in 2013, although some experts anticipate increased U.S. drug-approval numbers in the future.

Ref. Medscape (free registration)

## Drug makers find interest in RNA drug development

Advances in RNA drug delivery and the approval of Kynamro, the first RNA-based drug from Isis Pharmaceuticals and Genzyme, are helping RNA drug firms attract more development partners. In the space of less than one week, Moderna Therapeutics, Santaris Pharma and Alnylam Pharmaceuticals announced deals worth more than a total of $1 billion. "These companies are showing that genetically targeted RNA-based therapies are a real and valid treatment modality," an analyst said.

Ref. Chemical & Engineering News

## Chinese herbal medicine helps control onset of type 2 diabetes

Patients with pre diabetes who took a combination of traditional Chinese herbal medicines were 32% less likely to acquire type 2 diabetes than those given a placebo, according to a study of 389 people in China. The trial was reported in the Journal of Clinical Endocrinology & Metabolism. Subjects took the herbs three times a day before meals. "Traditional Chinese herbs may offer a new option for managing blood sugar levels, either alone or in combination with other treatments," said the University of Chicago's Dr. Chun-Su Yuan, an author of the study.

Ref. Diabetes.co.uk (U.K.)

## Gimps of Health Camp at Gangasagar organized by IPA, Bengal Branch & IPA Bengal Pharma & Health Care Trust



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