



# Drug Information Bulletin

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**Regulatory Affairs Division (RAD), IPA**

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## *Editorial*

In the recent past a few Pharmacy Councils have taken some steps against violations like- dispensing by a person other than a pharmacist, engaging a Pharmacist more than one place at a time is a silver line, when profession is crying for stringent implementation of the Pharmacy Act and Pharmacy Practice Regulation -2015 (PPR-2015).

Engagement of Pharmacist in serving the prescription of a registered practitioner has been made mandatory by an amendment of sec 42 of Pharmacy Act 1940, in the year of 1984 and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year. Dispensing by pharmacists is mandatory worldwide for better health care services.

Promulgation and notification of Pharmacy Practice Regulation 2015 in the month of January 2015 by Pharmacy Council of India (PCI) is a landmark event in the history of Pharmacy Profession in India, which will certainly help in giving proper shape to the unorganized state of Pharmacy Practice in India. In the present regulation the Pharmacy Practice is well defined and the same has set up certain regulation to regulate the same.

Indian Pharmaceutical Association has requested all State Health Secretaries and all state Drugs Controllers time and again for proper implementation of PPR-2015, but there is hardly any positive result. Hope all state pharmacy councils and all state/UT drugs control organizations will be more positive for stringent implementation of this regulation for the interest of the health of the people.

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## **Important resolution of 82<sup>nd</sup> meeting of Drug Technical Advisory Board(DTAB)**

CONSIDERATION OF THE PROPOSAL TO REPLACE THE WORDS “CHEMISTS & DRUGGISTS” BY “PHARMACY” IN RULE 65(15)(b) & RULE 65(15)(c) OF THE DRUGS AND COSMETICS RULES, 1945

The Board was apprised that, representation was received to remove the words “Chemists and Druggists” from Rule 65(15)(b) of the Drugs and Cosmetics Rules and replace it with “Pharmacy” in order to give trade of medicines a better professional recognition. As per Rule 65(15)(b) of the Drugs and Cosmetics Rules, the description “Chemists and Druggists” shall be displayed by those licensees who employ the services of a Registered Pharmacist but who do not maintain a “Pharmacy” for compounding against prescriptions. Similarly in Rule 65(15)(c) of the Drugs and Cosmetics Rules, the description “Pharmacy”, “Pharmacist”, “Dispensing Chemist” or “Pharmaceutical Chemist” shall be displayed by such licensees who employ the services of a Registered Pharmacist and maintain a “Pharmacy” for compounding against prescription. However, in the current scenario, the compounding of medicines by registered pharmacists hardly exists due to capable pharma industry in place in the country. The term ‘Chemists and Druggists’ was coined in 1945 and is quite old and has lost relevance and also, at present the word ‘drug’ is looked upon as more clandestine and as addiction for chemicals, hence not suit to refer a professional pharmacist. It was requested to amend the Rule 65(15)(b) and Rule 65(15)(c), so that medical shops may be called Pharmacy as this is in concurrence with the international practice of calling a medical shop selling medicines by this name and also provide an identity and sense of value to the practicing pharmacist at the outlets. This matter was deliberated in 55th DCC meeting held on 31.01.2019 & 01.02.2019 and recommended

to replace the words ‘Chemists and Druggists’ by ‘Pharmacy’ in Rule 65(15)(b) of the Drugs and Cosmetics Rules, 1945. Accordingly, the proposal is placed before the DTAB for deliberation. DTAB deliberated the matter and agreed to amend Rule 65(15) of the Drugs and Cosmetics Rules, 1945 to provide that all licensees in Form 20/Form 21, they should display the word “Pharmacy”.

For details: [www.cdsc.gov.in](http://www.cdsc.gov.in)

## **Greater transparency, fairer prices for medicines ‘a global human rights issue’, says UN health agency**

While developing countries have long struggled with the price of medicines, today’s costs have rendered it a world-wide challenge, and the key topic of concern at a global medicines forum in South Africa, co-sponsored by the World Health Organization (WHO).

“This is a global human rights issue”, said WHO Assistant Director-General for Medicines and Health Products Mariângela Simão on Saturday at the WHO Forum on Medicines in Johannesburg. “Everyone has a right to access quality healthcare”.

The forum on fair pricing and access to medicines provided a discussion platform for governments, civil society organizations and the pharmaceutical industry to identify strategies to reduce prices and expand access for all.

It also called for greater transparency around the cost of research, development and production of medicines, to allow buyers to negotiate more affordable prices.

According to WHO, the price of out-of-pocket medicines each year has pushed 100 million people into poverty. Moreover, health authorities in high-income countries are increasingly having to ration medicines for cancer, hepatitis C and rare diseases. And the problem extends to older medicines whose patents have expired, such as insulin for diabetes.

“Medical innovation has little social value if most people cannot access its benefits,” stressed Ms. Simão.

A 2017 WHO report showed that the cost of producing most medicines on its [Essential Medicines List](#) was a small fraction of the final price.

Some forum delegates noted that a lack of transparency around prices paid by governments actually translates into many low- and middle-income countries paying more for certain medicines than wealthier countries do.

Positive steps forward:

Among other successful examples of countries’ collaboration around achieving more affordable medicine prices, information-sharing between the so-called Beneluxa network – Belgium, Netherlands, Luxembourg and Austria – was cited as having yielded promising results, as was a bulk-rate discount when several regional countries purchased medicines as a block.

The forum highlighted WHO’s database on vaccine markets and shortages, called [MI4A](#), as a useful tool to achieve competitive vaccine prices. It also pointed out that some European countries have been sharing policies to expand access to medicines through the WHO-supported Pharmaceutical Pricing and Reimbursement Policies ([PPRI](#)).

Industry bodies at the forum supported access to medicines for all, and recommitted to the [2030 Agenda](#) for Sustainable Development, which calls for private partnerships to address global challenges, such as access to medicines.

WHO announced that over the coming weeks, it will launch a public consultation online to collect views from relevant participants on what actually constitutes a fair price.

### **EMA panel approves HIV drug combo**

The European Medicines Agency’s Committee for Medicinal Products for Human Use has granted marketing approval to

GlaxoSmithKline’s Dovato, or dolutegravir and lamivudine, for the treatment of adult patients with newly diagnosed HIV infection. In studies, Dovato showed the same tolerability and efficacy as a standard three-drug regimen in suppressing HIV.

Ref.: [Reuters](#)

### **'Fingerprint database' could help pinpoint environmental cancer causes**

Scientists from King’s College London and Cambridge University have a catalogue of DNA mutation ‘fingerprints’ that could help doctors pinpoint the environmental culprit responsible for a patient’s tumour.

The database can even show some of the fingerprints left in lung tumours by specific chemicals found in tobacco smoke.

Up until now, scientists have had only a limited number of tools for working out the cause of an individual’s tumour. As it is now possible to study the entire human genome very rapidly, scientists have been able to find all the mutations in a patient’s cancer, and see patterns – or ‘mutational signatures’ – in these tumours.

The study, published in the journal *Cell*, showed that the researchers had developed a comprehensive catalogue of the mutational signatures caused by 41 environmental agents linked to cancer, and in the future they hope to expand it further, using similar experimental techniques, to produce an encyclopaedia of mutation patterns caused by environmental agents.

“Mutational signatures are the fingerprints that carcinogens leave behind on our DNA, and just like fingerprints, each one is unique,” said Dr Serena Nik-Zainal from the University of Cambridge. “They allow us to treat tumours as a crime scene and, like forensic scientists, allow us to identify the culprit – and their accomplices – responsible for the tumour.”

The researchers also identified the fingerprints left behind by common chemotherapy drugs, some dietary chemicals and some present in diesel exhaust fumes.

For details:

<http://www.pharmatimes.com/news/fingerp rint database could help pinpoint environ mental cancer causes 1284944>

### **Combination NRT linked to higher smoking quit rate than single forms**

Researchers in a Cochrane review analysed 63 trials comprising more than 41,000 patients and found that a combination of nicotine replacement therapies increased the chance of the patient stopping smoking altogether.

Using combination nicotine replacement therapy (NRT), such as a patch plus a gum or lozenge, can increase the chances of successfully stopping smoking by 15% to 36%, compared to using single-form NRT, results of a Cochrane review have revealed.

The researchers searched the Cochrane Tobacco Addiction Group trials register and trial registries for papers mentioning NRT in the title, abstract or keywords. Trials that did not assess smoking cessation as an outcome and had a follow-up of less than six months were excluded.

**For details:** The Pharmaceutical Journal, 25<sup>th</sup> April 2019

### **FDA Maharashtra to curb Homoeopaths performing cross-pathy**

The state Food and Drug Administration (FDA) will initiate action against homoeopathy practitioners who have come under the lens of the FDA for allegedly

The FDA officials have confirmed that letters have been sent to around 25 homeopaths seeking an explanation over their large stocks of allopathic drugs. The matter came to the fore after an audit of bills that was conducted in March when the drug regulator had come across several 'big' purchases of allopathic medicines by homeopathy practitioners from wholesalers.

Following the audit, the FDA officers enquired the homeopathic practitioners regarding the purchase of alternative medicines, how they were stored and dispensed.

The FDA commissioner Dr Pallavi Darade said, "Acting on tip-off, we began the exercise but for now this drive is unlikely to be extended beyond Dombivli. We are investigation regarding the storage of these cross-pathy (prescribing homoeopathy and ayurvedic drugs along with allopathy medicines) medicines, which is against norms of the Drugs and Cosmetics Act."

Ms Darade further added, "We've found that the homeopathy practitioners were found handing out loose medicines and storing allopathy drugs in huge quantities. There was anything between four and 10 bills for each doctor."

The FDA exercise was also meant to check if the wholesalers were fudging records in supplying the medicines to these people.

Ref.: The Asian Age



### **News**

Dr. V.S.V. Rao with FIP President –Mr. Dominique Jordan and FIP CEO Dr. Catherine Duggan during-

## **1<sup>st</sup> Regional Congress of FIP**

held at Amman, Jordan

During 25-26 April 2019

### **DISCLAIMER:**

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.