



# Drug Information Bulletin

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## *Editorial*

Framing and notification of Pharmacy Practice Regulation 2015 in the month of January 2015 is a landmark event in the history of Pharmaceutical 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. *Practice in Pharmacy is existing in India since long back, with a different name and structure and it has got a regulated structure since implementation of Pharmacy Act 1948. 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.* In the mean time a few states like Kerala have implemented the same through notification by the state Government. Indian Pharmaceutical Association is pursuing all state Governments/ UTs for its implementation by sending memorandum to the Health Secretaries and Drugs controllers of all states/UTs, but the response from the authorities is not so encouraging. Hope all professional organizations will take up the issue with the concerned authorities, so that all state governments implement the act immediately for improving the health care outcome.



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## **Patent Working Information Is Not “Confidential”: Delhi HC**

The Delhi High Court, on Wednesday, made it clear that patent working information is not “confidential” and has to be mandatorily submitted by all patentees.

The Court was hearing a Writ Petition filed by Prof. (Dr.) Shamnad Basheer who has alleged non-compliance with the provisions of Patents Act, 1970 on the part the Controller General of Patents. The Petition demands that the authorities be directed to enforce the statutory obligations under the Act. In addition, it also seeks a direction to constitute a committee for examining the present format for filing of "Patent working" documents as prescribed by Form-27.

During a recent hearing, Mr. Basheer pointed out serious lapses in the filing of Form 27 by various patentees. Form 27 filings are meant to indicate how patentees have, or have not, worked the patent to the public benefit. He alleged that even those who had filed such documents had submitted only scanty information. He further contended that despite the failure of the patentees to comply with such requirements, no action had been taken against them.

In this regard, Mr. Basheer drew the Court’s attention to the Annual Report 2012-13 submitted by the Office of the Controller General of Patents. According to the Report, while 43,920 patents were issued during the year 2012-13, returns as prescribed under Form-27 have been received only in 27,946 cases, out of which only 6,201 patents were found to have been worked by the patentees. He also submitted an RTI response to support his claim that no action had been initiated for non-submission of Form-27.

Besides, Mr. Basheer pointed out several instances of such lapses. He submitted that NATCO Pharma, that was granted a compulsory license over an important anti cancer drug, did not disclose as to how it was operating the license. This is despite the fact that the Act requires such reporting on working of patents

even from licensees. In fact, the compulsory licensing order had mandated that NATCO submit all information pertaining to quarterly sales. Ericsson had also, in one of its forms, refused to disclose licensing details citing “confidentiality” or trade secrecy. No action has, however, been taken on such violations of the provisions.

On Wednesday, the Court largely agreed with the contentions put forth by Advocates Sai Vinod and Abhimanyu Bhandari, who are representing Prof. Basheer.

The Bench comprising Acting Chief Justice Gita Mittal and Justice C. Hari Shankar then observed, “It is pointed out that so far as the grant of patents are concerned, information in regard thereto is available on the website of the Patents Office. All that the patentees submitting Form-27 are required to submit, is the details of the licenses and sublicenses. This information certainly cannot be termed “confidential” and therefore, the Patents Office has to treat such suppression as failure to comply with the requirements of Section 146 of the Patents Act, 1970 and to take action against the patentees who do not furnish the required information.”

The Court further noted that the petition has been pending since 2015 and that it does not have any information as to whether there has been a change in the manner of compliance since then. It, therefore, allowed Mr. Amit Mahajan, who was appearing on behalf of the Central Government and the Controller General, to inform the Court about the action taken against patentees for such non-compliance.

**Citation:** Shamnad Basheer vs Union of India & Ors., High Court of Delhi, WP (C) 5590/2015, D/d 10.01.2018

Source: Drugs Contro.org

### **Safety issues:**

#### **Chlorhexidine Risk of serious allergic reactions**

The Health Sciences Authority (HSA) has informed health-care professionals about the outcome of its review on the known risk of allergic reactions, including anaphylactic reactions, with

chlorhexidine-containing products. Chlorhexidine is a broad-spectrum antiseptic which is effective against gram-positive and gram-negative bacteria on the skin and is widely used to reduce the risk of bacterial infection. This review was conducted following recent international safety alerts regarding serious allergic reactions reported with antiseptic products containing chlorhexidine. The review concluded that there was no significant increase in the total number of adverse event reports associated with chlorhexidine hypersensitivity received by the HSA over the past years. Fifteen reports of anaphylactic reactions related to chlorhexidine were identified over a span of 36 years (1981 to 2017). Health-care professionals are advised to inform patients to stop using the product and seek immediate medical attention if they experience symptoms of a serious allergic reaction, such as wheezing, swelling of the face, or severe rashes.

Reference: Product Safety Alerts, HSA, 29 September 2017 (<http://www.hsa.gov.sg/>) (See Page 5 and WHO Pharmaceuticals Newsletters No.2, 2017: Rare but serious allergic reactions in the USA and No.3, 2016: Serious allergic reactions in Canada)

### **Finasteride Risk of depression and suicidal thoughts**

L'ANSM has informed patients and health-care professionals of the risk of depression and suicidal thoughts with the use of finasteride. L'ANSM recommends treatment interruption and additional monitoring should be considered if patients experience a change in mood during treatment with finasteride. Cases of depression and, more rarely, suicidal ideation have been observed in men treated for hair loss with finasteride 1 mg. The risk of depression is also associated with finasteride 5 mg treatment for benign prostatic hypertrophy. Finasteride at a dose of 1mg (Propecia® and generics) is indicated for the treatment of androgenic alopecia and, at a dose of 5mg (Chibro-Proscar® and generics), is indicated to treat and control benign prostatic hyperplasia. Since the commercialization of Propecia®, psychiatric adverse effects have been reported, suggesting a possible link between

finasteride and depression or suicidal thoughts. The risk of depression is also mentioned in the Summary of Product Characteristics (SmPC) and package leaflet of ChibroProccar®. Following the latest European safety report on these medicines, the EMA has requested an amendment to the information documents for all 1 mg and 5 mg medicinal products to warn health professionals and patients about the risk of mood changes, suicidal ideation and depression. Finasteride treatment should be discontinued in the presence of any psychiatric symptoms. The ANSM also reminds health care professionals that adverse drug reactions related to decrease in libido, erectile dysfunction and ejaculation disorders can persist after stopping the drug.

Reference: Point d'information, ANSM, 26 October 2017, France ([www.anism.sante.fr](http://www.anism.sante.fr))

### **Gabapentin Risk of severe respiratory depression**

The MHRA has stated that gabapentin (Neurontin®) has been associated with a rare risk of severe respiratory depression even without use of concomitant opioid medicines. Gabapentin is an anti-epileptic drug indicated for: partial seizures with and without secondary generalisation peripheral neuropathic pain such as painful diabetic neuropathy and postherpetic neuralgia in adults. In the United Kingdom, there have been 50 reports of respiratory depression or dyspnoea associated with gabapentin between 19 February 1996 and 1 September 2017. Of these cases, 17 report opioids as co-suspect or concomitant medications. The MHRA has advised healthcare professionals to be aware of the risk of central nervous system (CNS) depression, including severe respiratory depression, with gabapentin and to consider whether dose adjustments might be necessary in patients at higher risk of respiratory depression, including elderly people, patients with compromised respiratory function, respiratory or neurological disease, or renal impairment, and patients taking other CNS depressants.

Reference: Drug Safety Update, MHRA, Volume 11, issue 3: 2, October 2017 ([www.gov.uk/mhra](http://www.gov.uk/mhra))

## India proposes government support for APIs made in-country

India's Department of Pharmaceuticals proposed in a draft policy released last week to reduce the country's dependence on imported active pharmaceutical ingredients by favoring purchases of locally produced APIs. The draft report also suggested exempting locally made APIs from price caps for five years.

Ref. [In-Pharma Technologist](#)

## Development on availability of TB drug

Japan's Otsuka Pharmaceutical licensed its multidrug-resistant tuberculosis medicine delamanid to a subsidiary of Mylan in India. Initially, Mylan will provide 400 courses of treatment with delamanid for free over the next six months; after that, a six-month treatment course would cost \$1,700.

Ref. [The Economic Times \(India\)](#)

## Drugmakers exploit regulatory loopholes to protect patents

Regulatory loopholes allow branded-drug makers to prevent competition, costing consumers billions of dollars each year, writes antitrust attorney David Balto, former policy director at the

Federal Trade Commission. Drugmakers abuse the FDA's Risk Evaluation and Mitigation Strategy program, citizen petitions and the Hatch-Waxman Act, and product-hopping is used to prevent the substitution of lower-cost alternatives, Balto writes.

Ref. [The Hill](#)

## Specialty-drug prices continue rising

Retail prices for some of the most commonly prescribed specialty drugs rose by 9.6% from 2014 to 2015, while prices for branded drugs rose 15%, and generic-drug prices dropped by 19.4%, according to an AARP analysis of data from Truven Health Research Databases. The average annual cost of specialty drugs studied was \$52,486, compared with \$5,800 for traditional drugs and \$523 for generics, the report showed.

Ref. [MedPage Today \(free registration\)](#)

## Forthcoming Event:

### Refresher course to registered Pharmacists

As per sec 4.2 of the Pharmacy Practice Regulations, 2015 refresher course will be provided by IPA- Bengal Branch. Details will be available soon.



IPA-Bengal Branch team receiving Outstanding branch award -2017 at Chandigarh



Health Camp at Gangasagar organized by IPA-Bengal Branch & IPA Bengal Pharma & Health Care Trust

## 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.