



# Drug Information Bulletin

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*Indian Pharmaceutical Association*

*Bengal Branch*

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



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## Editorial

Recent Order of Guahati High Court dated 30.08.2019 on a PIL no. 47/2019 and subsequent direction of the Commissioner of Food Safety & Drug Administration, Assam is a land mark decision in the history of health care of India. In order to comply the order of the Guahati High Court the commissioner directed Drug Control officers to ensure full time presence of Pharmacists in retail sale of medicines. Though presence of pharmacists is mandatory as per the Pharmacy Act 1948 and the Drugs and Cosmetics Act 1940 and rules 1945 absence of pharmacists is a common feature throughout India.

The main concern of this order is to (a) stop selling of medicines by the pharmacies without the presence of registered Pharmacists, (b) stop dispensing all categories of Medicines by the Pharmacies by taking restricted licences, (c) necessity of taking appropriate step to regulate the mandate of the Pharmacy Act 1948 as well as Drug and Cosmetics Act 1940 and rules 1945 which are of vital interest to the society.

It is very unfortunate that High court has to intervene to implement the existing Acts and rules, which proves the inefficiency of the existing drug regulatory system in our country.

Hope this order will be a shot in the arm to the existing regulatory system to ensure patient safety.

**Dr. Subhash C. Mandal**

**Editor**

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Direction of Commissioner of Food Safety and Drug Administration, Assam to the Drug Control officers to ensure service of Pharmacist in Pharmacies in the interest of public health and patient safety

GOVERNMENT OF ASSAM  
OFFICE OF THE COMMISSIONERATE OF FOOD SAFETY  
DISPUR, GUWAHATI-6

25/11/19

No. Food Safety/PS/PA/1/2019/26 Dated Dispur, the 20<sup>th</sup> November 2019.

To : 1. The Joint Drug Controller (I/c),  
O/o the Director of Health Services, Assam,  
Hengerabari, Guwahati-36.

2. All Drug Inspectors of Assam

Sub : Hon'ble Gauhati High Court's Order dated 30/08/2019 and  
Reference Case No. PIL.47/2019 - direction for the greater  
interest of public health and patient safety.

- You are to conduct enquiry in the pharmacy premises of the State of Assam in to the ongoing violation of the provisions of Pharmacy Act 1948 as well as Drugs and Cosmetics Act 1940 and Rules 1945.
- To cancel the drugs licenses and stop in running Pharmacies for retail sale of Medicines without full time presence of Pharmacists.
- To cancel/suspend the drug licence of Restricted Premises pharmacies for violating the provisions of the Drug and Cosmetics Act 1940 and rules, 1945.

The main concern here is to stop (a) selling of medicines by the pharmacies without the presence of Registered Pharmacists, (b) dispensing all categories of Medicines by the Pharmacies by taking Restricted Drug Licence, (c) necessity of taking appropriate step to regulate the mandate of the Pharmacy Act, 1948 as well as Drug and Cosmetics Act, 1940 and Rules, 1945 are vital interest to the society.

All are directed to act as above and report compliance within a short time.

(Dr. Chandrima Baruah, IAS)  
Commissioner of Food Safety & Drug Administration, Assam  
Dispur, Guwahati-6

Memo No. Food Safety/PS/PA/1/2019/26-A Dated Dispur, the 20<sup>th</sup> November, 2019.  
Copy to:

The Principal Secretary to the Govt. of Assam, Health & Family  
Welfare Department, Dispur, Guwahati-6

Commissioner of Food Safety & Drug Administration, Assam  
Dispur, Guwahati-6

## **New Drug: Acalabrutinib capsules for oral use**

First approved in U.S in the year of 2017 under the brand name of Calquence.

**INDICATIONS AND USAGE:** Acalabrutinib capsule is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. (1) This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**DOSAGE AND ADMINISTRATION:** Recommended dose is 100 mg orally approximately every twelve hours;• swallow whole with water and with or without food. Advise patients not to break, open, or chew capsules.

• Manage toxicities using treatment interruption, dose reduction, or • discontinuation.

**DOSAGE FORMS AND STRENGTHS:** Capsules: 100 mg.

**CONTRAINDICATIONS:** None.

**WARNINGS AND PRECAUTIONS:** Hemorrhage: Monitor for bleeding and manage appropriately. • Infections: Monitor patients for signs and symptoms of infection and• treat as needed. Cytopenias: Monitor complete blood counts monthly during treatment. • Second Primary Malignancies: Other malignancies have occurred in• patients, including skin cancers and other carcinomas. Advise patients to use sun protection. Atrial Fibrillation and Flutter: Monitor for atrial fibrillation and atrial • flutter and manage as appropriate.

**ADVERSE REACTIONS:** Most common adverse reactions (reported in  $\geq 20\%$  of patients) were: anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising.

**DRUG INTERACTIONS:** CYP3A Inhibitors: Avoid co-administration with strong CYP3A• inhibitors. Dose adjustments may be recommended. CYP3A Inducers: Avoid co-administration with strong CYP3A• inducers. Dose adjustments may be recommended. Gastric Acid Reducing Agents: Avoid co-administration with proton• pump inhibitors (PPIs). Stagger dosing with H2-receptor antagonists and antacids.

**USE IN SPECIFIC POPULATIONS:** Lactation: Advise women not to breastfeed.

**Status in India:** CDSCO approved on 18.10 2019 Acalabrutinib 100mg capsules for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

### **30% Cap on trade margins will reduce prices of nearly 80% of formulations**

The domestic drug industry and trade have agreed to the government's proposal to cap trade margins for all medicines outside price control at 30%, a move that will reduce the prices of nearly 80% of formulations. A consensus to this effect was reached at a recent meeting between the drug pricing regulator, pharma lobby groups and industry associations, said people present at the meeting. The 30% cap on trade margins was preferred over other proposals such as imposing a flat 100% trade margin on all medicines, including those within price control.

The move is likely to hit big pharma companies with generic divisions, such as Sun Pharma, Cipla and Lupin, as they will have to reduce the maximum retail price (MRP). Since the margins of stockists and retailers will be significantly squeezed, the lobby groups for these segments may ask manufacturers to compensate them for the loss. In 2013, when many non-scheduled drugs were brought under price control, stockists and retailers had forced manufacturers to continue to pay them a minimum 30% margin against the stipulated 24% for price-controlled drugs. The proposed margin cap will have an impact on a wide range of pharmaceuticals, ranging from vitamin D supplements to antibiotics. Non-scheduled drugs, or formulations outside price control, account for Rs 10,000 crore of sales in the Rs 1-lakh-crore Indian drug market.

"The Indian Pharmaceutical Alliance, IDMA and the Organisation of Pharmaceutical Producers of India were supportive and willing to follow the cancer drugs model. There were a couple of reservations. The All India

Chemists and Druggists Association sought higher margins of 12.5% (for stockists) and 25% (for retailers),” said another person present at the meeting on Friday.

Some analysts are, however, not impressed. Phillip Capital analyst Surya Patra said medicines not under price control already have a 30% cap on trade margin (20% for retailers and 10% for wholesalers), and therefore there will not be any significant reduction in prices.

Trade margin is the difference between the price at which manufacturers/importers sell to stockists and the price charged to consumers. Currently, the National Pharmaceutical Pricing Authority (NPPA) fixes prices of scheduled drugs (medicines under price control). The prices of non-scheduled drugs can be raised by up to 10% a year. For nonscheduled drugs, the industry norm has been to give 10% margin to stockists and 20% to retailers. However, there have been allegations that actual margins are far higher.

By making trade margins explicit, there will be less scope for exploitation by large institutions, said one of the persons cited above. “Margins will go down for trade, making drugs cheaper,” he said.

According to data available with the health ministry, 70% of India’s total healthcare spending goes towards medicines. Data available with the department of pharmaceuticals shows that there are 10,600 non-scheduled drugs. Some industry experts present at the Friday meeting also expressed concern over distribution and availability of generic-generic drugs and traded business (commodity business model). They said these drugs — supplied to villages and small towns — have a ‘no-return policy’, where traders cannot return expired or damaged products to stockists or manufacturers.

A proposal to exempt lower-priced medicines — that cost Rs 2-5 per unit — from the margin cap was also discussed. But this was opposed by consumer activists. “We support the capping of trade margins across all non-scheduled medicines. Drugs priced less than Rs 5 per unit should not be excluded from this cap. A large population suffers from chronic diseases. Many of the medicines for managing these conditions could fall in this category. Ensuring affordable access is crucial where patients need medicines continuously,” said Malini Aisola, co-convenor of All India Drug Action Network (AIDAN), a grouping of several non-governmental organizations.

Source: ET HealthWorld

### **More current Polio cases have been caused by Vaccines than the wild Virus: WHO report**

There are now more people who have contracted polio through vaccines than the wild virus itself.

The World Health Organization (WHO) [published a report last week](#), which recorded nine new polio cases that were caused by the vaccines in four African countries in Nigeria, Central African Republic, Angola and the Congo. A total of 16 countries have had similar outbreaks. That includes cases in other African counties, and in Asia in places such as the Philippines, China, Myanmar. It’s risen the count of polio cases caused by vaccines to 157. Afghanistan and Pakistan, the two countries where polio continues to be endemic, have a reported 107 cases of wild polio. According to the Associated Press, all the current cases where people have contracted polio through the vaccine, have been caused by a Type 2 virus, whose wild form has been eliminated since 2015. Last week, donors pledged \$2.6 billion to combat polio, but the process of eradication started in 1988.

**SOURCE : NATIONAL POST**

#### **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.