



# Drug Information Bulletin

*Drug Information Centre (DIC)*

*Indian Pharmaceutical Association*

*Bengal Branch*

Tele fax: 033 24612776, E-mail: [ipabengal.dic@gmail.com](mailto:ipabengal.dic@gmail.com)

Web Site: <http://www.ipabengal.org>

Contact: 09830136291

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## *Editorial*

Pharmacy Council of India (PCI) has published a draft of the Pharmacy Exit Examination (DPEE) with an “objective to ensure that a candidate applying for registration as pharmacist with the State Pharmacy Council has undergone pharmacy education and a comprehensive practical training programme in Diploma in Pharmacy (D.Pharm) Course as provided in the Education Regulations, 1991 or the regulations that may be in force from time to time in an institution approved by Pharmacy Council of India under section 12 of the Pharmacy Act 1948 and acquired core competencies in dispensing of medicines and other areas of pharmacy practice and to reinforce his discipline, integrity, judgement, skills, knowledge and quest for learning so that after having passed the examination he is able to become a registered pharmacist who is able to exercise his professional skills in addition to carrying his duty and responsibilities professionally”.

PCI hosted it in their website for public comments till 31<sup>st</sup> December 2018. In the mean time professional experts expressed mixed response about it. One school is welcoming this as a stepping stone for ensuring quality of Pharmacy practice like other countries round the globe and suggested that it should be mandatory for anybody and everybody wish to register as pharmacist in India. The other school is apprehensive about its implication. Hope PCI will take a rational decision after considering the suggestions expected to be submitted for consideration.

**Dr. Subhash C. Mandal**  
**Editor**

E mail: [subhash.mandaldr@gmail.com](mailto:subhash.mandaldr@gmail.com)  
Mob. 9830136291



## New Drug: Tildrakizumab for psoriasis

Approved indication: psoriasis

Ilumya (Sun)

pre-filled syringes containing 100 mg/mL

Immune mechanisms are involved in the inflammation seen in psoriasis. Several pro-inflammatory cytokines, such as the interleukins, are implicated and this has led to the use of cytokine modulators when the psoriasis is severe enough to require systemic therapy. These include tumour necrosis factor alpha antagonists, such as etanercept, and the monoclonal antibodies ixekizumab, secukinumab and ustekinumab. Tildrakizumab is a monoclonal antibody which blocks the interaction of interleukin 23 with its receptor and this inhibits the release of pro-inflammatory cytokines.

Tildrakizumab has to be given by subcutaneous injection. The drug is slowly absorbed. In the recommended regimen of one injection followed by another after four weeks and then every 12 weeks, steady-state concentrations are reached at 16 weeks. The antibody is catabolised with a half-life of 23 days. No studies have been done in patients with hepatic or renal impairment.

A phase II trial studied several different doses of tildrakizumab in 355 patients with moderate–severe plaque psoriasis. To be included in the trial the patients had to have a Psoriasis Area and Severity Index (PASI) score of at least 12 (moderate severity). After 16 weeks this score had reduced by at least 75% in 33–74% of the patients. This response was significantly better than the 4% rate seen in a placebo group. At the recommended dose of tildrakizumab 100 mg, 62% of the patients had cleared or minimal psoriasis.<sup>1</sup>

The main trials of tildrakizumab (reSURFACE 1 and 2) studied doses of 100 mg and 200 mg in patients with moderate–severe plaque psoriasis (PASI score  $\geq 12$ ). The participants in reSURFACE 1 were randomised to tildrakizumab or placebo, while in reSURFACE 2 patients were randomised to tildrakizumab, etanercept or placebo. After 12 weeks the patients in the placebo groups were re-randomised to one of the tildrakizumab groups. The PASI score fell by at least 75% (PASI 75) in 6% of the placebo groups at 12 weeks. In contrast,

this outcome was achieved by 61–64% of the patients given tildrakizumab 100 mg, 62–66% of those given 200 mg and 48% of the etanercept group. At 28 weeks the PASI 75 outcome was achieved by 73–82% of the patients who continued tildrakizumab and 54% of those taking etanercept. Favourable responses were also seen in 55–86% of the patients who switched from placebo. With tildrakizumab 100 mg, the psoriasis was clear or minimal in 55–58% of the patients at 12 weeks and in 65–66% of those who were treated for 28 weeks.<sup>2</sup>

During the phase III trials only about 1% of the patients discontinued tildrakizumab 100 mg because of adverse effects.<sup>2</sup> Common effects included injection-site reactions, nasopharyngitis and fatigue. Injecting an antibody that alters the immune response has some potentially serious adverse effects. Cancer was more frequent with tildrakizumab than placebo (0.2 vs 0%). During treatment 6.5% of the patients developed antibodies to tildrakizumab. This led to minor decreases in efficacy, but no apparent increase in adverse events. Tuberculosis should be excluded before treatment. Live vaccines should not be given during treatment and for at least 17 weeks afterwards.

In all clinical trials, 1994 people received tildrakizumab and the mean duration of treatment was 53.9 weeks. As psoriasis is a chronic disease, longer term safety data will be needed, including safety in pregnancy and lactation. Although the efficacy of tildrakizumab is probably similar to that of other monoclonal antibodies, its onset of action is slower. More patients will achieve a PASI 75 response with tildrakizumab than with etanercept, but the difference in patients with minimal or cleared psoriasis at 12 weeks is not statistically significant.<sup>2</sup>

### References

1. Papp K, Thaçi D, Reich K, Riedl E, Langley RG, Krueger JG, et al. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial. *Br J Dermatol* 2015;173:930-9.
2. Reich K, Papp KA, Blauvelt A, Tying SK, Sinclair R, Thaçi D, et al. Tildrakizumab versus

placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet 2017; 390:276-88.

Ref.: Australian Prescriber

**Note:** Indian pharma company Sun Pharmaceuticals has already marketed this drug in US, but no such drug is approved for manufacturing in India till date.

### **Marketing of Buclizine as appetite stimulant is prohibited by Government of India since 13.12.2018**

Government of India has formed an expert committee to examine the rationality of use of Buclizine as appetite stimulant and the committee has stated that no clinical trial study report on human beings to justify the use of the Buclizine as an appetite stimulant has been produced by the manufacturers and hence, the said committee has not recommended the continued marketing of the aforesaid drug as an appetite stimulant;

The Drugs Technical Advisory Board has also considered the said matter and recommended for prohibiting the manufacture, sale and distribution of Buclizine for the indication “as appetite stimulant” in public interest.

Hence the Central Government, on being satisfied that it is necessary and expedient in public interest to regulate the manufacture, sale or distribution of Buclizine and its formulations for use in human beings subject to the conditions that the manufacturer shall label the container of Buclizine and its formulation and also mention in conspicuous manner on the package insert and promotional literature of Buclizine and its formulation with the words “Not to be used as appetite stimulant”. Vide. S.O. 616(E) dated 13.12.2018.

### **China approved Roxadat ahead of West for First Time**

China has for the first time approved a treatment from a global drug maker before any other country, illustrating its recent push to bring in cutting-edge medicines—as well as Western companies’ growing interest in the market.

The country’s medicines regulator recently approved Roxadustat, a new anemia drug from AstraZeneca PLC and Fibrogen Inc., well ahead of any other nation.

Roxadustat (INN ; FG-4592) is a drug which acts as a HIF prolyl-hydroxylase inhibitor and thereby increases endogenous production of erythropoietin, which stimulates production of hemoglobin and red blood cells- claimed by the manufacturer.

Ref. <https://www.wsj.com>

### **Maharashtra Medical Council says no to crosspathy**

Medical Councils of 24 states recommends that government ban rampant prescription of allopathy drugs by doctors of other branches. While the practice of cross prescription of medicines has become a common practice amongst physicians, medical councils across the country have decided to take a stand against the practice of prescribing homeopathy or ayurvedic medicines along with allopathy drugs.

A decision was taken in a recent meeting held between medical councils of over 24 states of India. A recommendation has been sent to respective state governments and also the central health ministry. Maharashtra Medical Council (MMC) has decided that only doctors that are registered with the council can prescribe allopathy drugs.

In Maharashtra, ayurvedic doctors are allowed to prescribe allopathic medicines to an extent. But it is not defined to what extent they can do it. These rules and regulations were placed back in 1990’s when the number of allopathy doctors was meagre and rural areas faced a lot of inconvenience. That’s why doctors from other branches of medicines working in the rural parts were allowed to prescribe emergency medicines. “The doctors during the 90’s were allowed to prescribe medicines for cold, cough, fever etc. But now we have as many as 6,000 allopathy doctors passing out every year in the state,” said Dr Shivkumar Utture, president of MMC.

Utture said, “The general concern was that as per the Medical Council Act of 1965, and as per the Supreme Court judgements, modern medicines

should be prescribed only by doctors who hold an MBBS degree.”

In other states there is a blanket ban on this practise and Utture expects the same will be implemented in Maharashtra soon. “Now that there are adequate allopathy doctors, other doctors should not be allowed to practice modern medicine,” added Utture.

Dr Dilip Sarada, member of MMC, said presidents of several state medical councils have commonly agreed that there should no cross prescription of drugs. “There are doctors which prescribe antibiotics rampantly and this leads to resistance to these drugs,” he said.

Sarada added that duration of pharmacology subject taught in other medicinal streams is merely six months, which is not adequate enough for treating a patient as it is half-baked knowledge.

Source: Pune Mirror

### **Bengal Chemicals keen on resuming Anti-Snake Venom production**

Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) which had forayed into anti-snake venom serum (ASVS) manufacture in India nearly half a century ago, is keen to resume production of this life-saving medication, shortage of which kills hundreds of people.

No records are available to pin point the exact year that the 118-year-old heritage company commenced ASVS production, but it is believed to

be somewhere around 1920s, a company official said.

Its capacity was about one lakh vials. BCPL was the first home-grown pharmaceutical and home products company. It has units in West Bengal, Uttar Pradesh and Maharashtra. Snake bite morbidity is high in the Indian subcontinent with over one million bites annually, figures culled from several reports show. ASV is an antidote to the snake venom action and is provided free in government hospitals. Yet, there are only a handful of pharma companies making this.

Union Health and Family Welfare Minister J. P. Nadda said in a informed Parliament statement in March 2016 that information regarding deaths reported due to non-availability of ASV is not maintained centrally.

However with the government proposing a strategic sale of BCPL, the ASVS project went to the backburner although BCPL sees it as a growth opportunity. Alongside BCPL also plans to step up production of anti-cancer drugs, cardio vascular medicines and hypolipidemic drugs.

Source: The Hindu

## **Forthcoming Event:**

**Gangasagar Health Camp**

**Date: 10-17 January 2018**

**Jointly organized by:**

**IPA Bengal Branch & IPA Bengal  
Pharma & Healthcare Trust**



Two finalists of IPA-DP National Elocution Competition 2018 from West Bengal - Ms. Anupama Banerjee and Mr. Avik Das at Amity University, Noida with Dr. Subhash C. Mandal, NEC –coordinator and Dr. A. Ramkishan, Dy, Drugs Controller, CDSCO(EZ)

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