Drug Information Bulletin

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Content

Editorial

Pharmacy community in India protested the recent move of converting “quacks” as “Pharmacist” for running retail Pharmacy in India. Pharmacists are an integral part of the health care system and are working hard for the improvement of the health care of the general mass. The Pharmacy practice in our country is regulated by two acts, which are Pharmacy Act 1948, and Drugs and Cosmetics Act 1940. Engagement of Pharmacists in serving the prescription of a registered practitioner has been 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 to protect the health of the people. The pharmacists are saving millions of lives through counseling about proper use of medicines.

Recently a vested interest group is moving with an ulterior motive for creating a group of “Quacks” as pharmacists giving misleading information to the Central Government. We are strongly opposing this move, because at this moment there is no dearth of Pharmacists in our country, but there may be an unequal distribution. Now we are getting more than one lakh of Pharmacists per year from more than 1500 colleges. Moreover thousands of pharmacists are jobless or under employed at this moment. If this step is taken by the Govt. it will jeopardize the healthcare system by compromising quality of health care and will result millions of jobless pharmacist as well as closure of the Pharmacy colleges, which will have tremendous impact on the economy of our country.

Indian Pharmaceutical Association (IPA) has submitted a representation against this move to the Union Health Minister and requested all state Government & all Drugs Controllers for immediate implementation of Pharmacy Practice Regulation 2015 (www.ipapharma.org). Pharmacy Council of India (PCI) has expressed that they are against this move. Experts believe that though some other organizations along with some Pharmacy college authorities have protested this move, a more intensified movement throughout India is expected to stall this move to protect the quality of he[illegible]

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New Drug: Blinatumomab

Approved indication: acute lymphoblastic leukaemia
Blincyto

Glass vials containing 38.5 micrograms powder for reconstitution
Australian Medicines Handbook section 14.2.1

Blinatumomab is indicated for adults with Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukaemia. It is a dual-action antibody that binds to CD19 expressed on all B cells (including acute lymphoblastic leukaemia cells) and CD3 on T cells. When these molecules are bound at the same time, the drug acts as a bridge between the T and B cells. This interaction activates the T cells and causes them to produce cytolytic proteins and inflammatory cytokines which kill normal and malignant B cells.

Blinatumomab is thought to be catabolised. Its mean half-life is 2.1 hours. The drug is not expected to affect cytochrome P450 enzymes but drug interaction studies have not been done.

Approval of this drug is based on one main study of 189 patients.[1] This was an open-label phase III trial with no comparator. Enrolled patients had relapsed or refractory disease with a bone marrow blast count of at least 10%. At baseline, over two-thirds of patients had a blast count of 50% or more. Blinatumomab was administered by continuous infusion in four-week cycles followed by a two-week treatment-free interval. Patients received the drug for a median of 42 days. Those with more rapidly progressing disease were given dexamethasone before treatment to reduce the incidence of severe cytokine release syndrome.

The primary outcome of the trial was a complete response (5% or less blasts in bone marrow, no evidence of disease and full recovery of peripheral blood counts) or a complete response with a partial recovery of blood counts, within the first two treatment cycles. After treatment, 33% of patients had a complete response, 10% had a complete response with a partial recovery of blood counts and 48% did not respond. The median overall survival of all participants was 6.1 months (95% confidence interval 4.2–7.5 months).[1]

In a safety cohort of 475 patients, adverse events were very common. The most serious events included infusion-related reactions (67% of patients), infections (63%), fever (60%), headache (34%), febrile neutropenia (28%), peripheral oedema (26%), nausea (24%), hypokalaemia (24%), constipation (21%), anaemia (20%), cough (19%), diarrhoea (18%), tremor (18%), neutropenia (18%), abdominal pain (17%), insomnia (15%), fatigue (15%) and chills (15%). Blood monitoring is recommended during treatment because of the haematological effects. Severe neurological events also occurred with blinatumomab and included encephalopathy, convulsions, speech disorders, confusion and problems with coordination and balance.

During the trial 23 patients died because of an adverse event. Fatalities were due to sepsis, pneumonias, and infections caused
by *Fusarium*, *Aspergillus*, *Candida*, *Escherichia coli* and enterococci.[1] As patients are immunocompromised, live virus vaccines are not recommended during, and for at least two weeks before, treatment.

Blinatumomab comes with a boxed warning about life-threatening cytokine release syndrome and neurological toxicities, and reactivation of JC virus infection. Treatment should be stopped immediately if any one of these is suspected.

A third of patients with Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukaemia had a complete response to blinatumomab. However, it is difficult to know how this benefit compares to conventional chemotherapy as there was no comparator in the trial. Serious adverse effects commonly occurred and were fatal for 12% of patients.

References

1. Topp MS, Gokbuget N, Stein AS, Zugmaier G, O'Brien S, Bargou RC, et al. Safety and activity of blinatumomab for adult patients with relapsed or refractory B-precursor acute lymphoblastic leukaemia: a multicentre, single-arm, phase 2 study. Lancet Oncol 2015;16:57-66. Ref. Australian Prescriber

68th Indian Pharmaceutical Congress concluded at Visskhapatnam

About 10, 000 participants from different field of pharmaceutical profession from India and abroad attended this 3 day programme. It has been reported that this 68th version has drawn record numbers of participants breaking all earlier records. The programme has been attended by Sri Chandrababu Naidu, Chief Minister of Andhra Pradesh and Sri G. S. Rao, Minister of HRD, Govt. of Andhra Pradesh. 61 speakers from India and abroad spoke on several subjects of importance. About 2600 posters were presented by researchers from different spheres of Pharmacy. There was an exhibition of Pharmaceutical equipments, products and services.

At the concluding session several resolutions have been passed which requires to be pursued seriously for its implementation. It is expected that besides IPCA all other federating organizations will also show serious interest for its implementation.

Pharmacy Council of India (PCI) firmly against AIOCD proposal to start refresher course for unqualified persons

With reports doing rounds that the Pharmacy Council of India (PCI) will support the proposal of All India Organization of Chemists and Druggists (AIOCD), to conduct a short term refresher course for the unqualified persons to enable them work as pharmacists, the president of the PCI has clarified his stand that the Council will not in any way support the proposal, but stand by the statutory provisions in the Pharmacy Act and Drugs & Cosmetics Act.

"Speculations of support for the refresher course by PCI are far from truth and the Council has no such idea," clarified Dr B Suresh Bhojraj, president of the PCI.

Responding to the issue after putting an end to all confusions, he said, with respect to the statutory provisions in the Pharmacy Act and D&C Act and also considering the public health aspect, the proposal made by AIOCD to the union government on November 5 will be rejected by the PCI. PCI stands for safeguarding the pharmacy profession and the pharmacy educational institutions. For regulating the profession of pharmacy, PCI has introduced the Pharmacy Practice Regulations 2015.

While interacting with Pharmabiz, he said currently there is no need of such a refresher course in India as there is no dearth of pharmacists in the country. As on today, the number of registered pharmacists in the country is approximately 10 lakhs and about one lakh pharmacists are coming out from various institutions every year. He said he was not deliberately silent on the issue, but was out of station.

"The Council has received the communication from the ministry of health and family welfare, asking for our views on the representation made by AIOCD in this regard. The said matter is

not only violation of various prevailing laws of the country but also not necessitated due to two primary reasons. One is that there are enough qualified persons available in the country to meet the requirements and the second one is that the safety of patients and the safe use of medicines are of utmost importance. The same views were expressed to the ministry".

Dr Suresh said PCI is responsible to get implemented the Section 42 of the pharmacy act by the governments and it will not allow a person other than a registered pharmacist to compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. If any contravention on this provision is found, PCI will initiate strict action against the violators.
The Supreme Court of India directed the central and state controlling authorities to keep strict vigil to ensure that the necessary statutory requirements for running a medical store by qualified pharmacists are duly complied with, he said.
Ref. Pharmabiz

UK levies heavy fine on Pfizer for price hike

The UK Competition and Markets Authority fined Pfizer $107 million for large price increases for phenytoin sodium capsules, an epilepsy treatment. Pfizer sold the drug's marketing rights in 2012 to another firm, which debranded it, leading to deregulation of its price.
Ref. Reuter

Pharma companies seek science partnerships for new breakthroughs

Even large pharmaceutical firms increasingly recognize that they must find outside academic partners to tackle the complex science of new drugs. Sanofi, for example, has funded research by Harvard professor Gregory Verdine to target relatively flat proteins inside cells that contribute to many diseases and have long been considered "undruggable."
Ref. The Wall Street Journal

India granted delay in effort to pool all combination-drug ban cases

India's Supreme Court gave the government one month to revise its transfer petition to group together all cases filed in high courts around the country against the ban on hundreds of combination drugs proposed by the health ministry after the Delhi High Court rejected the initial ban. The health ministry's effort to ban 344 fixed-dose drug

ombinations drew challenges from several drug manufacturers.
Ref. The Economic Times (India)

Indian Pharmaceutical Association Bengal Branch received outstanding Branch Award 2016

Mr. Asit Ranjan Bhattacharyya received IRF Lifetime achievement Award