



Drug Information Bulletin

Drug Information Centre (DIC)

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Regulatory Affairs Division (RAD), IPA

Volume: 10

Number: 23

11th February 2017



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Editorial

Once again unified protest from most of the professional organizations elicits result. Recently Assam Public Service Commission cancelled their advertisement number 15/2016 dated 26th October 2016 vide Govt. letter No. HLA.662/2012/84, dated 16th Nov. 2016, in which they wanted to recruit unqualified persons as Drugs Inspectors violating Drugs and Cosmetics Rules. Indian Pharmaceutical Association (IPA) along with All India Drugs Control Officers, Confederation (AIDCOC) and some other organizations protested vigorously against this advertisement by submitting memorandum to the health minister of Assam Government and pursued the matter with grit resulting cancellation of the advertisement. Hope the concerned organizations will pursue the Assam Government to take immediate step to recruit Drugs Inspectors as per the Drugs and Cosmetics Rules immediately for smooth running of Assam Drugs Control to protect the health of the people.

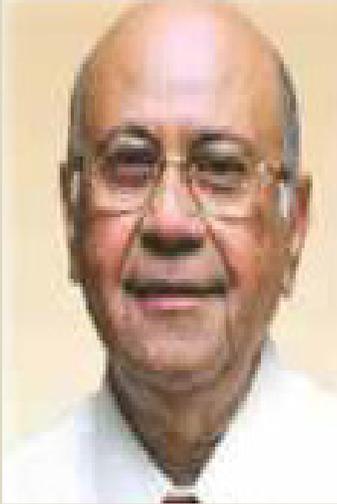
It is good to see that most of the professional organizations and stakeholders are supporting amendment of Rule 64 of the Drugs and Cosmetics Rules to make only Pharmacists as competent person in whole sale licenses. I strongly believe that consorted effort of all professional organizations will be successful in future also.



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Message: Shri Prafull D Sheth, Past President, IPA and Past Vice President, FIP on the eve of a decade's service of DIB for mission "Health Care"



Dear Subhash

Thank you for your mail. I confirm that I regularly receive the bulletin and go through the contents with interest. This format of the bulletin is very useful and saves time as I do not have to go through several reports as the bulletin captures and summaries important information. I congratulate you and your team for your hard work and painstaking efforts.

With my very best wishes for the continued success of the bulletin.

Warm regards
PDS

New Drugs: Mepolizumab

Approved indication: asthma
vials containing 144 mg powder for reconstitution

Australian Medicines Handbook
section 19.1.6

Some patients with asthma have severe disease that is not well controlled by inhaled treatments. They may require regular oral corticosteroids to control airway inflammation. In some patients there can be high concentrations of IgE which may respond to treatment with omalizumab. Other patients have high concentrations of eosinophils so these cells are potential targets for new drugs such as mepolizumab.

The life cycle of eosinophils is controlled by interleukin 5. This cytokine may be overproduced in patients with eosinophilic asthma. Mepolizumab is a humanised monoclonal antibody that binds to interleukin 5. This prevents interleukin 5 from binding to its receptors on the surface of eosinophils.

A dose of mepolizumab will reduce eosinophils by at least 50%.

As mepolizumab is an immunoglobulin (IgG) it has to be given by injection. When reconstituted with water for injection, the powder forms a solution with a strength of 100 mg/mL. The usual dose is 100 mg injected subcutaneously every four weeks. After injection into the arm the bioavailability is 74–80%. The peak concentration is reached in 4–8 days and the terminal half-life following metabolism is 16–22 days. There have been no formal studies of hepatic or renal impairment or of drug interactions.

The Cochrane Airways Group has reviewed eight trials comparing mepolizumab with placebo in 1707 patients. Due to the heterogeneity of the studies the role of mepolizumab was uncertain, but it did reduce exacerbations and improve health-

related quality of life in patients with severe eosinophilic asthma.¹

One of the studies in the review randomised 621 patients with eosinophilic inflammation to intravenous infusions of placebo or mepolizumab 75 mg, 250 mg or 750 mg. Thirteen infusions were given at four-week intervals. Mepolizumab significantly reduced the numbers of eosinophils in the blood. There were 806 asthma exacerbations which required treatment with oral steroids. Compared to placebo the number of exacerbations per patient per year was reduced significantly by all doses of mepolizumab. For example, there was a 48% reduction with the 75 mg dose.²

A subcutaneous regimen was included in a trial involving patients with severe eosinophilic asthma who had experienced at least two exacerbations of asthma in the previous year. Treatment was given every four weeks for 32 weeks. There were 449 exacerbations. In the 194 patients assigned to receive mepolizumab 100 mg subcutaneously, the annual exacerbation rate was 0.83 compared with 1.74 in the 191 patients assigned to placebo.³

Another trial assessed whether subcutaneous mepolizumab can reduce the amount of oral corticosteroids consumed by patients with severe eosinophilic asthma. The 135 patients in the trial had been taking 5–35 mg of prednisone or equivalent for at least six months. After injecting mepolizumab or a placebo every four weeks for 20 weeks their use of corticosteroids was reassessed. The median reduction from their baseline dose was 50% for the

patients taking mepolizumab. There was no reduction in the placebo group. The annual exacerbation rate was 1.44 with mepolizumab and 2.12 with placebo.⁴

Safety information is available for 1018 patients who took mepolizumab 100 mg subcutaneously. Common adverse events were headache and nasopharyngitis. Injecting an antibody can cause hypersensitivity reactions which may have a delayed onset. Approximately 6% of patients developed antibodies against mepolizumab. Injection site reactions affected 8% versus 3% of the placebo group. As eosinophils have a role in the immune response, mepolizumab may alter the response to parasitic infections. Although there were only a few cases of herpes zoster, two of them were serious. There is currently no information about the drug's safety in pregnancy, lactation or in children younger than 12 years.

The optimum use of mepolizumab is yet to be determined. Not all patients benefit, for example 36% were unable to reduce their dose of oral corticosteroid, withdrew from treatment or had a lack of asthma control.⁴ Some of the patients suitable for treatment with mepolizumab may also qualify for treatment with omalizumab so the treatments should be compared. If a patient with severe refractory eosinophilic asthma is prescribed mepolizumab, how long should they take it for? A follow-up of some of the patients in the trials found that after stopping treatment there was a rise in eosinophil count and an increase in asthma symptoms and exacerbations.⁵

References:

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Source.: Australian Prescriber

India pharma exports may see near double-digit growth in FY17

Indian pharma exports in the current financial year may see a near double-digit growth and might end up on the lines with that of last year, a senior Ministry of Commerce and Industry official said here today.

"Pharma exports have done better than many sectorial exports and we are in near double digit growth. Last month, growth has also been good it is about 8 per cent. So I see that despite overall contraction and slowdown, pharma exports doing relatively better. I don't think that it (double digit growth) would be possible," Sudhanshu Pandey, Joint Secretary, Commerce Ministry told reporters on the sidelines of BioAsia-2017, when asked if the exports would see double digit growth this year.

"We should be some way between 8 to 10 per cent. That is what is the anticipation, he said."

Indian Pharma exports stood at USD 16.9 billion in the last financial year, growing at 9.44 per cent with USD 5.7 billion to USA and USD 3.3 billion to Africa, as per the statistics supplied by Pharmexcil. The exports stood at USD 15.4 billion in 2014-15.

Pandey said there may not be much impact of Brexit on pharma exports in either Britain or Europe as the situation has stabilised with regard to exports to those geographies.

"You have already seen impact on the exports but now exports have in fact stabilised and there is growth in the last month. So I think the trend would be in that direction," he said.

Replying to query, he said Indian Institutes of Chemical Technology (IICT) will offer space to industry either for setting up a startup incubator or for research purpose.

According to Pandey, NITI Aayog is working on model wherein the government will be able to invest in some of the risk oriented research programmes.

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