Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291
&
Regulatory Affairs Division (RAD), IPA

Volume: 08 ***Number: 19*** ***21st December 2014***

Content

Editorial

Pharmacoeconomics and outcome Research is a new branch of science in India involving Medical, Pharmaceutical, Social science. Though it has long history in some other countries but its application is not so popular in the past. Though this science is in its infancy in India, a few groups are trying to promote this branch of science in India. Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. It is a sub-discipline of health economics. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life) of a pharmaceutical product. There are several types of pharmacoeconomic evaluation: cost minimization analysis, cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis. Pharmacoeconomic studies serve to guide optimal healthcare resource allocation, in a standardized and scientifically grounded manner. Pharmacoeconomic evaluation is an analytical tool used with increasing frequency to assist decision making in the financing and management of pharmaceutical products in the health care system or national health insurance programs of an individual country. Pharmacoeconomic (PE) guidelines can be used as a standard for preparation of studies to be included in application for reimbursement, a guide for designing and conducting a study, or a template for evaluating the economic study reports. In India it has tremendous scope in price control mechanism, new drug approval and reimbursement mechanism. It is being suggested introducing this subject in the course curriculum of Medical, Pharmacy and other health care specialties. A draft Pharmacoeconomic guidelines is available at www.ispor.org for comments.

Dr. Subhash C. Mandal
Editor

New Drug: Umeclidinium Bromide

Umeclidinium bromide
Incruse Ellipta (GlaxoSmithKline)
62.5 microgram as dry powder for inhalation
Umeclidinium bromide with vilanterol
Anoro Ellipta (GlaxoSmithKline)
62.5 microgram/25 microgram as dry powder for inhalation
Approved indication: chronic obstructive pulmonary disease
Australian Medicines Handbook section 19.1

For more than a decade tiotropium bromide was the only long-acting anticholinergic bronchodilator available in Australia. In 2014 glycopyrronium bromide (Aust Prescr 2014;37:64-71), aclidinium bromide (Aust Prescr 2014;37:172-79) and umeclidinium bromide emerged.

Like the other members of its class, umeclidinium bromide is an antagonist at acetylcholine receptors. In the lungs this causes bronchodilation which begins within 15 minutes of an inhalation and lasts for over 24 hours. The bioavailability of an inhaled dose is about 13% with most of the absorbed dose being metabolised and then excreted in the faeces. Although this metabolism includes cytochrome P450 2D6 and umeclidinium is a substrate of P-glycoprotein, there are unlikely to be clinically significant pharmacokinetic drug interactions. No dose adjustments are needed in patients with renal or moderate liver impairment.

The recommended dose of 62.5 microgram once daily refers to the amount of umeclidinium, rather than umeclidinium bromide, in each blister on a foil strip. When the contents are inhaled through a specific device, a dose of 55 microgram umeclidinium is delivered.

A short-term trial compared umeclidinium with placebo in patients with chronic obstructive pulmonary disease (COPD) and a smoking history of at least 10 pack-years. At the start of the study the mean value of the forced expiratory volume in one second, before the next dose (trough FEV1), was 1.21 L in the placebo group and 1.26 L in the umeclidinium 62.5 microgram group. After 12 weeks this had not risen in the 68 patients given placebo, but trough FEV1 increased by 120 mL in the 69 patients who inhaled umeclidinium 62.5 microgram.

In a larger study, 418 patients inhaled umeclidinium 62.5 microgram and 280 inhaled placebo for 24 weeks. The mean trough FEV1 was 1.2 L in both groups at the start of the study. It rose by 115 mL after 24 weeks of umeclidinium, but was unchanged in the placebo group. This study also included 421 patients who inhaled vilanterol 25 microgram (a long-acting beta2 agonist) and 413 who inhaled a combination of umeclidinium 62.5 microgram and vilanterol 25 microgram. The combination increased trough FEV1 by a further 52 mL compared with umeclidinium alone, and by 95 mL compared to vilanterol alone. All the active treatments reduced dyspnoea, and exacerbations were less frequent than with placebo (7-9% vs 13% of patients).1

Common adverse events with umeclidinium were headache, cough and nasopharyngitis, but their frequency was similar in the placebo groups. The longer-term safety of a higher dose (125 microgram) was assessed in 227 patients. They were compared with 109 patients randomised to take a placebo. After 52 weeks adverse events which were more frequent than with placebo included supraventricular tachycardia, sinus tachycardia and supraventricular extrasystoles. These arrhythmias are probably the result of antimuscarinic

effects. Caution is therefore needed when prescribing umeclidinium for patients with arrhythmias and those at risk of narrow-angle glaucoma or urinary retention. There are no data about umeclidinium in pregnancy and lactation.

Umeclidinium is suitable as a maintenance treatment for chronic obstructive pulmonary disease and can be combined with a long-acting beta2 agonist for more severe cases. However, there is little information about how this drug compares with similar treatments. One trial in the drug's development included patients who were randomised to take tiotropium 18 microgram once daily, but they were not compared with patients who took umeclidinium alone. Taking a combination of umeclidinium and vilanterol (62.5/25 microgram) for 24 weeks resulted in an average trough FEV1 value that was 60 mL higher than with tiotropium alone.

Like other bronchodilators, not all patients will have a clinically significant response to umeclidinium. In the 24-week efficacy study only 53% of the patients inhaling umeclidinium had a clinically important difference in dyspnoea, while the response rate to placebo was 41%.1

References:

Donohue JF, Maleki-Yazdi MR, Kilbride S, Mehta R, Kalberg C, Church A. Efficacy and safety of once-daily umeclidinium/vilanterol 62.5/25 mcg in COPD. Respir Med 2013;107:1538-46.

Toll free number for ADR reporting

Now, consumers can call to directly report adverse reactions or their bad experiences from any medicine. The health ministry has launched a toll-free number where people can call and report the side-effects and problems faced by them along with details of the medicine, suspected to have caused the adverse reaction.

The information received would be then screened and assessed by the Adverse Drug Reaction Monitoring Centers by using international parameters set by the World Health Organisation (WHO), a senior official said. Thereafter, the analyzed information would be forwarded to the national coordinating centre, which maintains a database for adverse drug reactions (ADRs).

The health ministry has also set up a steering committee which will periodically review the data and suggest any intervention that may be required, the official said.

The government would also share this database with international agencies including WHO, which manages the Global Pharmacovigilance Database.

The ministry also plans to make it mandatory for pharmacists, hospitals and other independent clinics to display the toll free number - 18001803024 - in public interest.

The idea is to empower consumers to report adverse reactions on their own. The move would also enable an environment that will allow reportage of adverse reactions from every nook and corner of the country.

Surveillance of medicine, after it is approved for marketing, has been a major challenge for the government and the drug regulator. In the absence of enough field force and mechanism, the regulator often struggles to gather post marketing data on medicines.

Since 2011, around 1,10,000 adverse drug reactions have been reported from across the country. However, this was after the government made it mandatory for hospitals to have a pharmacovigilance cell. Still, officials say, there are only few hospitals across the country operating with a proper cell.

Currently, there are only 150 hospitals across the country which have pharmacovigilance cell, the official cell. However, the health ministry and the drug regulator are making efforts to ramp up such cells.

Experts say lack of awareness has also been a major roadblock because those facing problems with a particular medicine would not know where exactly to report.

"A toll free number would empower the consumer along with medical practitioners to directly report adverse reactions," the official said, adding the information provided by consumers or doctors would be handled in strict confidence.

Source: The times of India

Patented price gouging and the enduring enigma of drug costs

In a momentous development for Indian patent law, the Supreme Court recently refused to entertain the appeal of Bayer AG, a German patentee at the receiving end of India's first compulsory licence. In 2011, the patent office decided that Bayer had priced Nexavar, its anti-cancer drug, at an exorbitant price (Rs.2.8 lakh a month) and allowed Natco Pharma Ltd, a generic company, to produce the same drug at 1/30th the price (Rs.8,800). As the name suggests, in sharp contrast to a voluntary licence, a compulsory licence is mandatorily imposed on the patentee, whether she likes it or not. Indian patent law is quite distinct from most other patent regimes in that such a permit is not merely a matter of government discretion but an entitlement in favour of any interested third party that demonstrates that the patented invention is not working for public benefit on account of it being unaffordable or not available in reasonable quantities to the public, as was the case with Nexavar. As expected, the patent office's decision met with brickbats and bouquets. Soon thereafter, Bayer appealed the verdict to the Intellectual Property Appellate Board, a specialized tribunal, which upheld the decision for the most part. Bayer then unsuccessfully approached the Mumbai high court through a writ petition. It finally trudged up all the way to the Supreme Court, only to have the apex court refuse to entertain its petition. The courts' dismissal effectively ends a legal saga that placed India under tremendous political and trade pressure from the US and the European Union. What is interesting to note is that Bayer took issue not only with the issuance of the licence, but also with the royalty rate imposed. A compulsory licence is not a free-for-all regime, but mandates that the person using the permit pay a royalty that accounts in some part for the value of the invention. Bayer rightly argued that its research and development (R&D) costs ought to be taken into account to determine the appropriate royalty rate. Surprisingly, however, Bayer refused to submit its R&D costs to the patent office, leaving it free to rely on a broad World Health Organization estimate of 6% as an average royalty rate under the circumstances. Read more at:

http://www.livemint.com/Opinion/HchIwyVexY5dSaY7FjCNHO/Patented-price-gouging-and-the-enduring-enigma-of-drug-costs.html?utm_source=copy

ANNUAL PICNIC
of
IPA Bengal Branch
4th January 2015
All members are requested to join with family
Venue: Samrat Gardens
Joinpur, South 24 Pgs.

Please Contact for enrolment:
Mr. Pradip Kumar Mallik: 9830574612
Dr. Sambhu Nath Dey: 9331040946
Mr. Ashok Kumar Maity: 9433579919
Mr. Sovon Bagchi: 9433112266