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

Volume: 07 ***Number: 30*** ***2nd November 2013***

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. This science is in its infancy in India. ISPOR-India Regional Chapter is trying to promote this branch of science since 2006 in our country. Recently some other chapters like-ISPOR-India Andhra Pradesh, ISPOR-India Karnataka & ISPOR-India West Bengal Chapters are working in this new branch of science.

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.

Drug Price Control Order-2013 mentioned that the price of "new drugs" will be fixed on the basis of "Pharmacoeconomic" principle. This is the first time "Pharmacoeconimics" has been mentioned in an official document in India. Teaching of this subject in Medical, Pharmacy, Nursing and other health care courses will make our health care system more efficient.

New TB drug Bedaquiline illustrates need for paradigm shift in developing and ensuring access to new treatment combinations

Without a new approach to developing and pricing new tuberculosis medicines, the global TB response will be unable to deliver the new treatment combinations needed to close the deadly treatment gap for drug-resistant tuberculosis (DR-TB), warned the international medical humanitarian group Medecins Sans Frontieres/Doctors Without Borders (MSF) at the Union World Conference on Lung Health in Paris.

'If I could change anything about having TB it would be the treatment; if we could have less toxic drugs and simpler, shorter treatment regimens, there would be fewer people dropping out of treatment and fewer people dying' said Phumeza Tisile, who received TB treatment through MSF's programme in Khayelitsha, South Africa.

In December 2012, a 50 year drought in TB drug research and development (R&D) came to an end with the approval in the U.S. of bedaquiline, a novel TB medicine marketed by Janssen, a subsidiary of Johnson & Johnson (J&J).
'This is a significant milestone for clinicians and patients, but there is no room for complacency or celebration yet. The new drug is obviously a boon, but what we really need are entire new combinations of drugs to treat DR', said Dr. Cathy Hewison, TB advisor for MSF. 'If we are unable to offer patients an entirely new, tolerable and more effective regimen in the coming years, the opportunity to radically improve DR-TB treatment will be squandered.'

The U.S. Food and Drug Administration fast-tracked the approval of bedaquiline, the World Health Organization (WHO) issued rapid guidelines for its use, and J&J has pushed for registration fairly widely; these are positive signals that the TB context is ready to respond quickly to new drugs. But achieving the goal of entirely new regimens requires a more fundamental change in the way TB drugs are researched and brought to market.

'We need much more collaborative research early on, instead of companies operating in silos, and this will require a massive commitment from the global research community, as well as a significant injection of funds at a time when the global investment for TB R&D is actually declining', said Sharonann Lynch, policy advisor for the MSF Access Campaign.

WHO estimates that fewer than 20% of the world's drug-resistant TB cases are diagnosed and treated. Because treatment is long, arduous, expensive and poorly effective, with global cure rates stagnating around 50%, scale-up of DR-TB diagnosis and treatment is extremely difficult. Affected countries should scale up efforts to diagnose and treat DR-TB today, so that robust programmes are in place to ensure responsible and effective use
of new treatment combinations once they are available. To achieve this, countries will need support, so a fully financed Global Fund to Fight AIDS, Tuberculosis and Malaria will be critical.

'We also need to be preparing the ground so that new treatments are affordable. J&J's pricing structure for bedaquiline leaves middle-income countries, some of which are among the hardest hit by DR-TB, paying US $3,000 for a six-month course', said Sharonann Lynch. 'That's for just one drug - bear in mind several drugs are needed for effective treatment.

If the new treatment combinations of the future cost in excess of several thousand dollars even in the poorest countries, as they do today, how on earth will countries be able to increase access and expand coverage?'

MSF is one of the largest non-governmental organisations providing DR-TB care. In 2012, MSF treated 29,000 patients for TB in 30 countries, and 1,780 patients for DR-TB in 18 countries.

MSF and the International Union Against Tuberculosis and Lung Disease today released DR-TB Drugs Under the Microscope, a report on the prices, sources, access environment and R&D landscape for DR-TB medicines. The report is available at: http://www.msfaccess.org/content/dr-tb-drugs-under-microscope3rd-edition.

Medication safety in community pharmacies and outpatient settings

Three new online resources funded by the Agency for Healthcare Research and Quality (AHRQ) and developed by the Institute for Safe Medication Practices (ISMP) can help community pharmacies and outpatient settings improve medication safety and protect patients from the adverse effects of medication errors.

- ***High-Alert Medications Consumer Leaflets*** are patient education checklists developed during a study of the impact of community pharmacies that counseled consumers who picked up prescriptions for certain high-alert medications including warfarin, fentanyl patches, and more.
- ***Assessing Barcode Verification System Readiness in Community Pharmacies*** is a free tool that helps community pharmacies assess their readiness and prepare for future implementation of a barcode product verification system.
- ***High-Alert Medication Modeling and Error-Reduction Scorecards*** **[HAMMERS™]** is a free tool designed to help community pharmacies identify their unique set of system and behavioral risks associated with dispensing certain high-alert medications and use a series of scorecards to estimate how often prescribing and dispensing errors reach patients and how the frequency will change if certain interventions are implemented.

To access these free Medication Safety Tools, go to: http://www.ismp.org/ahrq/default.asp

52nd National Pharmacy Week Celebration

Inaugural Programme

Date:
17th November 2013 (Sunday)

Venue:
Shri Shiskhayatan School Auditorium, 11 Lord Sinha Road, Kolkata-700071

Time: 10.00 am
Organizer:
IPA, Bengal Branch

FDA takes two important actions on drug shortages

FDA is taking two steps to further enhance the agency's efforts to prevent and resolve drug shortages. First, FDA is releasing a strategic plan called for the

Food and Drug Administration Safety and Innovation Act of 2012 to improve the agency's response to imminent or existing shortages, and for longer term approaches for addressing the underlying causes of drug shortages. Second, the FDA issued a proposed rule requiring all manufacturers of certain medically important prescription drugs to notify the FDA of a permanent discontinuance or a temporary interruption of manufacturing likely to disrupt their supply.

Researchers identify 11 genetic loci linked to Alzheimer's

The International Genomics of Alzheimer's Project has identified 11 previously unidentified loci and a number of new pathways involved in the development and progression of Alzheimer's disease. Of particular note is a link between Alzheimer's and a locus that plays a role in immune and inflammatory functions. The genomic region has also been linked to Parkinson's disease and multiple sclerosis, providing a possible avenue for a common therapeutic approach. The discovery may lead to possible targets for the development of drugs aimed at prevention or delaying disease progression, according to the study published in Nature Genetics.

India extends anti-dumping duty on drug from China

India's Central Board of Excise and Customs has placed an anti-dumping duty of $787 per ton on imports of the analgesic drug Paracetamol from China for five years. The duty was first imposed in 2001 and extended through 2013, after the Directorate General of Anti-Dumping & Allied Duties found that imports were damaging India's domestic industry.

Drug price review pleas of top drugmakers denied in India

The review petitions filed by Abbott and Dr. Reddy's Laboratories on the ceiling prices of their drugs were denied by India's Department of Pharmaceuticals, citing provisions of the country's new Drug Price Control Order. Abbott's review application for its 25mg/ml Promethazine injection as well as its 30mg and 60mg Phenobabitone tablets was denied by the agency, and so is Dr. Reddy's review petition for its 20mg omeprazole capsules. The agency also rejected Alembic Pharmaceuticals' review petition for its 500mg Azithromycin tablets.

Forthcoming Event

One Day Workshop on

"Clinical Trial: Recent Development in Science and Regulation"

18th November 2013

at

The Stadel

Yuba Bharati Krirangan Gate No: 03 Salt Lake, Kolkata -700098

Organized By:

Indian Pharmaceutical Association, Bengal Branch

Collaborators:

Apollo Pharmacy

Sanofi India Ltd.

Registration:

Rs. 2000 per participant

Rs. 1500 per participants (IPA Members)

Contact: Mr. P.K.Mallik

E-mail:

ipabengalbranchn@gmail.com

Mob. 09830574612