FOREWORD

Prof. Dr. Suresh Nagpal

Chief Patron,

Chairman, Krupanidhi Educational Trust, Bangalore

Dear Professionals,

It is a big challenge for all of us today to contribute and improve Medication safety. The theme of the conference is very relevant. Government of India is taking few steps to provide subsidized health care for all. We must see that medication safety is above anything. There should be proper health for all by 2020. I am sharing an important knowledge base review. India makes cheaper generic drugs prescription compulsory in public hospitals.

Indian health ministry has asked all the public hospitals and autonomous medical institutions to compulsorily prescribe cheaper generic versions of branded drugs.

Whenever any branded drug is prescribed in the central government-funded hospitals and autonomous institutions under the Ministry, it shall invariably also be mentioned that any other equivalent generic drug could also be provided.

Generic medicines are therapeutically equivalent copycats of usually costlier branded medicines. Brand names are generally costlier because they are usually patent-protected and are not restricted by any price control.

Drug companies also sell drugs using their brand names charging a premium. Generic versions of most of the branded formulations are available in the market. Because their action and other properties are similar to that of any branded drug generics can be substituted for any branded medicine.

With the prescription of generics being made mandatory the hospitals could have the flexibility of providing cost-effective versions of generic equivalents of the prescribed medicine.

The Union Ministry of Health & Family Welfare has taken in the light of the fact that generic drugs are usually much cheaper than branded drugs, according to a release by Press Information Bureau, under the government of India.

This will also curb the often observed practice of prescribing specific brands of medicine with a rider that no substitute should be supplied.

The Directorate General of Health Services will regularly monitor the prescriptions in the above mentioned institutions for the compliance of the Order, the release said.

India's western state of Rajasthan has recently started an initiative that all the public hospitals would start prescribing cheaper generic drugs promoted by the government through its Jan Aushadhi programme, instead of the usual branded formulations of commonly used drugs.

The government of Rajasthan has already issued guidelines to the doctors in the government hospitals to prescribe generic drugs.

The ambitious Jan Aushadhi programme has been started by the government of India to ensure availability of medicines at low cost to the common man across the length and breadth of India.

The chemicals and fertilizer ministry, under the government of India, which oversees the drug sector, was planning to supply unbranded generic versions of all essential medicines at a price about 50% less than they cost in the market through setting up a chain of round the clock retail outlets in all districts of the country.

Under the scheme, the government provides the space needed to set up the medicine outlet free of cost, apart from a credit facility for medicines for 45 days, to a non-governmental organization that will be responsible to run the shop.

Unbranded versions of generic medicines (sold under the chemical name), including popular antibiotics, pain-killers, cough and cold medication were to be sold at these 'Jan Aushadhi' stores. The medicine for these retail outlets were to be sourced from the public sector drug manufacturers including Indian Drugs and Pharmaceuticals, Hindustan Antibiotics, Rajasthan Drugs and Pharmaceuticals and Bengal Chemicals and Pharmaceuticals.

India government is planning to supply cancer drugs also at discounted rates to patients through public retail outlets meant for low-cost generics.

Kindly deliberate on all the presented and published scientific work. Help the nation grow further with your effective contributions.

Dr. Raman Dang

Chairperson - Local Organsing Committee
&
Principal, Krupanidhi College of Pharmacy

Dear Readers,

It is a moment of pride for us to bring out a special conference issue. ACPI-KSPOR have taken up a huge task on their hands. The association is tirelessly organizing conferences and arranging community programmes. Dr. Udupa - President KSPOR and Dr. Anantha Naik Nagappa – President ACPI are doing a commendable job. The Faculty and staff should attend their workshops and conferences; all are beautifully designed and have a very relevant content base. The entire team at Krupanidhi especially the Convener has taken extra care to give you the best in Medication Safety and Pharmacoeconomics. The published abstracts have been extensively reviewed. They will definitely benefit you to bring out a quality research plan. A note on Pharmacovigilance in its present status and of course the tremendous future is briefly discussed here.

Current Trends

In recent times, pharmacovigilance has started gaining importance in the media as the number of stories on drug recalls increases. Since clinical trials involve only smaller numbers and selected groups of patients, less common adverse events are often unknown at the time when a drug enters the market. Also, use of drugs in organ-impaired patients and use in special populations like pregnant women and children are not studied extensively in clinical trials because of ethical limitations.

Postmarketing pharmacovigilance gains much importance, since it uses tools such as data mining and investigation of case reports to identify the relationships between drugs and ADRs. India is now coming to understand that the benefit-risk ratio of pharmaceutical products is a dynamic variable and that it has to be continuously monitored.

Early detection of signals from both clinical trials and post-marketing surveillance studies are done by global pharmaceutical companies in order to identify the risks associated with the medicinal products and effectively manage the risks by applying proactive risk management plans throughout the life cycle of the product.

Indian pharmaceutical companies with international presence have understood these changes in the global scenario and are also starting to apply the same strategies.

Signal detection and risk management have added new dimensions to the field of Indian pharmacovigilance and as evolving disciplines, they require ongoing refinement in order to increase their applicability and add value to the public health aspect in India. With the Indian pharmaceutical industry entering into a good number of joint ventures with multinational pharmaceutical companies and considering the phenomenal increase in export of Indian-made drugs to the developed world, the pressure is mounting on the Indian pharmaceutical companies to invest in pharmacovigilance either by setting up their own team completely or outsourcing parts of it to contract research organisations.

Till recently, the Indian drug market has mostly seen the launch of only those products that were already approved and marketed in the regulated markets. For assessing the benefit-risk profile of a drug and to take appropriate corrective actions, the Indian pharmaceutical companies as well as the regulators have been depending on the experiences gained from these markets.

Due to this reason, pharmacovigilance was considered to be non-vital and little emphasis was placed on establishing an India-specific pharmacovigilance system. However, with drugs getting global approvals almost simultaneously, the lead time Indian regulators used to get before deciding on the approval of a drug has decreased so much that the longer-term safety data from the regulated markets is no longer available.

The capability that Indian drug companies have built in getting close to bringing their own research molecules to the market has indicated that implementing sufficient internal pharmacovigilance standards to detect adverse drug events is something that they cannot ignore any more. Moreover, with Indian companies launching biosimilars which cannot be considered as replicas of the innovators' molecules due to their complex structure and high molecular weight, special pharmacovigilance planning is needed for this set of drugs.

With expansion of the medical devices market in India and augmented awareness of Adverse Events Following Immunisation (AEFI) through the media, the significance of the pharmacovigilance of medical devices and vaccines is now being realised. Thus, globalisation seems to have played a major role in breaking the 'innovator company – generic company' divide.

Another point to ponder is that most of the high-profile drugs that have been recently withdrawn were available in Indian market. In such cases, the Indian regulatory agency could not count on the experience of other regulated markets to assess the benefit risk balance of the said drug. In fact, we are not even sure as to whether those drugs harmed Indian patients to a lesser extent or if they did so more seriously. This point stresses the importance of developing our own adequately designed pharmacovigilance system for India. All these factors have drawn the attention of the Indian regulators and the pharmaceutical companies toward the inadequacy of pharmacovigilance systems in India.

The Future

Though the PvPI is a huge step forward in the right direction for accumulating Indian pharmacovigilance data, it is currently restricted to the approved medical college hospitals in India, public health programmes, and autonomous institutes like the Indian Council of Medical Research (ICMR).

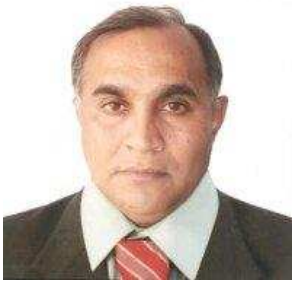
The data received by PvPI is shared with the WHO through their VigiFlow and PaniFlow software but not shared with the concerned pharmaceutical companies, which misses the opportunity for understanding and managing the risks identified.

However, it is understandable that, being the beginning, it is not possible to set up a holistic pharmacovigilance system overnight and hopes are bright that the PvPI will become the centre of excellence for Pharmacovigilance in the Asia Pacific, as it targets, in due course.

It is strongly felt that, apart from the PvPI, Indian pharmaceutical companies also should educate all their staff on adverse event reporting and ensure that a proper pharmacovigilance plan is put in place for the products they market in India, as they do for their international operations in the regulated markets.

This will not only make them compliant with the DCGI's regulations (especially when the submission of Periodic Safety Update Reports has been made mandatory by the DCGI) but also instill the confidence among healthcare professionals and consumers about the commitments of the pharmaceutical companies to pharmacovigilance. It will also help the pharmaceutical companies monitor their medicines for risk and to devise and implement effective risk management plans to define their use in difficult circumstances in India, as they do in the regulated markets. The DCGI could be the regulator for this system which, if implemented, will complement the PvPI and ensure that Patient Safety of the highest order gets established in India within the next few years.

Good Luck & Best wishes



Dr. Anantha Naik Nagappa

President ACPI

www.acpikspor.in

Dear Friends,

I am very happy to present you with the proceedings of the **5th P4- National Conference on Role of Clinical Pharmacists in improving Medication Safety and Pharmacoeconomics,** held on 22-23 August 2015, Bangalore. The P4 conference offers opportunities for the young budding Pharmacists with experience of latest professional development in the area of patient care and patient safety. New diseases invites introduction of new molecules with new risks and new opportunities for the pharmacist to develop new Pharmaceutical Care Program. The conference has 16 speakers and covering various topics like Pharmacoeconomics, Patient Safety, Pharmacovigilance and Outcomes research. The main objective of this proceedings is to document the conference and showcase the feature trends of Pharmacy Practices in India. Presently after central gazette notification on Pharmacy Practice guidelines new hopes have been raised to initiate Pharmacy Practices in the country. These proceedings are going be eyewitness and capture the trends of Pharmacy Practices in the country. Consortium of **Association of Community Pharmacists of India & Kautilya's Society for Pharmacoeconomics and Outcome Research** is the mixing of two NGOs based on the promotion of establishing practice and utilization of Community Pharmacy, Pharmacoeconomics and outcome research.

Prof N. Udupa

President - KSPOR

www.acpikspor.in

Consortium of **Association of Community Pharmacists of India & Kautilya's Society for Pharmacoeconomics and Outcome Research** is the mixing of two NGOs based on the promotion of establishing practice and utilization of Community Pharmacy, Pharmacoeconomics and outcome research. The Pharmacoeconomics and outcome research are the latest approaches in clinical practice and are the extension of therapeutics. The chronic diseases like diabetes, hypertension, and asthma are causing burden and morbidity to the patient and care giver and also causing huge budgetary demands on government. The societal burden is alarming high pushing the family in the downward scale of economics. There is utmost need to develop appropriate technology and also smart approaches to identify lacunae in the current system of health care. Hence importance of Pharmacoeconomics, outcome research and health technology assessment is becoming very essential inputs for decision making. From an individual patient prospective to societal prospective the P4 conferences promoted by consortium of **Association of Community Pharmacists of India & Kautilya's Society for Pharmacoeconomics and Outcome Research** is the attempt to create awareness regarding scope of pharmacoeconomic and outcome research.

Rajeswari R.

Convener- Local Organizing Committee,

Associate Professor, Department of Pharmacy Practice,
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Dear Clinical Pharmacists,

The last three decades witnessed affordable and accessible healthcare for a majority of Indians. To further capitalize on this surge - ACPI KSPOR creates awareness among the practitioners on the 4Ps (Pharmacoeconomics, Pharmacovigilance, Pharmaceutical care, Patient reported outcome) essential for successful pharmaceutical healthcare.

The **5th P4 - National Conference on Role of Clinical Pharmacists in improving Medication Safety and Pharmacoeconomics** is one such initiative. The ACPI KSPOR Bangalore City Chapter headquartered in Krupanidhi College of Pharmacy is highly committed to promote the P4 credo, which has led to the hosting of this National Conference.

In this juncture, I want to thank the Management & Principal of the Krupanidhi College of Pharmacy, for entrusting me with this task, all my committee colleagues who had put their hearts and soul for this effort, the members and the students for their tireless efforts and nonetheless the resource persons and researchers in this domain who are a part of this 5th P4.

I thank the editors of ***Journal of Pharmaceutical Research*** for releasing this special edition to document the proceedings of the 5th P4 National Conference.