EMPRO

Current Research in Pharmaceutical Sciences

Available online at www.crpsonline.com

CRPS 2011; 01: 15-19

Received: 13/11/2011
Revised: 24/11/2011
Accepted: 29/11/2011

Ashish Chauhan, Manoj Goyal

I.P.S.college of Pharmacy,Gwalior.

PHARMACOVIGILANCE : AN OVERVIEW

Ashish Chauhan, Manoj Goyal*

ABSTRACT

Pharmacovigilance is an important and integral part of clinical research. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines. This addresses what exactly is pharmacovigilance? What do we know of its benefits and risks, challenges and the future hold for pharmacovigilance in Indian medicine. Here the main focus on the aims and role of pharmacovigilance in medicines regulation and their Partners. This article describes and discusses the National programme of pharmacovigilance and centre in India. There role in collecting the reports ADRs of medicines. Further effectiveness and risk assessments of therapies are been discussed. The important role played by health care professional, pharmaceutical industries, media, and programmes carried by WHO. Finally the conclusion describes the major challenges and achievements for the future pharmacovigilance programme.

Keywords: Pharmacovigillance, National Programme

1. INTRODUCTION

"The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem" - According to WHO Pharmacovigilance is an important and integral part of clinical research[1]. Bothclinical trials safety and post marketing pharmacovigilance are critical throughout the product lifecycle. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines." Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about the discipline.While major advancements of displine of pharmacovigilance have taken place in the western countries not much has been achieved in India. There is an immense need to understand the importance of pharmacovigilance and how it impacts the life cycle of the product. This will enable integration of good pharmacovigilance practice in the process and procedures to help ensure regulatory compliance and enhance clinical trials safety and post marketing surveillance.Pharmacovigilance is not new to India and has infact been going on from 1998[2]. In recent years many Indian companies are increasing the investment in research and development and are enhancing their capacity to develop and market new drugs with their own research efforts.Further India is becoming a hub for clinical research activities due to its large population high enrolment rate and low cost [3].

Aims of Pharmacovigilance

1. Improve patient care and safety in relation to the use of medicines and all medical and Para medical interventions[4].

Correspondence:

Dr. Manoj Goyal

I.P.S.college of Pharmacy,Gwalior.

E-mail:manojpharmagwl@gmail.com

2. Research the efficacy of drug and by monitoring the adverse effects of drugs right from the lab to the pharmacy and then on for many years.

3. Pharmacovigilance keeps track of any drastic effects of drugs.

4. Improve public health and safety in relation to the use of medicines.

5. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use.

6. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

Adverse Drug Reaction (ADR) in Pharmacovigilance

A reaction which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function

Types of Adverse Drug Reactions (Rawlins and Thompson Classification)

Typtes A Effects (Augmented)

1.Due to pharmacological effects.

2.Are dose related – may often be avoided by using doses which are appropriate to the individual patient.

3.Example: hypnotic effect after H_2 antihistaminics.

Types B Effects ("Bizzard", Idiosyncratic Reactions)

1.Generally rare and unpredictable.

2.Occur in predisposed, intolerant patients – can be explained by rare genetic polymorphism, allergic reactions.

3.Example: Penicilline allergies.

Types C Effects ("Continuous")

1.Adverse reactions after long term therapy.

2.There is often no suggestive time relationship and the connection may be very difficult to prove. The use of a drug increases the frequency of "spontaneous" disease.

3.Example: carcinogenesis.

Types D Effects ("Delayed")

1.Adverse effect may be presented years after a drug was used.

2.Example: Vagina cancer of daughters when their mother was treated by diethylstilbestrol.

Types E Effects ("Ending"):

1.Absence of drug after withdrawal – rebound effect.

2.Example: corticosteroids in asthma treatment.

Why Do We Need Pharmacovigilance?

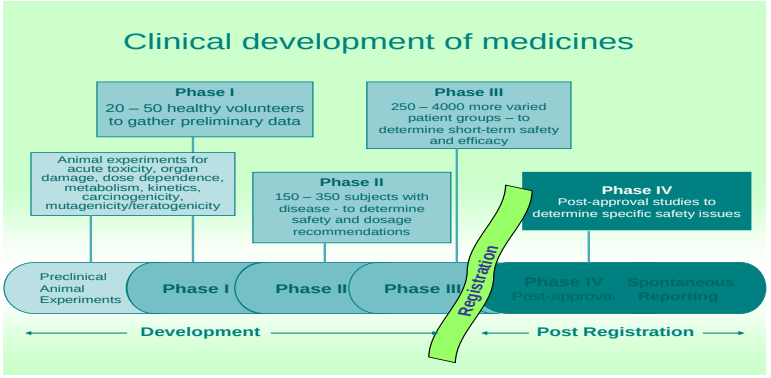
Reasons:

1.Humanitarian concern –

-Insufficient evidence of safety from clinical trials

-Animal experiments

-Phase 1 – 3 studies prior to marketing authorization



2. Medicines are supposed to save lives.Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable. Lepakhin V. Geneva 2005.
3. ADRs are expensive.
4. Promoting rational use of medicines and adherence.
5.Ensuring public confidence.(If something can go wrong, it will – Murphy's law)
6. Ethics (To know of something that is harmful to another person who does not know, and not telling, is unethical.)

2. REAL SCOPE OF PHARMACOVIGILANCE[18,19]

In general, pharmacovigilance is a multidisciplinary issue: basic and clinical pharmacology; clinical medicine; toxicology; epidemiology; and (pharmaco) genetics are the major disciplines involved in this scientific process, which is coordinated by a stringent regulatory framework.The ultimate aim of pharmacovigilance is the optimisation of therisk–benefit ratio of

marketed drugs at the individual level (ie, thechoice of the most suitable treatment for a given patient) and at the population level (ie, maintenance or removal of a drug from the market, informing prescribers of its potential risks, etc).

3. PARTNERS IN PHARMACOVIGILANCE

The management of the risks associated with the use of medicines demands close and effective collaboration between the key players in the pharmacovigilance[6]. Sustained commitment to such collaboration is vital if the future challenges in pharmacovigilance are to be met, and if the discipline is to continue to develop and flourish. Those responsible must jointly anticipate, describe and respond to the continually increasing demands and expectations of the public, health administrator policy officials, politicians and health professionals However, there is little prospect of this happening in the absence of sound and comprehensive systems which make such collaboration possible. The constraints typically include lack of training, resources, political support, and most especially scientific infrastructure. Understanding and tackling these are an essential prerequisite for future development of the science and practice of pharmacovigilance.

4. PHARMACOVIGILANCE IN THE REGULATION OF MEDICINES

Robust regulatory arrangements provide the foundation for a national ethos of medicine safety, and for public confidence in medicines. To be effective,the remit of drug regulatory authorities needs to go further than the approval of new medicines, to encompass a wider range of issues relating to the safety of medicines, namely:

• clinical trials;

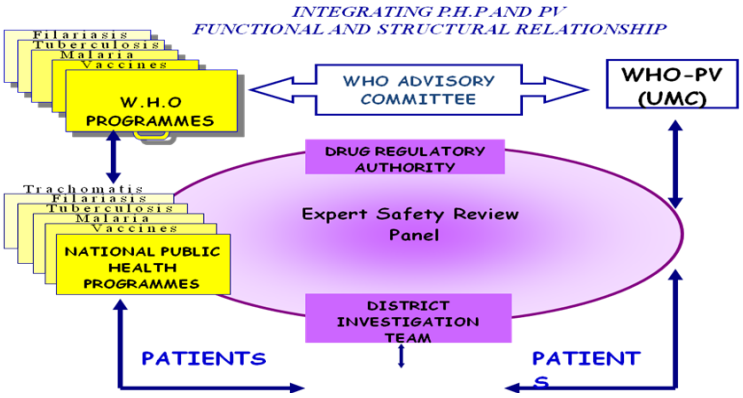
• the safety of complementary and traditional medicines, vaccines and biological medicines;

Pharmacovigilance in Clinical Practice

Safety monitoring of medicines in common use should be an integral part of clinical practice. The degree to which clinicians are informed about the principles of pharmacovigilance, and practise according to them, has a large impact on the quality of health care. Education and training of health professionals in medicine safety, exchange of information between national pharmacovigilance centres, the coordination of such exchange, and the linking of clinical experience of medicine safety with research and health policy, all serve to enhance effective patient care. A regular flow and exchange of information in this way means that national pharmacovigilance programmes are ideally placed to identify gaps in our understanding of medicine-induced diseases.

Pharmacovigilance in Disease Control Public health Programmes

The monitoring of medicine safety in countries where there is no regulatory or safety monitoring system in place, or in remote areas with little or no health care surveillance or infrastructure, has been identified as a matter for concern. The problems are especially apparent in situations that involve the use of medicines in specific communities, for example, for the treatment of tropical diseases such as malaria, leishmaniasis and schistosomiasis, and for the treatment of HIV/AIDS and tuberculosis. Pharmacovigilance should be a priority for every country with a public health disease control programme.



Pharmacovigilance of Herbal Medicines:

The safety of herbal medicines has become a major concern to both national health authorities and the general public. [16,17] The use of herbs in Traditional medicines continues to expand rapidly across the world. Many people now take herbal medicines or herbal products for their health care in different national health-care settings. However, mass media reports of adverse events tend to be sensational and give a negative impression regarding the use of Herbal medicines in general rather than identifying the causes of these events, which may relate to a variety of issues.

5. NATIONAL PROGRAMME OFPHARMACOVIGILANCE

Before a product is marketed, experience of its safety and efficacy is limited to its use in clinical trials, which are not reflective of practice conditions as they are limited by the patient numbers and duration of trial as well as by the highly controlled conditions in which Clinical Trials are conducted. The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed.Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions is often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine.

Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products.

1.Assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use

2.Providing information to users to optimise safe and effective use of medicines

3.Monitoring the impact of any action taken

The National Pharmacovigilance Centres

At present, post-marketing surveillance of medicines is mainly co-ordinated by national pharmacovigilance centres. In collaboration withthe Uppsala Monitoring Centre (UMC) the National Centres have achieved a great deal in:

1.Collecting and analysing case reports of ADRs

2.Distinguishing signals from background 'noise'

3.Making regulatory decisions based on strengthened signals

4.Alerting prescribers, manufacturers and the public to new risks of adverse reactions.

National Pharmacovigilance Centres are Responsible For

1.Promoting the reporting of adverse reactions;

2.Collecting case reports of adverse reactions;

3.Clinically evaluating case reports;

4.Collating, analyzing and evaluating patterns of adverse reactions;

Roles and Responsibilities[7,9,10]

Where established, the national pharmacovigilance centre will be responsible for the development of pharmacovigilance in the public health system, will promote pharmacovigilance in the PHPs and sensitize professionals and public health staff to the reporting of adverse reactions and irrational use of medicines.

6. ROLE OF PHARMACIST[8,11,12]

1.Participate in spontaneous Reporting of Adverse Events.

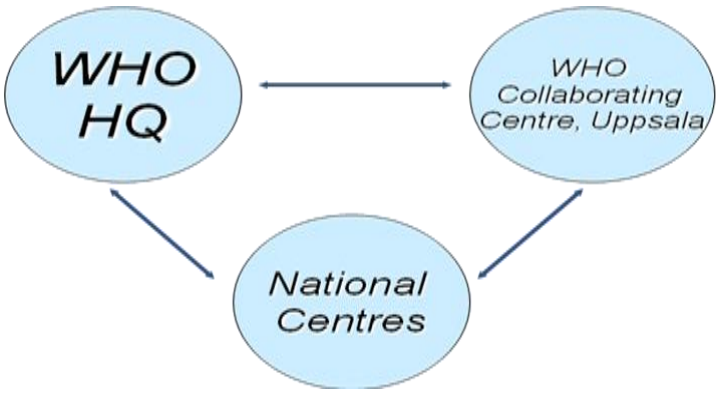
2.Also report (even if no adverse event).

3.Medication errors.

4.Exposure during pregnancy

Who Programme for International Drug Monitoring

National pharmacovigilance centres are functioning as an international network coordinated by the WHO Programme for International Drug Monitoring. The Programme has achieved much in improving the activities, support and recognition of individual national pharmacovigilance centres.It plays a key role as a communication and training centre and clearing-house for information on the safety of medicines. The WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden manages the international database of adverse reaction reports received from national centres. In 2005 this database held over 3.5 million case reports. The majority of contributing national centres has ready electronic access to these. The Centre has established standardized reporting by all national centres and has facilitated communication between countries to promote the rapid identi?cation of signals. The terminologies developed within the WHO programme for coding adverse reactions to medicines have been widely adopted by national centres, manufacturers and medicine regulators.



Major Challenges are[5,13,14,15]

1.Globalization

2.Web-based sales and information

3.Broader safety concerns

4.Public health versus pharmaceutical industry economic growth

5.Developing and emerging countries

6.Attitudes and perceptions to benefit and harm

7.Detection of ADRs

8.Assessment of ADRs

9.Communication

7. CONCLUSION

Despite its 40-year history, pharmacovigilance remains a dynamic clinical and scientific discipline. It continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines, all of vitamins unpredictable potential for harm. When adverse effects and toxicity do appear especially when previously unknown it is essential that these are reported, analysed and their significance communicated effectively to an audience that has the knowledge to interpret the information. Which carry an inevitable and some-For all medicines there is a trade-off between the benefits and the potential for harm. The harm can be minimized by ensuring that medicines of good quality, safety and efficacy are used rationally, and that the expectations and concerns of the patient are taken into account when therapeutic decisions are made. To achieve this is to:

1. Serve public health, and to foster a sense of trust among patients in the medicines they use that would extend to confidence in the health service in general;

2. Ensure that risks in drug use are anticipated and managed;

3. Provide regulators with the necessary information to amend the recommendations on the use of the medicines;

4. Improve communication between the health professionals and the public;

5.Educate health professionals to understand the effectiveness/risk of medicines that they prescribe. This is the important role of pharmacovigilance.

REFERENCES

1.Pipasha B, Arun KB. Setting standards for proactive pharmacovigilance in India : The way forward. Indian J pharmacol. 2007;39(3): 124-128.

2.Kumanan R, Sudha S, Vijayashre P, Charumath S, Gowridevi KC, Mahesh M. Imperative Approach on pharmacovigilance in Indian systems of medicines. International journal of pharma sciences and Research (ijpsr). 2010;1(9): 378-390.

3.Deepa A. Pharmacovigilance obligations of the pharmaceutical companies in India. Indian J pharmacol. 2008;40: S13-S16.

4.WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.

5.WHO, Safety of medicines in public health programmes : pharmacovigilance an

essential tool,WHO,2006.

6.Yves S. Pharmacovigilance for pharmacist, Johnson &Johnson (2006).

7.Edwards IR. The accelerating need for pharmacovigilance. Journal of the Royal college of Physicians. 2000;34: 48-51.

8.Lazarou J. Incidence of ADR in hospitalized patients: A meta analysis of prospective studies. Journal of the American medical association. 1998; 279:1000-1008

9.Meyboom RHB, Egberts ACG, Gribnau FWJ, Hekster YA. Drug Safety: Pharmacovigilance in perspective. 1999; 21(6): 429-447.

10.Mary R. couper and shanthi pal :Quality assurance and safety of medicines ,WHO, Geneva (2008).

11.Sten O. Pharmacovigilance training with focus on India. Indian J pharmacol 2008; 40: S28-S30

12.Talbot JCC, Nilsson BS. Pharmacovigilance in the Pharmaceutical industry. British Journal of Pharmacology. 1998; 45:427-431.

13. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, World Health Organization, Geneva (2004).

14. Rahman SZ, Singhal KC. Problems in pharmacovigilance of medicinal products of herbal origin and means to minimize them, Uppsala Reports, WHO Collaborating Center for ADR monitoring, Uppsala Monitoring Centre, Sweden, (2002): 1-4.

15. Edwards R. The future of pharmacovigilance: a personal view. Eur J Clin Pharmacol. 2008; 64:173-181.