RECOGNITION AND REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS USING SDA-PHARMACOVIGILANCE

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INTRODUCTION

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at the country level. At the end of 2010, 134 countries were part of the WHO PV Programme. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.

AIM OF THE STUDY

- The purpose of this work is to present the significance and development of pharmacovigilance as part of the pharmaceutical and healthcare work, the centers and participants in the system of pharmacovigilance, side effects of the drugs and the correct manner of their reporting, and post-marketing monitoring of drugs.

MATERIALS AND METHODS

- Primary, secondary and tertiary literature
- Guidelines and recommendations according to WHO, EMA and FDA
- Data from Register of medicines of Republic of Macedonia
- Evaluation of documents from centers for monitoring adverse drug reactions and the written regulations of Republic of Macedonia.

RESULTS

The system of pharmacovigilance has an international character. The international cooperation center for monitoring of medications (The Uppsala Monitoring Centre - UMC) which is under WHO Headquarter guidance, is a network of eighty National Centers that are collecting and reporting suspected adverse reactions to drugs (ADRs). It is the largest database of ADRs reports in the world, and it is main source for generating signals of previously unknown ADRs, also studying the issues of medication safety. Regulation in the Republic of Macedonia are fully harmonized with the recommendations of the WHO and the EU, however, the reports for adverse reactions to the National Center are significantly less than the other European countries.

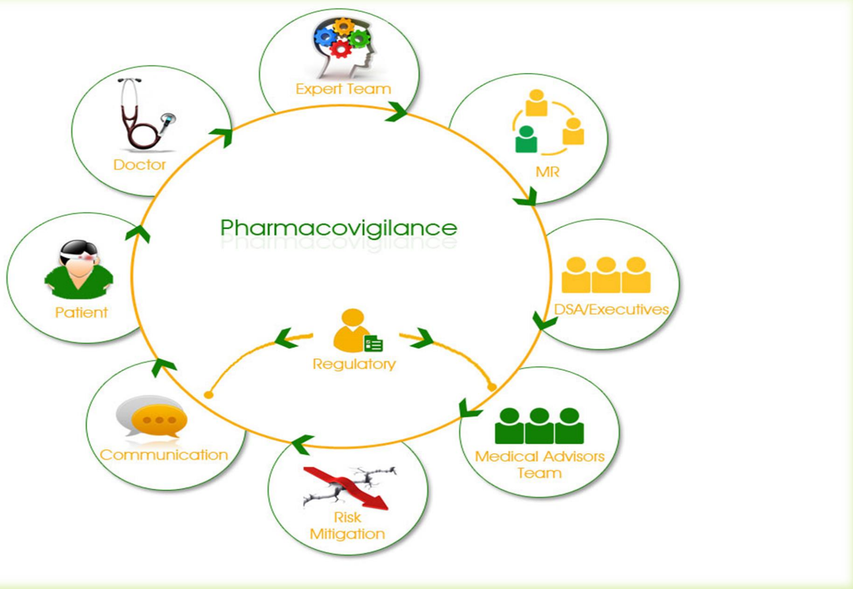

Fig.1. Pharmacovigilance system

Fig.2. Most commonly reported adverse drug reactions

CONCLUSION

With more involvement and increased responsibility of healthcare professionals, the patients themselves, researchers, pharmaceutical industry, regulatory authorities and international organizations, safety of the treatment significantly would be improved and would reduce health care costs.

REFERENCES

1. The safety of medicines in public health programmes: Pharmacovigilance an essential tool, World Health Organization, 2006
2. Good Pharmacovigilance Practice Guide, Medicines and Healthcare products Regulatory Agency, 2009
3. Best practice in reporting of individual case safety reports, Medicines and Healthcare products Regulatory Agency, 2011