MATERIOVIGILANCE IN NORTH MACEDONIA- REGULATION AND HARMONIZATION

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INTRODUCTION

Medical devices equally as medicines, are an important segment for normal functioning of the health system and an integral part of pharmacy practice. Diversity and specifics are complicating the harmonization of the regulative. The care and actions which ensure safe and proper use of medical devices as well as monitoring of possible safety problems and adverse reactions, are the subject of numerous recommendations, regulations and standards.

METHODOLOGY

The purpose of this study is: to analyze the recommendations of the WHO, EU, FDA, PGEU and their implementation in developed countries and RM, to realize the aim of harmonizing the vigilance system, to define the specifics on the classification, the quality standards of materiovigilance that guarantee safety for using the medical devices and legal support that it provides, the opportunities and the degree of harmonization of the vigilance system in North Macedonia compared to other countries.

RESULTS AND DISCUSSION

In order to achieve the set goals, we reviewed relevant literature sources of primary and secondary literature, documents and recommendations of the WHO, EU, FDA, PGEU and specific regulatory authorities for nomenclature, classification, standardization and quality assurance. We made a comparison of the regulation systems of materiovigilance in America, Australia, England, India and Macedonia. The obtained results show that there is a high degree of harmonization of regulatory systems of the Republic of Macedonia with other members of GHTF which guarantees a high level of efficiency, security and accuracy, partly limited by the possibility of parallel imports.

Table 1. Difference in vigilance systems in UK, USA, Australia and India

Table 3 Differences in vigilance systems of US, UK, Australia, and India

Parameters of countries	FDA	TGA (Australia)	MHRA	CDSCO (India)
Definition of medical device	Includes all instruments, appliances, materials, machines, in vitro diagnostic agents, implants, software, accessories, and disinfectants	Excludes tampons and hospital, household, and commercial-grade disinfectants	Excludes materials used for disinfection of medical devices	10-device category regulated as drug
Medical device classification	3 classes: class I, class II, and class III	5 classes: class I, classes IIa and IIb, class III, and class AIMD	4 classes: class I, class IIa, class IIb, and class III	No defined classes for devices
Basis of classification	Level of control Medical specialties	Classification rules	Classification rules	NA
Postmarketing surveillance activities	Medical device tracking MDR MDR event files, records, and written procedures Complaint handling Recall procedure and seizures	Adverse event reporting Vigilance exchange program Enforcement activities Distribution records Audits	Adverse event reporting FSCA and field safety notices Enforcement Postmarket clinical follow-up Records	Adverse event reporting For importers adverse event reporting procedure for distribution of records procedure for recall
Medical device tracking	Have established tracking system since 1993	IMDTS developed recently for tracking of patients with implantable medical devices	AITS developed to investigate the failure modes of the device by assessment of user reports	In labeling provisions, the lot number/batch number for device is mandatory for easy traceability
Who need to report AE	Manufacturers, importers, user facilities, users, distributors, and health professionals	Manufacturers, sponsors, users, health professionals, and TGA	Manufacturers, users, health professionals, authorized representatives, and MHRA	Manufacturers only
Criteria for reporting	Death or serious injury Device malfunctions User error Injury/illness requiring medical intervention	Event has occurred Medical device's association with the event Event led/might lead to death/ serious injury	Event has occurred Medical device's association with the event Event led/might lead to death/serious injury	Event has occurred Medical device's association with the event Event led/might lead to death/ serious injury
Not-reportable incidents/events	Manufacturers can apply for RAE, eg, Erroneous information When other manufacturer makes the device	User-detected deficiencies Root cause of the adverse event is due to the patients' pre-existing condition Exceeded service life of device Likelihood of adverse event is acceptable after risk assessment Side effects clearly identified in the manufacturer's labeling and documented in device master record	User-detected deficiencies Root cause of the adverse event is due to the patients' pre-existing condition Exceeded service life of device Likelihood of adverse event is acceptable after risk assessment Side effects clearly identified in the manufacturer's labeling and documented in device master record	User-detected deficiencies Root cause of the adverse event is due to the patients' preexisting condition Exceeded service life of device Likelihood of adverse event is acceptable after risk assessment Side effects clearly identified in the manufacturer's labeling and documented in device master record

(*Continued*)

CONCLUSION

Medical devices equally as medicines, are an important segment for normal functioning of the health system and an integral part of pharmacy practice. We conclude that Implementation of the system of materiovigilance is in accordance with the recommendations of the WHO, EU and specific bodies established for that purpose.