Overview of the legislative framework for pharmaceutical care and its role in the recognition, prevention and management of adverse drug reactions

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Background Pharmacists are the most accessible healthcare professionals and pharmacotherapy consultants. Increasing the patient awareness of medicines is a key aspect of the good pharmacy practice (GPP) documents worldwide. Therefore pharmaceutical care could be used as a tool for promoting pharmacovigilance activities in society.

Purpose The aim of the study is to explore the European legislative framework, national and international guidelines regarding pharmaceutical services and concept of pharmaceutical care. The main objective of the work is to analyze the ?preventing harm from medicines component? of the GPPs in the context of the new pharmacovigilance legislation.

Method The main European legislative documents regarding medicines for human use and the implementation of their requirements on national level has been analyzed. The special emphasis was put on the role of the pharmacist as a highly qualified consultant and source of information on the healthcare system and medicinal products. The FIP/WHO guideline on GPP, the Bulgarian rules for GPP and the PGEU annual data and factsheets have also been included in the analysis. We specify the main components of the pharmaceutical care and show the feedback from some newly developed pharmacy services programs in several member states.

Findings The general framework of the European pharmaceutical legislation is focused on providing the patient with safe and effective medicinal products of high quality. As well as the requirements regarding manufacturing process, clinical trials and prescribing, another main component is the communication between pharmacist and patient which aims at informing and consulting consumers for both the benefits and the potential risks of the therapy. These requirements are based on the GPPs and are implemented in Bulgarian legislation. PGEU data from several member states showed that additional pharmacy services other than dispensing medicines could improve patient compliance and facilitate treatment process. They are also a tool to help society understand better the medicinal product life cycle, the importance of adverse drug reactions reporting and the impact this could have on the development of the pharmaceutical system.

Conclusion Pharmaceutical care is the most accessible and patient-friendly method to show that the main focus of the healthcare systems worldwide is patient safety. Broadening the scope of pharmacy services by including information on pharmacovigilance and adverse drug reaction reporting could help patients take a more active part in the treatment process, improvement of compliance, adherence and drug safety.