ABSTRACT

Background: Pharmaceutical care will become a standard of performance only when all pharmacists accept their social responsibility regarding the safe and effective drug therapy of each patient. Achieving therapeutic goals of pharmacotherapy requires collaboration between prescriber, pharmacist and patient to assess its precise drug therapy. Pharmaceutical care is aimed at providing drug therapy responsibly, to achieve specific results that increase the quality of life of the patient. Many studies have been published on the effects of pharmaceutical care.

Objective: Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist’s actions. We conducted a comparative analysis of the supply, impact and experience of participating in pharmaceutical care services around the world. Setting: International pharmacy practice. Methods: The literature search was conducted in 2012. Researched materials based on literature review are: literature data based on keywords in scientific databases: Scopus, Medline, Google Scholar, Springer and others, regulatory documents on national level and developed national guidelines on the nature of the Pharmaceutical care services. The collected information was statistically preceded by Microsoft Office Excel 2003. Main outcome measure: There were found 43 literature sources: 18 articles, 3 books, 10 regulatory documents, 6 guidelines on the nature of Pharmaceutical care services and 6 internet sites. Results: There is available data for 24 European countries, Australia, Canada and USA. In 16 of the countries examined there are legally regulated services directly communicating with the concept “Pharmaceutical care”. In 7 of the countries the patient is not charged for “Pharmaceutical care” and in 3 of the countries – the patient pays part of the cost. The pharmacist, providing the service is paid in 8 of the countries. The universities of
18 of countries have an advocated program of “Pharmaceutical care”. **Conclusion:** The review show huge differences in the definition, offering and applying the Pharmaceutical care services around the world. Important gains can be made by using existing resources more efficiently if the positive examples are applied, without increasing the resources for this service.

**Keywords:** Pharmaceutical care; Legislation; Pharmaceutical education; Pharmaceutical practice.

**INTRODUCTION**

"Public health interventions, pharmaceutical care, rational medicine use and effective medicines supply management are key components of an accessible, sustainable, affordable and equitable health care system which ensures the efficacy, safety and quality of medicines. It is clear that pharmacy has an important role to play in the health sector reform process. To do so, however, the role of pharmacists needs to be redefined and reoriented.” WHO, 2006 [1].

The professional development of a pharmacist today is connected with his/her social responsibility – participating in drug therapy along with other health care providers (specialists) with the aim to optimize it, which includes reducing and avoiding drug-related problems (DRPs), developing an individual treatment plan or making changes to the current one as well as managing treatment in the long term.

Numerous studies have shown that there exists an important link between morbidity, mortality and optimal pharmacotherapy. Through the SPO paradigm (refer to Donabedian) it is possible to evaluate the benefits of pharmaceutical care (PhC) for patients' health and ultimately to society. The implementation of PhC is effective for patients with chronic diseases such as diabetes, hypertension, asthma, hyperlipidemia, chronic pain, rheumatic diseases, mental disorders, and in cases of polypragmasia patients [2]. Achieving therapeutic goals requires collaboration between physician, pharmacist and patient to assess its precise drug therapy [3].

In the profession of pharmacy require not only excellent knowledge of drug action, possible adverse drug reactions and interactions, but also the development of excellent communication capabilities.
Pharmaceutical care services (PhCS) are yet another revolution in pharmacy. Only the uptake and application of this concept in practice will ensure job satisfaction for pharmacists and for patients - satisfaction of this medical service and eliminating DRPs [4].

PhC will become a standard of performance only when the policymakers, health care providers and primarily pharmacists accept their social responsibility regarding the safe and effective drug therapy of each patient.

PhC is aimed at providing drug therapy responsibly, to achieve specific results that increase the quality of life of the patient. PhC focused on the patient enhances the safe use of medicines and helps in avoiding unnecessary visits to the specialist, helps in reducing side effects and helps in solving DRPs [5].

In a study of patients enrolled in the California's Multipurpose Senior Services Program, for the period 2004-2006 it was found that there are mechanisms for reimbursement and assessment of the value which facilitate and increase the identification and resolution of DRPs in elderly patients [6].

AIM OF THE STUDY
Based on the above, we aimed to conduct a comparative analysis of the supply, impact and experience of participating in pharmaceutical care services. To improve the evidence base for pharmaceutical care around the world this study is marking the benefits achieved and the problems that are still to be solved in the process of proper patient care in pharmacy condition.

METHOD
Cross-national comparison and analyses of the available information were provided. Researched materials based on literature review are: literature data based on keywords in scientific databases: Scopus, Medline, Google Scholar, Springer and others, regulatory documents on national level and developed national guidelines on the nature of the service Pharmaceutical care. The collected information was statistically preceded by Microsoft Office Excel 2003.
RESULTS
Researched materials based on literature review are: articles, abstracts, regulatory documents on national level and developed national guidelines on the nature of the PhCS. The results show that there is available data for the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Lithuania, Norway, Poland, Portugal, Republic of Macedonia, Romania, Slovakia, Spain, Sweden, Switzerland, The Netherlands, United Kingdom and USA.

In 16 of the countries examined there is a defined service “Pharmaceutical care”, in 9 of them the term is not used, or it is used, but not in the sense of the concept of “Pharmaceutical care”. For two countries - Lithuania and Norway, there is no evidence for defining services with that name (Table 1).

In the reviewed documents and guidelines for 5 countries, there is evidence about regulation of the service “Drug/Medicine Use Review”, in 12 countries - no such service is defined, because either a different name is used or elements of this service are part of the main activities of the pharmacist. For the other 10 countries no evidence of such service exists (Table 1).

Only 4 of the countries examined offer “Cognitive Pharmaceutical Services” (CPS) and in 3 of them these services are included in guidelines, codes or agreements. For France, no evidence of legal regulation of services by that name exists, but it is used in literature as a term for the application of some of the elements of the concept “Pharmaceutical care”. In 11 of the countries examined is not used the term CPS, and for 12 countries no data for usage of this term for pharmaceutical services exists in either literature or legislative documents (Table 1).

"Drug/Medicine Use Review" is used in 6 of the reviewed countries, in e 5 of them – there are no services defined by this name and in the rest 16 there is no evidence for such service (Table 1).

In 16 of the countries examined there are legally regulated services directly communicating with the concept “Pharmaceutical care”, but the level of implementation is not equally supported in each. In 9 countries no legally regulated services that are related to the concept of “Pharmaceutical care” exist, while in the remaining two countries - Finland and
Switzerland, no evidence of a specific definition in the legislation that sets out the provision of “Pharmaceutical care” as a compulsory part of pharmacy practice exists, but in both countries there are studies and various national projects for the implementation of such a service (Table 2).

In 7 of the countries the patient is not charged for “Pharmaceutical care” and in 3 of the countries– the patient pays part of the cost (in Germany for example - 10%). For the remaining 17 countries - no data is presented. (Table 2)

The pharmacist, providing the service is paid in 8 of the countries. In 7 of them the pharmacist gets not payment, as one of the possible reasons for these findings is that the “Pharmaceutical care” service does not exist. For the other 12 - no data is presented (Table 2).

The universities of 18 of countries have an advocated program of “Pharmaceutical care”. In the remaining 9 states there is no evidence whether and how “Pharmaceutical care” is included in the curriculum (Table 2).

Table1. Availability of Pharmaceutical care, Medication management, Cognitive Pharmaceutical Services, and Drug Use Review in the countries studied

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Table 2 Summarized data of the legal basis, patient’s payment for this service, the availability of financial compensation for the pharmacist, and the presence of Pharmaceutical care education.
DISCUSSION

In many of the studies countries there are legislation documents and guidelines that force the implementation of the Pharmaceutical care concept in the everyday pharmacy practice, based on good educational basis.

Since 1990, in Australia, agreements between community pharmacies (Community Pharmacy Agreement) are signed, in regards to changing the direction and funding of pharmaceutical services. By 2010 an effective 5th Community Pharmacy Agreement is presented between community pharmacies, which include various initiatives: Medication management (management of drug therapy), Research and development, mandatory services, regional rules, Pharmacy practice incentives (encouraging the practice of pharmacy) and others. Medication Management itself consists of several programs:
- MedsCheck and Diabetes MedsCheck (MedsCheck services) provide for an in-pharmacy review of consumers who are taking multiple medications and/or have newly diagnosed or poorly controlled type 2 diabetes. These services are aimed at enhancing the quality use of medicines and reducing the number of adverse drug events experienced by consumers.

- Home Medicines Review (HMR) Funding of up to $52.11 million is provided under the Fifth Community Pharmacy Agreement for the HMR program. The HMR program is designed to assist individuals living at home to maximize the benefits of their medicine regimen and prevent medication related problems.

- Residential Medication Management Review (RMMR) program. The RMMR program aims to enhance the quality use of medicines, and reduce the number of adverse medicines events by assisting residents and their careers with their medication regimens [7].

In 1998 the Austrian Chamber of Pharmacists launches Initiative for “Pharmaceutical care” for patients with asthma.

According to van Mil and Schulz in Belgium, the Flemish pharmacist association underlined the priority of PhC (farmaceutischez org) in 1994, and Haems published pharmaceutical care guidelines in the Flemish pharmacist journal in 1995 [8]. Even so, full development started relatively late. In 2005, the provision of pharmaceutical care became a legal duty for the community pharmacist [9]. Implementation remains difficult in this country, because usually there is only one pharmacist per relatively small pharmacy [10]. Universities in Ghent, Leuven and in Antwerp have established training in “Pharmaceutical care”.

In Bulgaria, the term “Pharmaceutical care” is adopted in 2002. Employing a framework for developing standards for “Pharmaceutical care” is part of the “Good Pharmaceutical Practice” which is mandatory under the Professional Association of Masters of Pharmacy Law since 2006, which introduced the concept of “Pharmaceutical care”, but did not define its essence. Different elements of PhC are applied, but no collaboration with other health professionals, a system for documenting and a system for reimbursement of this service still exist. Universities have established training in “Pharmaceutical care”, set out in the National state requirements as part of a Master's degree in Pharmacy and a number of studies have been conducted in this area.
According to “Tenth pharmacy trends report” by Rogers Media, cognitive pharmaceutical services are provided in Canada, and they are clearly regulated, and in exchange for their application the pharmacist receives remuneration [11]. Canadian Pharmacy Services Framework was established. that consists of three main elements, which are focused on the therapeutic role of the pharmacist in the treatment process. In its entirety and continuity they provide an appropriate, safe and effective drug therapy:

- core dispensing services;
- enhanced medication related services;
- expanded patient care services, part of which is management of drug therapy [12].

In Law on Pharmacy of the Republic of Croatia, “Pharmaceutical care” is regulated as part of the practice of pharmacy and the services covered by this term are defined [13]. In Croatia there is a pharmaceutical high quality system, but there is no good communication between the various participants in the health system [14]. The same also is valid for the Hungarian system of pharmaceutical care. “Pharmaceutical care” training at the university level in Zagreb started in the 2009/2010 academic year.

In the Czech Republic, the Law on Public health № 20/1996 regulates the so-called “Pharmacy care”. Some elements of “Pharmaceutical care” are part of the “Pharmacy care”. Elements of “Pharmaceutical care” are also introduced in the “Code of Ethics of the Czech Pharmaceutical Chamber”, adopted in 1991.

In Denmark, pharmaceutical care is one of the professional standards for work in a pharmacy since 1992 [15]. Besides drug counseling and measurement of cholesterol, blood sugar and blood pressure, different practical models of Pharmaceutical care are developed there. These models include "Self-medication and personal drug usage" and "pharmaceutical care at-the-counter model" (pharmaceutical care in community pharmacies), which are focused on identifying, resolving and preventing drug-related problems associated with each particular disease. Besides, each year is dedicated to a specific topic and most pharmacists are actively involved in the provision of “Pharmaceutical care”, e.g. diabetes or pharmacovigilance (patient safety).

In the Baltic countries, PhCS is not applied, unlike other countries of the European Union. In Estonia, for example, the government does not put into focus the implementation of
“Pharmaceutical care”. However, over the past two decades, pharmacists have offered patient-centered pharmacy services [16].

In Germany, in 1994 the “Foundation of Pharmaceutical care” was created to promote and support researches in the field and applying the concept in practice. Currently there are Cognitive pharmaceutical services. They have been in development for more than 12 years. The Federal Union of German Associations of Pharmacists (ABDA) developed procedural instructions and explanations for counseling patients about the proper use of dosage forms (2011). [17]

In Finland, 26 pharmacists take part in a pilot project regarding “Review of drug use”. This is part of a course of continuing education at the University of Kuopio, coordinated and conducted through a training center there. Pharmacists provide drug information to specific groups of patients and other healthcare professionals. Through pharmacy software, instructions may be given to patients: like checking for repeated drug prescriptions and drug interactions (but not more than two drugs) [15]. Advising patients on drug therapy is established in Finland law and since 2000 improvement is noted in the levels of drug counseling.

In France the law does not define the term pharmaceutical care. Part of the mandatory activities of the pharmacist in a community pharmacy are pharmaceutical consultation (Article 1411-11) [18], collaborative work with other health professionals [19]. In Article 1161-1 the term therapeutic training is used as part of patient care. The skills and competencies that the pharmacist should have to train patients to improve their treatment are also defined. The health minister by order authorizes the creation of therapeutic education programs for patients, which need to be applied by at least two health professionals from different backgrounds so a personalized program for each individual patient can be created [20, 21].

In Hungary, the implementation of pharmaceutical care is regulated by law, and thus the professional competence of pharmacists as health professionals is legitimized. To apply “Pharmaceutical care” in a community pharmacy, the pharmacists must have a license. The Ministry of Health concluded the necessary agreements with the Chambers of Pharmacists and the National Committee of Pharmaceutical Care to co-ordinate the “Pharmaceutical care”
process. The University of Debrecen is advocating training in pharmaceutical care in the first semester of the fifth year [22].

According to Knowlton and Penna, the first country to legally regulate the concept of “Pharmaceutical care” through the Pharmaceutical Act No 93/1994 is Iceland.

In Italy no evidence exists for the application of PhC. In research of the pharmaceutical system of Europe in 2006 it is reported that “clinical pharmacy has been important since the 1990s, pharmaceutical care seems to be the domain of hospital pharmacy and does not have the same meaning as it does elsewhere in Europe.”[10, 23].

In Lithuania, the study showed that only 2% of pharmacies are willing to offer a full range of PhCS. But the majority of pharmacies introduced individual components of PhC such as blood pressure measuring or administering written information to the patients [24].

In the Medicines Act of Norway from 1992 and the amendments to the Law of 2011 there is no definition of the term PhC present [25, 26]. As part of the so-called “Nordic health system” in Norway the rules for “Good Pharmaceutical Practice” are applied – these have been adapted to the conditions of the country. The program for master pharmacists at the University of Oslo includes training in “Practical Pharmacy”, which is associated with a 6-month pharmacy practice and focus on skills related to solving drug-related problems and active contact with the patient and other health professionals. This is achieved by applying some elements of “Pharmaceutical care”: recipe management, supervision of medicinal products, logistics and finance/ administration/ supervision [27].

According to a report from the Nordic Working Group on Professional Responsibility in Pharmacy (PAPA): “Over the last 20-30 years, pharmacists in Norway have developed a consulting service for hospitals and community health services (nursing homes and home care services). The consulting service has also resulted in close collaboration between nurses, physicians and pharmacists”.

According to Foppe van Mil and Schulz: polish pharmacists displayed their interest in the topic during their first pharmaceutical care conference in 2001 [10].

Since 1999, the Portuguese pharmacist association (ANF) has developed a strategy, methods and tools (documentation forms, software applications, pharmacist’s intervention protocols,
etc.) for pharmacy-based disease management programs. While they are labeled “disease management,” these programs are in fact counseling-oriented pharmaceutical care. Currently programs have been established for patients with asthma, diabetes and hypertension [28, 29]. The diabetes program is supported by the Portuguese National Health Service (SNS). Patients who register in this program pay a monthly fee of € 15; the SNS covers 75% of it [14]. A review of the pharmaceutical practice in the Republic of Macedonia shows that “Good Pharmaceutical Practice” was developed in 2009 [30]. The concept “Pharmaceutical care” is introduced, but its nature was not defined. In the current Macedonian legislation pharmacy services and the role of the pharmacists is defined as more product-oriented, rather than orientated towards the patient [31, 32]. No approved training for students at the university level in PhC is established. The term “Pharmaceutical care” was introduced and profiled as an optional course (elective subjects) that deals with prescription medicines and communication with the patient. (Drug Dispensing and Communication), which is part of the fifth module “Social Pharmacy” out of seven modules in the final year of studying [33].

In the Romanian pharmaceutical Act of 2008 the regulated PhC is different from the concept of PhC. Services offered include consulting and informing the patient about the proper use of medicines, which is just one element of the concept of PhC.”Training in Pharmaceutical care” (Asistenţă farmaceutică) is done in the last year of study for pharmaceutical students [34].

In Slovakia, the term “Pharmaceutical care” is used in the broad sense of providing affordable pharmaceutical services but does not offer services that match the concept of “Pharmaceutical care”[35].

In Spain PhC and the responsibility for its implementation was established through law. In addition to services such as blood pressure, body weight and cholesterol measurement, in 2005 cognitive services were brought in, some of them remunerated [10, 36]

In Sweden there are several initiatives regarding the implementation of PhCS. There exist annual thematic campaigns aimed at specific groups of patients, documenting of drug-related problems and other. A classification system is developed and implemented for documenting drug-related problems and pharmaceutical services, as well as specific techniques of counseling patients. The main focus is on drug-related problems. In 2001 documenting of drug-related problems in patients with a prescription became mandatory for all Swedish pharmacies [15].
According to Guignard and associates, the developed and reformed professional practices in Switzerland make it possible for services such as PhC to be applied. Some activities existed since 2001 (“Leistungsorietierte Abgeltung” or LOA), but the implementation in both the German and French speaking parts started lately [37]. In terms of training: In Basle, Switzerland, 2000 “Pharmaceutical care” is introduced into the new curriculum for pharmacists. According to Knowlton and Penna in 2001 the Federal Social Insurance Office introduced a new service-oriented remuneration for community pharmacies [10, 15].

In the Netherlands, the “Pharmaceutical care” service is better known as “Pharmaceutical care to patients”. The Royal Dutch Association for the Advancement of Pharmacy (KNMP) defines it as the provision of pharmaceutical care by the collective, running the pharmacy aimed at the individual patient, in terms of pharmacotherapy with the aim to enhance the quality of life of the patient. The Dutch law on quality in the organization of health care defines that the service must be of good quality, effective, efficient, targeted directly at the patient and their actual needs. Training in PhC in universities was established in 1991. The service is regulated by law. In 1997 the KNMP published standards and protocols for PhC. In the Netherlands the focus is put on maximizing the benefits for the patient and motivation through payment is not emphasized [15].

In the UK, the concept of PhC is called "Medicines management", and although there is a little difference in the meaning, this activity is oriented exclusively to patients. Meanwhile Scottish pharmacist organizations use the name “Pharmaceutical care” for describing this service. In 2005 the National Health Service of Great Britain entered into the practice a contract with pharmacies that aims to provide the seven basic services related to “Pharmaceutical care” as well as a high quality of service [38].

In the UK National Health Service law from 2006, in the “guidelines for pharmaceutical services” (advanced and enhanced services) (England, 2011), in Part 2: "Advanced services: performers of pharmaceutical services” two types of services are defined: medicine use review (MUR) and new medicine service (NMS) that is of limited duration, that starts on the 1st October 2011 and should be completed in March 2013. The legal basis for the two services is given in the instructions of the Secretary of State for Health [39, 40].
The review of legislation in the United States shows that it is legally regulated service [41], but the term PhC is not used, although the originators of the concept - Strand and Hepler, work in this country. The service offered to patients is "Medication Therapy Management". It has five core services and the Medication therapy review is the first of them. The other four elements are: “Patient medical record”, a Medication-related action plan, intervention and/or referring to another health professional, documenting the process and follow-up [42]. Reimbursement is regulated by federal law and state laws determine the amount charged in each the state. University education in the field is widespread. Depending on various factors such as the count of drug related problems permitted, consultation length and interventions made, the possible payment can scale between $ 27 and $ 170 per review. [43].

CONCLUSION
The literature review and the review of various national guidelines in various European countries, Australia, Canada and USA show huge differences in the definition of the PhCS and the legal regulation applied in regards to it. But the general trend is putting services aimed at optimizing the treatment of each patient in practice.

PhC can be administered to any patient, but the most suitable group are patients with chronic illnesses such as diabetes, that are treated for long periods of time and take multiple medications and thus are largely the most endangered by drug-related problems. Canada provides the most comprehensive PhCS, which manages to cover eight elements out of the eight examined. In the U.S. and Australian variants of “Pharmaceutical care” - six of the eight examined elements are present. The European countries that set positive examples for offering and applying PhC are: Germany, Britain and the Netherlands.

In other countries, the concept is to be regulated by law and many difficulties will have to be addressed - these services need statutory definition, further, highly qualified pharmaceutical staff will have to be engaged and the work process will have to be set down so the services can be applied; in addition, pharmacists will need the support from other health professionals so that collaboration can ensue and, lastly - remuneration for pharmacists providing high quality pharmaceutical services will have to be ensured.

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