

# Pharmacy practice in the Republic of Macedonia

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## Abstract

As part of wider reforms within the pharmaceutical sector, the pharmaceutical care concept has been introduced in the Republic of Macedonia. This article provides discussion on current opportunities and challenges which pharmacy practice face in Macedonia. The emphasis is on three prerequisites for the implementation of pharmaceutical care including: organization of pharmaceutical services, legislation, and professional training. The author argues that Macedonia possesses a favorable pharmacy workforce, solid legal basis and supportive structures of healthcare services in order to implement pharmaceutical care. Implementing pharmaceutical care has not been without its challenges, such as: lack of clinical skills, inadequate continuing education and the current remuneration structure for pharmacy services. While Good Pharmacy Practice (GPP) Guidelines have been developed, wider professional debate and practical steps have not been undertaken to promote the concept of pharmaceutical care nationally. Therefore, an integrated national approach to develop strategy, standards and tools for patient-oriented pharmaceutical practice has to be formulated. In addition, there is a need to undertake more comprehensive analysis of current pharmacy practice, to explore the awareness and willingness of the pharmacists to embrace pharmaceutical care practices, and to identify the opportunities and barriers for implementation of pharmacy practice.

**Keywords:** Pharmaceutical care, pharmacy practice, Republic of Macedonia, organization of pharmaceutical services, legislation, professional training.

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## Introduction

The pharmacists' role has gradually shifted from compounding to dispensing medicines, and recently towards patient-centered services based on models of clinical pharmacy and pharmaceutical care<sup>1-3</sup>. The potential barriers for implementing pharmaceutical care in practice have been classified into four categories: education, skills, resources and environment. Other barriers include: deficient clinical knowledge and communication skills, insufficient time and inappropriate space, absence of a recognized reimbursement system, lack of adequate drug information resources, poor relationships with doctors and lack of access to patient health records<sup>4</sup>.

The pharmaceutical care concept has been recently introduced in the Republic of Macedonia, as part of wider reforms within the pharmaceutical sector<sup>5</sup>. This article seeks to discuss current opportunities and challenges which the pharmacy profession faces when implementing pharmaceutical practice in Macedonia.

## Country healthcare profile

The Republic of Macedonia is a small Balkan country in South Eastern Europe with around two million inhabitants<sup>6</sup>. The

country gained independence from the Federation of Yugoslavia in 1991 in a peaceful secession and established its own political system as a parliamentary democracy. The country has been going through slow transition from a centrally planned to a free market economy and the ongoing reforms include the health sector, supported by the World Health Organization (WHO) and the World Bank<sup>7,8</sup>. The disease prevalence pattern is similar to other European countries, with cardiovascular diseases, cancer, mental health problems, injuries and violence, and respiratory diseases as the most prominent causes of morbidity and mortality, while other diseases like HIV and TB are less prevalent<sup>7</sup>.

The World Bank classifies Macedonia as an upper middle income country with a GDP per capita of US\$ 4,520 in 2010<sup>9</sup>. According to the WHO 2009 estimates, the total health expenditure as a percentage of GDP was 6.9%<sup>10</sup>. The total pharmaceutical expenditure as a percentage of total health expenditure was estimated to be 13.5%<sup>10</sup>. Health insurance coverage in Macedonia is universal and the basic benefit package is broad, covering all health services within the public healthcare system<sup>11</sup>. The general government expenditure on health as a percentage of total expenditure on health was 66.5%<sup>7,10</sup>.

## Organization of pharmaceutical services and resources

Following independence, reforms in the pharmaceutical sector included the adoption of a National Drug Policy, development of the foundation of the Medicines Information Centre and the Adverse Drug Reaction Centre, while the Centre for Pharmacovigilance is yet to be established<sup>7</sup>. The pharmaceutical sector operates on the basis of a positive list of medicines that defines which medicines are covered by the health insurance system<sup>11</sup>. Some of the biggest challenges in the pharmaceutical sector during the transition period comprise: sporadic shortages of medicines from the positive list, lack of any systematic development of treatment protocols and guidelines and irrational prescribing practices<sup>7</sup>.

Over the past 20 years, the nation-wide chain of state-owned pharmacies has been privatized and the number of new community pharmacies has grown significantly. At present, all community pharmacies are privately owned and only pharmacies that provide medicines supply to medical centres and hospitals remain under public ownership<sup>7</sup>. Community pharmacies have to enter into annual contractual agreements with the national Health Insurance Fund (HIF) in order to dispense medicines eligible for reimbursement to insured patients<sup>12, 13</sup>. Community pharmacies are licensed and regulated by the Ministry of Health through the National Medicines Agency<sup>14</sup>. The pharmacy minimum area must be 16m<sup>2</sup>. Ownership of pharmacies is not restricted to pharmacists, so there are many chain pharmacies owned by pharmaceutical wholesalers, or local pharmaceutical manufacturers. As in other countries undergoing transition, this wide spread liberalization led pharmacy to be increasingly seen as part of the commercial sector and, less part of the professional system within healthcare<sup>15-17</sup>.

Prescribing of prescription-only medicines is restricted to medical doctors, while dispensing is limited to pharmacists working in pharmacies<sup>7</sup>. The pharmacy remuneration fees are related to pharmacy dispensing services. Official data indicates the existence of 874 pharmacies in the country; 841 are community pharmacies (746 have contracts with the HIF) and 33 are internal pharmacies attached to medical centres and hospitals. The community pharmacy to population ratio is 1:2,500<sup>18</sup>. No geographic or population standards have been set for the establishment of new pharmacies. As a result, pharmacies are mostly concentrated in towns leaving a number of rural settlements with limited or no access to pharmacy services<sup>19</sup>.

There are currently about 1960 registered pharmacists in Macedonia, equating to a pharmacist to population ratio of approximately 1:1,000, even though not all pharmacists work in pharmacies<sup>19</sup>. The role of community pharmacists involves dispensing of medicines and providing information to patients on proper medicines use. In the public hospital sector, pharmacists are often substituted by pharmacy technicians or nurses. Located within the central pharmacy, hospital pharmacists only provide, and internally distribute, medicines prescribed by medical doctors and administered by nurses, and do not interact with patient-care teams in the hospital wards.

## Legal provision

The Macedonian pharmaceutical sector's regulation was harmonized with the EU legislation in 2007. The Law on Medicinal Products and Medical Devices was revised and a number of by-laws were passed<sup>20</sup>. In the current Macedonian legislation, pharmacy services and pharmacists' roles are still mostly defined from more of a product-oriented view and less frequently from a patient-care perspective.

For instance, the Law on Health Care from 1997 (article 118) describes pharmacies as product-oriented premises where pharmaceutical activities comprise of *acquisition, custody, storage, dispensing of medicines, analysis and quality control of medicines, preparation of magistral formula and galenic medicines, acquisition and dispensing of children items, dietary products, orthopedic aids and medical equipment, including only instructions on use of dispensed medicines* as a pharmaceutical care component<sup>21</sup>.

Unlike some developed countries, there is no special pharmacy law that regulates the practice of pharmacy and the scope of pharmacists' activities. Instead, it is the Law on Medicinal Products and Medicinal Devices from 2007 (articles 81, 82) that outlines details on the activities related to medicines retailing within pharmacies<sup>22</sup>. This Act considers pharmacies to be legal entities where purchase, storage, keeping and dispensing of medicines are undertaken. It is very encouraging that this law creates new opportunity for pharmacists by endorsing the need to introduce quality systems and to organize work process according to the principles of good pharmacy practice<sup>22</sup>.

In response, the Guidelines for the Principles for Good Pharmacy Practice were developed in 2009<sup>5</sup>. This document provides directions for the evolution of pharmaceutical activities into a pharmaceutical care concept. The guideline clearly places improved patient health as an ultimate objective of pharmaceutical care activity. The GPP guidelines define four core activities of pharmacists: 1) public health functions related to health promotion and disease prevention 2) supply of medicines and medical products of good quality as well as provision of relevant patient instructions and advice on medicines use 3) self-medication activities and related patient advice and 4) pharmacist contribution to rational prescribing and appropriate use of medicines<sup>5</sup>.

The GPP guidelines explicitly quoted the need for development of national GPP standards to guarantee professional roles of pharmacists and to ensure essential conditions are in place for GPP implementation<sup>5</sup>. Unfortunately, there has been no further follow up on the GPP guidelines in the country. To date, neither national GPP standards have been developed, nor has wider professional debate been initiated to promote the concept of pharmaceutical care on a national basis.

## Training and professional development

Pharmacists in the Republic of Macedonia require work licenses in order to work in pharmacies. Pharmacists have to complete a five year Master of Pharmacy degree and one year residency

programme, as well as passing the state license exam<sup>21,23</sup>. In contrast to the previous emphasis on chemistry, the pharmacy curriculum has been revised to integrate more practice-based subjects (social pharmacy, medicines information, pharmacotherapy, clinical pharmacy) which have mandatory course status<sup>24,25</sup>. However, teaching of pharmaceutical care remains theoretical. During residency programmes, hospital rotations under the supervision of a licensed pharmacist still lack the appropriate clinical component. The university pharmacy practice departments have not been established yet, which perhaps could contribute toward research in this area<sup>24,25</sup>.

In Macedonia, the initial work license must be renewed every seven years by attending continuing education courses, accredited by the Pharmacists' chamber<sup>7,21</sup>. These are crucial activities for professional improvement because many licensed pharmacists have been trained under previous curricula and therefore, they lack the appropriate clinical skills. However, the accreditation criteria for continuing education courses are not clear. This reflects a lack of strategy by professional bodies of pharmacy in order to produce pharmacists competent to deliver pharmaceutical care services in Macedonia.

Pharmaceutical care only appeared once on the agenda of the continuing education courses. The Ministry of Health and the Pharmaceutical Chamber, supported by the World Bank, organized a training seminar titled "Developing pharmacy practice - pharmaceutical care" for community pharmacists in 2009<sup>26</sup>. The event has had the relevant objectives of presenting the pharmaceutical care concepts and to describe the new roles, skills, added benefits, challenges and opportunities available to pharmacists, and it aroused considerable interest amongst the audience<sup>26</sup>. Unfortunately, since then clinical courses have not been included in continuing education programmes and follow-up activities have not been undertaken to assess current pharmacy practices.

## Key findings and discussion

Following independence in 1991, the Republic of Macedonia pharmaceutical sector has undergone numerous reforms. These reforms include the privatization of state-owned pharmacies, an increase in numbers of new community pharmacies and uneven territorial distribution of pharmacies. As in other countries undergoing similar reforms, this wide spread liberalization has led pharmacy to be increasingly seen as part of the commercial sector and less part of the professional system within healthcare.

The role of community pharmacists is reflected in the dispensing of medicines and the provision of information to patients on the proper use of medicines, while public health activity does not feature. Hospital pharmacists only provide and internally distribute medicines from central pharmacies and have no access to and little interactions with patient care teams in the hospital wards.

Official data demonstrate an optimal community pharmacy to population ratio of 1:2,500 and pharmacist to population ratio of 1:1,000. These are essential prerequisites for the provision of

pharmaceutical care services<sup>18,19</sup>. Despite this, the implementation in practice might be difficult if there is only one pharmacist per relatively small pharmacy and if there are no regular pharmacy users due to sporadic shortages of medicines from the positive list. Furthermore, current remuneration of pharmacies is related to their dispensing services, and not to other aspects of patient care, which is important to consider given that all community pharmacies are private and commercially oriented.

The current legislation in Macedonia defines the pharmacy practice mostly from a product-oriented and less frequently from a patient-care perspective. However, it is encouraging that the Law on Medicinal Products and Medicinal Devices emphasizes the need to introduce quality systems and to organize work processes according to the principles of GPP<sup>22</sup>. This has led to development of the Guidelines for the Principles for Good Pharmacy Practice in 2009. These guidelines aim to facilitate the implementation of pharmaceutical care in practice by defining pharmacists' core activities. They also call for the development of national standards for GPP. Unfortunately, there has been no follow up on the GPP Guidelines. Neither national GPP standards have been developed, nor has there been wider professional debate promoting the concept of pharmaceutical care nationally.

Pharmacy education in the country offers a theoretical basis for pharmaceutical care subjects. However, the concept of pharmaceutical care is not integrated within the healthcare system, especially not in the hospitals. Therefore, the clinical component is usually missing from rotations and residency programmes. Continuing education for pharmacists is mandatory for all holders of work licenses. However, courses have unclear accreditation criteria, and the quality of education, relevance to practice and conflict of interest policy is not being assured.

## Conclusions

The concept of Pharmaceutical Care has recently been introduced in the Republic of Macedonia. Pharmacists still face the challenge of embracing this concept in their daily practice, even though the country possesses a favorable pharmacy workforce, solid legal basis and supportive organization of health care services. This viewpoint highlights the need for clear and integrated national approach to develop a strategy for patient-oriented pharmaceutical care. Analysis of current pharmacy practices and identification of opportunities and barriers for pharmaceutical care implementation need further attention, if Macedonia is to advance its pharmacy practice activities and thereby improve patient care.

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## Conflict of interest

None

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