

**ASSESSMENT OF THE COMMUNITY PHARMACY PRACTICE IN THE REPUBLIC OF MACEDONIA - BUILDING PLATFORM FOR IMPLEMENTATION OF GOOD PHARMACY PRACTICE**

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ABSTRACT

The objective of the study was to evaluate the actual status of the community pharmacy practice and quality of services and to identify the gaps and barriers to implement the best pharmacy practice and care. Cross-sectional descriptive survey was conducted for the pharmacies/pharmacists where pre-coded multiple choice closed questions were used with response format: activity fully applied, partially applied, applicable or not applicable. Set of 155 indicators was developed covering five essential components: pharmacy structure and practice; patient safety; manufacture practice; staff workflow and competences and quality assurance. The actual score was 64 out of 100. Pharmacy services related to manufacture practice and quality assurance were identified as the areas of highest priority for improvement, followed by the services related to patient safety. Priorities for intervention by key stakeholders (national authorities, academia, professional associations and pharmacists) and recommendations for introducing new and improving the existing roles of the pharmacists were defined.

Key words: community pharmacy practice, services, standards, Republic of Macedonia

INTRODUCTION

Republic of Macedonia (RoM) is a landlocked country in the heart of the Balkan Peninsula with an area of 25.713 km² and around 2.000.000 inhabitants (60 % live in urban areas). With a gross national income per capita of around \$4120 in 2008, the RoM is a lower middle-income country with high official unemployment (29.1%). According to WHO estimates, total health expenditure as a percentage of GDP in the RoM amounted from 6.8% in 2002 to

6.9% in 2009. The health care expenditure per capita amounted to US\$ 341, with 84.7% of health expenditure coming from public sources. Expenditure for investment in the health sector (0.7%) is insufficient¹.

For the last 10 years numbers of reform initiatives in the field of health care were undertaken with an aim of sustaining access for the whole population to a comprehensive health system as well as to improve the quality of health services and enhance financial

sustainability². The major reform in pharmacy sector was the process of privatizing publicly-owned pharmacies by sale or leasing initiated in 2005 and completed in 2007³. With the privatization process, pharmacists and pharmacy managers (not obligatory having pharmaceutical education) became owners of the space and equipment only, with the same level and scope of services (i.e. procurement, storage and dispensing of medicines) and lot of professional problems typical for the countries in transition. The privatization system intended to spread liberalization, however, led pharmacy to be increasingly seen as a part of the commercial sector rather than a part of the professional system within health care. According to the demographic data collected by the end of 2012 there are 740 private-owned community pharmacies all around the state with unbalanced distribution in some geographic regions^{4,5}. There are 3.5 pharmacies per 10 000 citizens, concentrated mostly in the cities (72.3%), with unbalanced access to medicinal products for the patients living in suburban (7.83%) and rural areas (3.02%). The ownership is not limited to pharmacists only, but there must be responsible (licensed) pharmacists in every pharmacy. There are 1,6 pharmacists and 2,08 pharmacy technicians per pharmacy as full time employed. There are no pharmacists with specialist competences such as competence in community pharmacy, clinical pharmacy, pharmacoinformatics, regulatory affairs, nutrition, etc. Only 1% of the community pharmacies have specialists mostly in pharmaceutical technology. Almost 1/3 of the community pharmacies dispense medicines for 1000-3000 patients and around 3000 prescriptions per month. The purchase of medicinal products is usually done daily, from the reputable wholesalers. The types of pharmaceutical care services (PCs) provided in the community pharmacies are mainly traditional pharmaceutical care services like drug dispensing and repeat dispensing. Services like medicine use reviews, blood pressure management, hypertension management, diabetes management and other services are offered in very low number of pharmacies on voluntary basis. The pharmacists are involved in all activities in the community pharmacy, administrative and traditional activities (drug supply and dispensing) as well as activities related to PCs (patient counseling and education, giving information on medicines and medical devices, etc.). Considering pharmacy technicians, they are mostly involved in drug dispensing (89.2%) and around 42.2% in drug supply. These data are logical consequence of the actual situation regarding employment in the community pharmacies. Almost all of the pharmacies have contracts with the Health Insurance Fund (HIF) for reimbursement of medicines (referent prices) from

the positive list⁶⁻⁸. The reimbursement is sufficient to satisfy the patient needs for medicines in only 63.05% of the community pharmacies, although the reimbursed medicines are available in the pharmacy each and every day in 83.73% of the community pharmacies. The reimbursement is for the medicaments plus fix margin according to the scale based on referent price of the medicine, lower fee for lower referent price, higher fee for higher referent price (lower is 0.2 euro, higher is 3.33 euro). The PCs are not recognized neither reimbursed by the contract.

There is no Pharmacy law as a single legislative act to regulate the pharmacy practice (PP) and scope of pharmaceutical activities and services⁹. Instead, in the Law on medicines and medical devices there are 2 articles that outline the activities related to the medicinal retailing within pharmacies (purchasing, storage and dispensing of medicines)¹⁰. The same Law creates the opportunity for pharmacies to organize work process according to the principles of GPP providing directions for the evolution of the pharmaceutical activities into the pharmaceutical care concept¹¹. Unfortunately, to date neither national standards have been developed, nor the wider professional debate has been initiated by the competent authorities to promote the concept of pharmaceutical care on a national basis.

The New Law of health protection issued in March 2012 clearly defines pharmacy practice giving real opportunity for the pharmacists to perform wide range of pharmaceutical activities and services¹². Considering the adoption of standards for pharmacy services in 2011 by WHO and FIP¹³ for establishing minimum national standards for each activity supporting the function and role of the pharmacists, the aim of this research was to set up a platform for improving the quality of the PP and PSs in community pharmacy settings by identifying the gaps and perceived barriers to implementing the GPP and assess the level of education and skills of the pharmacists and their attitude towards PP, PC and continuing professional development (CPD). The assessment tool for quantification of the PP status and quality of PSs was designed to provide identification of the main priorities for intervention to improve the quality of the PP and PC and to facilitate the comparison of the results over time within and between the community pharmacies.

METHODOLOGY

For achieving the aims a descriptive indicator study has been conducted. Structured and standardized

questionnaire was designed. The pharmacists and pharmacy technicians employed at the community pharmacies on the territory of RoM were the population of interest. Simple random sample design was used, so the questionnaires were delivered to 500 community pharmacies (in 8 country regions, individual and chain pharmacies) by e-mail or mail using data base for the pharmacies of the Pharmaceutical Chamber of Macedonia (PCoM). The responses were collected partly by e-mail or mail (using the Dillman Method¹⁴) and partly by face-to-face in the pharmacy where the respondent works, in period May-June, 2012.

In the design of the assessment tool, various publications of survey questions, guidelines and already published indicators for assessing specific topics around the PP and services were consulted¹⁵⁻²². No questionnaire adequate for evaluation of the community PP in the RoM has been designed so far. Set of 155 structural process and outcome indicators were identified covering five essential areas: (I) Pharmacy structure and practices (60 indicators for premises, equipment, supplying, storage and stock, dispensing and access to drug information); (II) Patient safety – access to patient data, communication, counseling and education (25 indicators); (III) manufacturing practice and drug quality control (13 indicators); (IV) Staff – workflow, competency and professional development (25 indicators) and (V) Quality assurance, risk and data management (32 indicators). The indicators describe the highest standards of PP and quality of PSs. A cross-sectional descriptive survey was conducted where multiple choice closed questions were used with type of response format: A - Activity fully applied; B - Activity partially applied; C - Activity not applied (applicable); D - Activity not applicable (Table 1). When calculating the GPP and PSs score, the maximum score of 100 (20 per section) and minimum zero were given for all the indicators if all indicators were responded to A and D, respectively. The weight of each indicator in the area depended on the number of the indicators in the area and if all responded to A, it was calculated by dividing 20 with the number of indicators. For example, if the total sum of indicators per area (I) is 60 and each indicator responds to A, the weight of each indicator would be 0.333 (20/60). The weight of the indicators responded to C was calculated as a half of the weight of the indicator responded to A (in the given example, it would be $0.333/2 = 0.166$), while the weight of each indicator responded to B was calculated by dividing the sum of the weights of the indicators responded to A and C by 2 (i.e. $(0.333 + 0.166)/2 = 0.249$). The weight of the indicator D was taken zero. The

individual scores of A, B and C in the corresponding area would be calculated as a sum of the values of each indicator under A, B and C, respectively. The actual score per area was a sum of the scores of A, B and C, while the individual scores of A, B and C depended on the number of pharmacies that for a given indicator responded under A, B or C, respectively.

The questionnaires were previously tested by involving the target group of 10 responders in the design to evaluate the specific questions, format, questions sequences and instructions, by which the apparent (logical) validity of the questionnaire was evaluated. A workshop for 30 pharmacists was organized during which the questionnaire was discussed and explanation given. In addition, a pilot study was designed in which the targeted group of 10 responders was asked to respond to the questionnaire at the beginning and after three weeks. High correlation (> 0.997) between the actual and individual scores in each area was obtained when the initial and three weeks after responds to the questionnaire were compared. The manual data collection sheet ensured independent data collection on site of all data required. The data were saved by Excel software and analyzed by excel-based assessment tool.

RESULTS AND DISCUSSION

The responses were received from 245 community pharmacies, 123 from the chain pharmacies and 122 from the individual pharmacies.

Pharmacy structure, supplying, storage and stock, dispensing, access to drug information:

The actual score of 16.38 out of 20 was obtained from the assessment of the pharmacy structure and the activities related to the medicines as well as access to drug information (fig. 1). Considering the premises, almost all of the pharmacies are clearly identifiable as health care facilities, with suitable waiting and counseling areas and separate areas for OTC drugs and dietary supplements. The dispensing area is suitable in size for the prescription volume and provides uninterrupted and safe workflow in app. 84% of the pharmacies. It is a common practice to use the dispensary area for health promotion. In very low number of community pharmacies (28 out of 245) there are separate manufacturing areas constructed according to the safety policies. All pharmacies are equipped with refrigerator, mainly used for storage of medicinal products. Each pharmacy is equipped with computerized system, which is used for dispensing medicines, recording

prescriptions, financial and stock management and partly used for obtaining information on medicines and treatments. In only 17% of the pharmacies it is used for generation of patient medication records, while in only 14% the computerized system is designed to alert for e.g. over/sub dosing, drug interactions, contraindications, etc. Barcode scanners for reading of medicinal products and prescriptions are used in every pharmacy. No pharmacy uses automatic devices for storage, distribution and dispensing of medicinal products.

Telephone ordering from reputable distributor is the most exploited way for purchasing medicinal products, but written policies and procedures for ordering, recipe and immediate supply are missing. Medicines are stored and shelved in designated areas, taking care to segregate products with similar names/packages and separate storage of hazardous/flammable substances. Use of auxiliary warnings or specific labels on packages of drugs with similar names/packages/labels is not fully applied. Pharmacy stocks are reviewed at least annually. The storage areas are not always under the control of the pharmacists. In less than 70% of the pharmacies the structured system for stock management is established and followed.

Written dispensing procedures are fully established in half of the pharmacies. The received prescriptions are printed on paper standardized form and routinely checked for legibility, validity and authenticity in all pharmacies. The pharmacists regularly obtain relevant patient information before dispensing and evaluate the prescriptions for possible problems. However, not always the prescriber is contacted when potential problem with the prescribed medicines is identified (53%), and even when contacted it is rarely documented (23%). The pharmacists routinely check expired dates and the medicinal products are additionally labeled (handwritten) providing information on dosage regimen, date and place of dispensing. Only 15% of pharmacists repack medicines into unit-dose package. In all pharmacies, national medicines formulary and drug catalogues are available and used. Pharmacists have access to user-friendly, up-to-date computerized information systems. However, access to important databases on biomedical literature, life science journals, online/printed books is limited for most of the pharmacies. It is interesting to note that app. 43% of the pharmacies declared that this activity is not applicable due to lack of finances.

Patient safety- access to patient data, communication, counseling and education:

The histogram in fig. 1 point out to the actual score of 15.98 out of 20. In dispensing process pharmacists

obtain patient data and information on drug history. They ascertain the clinical purpose of each prescription, consider the need for dose adjustments and take steps to understand the cultural issues and overcome barriers (language, visual or hearing). In addition, they attempt to identify any drug related problems patients may experiencing and use time for patient counseling and education. The patients are encouraged to ask questions. However, all these activities are rarely documented. Considering level and quality of provided PC the results pointed the need for improvement. A procedure for informing the pharmacy staff when to refer patient exclusively to the pharmacist is not established in almost half of the pharmacies. The policy for assisting individuals who may be abusing/misusing non-prescribed medicines and regular audit by the pharmacists is missing. Considering the number of pharmacists in each pharmacy (mostly one) there are no staff members who are specially trained to provide advice on the use of non-prescription medicines. In only 10% of pharmacies educational programs for all or specific patient groups are developed and organized with the aim to improve the use of medicines.

Manufacture practice and drug quality control:

Very low actual score for this section was obtained (2.8 vs. 20; fig. 1). Only 28 (out of 245) pharmacies produce pharmaceuticals for individual patients, while 11 of them for all patients. App. 75% of the responders declared that this pharmacy activity is not applicable in their locations due to the specific structure and low space requirements for establishing a pharmacy, while app. 15% of them replied that there are preconditions for producing pharmaceuticals, but this activity is not applied. Up-to date policies and procedures for manufacturing of the products are fully or partially established and the pharmacy staff is competent for the manufacture process in only 3 of the community pharmacies. The production and quality control of pharmaceuticals complies mostly with the national legislation, but in only 2 pharmacies records for compounded products are easily retrievable and stored for at least five years.

Staff - work flow, competency and professional development:

At the histogram in Fig. 1, actual score (15.52) is presented for the indicators assessing workflow and staff availability and qualifications. Adequate, sufficient and trained staff is employed to ensure that patients are timely served in app. 95% of the pharmacies. It must be emphasized that the staff is sufficient for traditional PSs, not considering PCs services for which the staff is sufficient in only 10%

of the pharmacies. All professional activities are carried out under the supervision of the pharmacist in any time in only half of the pharmacies. Pharmacy students/residents are trained in app. 60% of the pharmacies. All employed pharmacists are registered at the PCoM (possess license for independent work). They are aware of their professional role and the associated boundaries and accountabilities. All pharmacists have competences for gathering, analyzing and providing drug information, patient counseling and education, while 31% pharmacists declared the competences for therapeutic drug monitoring and evaluation of the outcome. The pharmacists are involved in the selection of the most appropriate medication and they are allowed to make generic substitution for prescribed medicines.

Considering continuous professional development (CPD) activities, the pharmacist accept the concept and collect credits by attending educational activities. For these activities they are not always financially supported by the pharmacy manager. Preparing own annual portfolio for continuing education (CE) is performed by 42% of the pharmacists. Pharmacists are trainers of pharmacy students and residents in 60% of the pharmacies and they are reimbursed for this activity by the PCoM and faculties, but in only 17% of the pharmacies they have reduced workload on account of the training activities.

Quality assurance, risk and data management:

With the indicators in area (V), the standards of quality assurance, risk and data management were assessed. The histogram with actual score (13.45) is presented in Fig. 1. All of the pharmacies are well supplied with medicines according to the patient needs. However, quality assurance policy is established, implemented and evaluated in only 50% of the pharmacies. In all pharmacies similarly packed products are stored and positioned in a manner that minimizes the possibility for mix-up, but the products with the narrow therapeutic index are highlighted in only half of the pharmacies. All pharmacists make interventions to avoid the errors that may occur during prescribing and dispensing. Also, pharmacists are instructed to report the medication errors and ADRs, but regular education on participating in medication error reduction process and a non-punitive anonymous medication error reporting system is missing. Patients are informed on the complain procedure and patients satisfaction is monitored, evaluated and documented in only half of the pharmacies.

The results about data management within the pharmacies point out that app. 95% of the pharmacies

protect the data obtained from/about the patients/prescriptions in compliance with the legislation. Pharmacists correctly endorse the prescriptions at each dispensing, but in only 69% of the pharmacists that information is registered in the prescription book and all entries in a chronological order are documented using a system that allow prompt retrieval of prescription dispensed. Only 40% of the pharmacies supply and dispense narcotic drugs.

Summarized data, priorities for intervention and recommendations for improvement:

The spidograph in Fig. 2 is designed to present all five areas with the actual scores, visualizing the strength and weakness of pharmacy practice depicted in one (mean) spidograph thus providing a simplistic visual overview of PP (shaded area), and allowing prioritization of interventions. It is obvious that practice and services related to manufacture practice and quality assurance, risk and data management are the areas with priority for intervention to improve the quality of the PP and PC in line with the National Drug Policy and WHO/FIP Guidelines on GPP. The final PP and PSs assessment score was based on the score of all indicators as a percentage of the actual score relative to the maximal possible score and for the PP and quality of PSs in the community pharmacy area in the RoM it is 64 out of 100. Considering the results obtained with this survey, it is obvious that the implementation of GPP and qualitative services through GPP standards in community (pharmacy) settings is of essential importance. National authorities, academia, professional associations and pharmacists have to put more efforts in this respect and the list of priorities is presented in Table 2. In addition, new pharmacists' roles have to be introduced and the existing ones improved (Table 3)

CONCLUSION

The study quantifies the status of PP and PSs in community pharmacy settings in the RoM and identifies the gaps and room for improvement in the regulatory framework, pharmacy structure and practice and competences and skills of pharmacists, building up a platform for improving the quality of PP. A modern Law on Pharmacy Practice is needed incorporating the requirements in line with Joint WHO/FIP Guidelines on GPP and the national needs of the health system and the population. Investments in pharmacy structure are essential. The contracts with the HIF and community pharmacies need to be revised in respect to recognizing different types of services. Services related to providing effective

medication therapy management in respect to managing and monitoring patients progress and outcomes need to be enlarged, documented, recognized and reimbursed. The level of education, knowledge and skills of the community pharmacists need to be improved by introducing inter-professional education and training. Pharmacists must strengthen their partnership with other health professionals for improving the effectiveness of the health system and public health as legislation and

other health-care providers do not recognize pharmacists as important part of the health care team.

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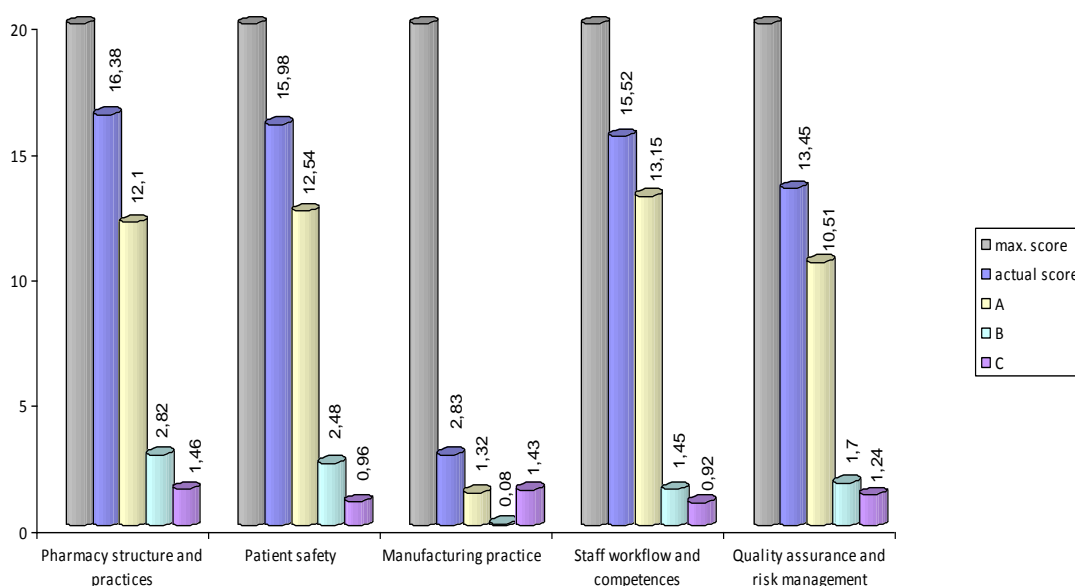


Fig. 1. Histogram depicting PP and PSs assessment scores in five areas for community pharmacies

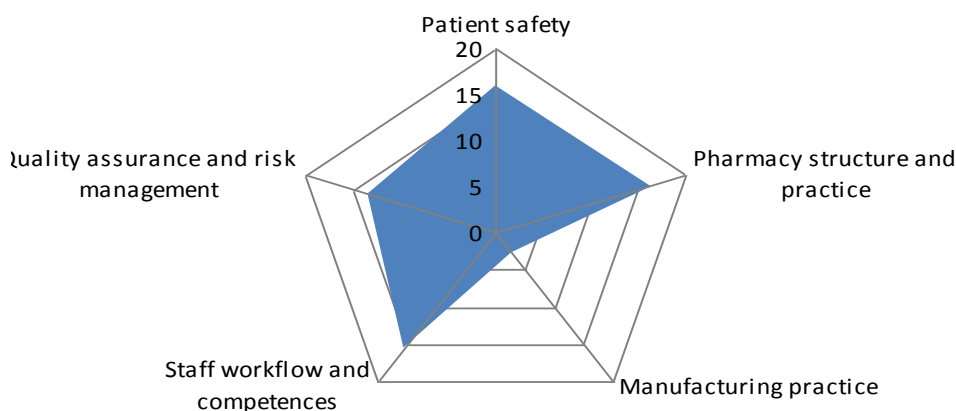


Fig. 2. Spidograph depicting PP and PSs assessment scores of the five areas

Table 1. Assessment tool for quantification of the status of pharmacy practice and services in community pharmacy

Statement-indicator	A	B	C	D
I PHARMACY STRUCTURE AND PRACTICE				
A. PHARMACY STRUCTURE				
1. The premises clearly identify the pharmacy as a healthcare facility				
11. The dispensing area is suitable in size for the prescription volume providing uninterrupted and safe workflow				
.....				
B. SUPPLYING, STORAGE AND STOCK				
27. Policies and procedures are established to ensure immediate supply of medicinal products (to ensure that a patient receives medication as required)				
35. Use of auxiliary warnings or specific labels on packages and storage bins of drugs with similar names, packages and labels is performed in the pharmacy				
.....				
C. DISPENSING				
45. All prescriptions are checked for legibility and reviewed on recipe to check name, address and prescribed therapy				
49. The pharmacists contacts the prescriber in cases when potential problem with the prescribed medicines is identified				
.....				
D. ACCESS TO DRUG INFORMATION				
56. Drug interaction references, guidelines and handbooks are used for medication use reviews				
58. The pharmacy provides access to important databases of biomedical literature, life science journals, online books (e.g. PubMed®, MicroMedex, HINARI, ...)				
.....				
II. PATIENT SAFETY - ACCESS TO PATIENT DATA, COMMUNICATION, COUNSELING AND EDUCATION				
64. Basic information on co-morbid and/or chronic conditions (e.g. diabetes, renal or liver, impairment, hypertension, pregnancy, lactation etc.), allergies, height and weight when patient is initially encountered are obtained when dispensing medicines				
66. In dispensing process, the pharmacist/dispenser ascertains the clinical purpose of each prescription to ensure that the prescribed therapy is appropriate for the patient's condition				
85. Pharmacists develop and organize educational programs for all or specific patient population groups to improve use of medications				
.....				
III. MANUFACTURING PRACTICE AND DRUG QUALITY CONTROL				
88. Up-to-date policies and procedures for manufacturing of the products are written and available to all personnel involved in these activities				
97. Analytical procedures are regularly performed to control the quality of the raw materials and pharmaceutical products				
.....				
VI. STAFF - WORK FLOW, COMPETENCY AND PROFESSIONAL DEVELOPMENT				
A. WORK FLOW				
99. Adequate staff is employed for traditional pharmacy activities (e.g. purchasing, dispensing...)				
105. All professional activities in the pharmacy are carried out under supervision of a pharmacist at all times				
.....				

B. COMPETENCY, CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT				
107. All employed pharmacists are aware of their professional role and the associated boundaries and accountabilities				
108. All staff is educated about new drugs added to the pharmacy inventory (e.g. via e-mail messages, package inserts placed in mailbox, written memo or alert, medicine monograph, etc.) and any associated guidelines, restrictions, and special precautions are understood before the medicinal product is dispensed				
112. The pharmacists have competencies for monitoring the medicine therapy and evaluation of the outcomes				
.....				
V. QUALITY ASSURANCE, RISK AND DATA MANAGEMENT				
A. QUALITY ASSURANCE				
125. Sufficient personnel is available to perform tasks adequately				
129. Up-to-date policies and SOPs are established and considered in everyday practice to ensure that reasonable workload levels and working hours are established and rarely exceeded				
133. The pharmacists perform interventions so that errors that may occur during prescribing and dispensing are avoided				
.....				
B. DATA MANAGEMENT WITHIN THE PHARMACY				
150. The pharmacists document all entries in a chronological order in a prescription book using an appropriate filing system that allows prompt retrieval of each and every prescription dispensed				
153. The pharmacy keeps evidence of dispensed medicinal products in the patients' records				
.....				

Table 2. Priorities for intervention by key stakeholders

Stakeholder	Priorities
Ministry of health, Drug Bureau, Health Insurance Fund, Government	<ul style="list-style-type: none"> ▪ Establishing Law on Pharmacy Practice ▪ Revising criteria for establishing pharmacies ▪ Introducing standards for GPP ▪ Recognizing the economic and health benefits of PC services ▪ Increasing the investment in the pharmacy sector ▪ Recognizing essential, advanced and enhanced PC services and their reimbursement
Academia, Professional Associations	<ul style="list-style-type: none"> ▪ Modernizing the education in pharmacy practice using information and health assessment technologies ▪ Introducing inter-professional training and training of trainers for pharmacy practice ▪ Increasing awareness of the necessity of basic and specialist competences ▪ Offering more educational, training and innovative programs and multiple CPD activities ▪ Promoting pharmacists role in the health care system ▪ Encouraging development of individual educational portfolios
Pharmacists/ pharmacies	<ul style="list-style-type: none"> ▪ Moving from commercial to patient care model ▪ Investing in pharmacy structure and processes ▪ Raising basic and specialist competences and skills ▪ Establishing better relationship with other health care providers ▪ Continuing assessment of PP status and quality of PC services

Table 3. Recommendations for improving/introducing the roles of the pharmacists

Roles for pharmacists	Recommendations (priorities for intervention)
Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medicinal products	<ul style="list-style-type: none"> ▪ Investing in premises and equipment ▪ Increasing basic competences ▪ Establishing written policies and procedures ▪ Developing guidelines and protocols
Provide effective medication therapy management	<ul style="list-style-type: none"> ▪ Investing in premises and equipment ▪ Introducing essential, advanced and enhanced PC services ▪ Developing specialist competences ▪ Establishing written policies and procedures ▪ Improving collaboration with patients and other health-care providers
Maintain and improve professional performance	<ul style="list-style-type: none"> ▪ Demonstrating CE and CPD in every-day practice ▪ Minimizing barriers for improving professional performance
Contribute to improve effectiveness of the health-care system and public health	<ul style="list-style-type: none"> ▪ Promoting rational pharmacotherapy ▪ Participating in preventive programs and campaigns ▪ Advocating and supporting national policies and regulatory bodies

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