

## PROSPECTS FOR DEVELOPMENT OF PHARMACY IN POLAND UNTIL THE YEAR 2030. THE DOCUMENT OF THE NATIONAL SECTION OF PHARMACEUTICAL CARE OF THE POLISH PHARMACEUTICAL SOCIETY

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**Abstract:** Modern society expects pharmacists to be more involved in monitoring and supervising pharmacotherapy. International documents clearly define pharmacists as guardians of the safety and effectiveness of pharmacotherapy, not coincidentally putting safety matters first. With regard to this issue, the National Section of Pharmaceutical Care of the Polish Pharmaceutical Society hereby presents its own proposal for the development of modern pharmaceutical practice in Poland. The purpose of the proposed actions is to increase the involvement of pharmacists from generally accessible pharmacies in ensuring the safety and effectiveness of pharmacotherapy applied outside of hospitals and improving health indicators within society over the next ten to twenty years.

**Keywords:** pharmacy practice, pharmaceutical care, pharmacists in a health system

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### Preamble

In every health system, pharmacotherapy constitutes a basic therapeutic method that is presently advocated not just by physicians, as it used to be, but also by other members of the medical profession. However, it is the pharmacist that possesses complex knowledge not only of the medication effects mechanism and its activity in the organism, but also of the factors which ensure its quality and stability in the environment in which it is applied. Modern society expects pharmacists to be more involved in monitoring and supervising pharmacotherapy. International documents clearly define pharmacists as guardians of the safety and effectiveness of pharmacotherapy, not coincidentally putting safety matters first. In today's era of specialized physicians, there is a strong need for a greater role to be played by pharmacists, whose knowledge covers many aspects connected with pharmacodynamics, pharmacokinetics and physicochemical medication properties – everything, which influences the therapeutic process.

Since public trust professions in accordance with the role attributed to them guard the public interest, placing the good of society and its individual units over the interests of their own group, it is important to identify a method which ensures that this aim will be fulfilled. The prestige of the profession is not simply the sum of the prestige of its individual representatives as the incorrect or, even worse, unethical actions of a small group of the profession's representatives may seriously undermine the positive view of the whole professional group in the society.

The significant and exceptionally fast changes that are currently taking place in pharmaceutical sciences indicate that the role of pharmacists is no longer limited to the distribution of medicinal products but also includes enabling members of society to fully take

advantage of the achievements of modern pharmacy. Pharmacists offer a service to patients as well as advice to physicians and other members of the medical profession, so they must be considered a full member of the health team, contributing their unique knowledge of active substances and medicinal products.

With regard to the above, the National Section of Pharmaceutical Care of the Polish Pharmaceutical Society presents its own proposal for the development of modern pharmaceutical practice in Poland. The purpose of the proposed actions is to increase the involvement of pharmacists from community pharmacies in ensuring the safety and effectiveness of pharmacotherapy applied outside of hospitals and improving indicators of society's health over the next ten to twenty nearest years.

### Part I. Programme for developing pharmaceutical practice in generally accessible pharmacies

The role of pharmacists in a health care system is not simply limited to dispensing medications and ensuring they are of sufficient quality. International pharmaceutical organizations have stressed for many years that it is essential to involve pharmacists in monitoring the use of medications by patients and health system personnel. It is every country's responsibility to formulate its own pharmacy development programme to ensure that pharmacists take at least partial responsibility for the safety and effectiveness of pharmacotherapy. Every society has to design its own service system in community pharmacies. In doing so, it is useful to draw lessons from the experience of countries in which additional pharmaceutical services have been provided over many years, and then adapt and adjust them to the conditions of one's own health system. Part I of this document therefore presents an overview of services considered in developed countries to be effective in monitoring the use of medicinal products in society. Implementing these services in community pharmacies in Poland would require pharmacists to take partial responsibility for the correct use of medications among patients.

For every service, the purpose of its provision and the tasks required for pharmacy personnel are presented and, in selected cases, groups of patients to which the service should be directed in the first place are proposed. Such specifically indicated groups include, inter alia:

- the geriatric population;
- the pediatric population (through cooperation with parents and caregivers);
- patients under polytherapy;
- patients suffering from organ failure in connection with the metabolism process and drug excretion

- tion – e.g., renal failure, liver diseases, damaged gastrointestinal tract;
- people with historical or current addictions to medications, alcohol, or drugs;
  - people with physical and/or psychical limitations which may influence therapy – e.g.,
    - people who are blind, deaf, suffer from perception disorders, e.g., color recognition disorders, or people with neoplastic diseases;
    - pregnant and breastfeeding women.

### I.1. *Medication reviews*

A medication review (MR) is a task that requires the professional competencies of a pharmacist in order to be undertaken. It is performed on the basis of data collected from a patient and constitutes grounds for assessing the correctness of an ill person's medication use. It consists of the following stages: (a) conducting a patient interview, (b) analyzing information collected from the patient, (c) preparing a report for a physician, (d) preparing a report for the patient, (e) establishing a programme

Table 1. Stages of Medical Utilization Review.

Conducting a patient interview	<p><b>Purpose:</b> collecting information on a patient's medication use.  <b>Description of procedure:</b> the pharmacist should collect information on all medications used by the patient in accordance with the following criteria:</p> <p><u>Medications prescribed by a physician:</u>          the trade name of the medication, dosage, form, amount possessed, how it is used (what dosage, how many times daily), who prescribed the medicine (name, surname, specialization), how to prepare before administering (if necessary), storage, purpose of use for the patient, have there been any problems when using it, were there any adverse effects, does the patient use the medication regularly, and did the patient decide not to buy the medication for e.g., financial reasons?</p> <p><u>Medications sold without prescription:</u>          the trade name of the medication, dosage, form, amount currently in home medicine cabinet, how it is used (how many dosages at one time/daily/time intervals), how often the patient takes the medication, how to prepare it before administering (if necessary), storage, purpose of use for the patient, is there a need to use it, have there been any problems when using it, were there any adverse effects?</p> <p><u>Supplements: medical products, dietary supplements:</u>          the trade name, dosage, form, amount currently in home medicine cabinet, how used (how many dosages at one time/daily/time interval), how often used, how to prepare it before administering (if necessary), storage, the purpose of use of medication/medical product/dietary supplement, is there a need to use the medical product/dietary supplement, who suggested the medication/medical product/dietary supplement, have there been any problems when using it, were there any adverse effects?</p>
Conducting a patient interview. Analysis of collected information	<p><b>Purpose:</b> detecting drug related problems, assessment of suitability of medication and its correct use.  <b>Description of procedure:</b> for every medication the pharmacist assesses: have any (real) drug related problems appeared; is there a risk that (potential) drug related problems will emerge in the future; is there a better (newer generation/more cost-effective) medication on the market that should replace the one used by patient? Note: in accordance with the adopted classification of drug related problems, it is necessary to mention any potential additional advice outside the scope of the adopted classification which may have an influence on medication use. In assessing drug related problems, one should take note of the influence of dietary supplements used by patient on the safety and effectiveness of pharmacotherapy.</p>
Preparing a report for a physician	<p><b>Purpose:</b> informing a physician about the patient's medication use and detected drug related problems in order to simplify future therapy.  <b>Description:</b> a report containing data on actual medication use by the ill person, detected drug related problems (real and potential), suggested changes (according to the adopted guidelines for the procedure), information on reimbursement rules for each medication, and information on the possible lack of dispensing due to patient's decision to not purchase.</p>
Preparing a report for the patient	<p><b>Purpose:</b> explaining to the patient how each medication should be used.  <b>Description of procedure:</b> a report including instructions on how the medication should be prepared before use (if necessary), information concerning medication use, a medication use calendar, any detected improper medication use, date of next medication review.</p>
Establishing a scheme of correct medication use	<p><b>Purpose:</b> determining the necessity for conducting the next medication utilization review.  <b>Description of procedure:</b> if a large number of drug related problems was detected and it is deemed that managing them may be hard for patient, it is necessary to establish a date for the next meeting with the patient, which would help determine whether the plan of action was implemented correctly.</p>

of correct medication use. Table 1 is documenting the purpose of each stage accompanied by a description of the relevant procedure.

### I.2. *Systems of individual medication packaging*

The problem of patient's lack of cooperation and nonadherence (noncompliance) is presently one of the most often mentioned drug related problems occurring in civilized societies, and the commonly used polytherapy increases its risk. The marketing authorization holder introduces medications to the market in individual packaging, usually containing the amount of doses which is necessary for a complete treatment course (e.g., in antibiotic therapy) or a treatment over a specified time interval (in the case of medications used over a longer time). However, in the case of most medications, the Summaries of Product Characteristic (SPC) specify various indications for its use and, in relation to them, often different doses to take at one time, which results in the full packaging being insufficient for the treatment designed for the ill person or specifying a dosage which exceeds the necessary amount. Introducing a system of individual medication packaging enables a medication to be repackaged and it to be dispensed in the amount which is appropriate for the treatment time specified by the prescriber. There are various forms of individual medication dispensation available:

1. dispensing every product in separate individual packaging, without dividing them into doses to take at one time - the patient receives a medication for e.g., 30 days of treatment, and the packaging is supplied with information on the prescribed dosage programme together with dates for beginning and ending the therapy;
2. dispensing all medication in collective packaging divided into daily doses, each of which comes with information on the day and hour of administration;
3. the patient receives all medication prescribed for use in collective packaging (multipack) with information on specific days and hours of administration.

Systems of individual medication packaging (SIMP) enable the preparation of medications for direct administration by patients. A pharmacy may apply a system of manual or automatic medications repackaging. It is possible to introduce a system of unit doses, particularly for specific groups of patients, e.g., elderly people, those using polytherapy, those using medications requiring variable dosages (e.g., anticoagulants), or patients with physical limitations which prevent or complicate the cor-

rect use of medications (e.g., visually impaired people). There are also systems with administration signalling devices which remind patients when it is necessary to take a medication. All individual dosage systems are presently only directed towards the dispensation of medications for oral administration. The role of the pharmacist providing such a service is to:

- draft protocols for preparing different formulation of medication;
- choose patients who may significantly benefit from the application of SIMP;
- establish correct medication application programmes for a patient within the SIMP framework;
- control an individual SIMP designed by qualified personnel for an individual patient, including the design of an information leaflet;
- release every prepared set to be dispensed to the patient.

Implementing such a system requires agreement with medication producers and recognizing situations in which the repackaging of medication from the original packaging is inadvisable/impossible due to a potential decline in stability or suitability for use. In some countries, forms of collective packaging are prepared specifically for use in repackaging.

The tasks of supervising bodies include preparing or adopting other countries' guidelines for individual medication packaging and specifying active substances or medicinal products which, due to possible changes in durability, cannot be covered by SIMP. Procedures that minimize errors which occur in the course of placing doses of medicinal products into packaging should be implemented.

### I.3. *Educating patients in community pharmacies*

Services provided by pharmacies should also include programmes for educating patients. These tools for raising health awareness among patients and influencing attitudes towards health are commonly applied in projects related to public health. Education is also strictly connected to the elimination of so-called functional illiteracy in areas related to medicine (health illiteracy). Pharmacists may provide individual forms of education not only to patients under care, but also to patients who use specified drug forms or medical devices, or suffer from specified illnesses.

Medication categories that should be taken into account in planning individualized, extended education programmes concerning the use of special medications include: eye drops, inhaled medications, medications for subcutaneous administration, lyophilizates and therapeutic systems (e.g., transdermal systems). Every time a pharmacist dispenses a

particular medication, he/she has to give the patient detailed instructions of how to use the given medicinal product/medical device, together with a demonstration. This may be conducted using the actual preparation being purchased by the patient or an instructional product containing inert substance.

Qualified personnel should also ensure that individualized leaflets are given to patients, especially when a patient receives medication for the first time. When providing individualized information about medication (which is separate from the Patient Information Leaflet, PIL), pharmacists should include the reasons for prescribing the medication (indications for use), the expected effect and methods of assessing a given preparation's effectiveness, individual dosage programmes (times of day, hours), food that should be avoided during medication use and warnings concerning its use that the patient should be aware of (e.g., dangers related to driving motor vehicles).

Offering extended education and information about medications in community pharmacies requires ensuring access to electronic systems enabling the storage and distribution of leaflets prepared for patients in electronic form, as well as using modern forms of communication with patients, e.g., the Internet, mobile phones. Another essentiality is the access to updated databases including leaflets about medications, SPC and to systems simplifying the preparation of leaflets, e.g., coupled with sale systems.

Pharmacists also can and should get involved in group training programmes for patients, e.g., asthma schools or diabetes workshops. Pharmacists providing health education may organize short meetings with patients during which a pharmacist's unique knowledge of a medication should be used to teach patients how to correctly use medications, including not only how they should be taken but also their preparation or storage.

#### ***1.4. Preparing medications in pharmacies***

The Council of Europe Resolution of January 2011 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients [CM/ResAP (2011)1] identifies officinal and magistral drugs as being of added value, which means that in pharmacies (including hospital pharmacies) only medications which are not accessible in ready form on the market should be prepared. This concerns, inter alia, ophthalmic drugs, preparations for parenteral nutrition and cytostatic drugs.

In pharmacies, a reconstitution should also be introduced. In the case of medicinal products requir-

ing preparation directly before administration, e.g., suspensions containing antibiotics or eye drops, a pharmacist should make sure that the medication will be correctly prepared by a patient or, alternatively, the pharmacist should prepare medication in a form ensuring its correct use. It is advisable to dispense a medication that is ready to be taken/administered by patients, e.g., by dissolving the lyophilizate of an active ingredient or preparing a suspension of lyophilizate. Introducing methods of this type will limit the number of situations of incorrect preparation of medication by a patient, e.g., using the incorrect solvent or inappropriate amount of solvent, thus leading to unintended increase/decrease in the dose.

#### ***1.5. Programmes of pharmaceutical care***

##### ***1.5.1. Pharmaceutical care for the elderly***

The geriatric population (people over 65 years old) requires special attention and the involvement of medical personnel, particularly because of two phenomena which commonly occur in this group of people: multidisease and polypharmacy. In pharmaceutical care programmes for this group, attention shall be paid to problems related to incorrect medication use and instances of noncompliance with therapeutic recommendations or polytherapy, among others.

- Noncompliance with therapeutic recommendations – in the case of elderly persons, irregular medication use often results from unintended reasons, including forgetting, unintentional discontinuation, or refusal to buy medications, e.g. for financial reasons. Monitoring such circumstances and eliminating them could be achieved using individual medication packaging systems. However, it is also necessary to control the factors leading to the intended discontinuation of drugs which include, above all, drug related problems (e.g., adverse effects). The role of pharmacists from generally accessible pharmacies is thus to design systematic mechanisms of detection and elimination of the occurrence of non-compliance with therapeutic recommendations.
- Polytherapy – this often leads to iatrogenic diseases, which, in turn, result in the use of subsequent medicinal products, often forcing patients to take multiple (up to a dozen or so) doses of medication per day. The role of pharmacists from community pharmacies is to conduct a detailed analysis of the pharmacotherapy of patients using polytherapy, and the tools which may be applied for this purpose are regular Medication Reviews. In essence, programmes of reduction of the polytherapy occurrence constitute a combination or devel-



opment of other services described in this document, such as MRs, individual medication packaging systems, systems to create individual leaflets for patients and group patient education systems.

#### I.5.2. Pharmaceutical care for chronically ill patients

Providing comprehensive pharmaceutical care should be obligatory in the case of all patients, regardless of their age, using medications chronically and requiring periodic control, in order to adjust pharmacotherapy to changing symptoms and disease indicators. This is because pharmaceutical care is a complex procedure, in the course of which a pharmacist detects and solves drug related problems, educates the patient and cooperates with other members of the medical team in a way which ensures improvement in the patient's quality of life.

Pharmacists providing pharmaceutical care are qualified to supervise the effectiveness of applied pharmacotherapy. Pharmacists should have the opportunity to keep their own records and to access medical records in order to supervise a patient's pharmacotherapy correctly (effectively). Pharmaceutical records should be treated the same as medical records (in a legal sense) and should constitute a possible basis for control in situations when pharmaceutical care will be financed from public funds. Pharmaceutical care should in the future become one of the reimbursed services offered by pharmacist in a pharmacy. The pharmacist would sign a contract with the National Health Fund (NFZ), drawn up on the basis of the contract of a physician of primary health care (POZ). Patients may get an opportunity to choose their own pharmacist in the same way they choose a POZ physician, nurse, and midwife. The role of the pharmacist would be to monitor pharmacotherapy and contact other members of the medical team providing care for the patient.

#### I.6. *Monitoring on safety and effectiveness of dispensing medications without prescription*

Pharmaceutical counselling when choosing over-the-counter (OTC) medication is an area in which pharmacists have a chance to apply their knowledge for ensuring correct medication use. However, it is essential to prepare detailed procedure standards setting out rules for pharmacists' conduct in relation to OTC medication dispensation. It may be also useful to prepare Standard Operating Procedures (SOPs) for chosen drug categories or ailments patients complain about.

Self-treatment counselling provided by a pharmacist should also include an interview to determine whether any medications bought without prescrip-

tion outside the pharmacy were used. The pharmacist, in applying such knowledge, may thereby prevent situations of abuse or incorrect use of these medications. He/she should also warn the patient that sometimes purchasing medications without specialist advice that can be provided only by pharmacist or physician may be unsuitable or even dangerous.

#### I.7. *Control of diet supplements use*

Diet supplements are products which should be used only in order to correct deficiencies of certain minerals and vitamins in a diet. Unfortunately, aggressive promotional and advertising campaigns of certain diet supplements producers result in people buying an increasing number of products in order to benefit from suggested health condition improvements, not only to correct natural deficiencies. Pharmacists should provide advice regarding the choice of diet supplements, especially for people with chronic illnesses. The present knowledge of interactions between these substances and medications is insufficient. The presence of diet supplements in a pharmacy's assortment should oblige a pharmacist to duly inform and provide specialist advice to the patient in order to prevent duplication or overdose of substances. The aim should be to ensure that, based on pharmacists' unique knowledge and competencies, the quality of diet supplements available in pharmacies is high and beneficial for society at large, as opposed to what non-pharmacy outlets offer their customers. Pharmacists should explain to patients the difference between medicinal products and diet supplements.

#### I.8. *Prophylaxis and health promotion*

The aim of prophylaxis and health promotion activities is to produce changes in the health behavior of patients, both among healthy persons who rarely visit the pharmacy and chronically ill persons, for whom behaviors of these kind may contribute to efforts to fight disease and an improvement in their quality of life. Prophylactic actions in pharmacies should be conducted in certain areas or time intervals. Attention shall be paid to preparing activities in pharmacies in accordance with areas of pharmacists' interests, i.e., directly related to the promotion of correct medication use or limiting its use to situations of necessity. Prophylaxis and health promotion programmes, introduced in generally accessible pharmacies, may include, inter alia.:

- smoking cessation programmes/nicotine replacement therapy counselling (NTZ);
- programmes of early disease detection (screening programmes): detecting hypertension, diabetes, hyperlipidemia, metabolic syndrome;

- prophylaxis of obesity;
- protective vaccinations;
- promoting healthy lifestyles (diet, physical activity).

It is a mistake to omit the role of pharmacist in programmes of early detection of chronic illnesses, since it is the pharmacist that often is the first person in health care system with whom an ill person comes into contact. Pharmacists should be prepared to identify a situation of chronic self-treatment without consulting a physician or seeing a diagnosis. The list of illnesses that may be identified with pharmacists' participation should include hypertension, diabetes, metabolic syndrome, hyperlipidemia, risk factors for neoplastic diseases, venous thromboembolic disease, peptic ulcer disease and respiratory system diseases evidenced by a persistent cough.

The role of pharmacist is to identify patients whose symptoms may indicate chronic conditions; the pharmacist's task is not to conduct studies whose results may constitute the basis for further investigation by a physician but, above all, to draw the patient's attention to the possibility that some symptoms may be related to serious conditions. It is important to indicate the conditions whereby informing a patient may contribute to the identification of disease at early stage and prevent, or at least considerably delay, exhibiting its most extreme consequences. The pharmacist's role is therefore to conduct a proper interview when the patient purchases OTC drugs – this concerns e.g., drugs from the proton-pump inhibitors group, non-steroidal anti-inflammatory drugs and antitussives/expectorants. Meeting with pharmacists in the course of screening programmes should also result in passing information to a patient for whom symptoms indicating a health problem were identified. The information should include factors such as which specialist a patient should turn to, whether a referral from a general practitioner is necessary and where to find information about specialist outpatient clinics.

The role of institutions and scientific associations is to design appropriate guidelines and procedural standards, as well as to indicate in cooperation with medical organizations the situations in which it is possible, with a properly conducted interview, to draw a patient's attention to health problems and the improvement of health attitudes.

#### **I.9. Pharmacists writing prescriptions**

In some countries, it is possible for pharmacists to prescribe medications of the *prescription only* dispensing category. Introducing this option increases the accessibility of medicinal products for patients but

requires a clearly specified scope of responsibility and competences for all professional groups prescribing medications. The UK may serve as the model country for pharmacists providing this type of service. The writing of prescriptions by pharmacists requires:

- specifying the pharmacist's competences and methods of controlling them through the creation of a training system for pharmacists authorized to write prescriptions;
- the preparation of guidelines including, inter alia, a descriptions of situations in which a pharmacist has no right to write a prescription and a list of categories of drugs which can't be prescribed by a pharmacist;
- the creation of a system for monitoring the issuing and dispensing of such prescriptions, as well as cooperating with the attending physician of patients for whom pharmacist issues a prescription.

Extending the group of professions authorized to prescribe medications enables significant savings in a health system, particularly if the newly authorized person is a pharmacist. However, in order to avoid prescribing a medicinal product for the purpose of increasing distribution, it is essential to create a system to monitor the substantive validity of issuing prescriptions by pharmacists. Writing prescriptions requires access to medical records for the authorized pharmacists in order to read diagnoses and complete records with information on the prescribed medications. Pharmacists must also be able to directly consult a physician to design the best possible treatment.

#### **I.10. Certification of pharmacists and accreditation of pharmacies to provide additional services**

Systems of quality management in the area of pharmaceutical care should ensure that the patient achieves the maximum possible therapeutic advantage and the necessary competences as well as the practical experience of pharmacists in work with individual patients should be specified and periodically verified. An important element in ensuring the quality of services are norms, procedures, and accurate records enabling the systematic assessment of progress and treatment results for individual patients, as well as registration and self-assessments of the professional activity of pharmacists.

Pharmacists should aim at creating a system which would ensure the provision of high quality services. In the framework of this system, it is necessary to establish institutions/teams confirming personnel qualifications and ensuring the appropriate quality of structures and processes related to pharmaceutical care. Within a system of this kind it is advisable to design frameworks for the certification

of pharmacists and accreditation of pharmacies providing pharmaceutical care and offering an extended scope of pharmaceutical services from this area.

## **PART II. Actions to increase the role of pharmacists in the health system**

A health care system is a complicated mechanism whose aim is to ensure access to programmes and technology which enable every member of society to regain, improve, or maintain their health. For every type of profession functioning within this system, tasks should be specified and areas of responsibility indicated. Part II of this document therefore includes a list of areas in a health system in which it is possible and desirable to employ pharmacists' knowledge. Extending the scope of responsibility will contribute not only to an increase in professional satisfaction among pharmacists from generally accessible pharmacies and raise the prestige of this professional group, but may also contribute to future improvements to the health indicators of society and the rational employment of financial means in areas related to pharmacotherapy.

### **II.1. Involving pharmacists in actions associated with the reimbursement policy**

At the present moment, the role of pharmacists in the reimbursement system is limited to involvement in the process of medication distribution in generally accessible pharmacies. However, in the course of designing the reimbursement system several areas were created to which pharmacists may and should contribute using their specialist knowledge of medicinal products. Therefore, within the system it is necessary to create mechanisms encouraging pharmacists to take up activities in such areas of the health system in which they can employ their knowledge and skills acquired during their education. Pharmacists can be responsible for:

- negotiations with pharmaceutical companies at the Ministry of Health Economic Commission;
- rationalizing activities within the framework of the NFZ (National Health Fund);
- health technology assessments (HTA) within the framework and by order of the Agency for Health Technology Assessment and Tariffs (AOTMiT);
- being active in the Transparency Council of AOTMiT;
- cooperating with pharmaceutical companies in conducting HTAs.

It is noteworthy that pharmacists possess unique knowledge of the research and development, and manufacture of medicinal products. However, it

is essential to create mechanisms in the education system for pharmacists to encourage them to acquire knowledge that blends economy and pharmacy, which would be exceptionally useful in areas related to medication reimbursement. Taking into account the education of pharmacists, their participation in the decision making processes for reimbursement seems obvious since pharmacists can, in reference to drug technologies:

- determine their clinical effectiveness;
- establish cost components related to their economic assessment;
- estimate cost-effectiveness indicators;
- determine the consequences of reimbursement for drug technologies.

### **II.2. Including pharmacists in medical teams caring for patients with selected illnesses – diabetics, asthmatics**

It is essential to work out a model for sharing responsibility for the correct pharmacotherapy of a patient between physicians prescribing medications and pharmacists monitoring their application. A basic task for a pharmacist, as a medical team member, is to take on partial responsibility for conducting effective, safe, and at the same time cost-effective pharmacotherapy. Performing this task takes place not only through direct cooperation with the patient and his education, but also through sharing knowledge and experience with representatives of other medical professions. In the guidelines of the Polish Diabetes Association, a pharmacist wasn't mentioned as a member of a diabetes care team. Unfortunately, in many documents of these kind, the role of the pharmacist as a potential educator of a patient is left out.

### **II.3. Increasing the involvement of pharmacists in monitoring the adverse effects of medications**

The provisions of Polish law impose on pharmacists an obligation to give information to relevant authorities on adverse effects reported by patients. Unfortunately, at the present moment, as statistics kept by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products show, the number of reports passed on by pharmacists is very small. This may be caused by a lack of knowledge on the specialist personnel's side regarding the purposefulness and significance of this kind of information and its relation to monitoring the safety of pharmacotherapy. Pharmacists should considerably increase their involvement in sending reports on adverse effects, particularly due to the fact that, under new provisions of EU law from July 2012, patients can also directly pass information on observed



adverse effects of drugs they use to monitoring institutions. Increasing pharmacists' involvement in monitoring adverse effects may help verify and substantiate reports given directly by patients. Pharmacists should pass on reports using the so-called "yellow cards" every time patients report suspected adverse effects, even if the effect was already mentioned in documents (SPC). Adverse effects are one of the most commonly occurring drug related problems. Their detection in the course of pharmaceutical care should always result in sending a relevant card.

It is worth paying attention here to a recommendation to report to medication producers instances of using medications among high risk groups for which proper research on safety and effectiveness wasn't conducted, such as newborns, infants, children, pregnant women and people with organ failure related to the metabolism process and drug excretion.

#### II.4. *Increasing pharmacists' awareness of and involvement in studies on pharmaceutical practice*

Practicing medicine is often coupled with scientific research. In university hospitals, as well as others, conducting therapy is often combined with research. On the other hand, practicing pharmacy in Poland is extremely rarely connected with conducting scientific studies, although – as examples of other countries show – such studies in the area of pharmaceutical practice may significantly contribute to improvements in the safety and effectiveness of pharmacotherapy. In research within the area of pharmaceutical practice, for the most part, the methodology of qualitative research applied in social sciences (sociology, anthropology, psychology) is employed. Chamber of Pharmacists and pharmacist organizations should promote the participation of pharmacists in studies of this kind and support them financially through awards and grants, particularly for individual pharmacists from generally accessible pharmacies who wish to pursue such activity. Polish research centres conducting such research without practical support or participation from pharmacists sometimes encounter serious difficulties or aren't even able to carry out research within the area of pharmaceutical practice. Conducting regular studies on pharmaceutical practice in generally accessible pharmacies enables working out new types of pharmaceutical services adapted to Polish conditions.

Attention should be paid to several elements that are significant from the point of view of researching pharmaceutical practice in Poland:

- all around the world, the assessment of medication use in out-patient and in-patient health care is performed on the basis of health data made available

by health care units, including, inter alia, data on drug application; however, Article 103 of the Pharmaceutical Law Act practically hinders obtaining data from pharmacies for the needs of studies conducted by scientific units, so assessment of the effectiveness of changes put into practice is possible only due to conducted clinical trials, in the course of which new types of services are introduced and tested directly in pharmacies. In the case of studies conducted with people's participation, the necessity of obtaining the approval of the relevant bioethical commission should be taken into account;

- changes to pharmaceutical practice require funding, part of which may be obtained through funds for conducting research, including European funds – a significant part of funding competitions often involves giving information on studies carried out to the public. This may cause problems related to the prohibition of advertising pharmacies' activity;
- studies conducted for patients require their consent, and the process of collecting and storing personal data or sensitive data containing information relating to a patient's health condition must be in accordance with the provisions on personal data protection.

### **PART III. Tasks for state institutions and public organizations**

Tasks for advisory teams, chamber of pharmacist, and scientific associations include designing guidelines and standards of procedure to ensure that pharmacies deliver high quality services. In preparing binding documents, the positions of the World Health Organization (WHO), the International Pharmaceutical Federation (FIP), and the Pharmaceutical Group of the European Union (PGEU) which specify the role of pharmacists and tasks for them in health care systems may be particularly helpful.

It is necessary to create a system of guidelines and recommendations concerning drug forms or groups, which should include extended education for pharmacists. With regard to actions taken in pharmacies, it is possible to establish guidelines concerning the treatment of chosen chronic diseases and adjust them to the specific needs emanating from pharmacists' work with patients, paying particular regard to the professional competences of pharmacists. Designing guidelines will help simplify work with individual patients.

#### III.1. *New tasks for chosen state institutions*

##### III.1.1. Tasks for Pharmaceutical Inspectorate

- Helping public scientific and research institutions to conduct studies in the area of pharma-

ceutical practice through jointly establishing procedural rules for conducting scientific and research activities in the environment of generally accessible pharmacies, paying particular regard to the applicable provisions of law.

- Supporting actions aimed at creating a system of certification for pharmacists and accreditation for pharmacies in the scope of providing additional services related to pharmaceutical care in community pharmacies.
- Participation through its representatives in designing guidelines and procedural standards for different types of pharmaceutical services related to pharmaceutical care – Pharmaceutical Inspectorate (IF) employees' knowledge may help in drafting documents in which the quality of services exceeds minimal legal requirements.
- Supporting activities aimed at making changes to the law in order to widen the scope of services provided in pharmacies and improve their quality:
  - proposing changes to applicable legal provisions which would support actions aimed at improving the quality of pharmaceutical services, including changes to the regulations of the Minister of Health concerning conditions for operating a pharmacy, among others;
  - assessing changes aimed at increasing the competences of skilled pharmacy employees proposed by other organizations and institutions;
  - indicating areas where change is required and taking active participation in work on changes to the law whose purpose is to extend the scope of pharmaceutical services and improve their quality.
- Including information on services related to pharmaceutical care in training programmes, and regular meetings of pharmaceutical inspectors performing control of generally accessible pharmacies, who should be acquainted with:
  - rules for conducting studies related to pharmaceutical practice;
  - modern services provided in community pharmacies in developed countries;
  - systems of implementation and quality control in community pharmacies;
  - guidelines and recommendations of pharmaceutical and medical organizations for the role of pharmacist in contemporary health systems (e.g., FIP, WHO).
- Participation of IF representatives in the work of Polish scientific associations and pharmacist organizations on improving professional practice. The greater the IF's knowledge of the real problems experienced within in the pharmaceutical services

market, the easier it will be to draft documents which will help improve pharmaceutical practice.

- Permanent participation of IF representatives in the work of international organizations acting towards improving pharmaceutical practice, i.e., the Pharmaceutical Group of the European Union and the Committee of experts on quality and safety standards in pharmaceutical practices and pharmaceutical care within the Council of Europe.
- Supporting the involvement of Polish researchers in international research related to pharmaceutical practice through working out a permanent model of cooperation with scientific and research units functioning at public higher schools.
- The active participation of IF representatives in actions aimed at making amendments to the law to improve pharmaceutical practice.

### III.1.2. Tasks for the Ministry of Health

- Proposing amendments to the law which would promote actions aimed at improving quality in the area of pharmaceutical practice, enabling future financing for additional pharmaceutical services from public funds.
- Including pharmacist representatives in teams permanently and periodically cooperating with the Ministry for the purpose of improving the national medication and reimbursement policy.
- Promoting quality in areas related to pharmaceutical practice.

### III.2. *New tasks for public organizations in pharmacy – chamber of pharmacists, scientific associations, foundations, and others*

#### III.2.1. Tasks for Chamber of Pharmacists

- Cooperation with and supporting the activity of scientific and research centres in the scope of conducting studies on professional practice through taking common initiatives, funding rewards for scientists from community pharmacies and promoting and supporting cooperation initiatives between businesses from the pharmaceutical practice sector and scientific institutions;
- Promoting the quality of pharmaceutical services provided in generally accessible pharmacies, creating teams in pharmacies and pharmacy organizations whose aim is to improve the quality of pharmaceutical services and creating a system of accreditation of pharmacies and certification of pharmacists;
- Designing guidelines and recommendations for services provided in community pharmacies;
- Preparing organizational and legal strategies for the development of pharmaceutical practice;

- Active seeking of funds for supporting activities within the area of pharmaceutical practice;
- Appointing a team (including members of organizations and scientific institutions) to prepare reports assessing the cost-effectiveness of additional services provided in pharmacies, which will enable them to be included in the list of services financed from public funds;
- Appointing a permanent representative at the Sejm (lower house of Parliament) of the Republic of Poland to lobby for the improvement of pharmaceutical practice;
- Working out a model for rewarding pharmacists from community pharmacies who conduct scientific and research activity or participate in it – e.g., increasing the number of educational points for participation in scientific research and conferences, as well as scientific publications;
- Working out a model of cooperation and sharing responsibility for pharmacotherapy between physicians and pharmacists;
- Conducting informational campaigns directed partly towards representatives of other medical professions and partly towards patients, with the purpose of providing information on the role of modern pharmacists in a health care system and presenting their competences and knowledge which should be used in actions for improving the health of society.

#### III.2.2. Tasks for scientific organizations and associations

- Designing guidelines and standards of procedure which will ensure that quality standards of additional pharmaceutical services provided in community pharmacies are maintained;
- Preparing research development strategies in the area of pharmaceutical practice, promoting the activities of scientific institutions engaged in studies on pharmaceutical practice, providing financial support to initiatives in this area, and initiating actions aimed at increasing the involvement of pharmacists from community pharmacies in research on pharmaceutical practice;
- Promoting and helping to publicize research results from the area of pharmaceutical practice – subsidizing attendance at scientific conferences and other forms of popularizing the results.

#### III.3. *New state and/or public teams and bodies*

- The creation of a team engaged in providing accreditation for pharmacies and certification for pharmacists that provide additional pharmaceutical services in community pharmacies;

- The creation of a team engaged in finding legislative solutions related to pharmaceutical practice.

#### III.4. *Development of permanent cooperative relationships between state institutions, public organizations, and private business representatives*

- Preparing documents specifying a common framework of actions for the state and private institutions;
- Devising a list of institutions, organizations, associations, and foundations engaged in different aspects of pharmaceutical practice.

#### III.5. *Changes to the law*

Changes in the area of pharmaceutical practice require amendments to existing implementing provisions. New legal provisions should take into account:

- keeping records of actions related to pharmaceutical care in community pharmacies;
- functional adjustments of pharmacies to the new professional activity of pharmacists;
- financing additional services in pharmacies from public funds;
- participation of pharmacists in actions for public health;
- employing resources from savings related to the reimbursement of medicinal products to conduct research related to pharmaceutical practice;
- actions related to the accreditation and certification of pharmacies and pharmacists;
- changes related to awarding educational points for scientific and research activity and publication of their results.

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