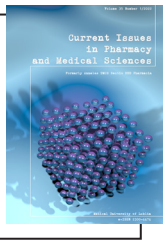
DOI: 10.2478/cipms-2024-0009 Curr. Issues Pharm. Med. Sci., Vol. 37, No. 1, Pages 52-58

Current Issues in Pharmacy and Medical Sciences
Formerly ANNALES UNIVERSITATIS MARIAE CURIE-SKLODOWSKA, SECTIO DDD, PHARMACIA

journal homepage: http://www.curipms.umlub.pl/



Changes in pharmaceutical prescription authorizations and their impact on the number of prescriptions issued by pharmacists in Poland

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ARTICLE INFO

Received 29 December 2023
Accepted 24 February 2024

Keywords:
pharmaceutical law, pharmaceutical prescription, legislative changes, pharmacists' qualifications, pharmacist in Poland.

ABSTRACT

The Pharmaceutical Law Act of September 6, 2001 (PLA) initially granted pharmacists the authority to issue pharmaceutical prescriptions upon its enactment. However, the legislation regulating this matter changed significantly in 2015. Article 96, section 4 of the PLA defined that, in the front of a direct health threat to a patient, a pharmacist could dispense a medication classified under the availability categories Rp or Rpz. In April 2020, the imprecise term "sudden" in relation to health threats was clarified and removed. Concurrently, all active pharmacists were granted the authority to issue prescriptions, commonly known as *pro auctore* and *pro familiae*. The aim of the study was to illustrate the influence of legislative processes on the number of prescriptions issued by practicing pharmacists. To conduct the study, we employed a legal and comparative analysis of relevant legal provisions, followed by a statistical analysis of data obtained from the E-Health Center about the number of prescriptions issued. The results indicated that since the extension of pharmacists' rights (after April 2020), the average number of pharmaceutical prescriptions issued per month was 151,082. Between May 2020, when pharmacists were granted the authority to issue *pro auctore* and *pro familiae* prescriptions, and October 2023, 1,460,385 such prescriptions were dispensed. As a result, a significant relationship between the form of the legislative norms empowering pharmacists to independently prescribe Rx status medicines and the effectiveness of these amendments as measured by the number of prescriptions issued was demonstrated.

INTRODUCTION

In the practice of the profession of pharmacy, there are many occasions when a patient requires the administration of a medicine that is only available on prescription without having the relevant document issued by an authorized person. Various scenarios, going from critical emergencies posing a direct threat to the patient's life, to less severe examples threatening their health, order immediate intervention. Considering the above, legislative amendments have been instituted to address this issue comprehensively. Through modifications to the Pharmaceutical Law (PLA) [1] and the Act of December 10, 2020, about the profession of pharmacy (referred to as the Pharmaceutical Profession Act (PPA)) [2], pharmacists have been empowered to dispense medications without a required prescription in cases of acute life-threatening situations and to independently prescribe in the event of a patient's health emergency. Notwithstanding the aforementioned, the category of authorized individuals, traditionally restricted to pharmacy managers, has been extended to include all practicing pharmacists.

It is worth noting that, regarding pharmaceutical prescriptions, prescribing rights are limited; nonetheless, pharmacists have the right to prescribe all medications except for psychotropic and narcotic drugs. In each case, the pharmacist independently assesses the medical conditions. If the pharmacist considers that the patient requires an antibiotic or other medication, they have the right to issue a pharmaceutical prescription because it is a medical emergency. The pharmaceutical prescription contains almost all the data characteristic of a physician's prescription, such as the patient's details, details on the prescribed medication product and the details of the person issuing the prescription.

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The reason for the prescription (description of the medical condition) is also required. It is not necessary to specify the level of reimbursement as a pharmaceutical prescription must be paid in full according to the Act. Pharmaceutical prescriptions can only be issued in a pharmacy. The Provincial Pharmaceutical Inspector controls them. Of course, in the case of infringements, pharmacists are subject to control by the authorities of the Pharmaceutical Profession Self-Government and to liability before the Professional Liability Ombudsmen and Pharmacy Courts. However, in the case of *pro auctore* and *pro familiae* prescriptions, pharmacists have been accorded rights nearly commensurate with those of physicians, with minimal exceptions, including the right to apply reimbursement criteria. In this case, the pharmacist is obliged to keep complete medical documentation and is fully responsible for the prescription. If reimbursement indications are used, there is an obligation to justify and document them. Therefore, it can be concluded that towards oneself and one's immediate family (the case of prescriptions *pro auctore* and *pro familiae*), to a certain extent, this also means the right to make a diagnosis.

The augmentation of statutory rights, the establishment of precise definitions, and geopolitical situations, such as a pandemic or war in Ukraine, have been reflected in the number of prescriptions issued by pharmacists. This trend is palpably evident in the data procured from the E-Health Center. For obvious reasons, the quantity of medicinal products designated for prescription in the minimal therapeutic packaging (excluding narcotic drugs, psychotropic substances, and category 1 precursors) that a pharmacist can dispense without a formal prescription during life-threatening emergencies remains unaffected by legislative modifications. The number of situations like this is impossible to predict; however, the associated risk has undeniably heightened. This is due, among other issues, to the introduction of the possibility for pharmacists to perform immunizations and the greater probability of anaphylactic shock in the presence of a pharmacist.

Consequently, the objective of this study was to conduct a legal and comparative analysis of the legal provisions delineating the rights of pharmacists to autonomously prescribe prescription-only medicinal products. Subsequently, the study aimed to highlight the impact of legislative amendments on the volume of prescriptions issued by pharmacists. To address the core inquiry of the research, the following question was posed: Does the alteration in regulations influence the broadening of pharmacists' rights, and is there a direct correlation between the specificity of the statutory definition and the quantity of prescriptions issued?

MATERIALS AND METHODS

Legal and Comparative Analysis

The initial phase of the study entailed a legal and comparative analysis of the regulatory framework governing the issuance of prescriptions by pharmacists independently, as well as the circumstances under which prescription-only medications can be dispensed without adherence to these regulations. The analysis encompassed legislative acts over the past two decades. Special attention was given to amendments made to the Acts, particularly the P.L.A and PPA.

Comparative analysis

To gather data concerning the quantity of pharmaceutical prescriptions dispensed, as well as the number of *pro auctore* and *pro familiae* prescriptions issued, a request for access to public information was lodged (case number WWOPI.0112.245.2023, dated October 16, 2023) [3]. Based on this request, data spanning from January 1, 2019, to October 17, 2023, was procured. The rationale for selecting this timeframe stems from the implementation of the e-prescription system in January 2019. This system consolidates all data within the Medical Information System (MIS) [4] about electronic prescriptions. Concurrently, this period encapsulated pivotal legislative amendments, notably in 2020. Within this timeframe, the authorization to issue *pro auctore* and *pro familiae* prescriptions was also instituted. The data obtained from the E-Health Center was statistical analysis.

Statistical analysis

The statistical analyses were performed using STATISTICA 13.1 software (StatSoft Inc., Tulsa, OK, USA). The obtained data were analysed using hierarchical cluster analysis (full linkage using Euclidean distance) and principal component analysis (PCA). The PCA model was estimated using the NIPALS iterative algorithm. The criterion of convergence was set at the level of 0.00001, and the maximum number of iterations was set at 50. The number of components was determined by determining the maximum predictive capability using the method of multiple cross-validations, and the maximum number of components was set at that level. The obtained optimal PCA model was then reduced to 2 components. The conducted PCA, the results of which are presented on the chart of PC 1 *vs*. PC 2 loads, allowed us to select variables with the most significant influence on the variability of the analysed database of results, as well as to select the most significant correlations between them. These two classification techniques (PCA and HCA) were applied to discover natural groupings in the data and examine differences between the analysed influences of the sum of the pharmaceutical prescriptions and pro autore and *pro familiae* prescription obtained by pharmacists in Poland. A one-way ANOVA was used to compare sum of pharmaceutical prescriptions and sum of *pro auctore* and *pro familiae* prescription issued during the half-year periods of 2019 to 2023. Statistical significance was considered when $p < 0.05$.

RESULTS

With regard to the legal and comparative analysis of the provisions determining the right to independent prescription authorization by pharmacists, the contemporary definition of a pharmaceutical prescription is articulated in Art. 96, section 4, PLA. The provision delineates: "*A pharmacist, authorized to practice the profession, may issue a prescription for individuals as referenced in Art. 95b, section 3, or, a pharmaceutical prescription in cases where there is*

a threat to the patient's health, (...)" [1]. It should be clarified that the eligibility for obtaining reimbursed *pro auctore* and *pro familiae* prescriptions is restricted in accordance with Art. 95b, section 3, points 1 and 2 of the PLA. Eligible individuals include the issuing the prescription person, their spouse, cohabiting partner, direct line relatives, and in-laws. Additionally, collateral line relatives are eligible up to the degree of relationship equivalent to the children of the issuing prescription person's siblings [1].

Since the enactment of the PLA in 2002, pharmacists have been authorized to dispense medications requiring a physician's prescription in cases of immediate threat to a patient's health or life. The pharmacist was required to document this action within the pharmaceutical prescription. Subsequently, the Act dated October 9, 2015, amending the Act on the health care information system and other related acts [5], which came into effect on December 12, 2015, introduced the provision for issuing pharmaceutical prescriptions as follows: "*In cases of a sudden threat to a patient's health, a pharmacist authorized to practice may issue a pharmaceutical prescription, subject to the following regulations*:

1. *is issued in electronic format* (…),
2. *can be issued for medicinal products categorized as Rp or Rpz, in quantities corresponding to the smallest available packaging size of the medicinal product sold in a pharmacy, authorized for distribution within the territory of the Republic of Poland. This excludes medicinal products containing narcotic drugs and psychotropic substances as defined in the Act dated July 29, 2005, on combating drug addiction* (…)" [6].

This definition encompassed two pivotal elements. Firstly, the feasibility of issuing a pharmaceutical prescription in electronic format merits consideration. While this provision was incorporated into the Act as early as 2015, its practical implementation only materialized at the outset of 2019 with the introduction of the e-prescription system. Secondly, the adjective "sudden" was crucial, serving to delineate the health status of a patient eligible for a pharmaceutical prescription. The term denotes an unforeseen, pressing circumstance that does not necessitate additional justification. Yet, when applied to health contexts, its precision diminishes, leading to various interpretive ambiguities. Establishing, for instance, whether prolonged elevated blood pressure over several hours constitutes an immediate event posed challenges. Similarly, determining if escalating fever over a day qualifies as a "sudden emergency" remained controvertible. The legislative ambiguity prompted natural caution among pharmacists, leading to concerns over the potential unauthorized issuance of pharmaceutical prescriptions. This provision remained unchanged for five years. Notably, it underwent significant change only in April 2020, amid the ongoing pandemic attributed to the SarsCov-2 virus. Changes were introduced on March 31, 2020, to amend a specific health protection act related to the prevention and combat against COVID-19, which poses a threat to life as of April 1, 2020 [7]. During the amendment, the adjective "sudden" was removed; the condition for issuing a pharmaceutical prescription is now only an "ordinary" health threat.

Simultaneously, the aforementioned Act introduced groundbreaking changes, granting pharmacists the right to independently prescribe prescription drugs for themselves and their close relatives. Article 96, section 4 of the PLA, is included in the definition: "*A pharmacist authorized to practice the profession may issue a prescription for the individual referred to in Art. 95b, section 3, or a pharmaceutical prescription in the event of a threat to the patient's health*" [8]. Such significant changes were undoubtedly influenced by the extraordinary situation in the entire healthcare system, particularly in pharmacies, which were visited by 21 million patients in one week in March 2020 [9]. Difficulties in accessing physicians made it necessary to facilitate the issuance of pharmaceutical prescriptions.

When analysing the aforementioned standard in detail, several important points should be emphasized. Firstly, the regulation grants pharmacists greater freedom in selecting the medicines they prescribe. However, as per Art. 96, section 4, point 2 of the P.L.A, an exception is made for medicinal products with the "Rp" availability category, excluding those containing narcotic drugs and psychotropic substances as referred to in the Act of 29 July 2005 on combating drug addiction [10]. The scope of the restriction arises from the natural caution of the legislator, who aims to minimize the risk of actions inconsistent with the purpose of the amendment. The number of medicines issued is limited by Art. 96, section 4, point 6 of the PLA, which directly pertains to the rights of nurses [1]. It allows, in the case of an electronic prescription, for the prescription of the amount of medicinal product (...) necessary for a patient for a maximum period of 180 days of drug use, as determined by the dosage method specified in the prescription (...). This represents a notable increase in prescription options compared to previous authorizations, where a pharmaceutical prescription could be issued for medicinal products categorized as Rp or Rpz, in the quantity of one of the smallest available packages in a pharmacy (...) [7]. While maintaining the rule resulting from the regulations, according to which a pharmaceutical prescription is filled with a 100% payment, in the case of *pro auctore* and *pro familiae* prescriptions, the legislator decided to introduce an absolute novelty, i.e. it gave pharmacists the right to determine the level of reimbursement, and thus to fill prescriptions with appropriate payment resulting from separate regulations [11]. Naturally, with pharmacists acquiring additional privileges, they also assumed responsibility for ensuring that the profile of prescribed medicinal products aligns with reimbursement guidelines and for any errors made in this regard.

The scope of obligations related to documenting the prescription of *pro auctore* and *pro familiae* prescriptions is crucial. Apart from several other conditions, the most important, following Art. 96 section 4 point 3 of the PLA [1], is the diagnosis of a disease, health problem or injury.

Owing to the dynamic advancement of the vaccination process in pharmacies, the definition of a pharmaceutical prescription was then broadened. During the subsequent amendment of Art. 96, section 4, PLA [1] added by art. 82, points 14, letter B, of the Act of March 9, 2023, on clinical trials of medicinal products for human [12] use changing the PLA, as of April 14, 2023, a revised version of Art. 96

was introduced by adding section 4 [13]. It currently states that: "*A pharmaceutical prescription may also be issued for an immunological product necessary to carry out protective vaccination against influenza in a generally accessible pharmacy – according to Art. 86 section 8a. The pharmaceutical prescription specified in the first sentence is the basis for the use of the medicinal product in the generally accessible pharmacy where the pharmacist issued the prescription*" [13]. This solution streamlines the patient's access to health services, such as influenza vaccination. Concurrently, the legislator determined that, in the context of vaccination, the justification for issuing a prescription is self-evident, as stipulated in the revised provision of Art. 96, section 4, point 3 of the PLA [1].

Regardless of the amendment to the provisions of pharmaceutical law, the authorization amendments are breakthrough changes primarily due to the introduction of the possibility for a pharmacist to provide pharmaceutical care as a health service. This definition is included in Art. 4 section 2 PPA: "*Pharmaceutical care is a health service within the meaning of Art. 5 points 40 of the Act of 27 August 2004 on health care services financed from public funds* (*Journal of Laws of 2021, item 1285, as amended*) (…)" [2]. The catalog lists five services that constitute pharmaceutical care. One of them is issuing prescriptions as a continuation of a physician's order. Although the PPA [2] entered into force on January 16, 2021, the provisions on continued prescriptions received a longer *vacatio legis* and came into force only on January 16, 2022.

By the same legal act, the content of Art. 96 PLA [1] was modified by adding paragraph 3a, which reads: "*In order to continue therapy with a medicinal product, food for particular nutritional purposes or medical device prescribed by a physician on a prescription, hereinafter referred to as* "*continued prescription*"*, a pharmacist may, as part of the pharmaceutical care referred to in Art. 4 section 2 of the Act of 10 December 2020 on the profession of pharmacist, issue a prescription for medicinal products, foodstuffs for particular nutritional uses or medical devices, to which the following rules apply*:

1. *is issued based on a physician's order recorded in the MIS [4] regarding the continuation of therapy with a medicinal product, food for particular nutritional uses, or a medical device prescribed in a continued prescription*;
2. *is being issued for medicinal products food for special medical purposes, or medical devices prescribed on a continuing prescription*;
3. *is issued within the period specified by the physician prescribing the continued prescription, no longer than 12 months from the date of issuance of the prescription*;
4. *the total amount of the medicinal product, food for particular nutritional uses, or medical device may not exceed the amount necessary for the patient for 360 days of use calculated based on the dosage method specified in the continued prescription, and the amount of the medicinal product on one prescription may not exceed the amount necessary to be used within the period specified by the physician*;
5. *is issued after the pharmacist has performed a diagnostic test, blood pressure measurement, or other activity as part of the provision of pharmaceutical care – if the physician issuing the continuing prescription orders their performance* (...);
6. *may be issued to medicinal products with the availability category Rp or Rpz* (...);
7. *it indicates the payment specified by the physician in the continued prescription unless the pharmacist issuing the prescription became aware of the need to change the payment*" [14].

The legislator aimed to introduce the possibility of continuing patient therapy by issuing a prescription by an authorized pharmacist based on the original medical prescription. Important elements of this standard are the right to maintain the patient's rights set out in the Reimbursement Act [11] and the fact that the physician indicates the possibility of providing another health service listed in the PPA [2], i.e. a diagnostic test. In the era of electronic prescription, Art. 96a section 2 point 1 of the PLA [1] allows the patient to be provided with the necessary medications for the 360-day treatment period, which means that a prescription continued as a service is not a priority or urgent solution. This is confirmed by the lack of progress in work on changing the systems through which electronic prescriptions are collected and administered.

Data analysis

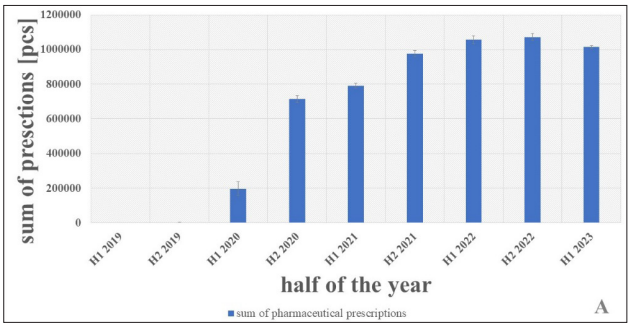
It is worth emphasizing that the most important legislative changes allowing pharmacists to issue prescriptions themselves took place in April 2020. There is no data connecting with the situation when a pharmacist dispenses a drug in the event of a life-threatening situation – the permissions do not oblige the pharmacist to issue prescriptions in such a situation. Due to dead records on continued prescriptions, in this case, too, no reliable figures exist.

In the analysed period, pharmacists issued a total of 6,437,024 pharmaceutical prescriptions. By comparing the number of pharmaceutical prescriptions issued, data was prepared and compiled on a semi-annual basis, limited only to data from fully completed periods. Therefore, the analysis does not take into account the H2 2023 period (second half of 2023). Detailed data on the number of pharmaceutical prescriptions issued, as well as data on the number of *pro auctore* and *pro familiae* prescriptions written, are presented in Table 1 and Figure 1A and 1B.

Analysing the above data, it can be noted that before the introduction of the changes discussed, i.e. in 2019, the number of pharmaceutical prescriptions issued on average per month ranged from 50 to 500 (periods H1 2019 and H2 2019), while after the introduction of the changes in law

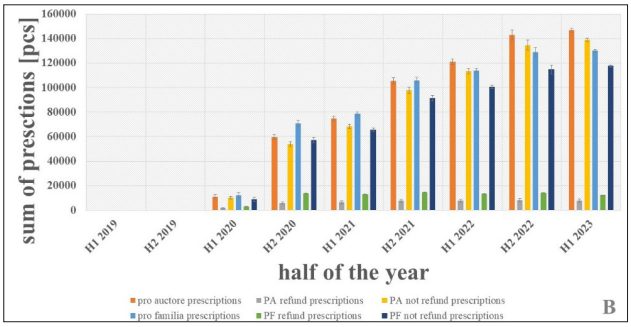
Table 1. The sum of pharmaceutical prescriptions, *pro familie* and *pro auctore* prescriptions divided into half-years (H) in the period from 2019 to 2023. Only full years are include

Half of the year	pharmaceutical prescriptions			*pro auctore* prescriptions					*pro familia* prescriptions				
	SUM	AVG	SD	SUM	AVG	SD	Sum of ref. pres.	Sum of not ref. pres.	SUM	AVG	SD	Sum of ref. pres.	Sum of not ref. pres.
H1 2019	228	38	10	0	0	0	0	0	0	0	0	0	0
H2 2019	2996	499	1152	0	0	0	0	0	0	0	0	0	0



H1 – first half of the year (means 01.01-30.06);
H2 – second half of the year (means 1.07-31-12)

Figure 1A. The sum of pharmaceutical prescriptions prescribed in each half-year (H) in the period from 2019 to 2023 (A)



H1 – first half of the year (means 01.01-30.06);
H2 – second half of the year (means 1.07-31-12)

Figure 1B. The sum of *pro familiae* and *pro auctore* prescriptions prescribed in each half-year in 2019-2023, divided into refund and non-refund prescriptions (B)

regulation, a statistically significant difference was observed in the average number of prescriptions issued by pharmacists on a semi-annual basis ($p<0.05$) – from 32,906 in H1 2020, to even 178,652 prescriptions in H2 2022. A statistically significant difference in the increase of prescriptions issued by pharmacists was also observed in the periods from H1 2020 (on average, approximately 120 thousand prescriptions per month) to H2 2021 (on average, about 160 thousand prescriptions were issued per month) ($p <0.05$). There were no statistically significant differences in the increase in the number of pharmaceutical prescriptions issued ($p >0.05$) during the H2 2021 period, and the number of prescriptions issued by pharmacists fluctuated around 175,000 per month (Table 1).

An almost identical trend can be observed in terms of the number of *pro auctore* and *pro familiae* prescriptions issued by pharmacists (Table 1). Statistically significant changes ($p >0.05$) in the number of prescriptions issued as a whole have not been observed since the second half of 2021 (H2 2021). It can also be noticed that originally there was a sharp increase in the number of *pro auctore* and *pro familiae* prescriptions issued, from an average of approximately 2,000 per month in H1 2020, to an average of 175,000 per month in H2 2021 ($p <0.05$). Notably, the data for both prescriptions *pro auctore* and *pro familiae* are nearly identical. This was confirmed in Table 1.

To confirm the analysed data, a hierarchical cluster analysis was performed. Analysing the data presented in Figure 2, it can be observed that pharmacists are relatively reluctant to issue reimbursed prescriptions both for themselves and their families because the two clusters marked in red in Figure 2 indicate that the number of *pro auctore* and *pro familiae* prescriptions is directly correlated with the number of unreimbursed prescriptions. However, in terms of the number of reimbursed prescriptions issued by pharmacists for themselves or their families, more or less similar values are observed, i.e. on average, in the range of 20,000-21,000 prescriptions per month in both cases, which is confirmed by the data presented in Table 1, as well as the blue cluster visible in Figure 2.

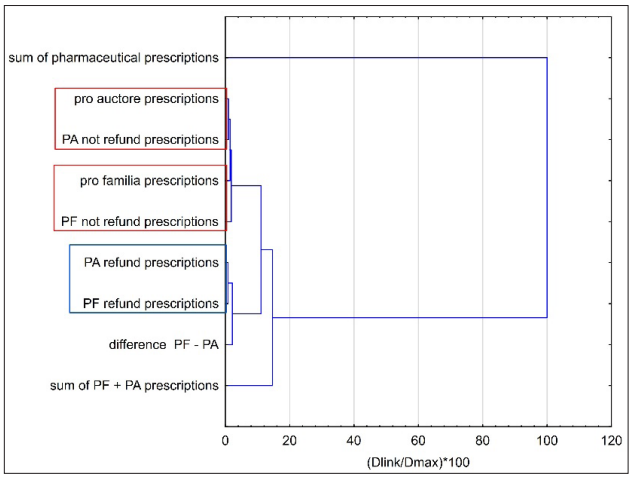


Figure 2. Cluster analysis obtained for pharmaceutical prescription included *pro familiae* and *pro auctore* prescription

PCA analysis (Figure 3) showed that, until the changes in regulations were introduced, the number of pharmaceutical prescriptions issued was significantly lower than in the periods after the introduction of legislative changes (three red circles visible in Figure 3 – the first containing the periods H1 2019, H2 2019 and H1 2020, the second containing the periods H1 2021 and H2 2021 and the third containing the periods H1 2022 and H2 2022 and H1 2023). The analysis indicates the existence of a breakthrough point, which falls in the H2 2020 period. From this moment, a clear increase in the number of pharmaceutical prescriptions can be observed, with a pronounced upward trend throughout 2021 and a stabilization of the quantity of issued prescriptions from the year 2022. The analysis conducted also confirms the fact that if a pharmacist issues prescriptions

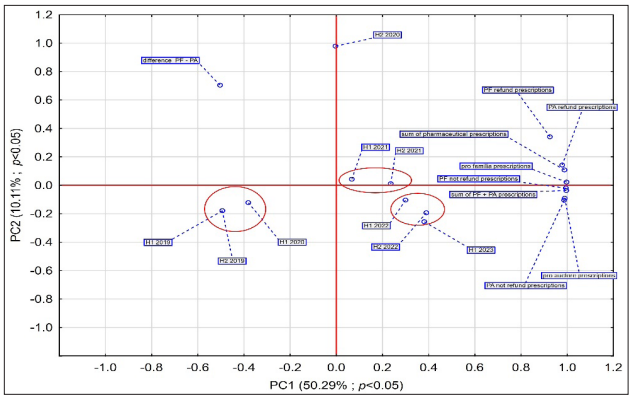


Figure 3. Principal component analysis obtained for pharmaceutical prescription included *pro familiae* and *pro auctore* prescription

for themselves or their family, they usually do it with 100% payment (Table 1).

DISCUSSION

Social political and economic changes also affect the professional rights of pharmacists. An aging society, an increasing number of people in need of health care, and a simultaneous shortage of medical staff naturally result in the transfer of powers assigned to physicians to other professional groups. Understanding the mechanisms that will enable the effective implementation of this process is crucial for the acceptance of this service – both by patients and by pharmacists themselves. This issue is not limited to the Polish healthcare system. The United Kingdom was a pioneer in this matter, granting pharmacists appropriate rights as early as 2004 [15]. Moreover, in Canada, pharmacists have the right to continue and adjust existing prescriptions and issue new ones [16].

The rights of independent prescription were extensively analysed in this regard by Ramos *et al*. in 2022 [17]. The results of their study indicated different acceptance and perceptions of medicines by different societies, depending on the level of knowledge and personal experience of patients and health care professionals, as well as the profile of pharmacists and the way medicines are prescribed. The study also highlighted challenges in pharmacists' prescribing practices. At the same time, the divisions were marked between dependent prescribing based on the continuation of medical prescribing and independent prescribing, where the patient's pharmacotherapy is based on the pharmacist's prescribing [17]. In the United States, pharmacists also have the right to prescribe drugs in 49 states in a dependent and independent model [18,19]. Both models were also introduced in Israel in 2013 and 2016, respectively [20].

Solutions adopted abroad are also cited in the summary report from 2021 [21], presented by the Pharmaceutical Care Group, which was designated by the Minister of Health based on the decree dated July 8, 2020 [22]. It refers to the scope of pharmaceutical services provided by pharmacists based on data from 32 European countries. The report presents the status of the provision of pharmaceutical services related to the issuance of medicines in Poland and indicates whether the current provisions of the PPA assume the possibility of providing this service in Poland. The results presented in the report showed that drugs with Rp status are issued in a situation of life-threatening emergency by 41% of all pharmacies in Poland (3% are reimbursed drugs). In a random situation, on the other hand, these drugs are dispensed by 34% of all of Poland's pharmacies (3% are reimbursable drugs) [21].

Based on studies from other countries, it seems reasonable to expand the prerogatives of Poland's pharmacists, which were analysed by Patryn and Drozd in 2021 [23]. Their research pointed out the new prerogatives of pharmacists, marking a division between continuing prescriptions, *pro auctore* and *pro familiae*, and pharmaceutical prescriptions according to the new legal definition.

Changes have been made at the legislative level for many years, but the number of prescriptions issued, and thus the number of patients assisted, depends on the structure of the legislative norm giving the pharmacist the authority to independent prescribing. Measures that began abroad nearly half a century ago, in Poland, have taken real form only since 2015, and the amendment of 2020 regulations should be considered the most significant change.

This study raised the question of the relationship between the form of legislation and the number of prescriptions issued and dispensed under pharmaceutical prescribing. The correlation between the calendar of the legislative changes and the popularity of these services was sought. The issues of acceptance of this form of prescribing by patients and pharmacists themselves were also analysed. To achieve the aims of the study, data about the number of prescriptions issued by pharmacists obtained from MIS were used. The sudden increase in pharmacist prescribing coincided with legislative changes that allowed pharmacists to prescribe for health risks rather than just 'sudden' health threats. This undoubtedly confirms the hypothesis of a significant impact of legislation increasing pharmacists' capacity in the context of self-prescription of medicines on the development of this service.

After the implementation of the changes, a statistically significant difference was observed in the average number of prescriptions issued by pharmacists. As a side note, it should be pointed out that, in terms of *pro auctore* and *pro familiae* prescriptions, the legislator has authorized pharmacists to also issue prescriptions for reimbursable medicines. As the results of the statistical analysis quoted above have shown, there is a significant disproportion between the number of non-reimbursed and reimbursed prescriptions issued by pharmacists in favour of the first ones. This is probably due to pharmacists' fear of incorrect indication of the level of reimbursement and the resulting financial consequences. Therefore, they opt for the safer option, *i.e*. the possibility of issuing prescriptions for reimbursed medicines while indicating 100% payment for the medication.

It is important to note that the change in the law allowing pharmacists to issue prescriptions for themselves and their relatives has generated significant interest. However, the entitlement to benefit from the right to reimbursement of medicines and the results determined by a regulation payment is rarely utilized by pharmacists. Poland's pharmacists accepted the newly gained rights relatively quickly – 6 months for *pro auctore* and *pro familiae* prescriptions. The study also shows that, with the current legislation, a level of saturation and/or stabilization in pharmacist prescribing has been achieved, as there has been no statistically significant variation in pharmacist prescribing since H2 2021 and the number of pharmacist prescriptions has stabilized at about 175,000 per month. It took pharmacists, as well as patients, roughly 1.5 years to accept the 'new' legislation and new entitlements (exactly 3 comparison periods). However, it should be mentioned that the changes introduced did not take effect until April 2020, i.e. in the first half of 2020.

The Polish experience confirms reports from other countries. Analysing 14 studies conducted between 2003 and 2017, Mills *et al*. [24] defined pharmaceutical prescribing as a natural extension of the pharmacist's role. At the same time, they concluded: "Many barriers are more potential than

real and they are diminishing. Addressing these will help to improve pharmacist prescription in primary care, leading to positive outcomes for both patient care and the pharmacy profession" [24].

CONCLUSION

The amendments to the legislation increasing the eligibilityThe amendments to the legislation increasing the eligibility for independent prescribing of medicines with Rx status have increased the number of prescriptions issued, and this number is directly dependent on the form of the specific legislative standard, even if the provision is adjusted in a seemingly minor way. This rule applies mainly to pharmaceutical prescriptions, where the barrier to qualifying as a health emergency has been removed by removing the "sudden" condition. The change was positively received by pharmacists and patients. As a result, 6,437,024 prescriptions were issued after the change in the regulation. Indeed, in the first six months, around 178,000 prescriptions were generated, compared to less than 33,000 issued by pharmacists before the change in the legislative standard. The wide-ranging change in law regulation to allow *pro auctore* and *pro familiae* prescriptions resulted in pharmacists being very interested in this new entitlement. However, the fear of having to determine the level of reimbursement themselves means that the vast majority of these prescriptions are issued at 100% payment for the medication. This is clearly illustrated by data showing that the average monthly number of reimbursed prescriptions *pro auctore* and *pro familiae* is only about 2.5-3.5 thousand.

De lege ferenda, it should be mentioned that, both by pharmacists and other prescribers, changes to legislation simplifying the process of setting reimbursement levels are awaited. The introduction of standards enabling the validation of reimbursement levels for medicines with the transfer of responsibility for its determination to IT systems should also be considered. A key issue also appears to be the practical enablement of the implementation of the continued prescription service. While pharmacist prescription in an independent model operates correctly, regulations regarding pharmacists issuing prescriptions in a dependent model are merely a lifeless legal norm and require broad changes at the legislative level. Another postulate *de lege ferenda* should be emphasized here, requiring a change in the role of the continued prescription, which, after appropriate amendments to the regulations (including granting pharmacists full access to the history of pharmacotherapy), should serve as an intermediary between the pharmaceutical and continued prescription in the current wording of the provision.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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