The Potential of Incorporating a Pharmacist-Only Medicine Category in Poland

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Abstract: Pharmacists play an important role, being increasingly focused on patient care and pharmaceutical services. This trend is also noticeable in Poland. Thus, we aimed to study the opinions of Polish pharmacists to determine the potential for introducing a new category of pharmacist-only medicines (POMs). This study was conducted during the COVID-19 pandemic. Hence, the survey (anonymous questionnaire consisting of 10 questions addressed to pharmacists) was only available in electronic form. A total of 500 correctly completed surveys were collected and subjected to further analysis. The vast majority of pharmacists (91.8%) revealed a willingness to expand their professional rights and 88% stated that the POMs implementation would be important. As a substance that should function as a POM instead of an OTC medicine, respondents most often indicated ketoprofen, sildenafil, and mometasone, accounting for 26.2%, 24.8%, and 24.4% of responses, respectively. In terms of funding pharmaceutical services, 54.2% of respondents indicated that costs should be covered partially by the patient and the payer. There is a clear need for the incorporation of the POM category in Poland. Polish pharmacists are anticipating the development of pharmaceutical services which should be partly covered by patients and payers.

Keywords: pharmacist-only medicines; access to medicines; pharmaceutical market; pharmacists

1. Introduction

For many years now, there has been a trend in global pharmaceutical markets to expand the professional rights of pharmacists [1]. It is intended, e.g., to utilize their competencies regarding access to healthcare services and patient care [1–3]. It is also noticeable in Poland, and recent legislative changes to the “Pharmacy for the Pharmacists 2.0” Act, the Act on the Pharmacist Profession, and the Polish Pharmaceutical Law Act have strengthened this trend [2,4,5].

Moreover, the document “State Drug Policy 2018–2022” issued by the Ministry of Health indicates national priorities in drug management. One is “Achieving the best possible health effect through rationalizing pharmacological treatment based on scientific evidence and clinical guidelines, adequate supervision, and efficient cooperation between physicians and pharmacists” [6]. Along with the Act on the Pharmacist Profession [4], pharmaceutical services like the Medication Review Program, vaccination in pharmacies, and expanded competencies within the pharmaceutical prescription move the professional rights of Polish pharmacists toward solutions known in the United States, Australia, or Western European countries [7,8]. Hence, the advisory nature of pharmacists’ work replaces the sales model [2,9–11].

Apart from the acts mentioned in the first paragraph, several different facets contribute to the shape of the pharmaceutical market. These are, for example, the globally observed...
drug shortages [12–16]. The problem concerns numerous medicines, including anticoagulants, antidiabetics, and some anticancer or neurological medications [17–19]. There are several reasons for medicine shortages, like reverse traffic of medicines, the COVID-19 pandemic, and the war in Ukraine [20]. Subsequently, if shortages occur, it leads to intense competition for products in short supply, which in turn causes price increases, making medicines non-affordable [19]. In addition, if a drug shortage is announced, consumers begin over-prescribing and stockpiling both in the Rx and OTC categories [20]. Thus, the scheduling of medicines might be supportive in reducing the public health burden of drug shortages and other phenomena like misuse of medicines.

In Australia, there are four schedules of medicines. Unscheduled medicines might be sold out of the pharmacy. Pharmacy medicines are restricted to pharmacies, but may be offered by a non-pharmacist employee. Pharmacist-only medicines (POMs), however, must be in accordance with the following:

➢ Supported by a pharmacist’s involvement in their sale to ascertain the therapeutic need and proper use of the medication;
➢ Stored out of public access;
➢ Individually labeled [21,22].

The POM category includes, for example, emergency contraceptives, oral treatments for vaginal thrush, respiratory medications, a number of analgesics, or sexual health medications [21]. There are also prescription-only medicines. Interestingly, equivalent classifications exist in New Zealand and Canada, and slight differences characterize systems in the United Kingdom and France [21]. In countries like Poland, with considerable growth of RX to OTC (general sale) switches (e.g., mometasone nasal spray, fenticonazole, or tadalafil), the following Australian scheduling could be an interesting solution.

Hence, we decided to investigate the potential for introducing POMs in the Polish pharmaceutical market. Furthermore, our goal was to determine the willingness of Polish pharmacists to provide new pharmaceutical services and to assess the preferred method of remuneration for these services.

2. Material and Methods

The analysis was conducted from December 2020 to September 2022 using an anonymous and self-designed questionnaire consisting of 10 questions (7 single-choice and 3 multiple-choice possibility questions; see the Supplementary Materials). We created the questionnaire based on the amended pharmacy acts in Poland, the literature, and our experience gained from the pharmacy practice. Before the exact study, we delivered the questionnaire to 10 pharmacists to assess the consistency and clarity of the questions. Based on the comments we received, we prepared the final version of the survey. For instance, we simplified the definition of POMs within the questionnaire.

The study tool was addressed solely to pharmacists. Pharmacy technicians were out of the present study’s scope. It results from the fact that pharmacy technicians are not equivalent employees to pharmacists in Poland. Additionally, this study was aimed at services like incorporating POMs which require a pharmacist’s involvement. Hence, pharmacists were the only possible target group of this study. Participation in the survey was voluntary, and no compensation was offered for it.

This study was conducted during the COVID-19 pandemic, so the survey was created using Google Forms and survio.com (accessed on 30 October 2019). We shared the survey link and a request to participate in the study on the closed Facebook pharmacists’ groups. We also emailed pharmacies a request to participate in the survey using publicly available pharmacy email addresses. Using information received from the pharmacy’s email, we marked numerically for anonymization. It prevented the presentation of, e.g., the pharmacy’s name and, consequently, the acquisition of advertising pharmacies, which is strictly forbidden in Poland. In case of a lack of response to our e-mail request, we repeated the inquiry after two weeks. Lack of response after a repeated attempt was treated as a
refusal to participate in the study. In addition, we shared the survey link on the Silesian and Greater Poland Regional Chamber of Pharmacists website.

Having collected more than 400 questionnaires, we decided that our goal was to gain 500 responses. A total of 500 correctly completed surveys were subjected to further analysis. Notably, the local bioethics committee confirmed that this study is not a medical experiment and does not require approval of the Bioethics Committee at Poznan University of Medical Sciences. The research tool is available upon request from the corresponding author.

Statistical Analysis

Nominal data were analyzed using the chi-square test of independence. All tests were considered significant at \( p < 0.05 \). Significant differences between % of group results were determined by analyzing the test of proportions (post hoc test).

3. Results

Most participants in the study were women (\( n = 375; 75\% \)). The average age of all respondents was 36 years old. The oldest participant was 81, and the youngest was 24.

The smallest numbers of respondents (6%) represented the rural area. However, 28.6% of respondents worked in cities with up to 50,000 inhabitants, and the same number worked in cities with over 500,000 inhabitants. A total of 36.8% of respondents worked in cities with 50,000 to 500,000 inhabitants.

The majority of respondents worked in chain pharmacies. Most of them (45.4%) declared working in a pharmacy chain (>15 pharmacies). A total of 13% worked in a medium-sized pharmacy chain (up to 15 pharmacies), and 19.0% of respondents worked in pharmacies belonging to a small chain (2 to 5 pharmacies). However, 22.6% of respondents were employed in individual pharmacies.

The vast majority of pharmacists participating in the study (91.8%) showed willingness to expand their professional qualifications, which may be necessary for introducing future new categories of drugs and pharmaceutical services. Considering that POMs are an innovative category for the Polish pharmaceutical market, we presented the POM definition within the questionnaire. Then, we asked study participants if they had already encountered this category of drugs. The majority (54.2%) responded that they had not yet faced such a category. However, it is interesting that pharmacists working in rural pharmacies more often (56.7%) indicated familiarity with the presented concept compared to other locations where the lack of previous contact with the POM category was greatest. Nonetheless, 88% of study participants stated that implementing a POM category would be a necessary solution, constituting a buffer in the trend of reclassification of drugs from Rx to OTC.

The pharmacists participating in the study were also asked (multiple-choice possibility) to indicate substances that, in their opinion, should be registered as POMs instead of OTC. Ketoprofen (26.2% of responses) was most often indicated here, followed by sildenafil (24.8% of responses) and mometasone (24.4% of responses). Some respondents took advantage of the possibility of showing a substance from among those not listed in the answer options. The most frequently mentioned were codeine, pseudoephedrine, dextromethorphan, furazidine (furaginum), emergency contraception, and proton pump inhibitors.

In the question concerning pharmacists’ willingness to provide selected pharmaceutical services, the most popular (26.3% of responses) response was the possibility of consulting with a patient to conduct, e.g., medication use reviews (MUR) and working with drugs categorized as POMs (26% of responses). A detailed distribution of answers given in this multiple-choice possibility question is presented in Figure 1. Interestingly, we found statistical significance between these leading answers and the following variants. The willingness to provide consultations like MUR and working with POMs revealed \( p = 0.0001 \) compared to the willingness to vaccinate in pharmacies. The leading answers also had statistical significance compared to the readiness to perform diagnostic tests, indicating
$p = 0.0016$ and $p = 0.0021$, respectively. In relation to consulting and working with POMs for home delivery, the $p$ was <0.0001.

Among respondents who chose the “other” option, there were answers related to AUR (appliance use review) or NMS (new medicine service). In addition, study participants agreed (93.8% of affirmative answers) that they would participate in additional and post-diploma courses to gain skills and formal qualifications to provide pharmaceutical services. Analyzing the issue of funding the provision of pharmaceutical services, the majority (54.2%) of participants indicated that an optimal solution would be a mixed variant where the value is covered partially by the patient himself and a payer. On the other hand, 39% of respondents stated that a public payer should finance pharmaceutical services, and 6.4% of study participants indicated that patients should pay for such services. A clear minority (0.4%) of participants stated pharmacies should cover the costs of implementing pharmaceutical services.

Regardless of the preferred model of paying for pharmaceutical services, the vast majority (92.2%) of respondents stated that the implementation of POMs and the introduction of pharmaceutical services would positively impact the improvement in healthcare quality. It would also result in other potential benefits, the structure of which is illustrated in Figure 2. We found general statistical significance ($p < 0.05$) between the leading answers indicating several benefits from pharmaceutical services’ incorporation of POMS and the statement indicating no benefits from such a development. It was not observed only between the variant “saved time for the patient” and the answer “there are no benefits” ($p = 0.0765$). Apart from the statistical significance ($p = 0.0205$) between the responses “better position at work” and “saved time for the patient,” we did not find $p < 0.05$ when comparing the rest of the leading answers to this question.
were rescheduled from pharmacy medicines to POMs, and then to prescription medicines would constitute a kind of buffer for uncontrolled access to such substances as ketoprofen, This is in line with our study results indicating that pharmacists support the introduction protect against non-medical use of medicines but may also facilitate greater control of the constitute a kind of buffer for uncontrolled access to such substances as ketoprofen, sildenafl, or mometasone, which in our study were indicated as clear candidates for such a category instead of medicines switched from RX to OTC. It aligns with the fact that most study participants (91.8%) want to expand their professional qualifications by providing pharmaceutical services. POMs would constitute a kind of buffer for uncontrolled access to such substances as ketoprofen, sildenafl, or mometasone, which in our study were indicated as clear candidates for such a category instead of medicines switched from RX to OTC. It aligns with the fact that most study participants (91.8%) want to expand their professional qualifications by providing pharmaceutical services. POMs would constitute a kind of buffer for uncontrolled access to such substances as ketoprofen, sildenafl, or mometasone, which in our study were indicated as clear candidates for such a category instead of medicines switched from RX to OTC.

In the era of many reclassifications from Rx to OTC, some medicines exist in double registration [23–25] or are generally accessible via the Internet [25,26]. Moreover, the advertising of OTC medicines may stimulate inappropriate demand and use [23,27]. POMs, however, require a greater level of professional involvement and may protect against misuse of medicines [28–31]. POMs are also beneficial to ascertain the therapeutic need for the medication, verify the user’s identity, and advise on proper pharmacotherapy [21]. This is in line with our study results indicating that pharmacists support the introduction of a POMs category and are ready to provide pharmaceutical services, including various aspects of pharmaceutical care and drug management. It is also consistent with Emmerton L.’s study [21], which found that in Australia, medicines containing pseudoephedrine were rescheduled from pharmacy medicines to POMs, and then to prescription medicines to curb sales intended for illicit purposes [21,28,31]. The POM category may not only protect against non-medical use of medicines but may also facilitate greater control of the appropriate use of medications already available without prescriptions (e.g., sildenafl, mometasone nasal spray, or furazidinum, which suppresses the growth of bacteria that cause urinary tract infections) or those that will be reclassified soon.

The expectation and willingness of pharmacists to expand their professional qualifications and provide pharmaceutical services align with the global trend of the evolution of the pharmacist’s role in the healthcare system [32,33]. In addition, services offered in community pharmacies have rapidly evolved and have undergone an undisputable expansion in recent years [34]. This is also a result of the COVID-19 pandemic, when community
pharmacies were frequently the first point of contact for information about medicines and therapy [34].

The time of the pandemic has contributed to the introduction of vaccinations against COVID-19 in community pharmacies. It is crucial because pharmacists are the most accessible healthcare providers in the community [7]. This is in line with Kirklade et al.’s study [35], where the flu vaccination service in community pharmacies was beneficial and is seen as an integral part of the healthcare system in countries like the United States, Canada, England, or Portugal [35]. Moreover, the participation of pharmacists in patient treatment with simultaneous pharmaceutical care improves patient health outcomes [33]. It may contribute to both health and economic benefits in healthcare.

As in our study, Merks et al. [33] revealed that pharmacists in Poland are willing to broaden the scope of services offered in community pharmacies [32,36]. However, most pharmacists in the study agreed that the public healthcare payer or private insurer and the patient should partially fund such services. A minority indicated that the patient should fully cover the cost of pharmaceutical services. This is in line with other studies. Hohmeier et al. [37] revealed that patients are willing to pay out of pocket for POCT, but the patient-accepted amount was nominal. In another study, Brewer et al. [38] found that patients were willing to receive HCV screening in community pharmacies but unwilling to pay for testing. Healthcare decision makers must face this issue by matching the funding to individual services and national needs.

5. Limitations

It would have been valuable to collect more responses. However, we received questionnaires from different regions of Poland, both urban and rural areas. Hence, the results might be considered representative. Nonetheless, further studies are needed to define the POM category clearly in Poland. Due to the lack of a standardized questionnaire, we created our study tool, which was distributed online. Given the COVID-19 situation, this was the only way to conduct such a study. As a result of the online research, we cannot determine the exact number of pharmacists who received information about the study and cannot provide the response rate. Although we aimed to collect the responses only from pharmacists, we can only assume that the pharmacists filled out the questionnaire exactly. We believe that all of the participants were fair. There were no incentives for participation in the study, so there was no point in filling out the questionnaire several times or for those outside the clearly stated target. We are also aware that pharmacists’ readiness to perform and provide pharmaceutical services or incorporate the POM category may be influenced by factors not mentioned in the questionnaire or presented within this paper. Other factors such as the type of pharmacy (individual or chain), local market characteristics, type of employment of study participants, or pharmacy location may influence the results. Therefore, it will be essential to consider these factors in future analyses to provide more detailed results and describe the possibility of implementing POMs in the Polish pharmaceutical market.

6. Conclusions

There is a need to incorporate the POM category in Poland. This study states that ketoprofen, sildenafil, and mometasone should exist as POMs instead of OTC brands; so, before the reclassification, medicines could be reviewed by healthcare professionals aiming at appropriate scheduling. Polish pharmacists anticipate the development of pharmaceutical services which patients and healthcare payers should partly cover.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/scipharm92010011/s1.

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**References**


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