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Evaluating the Possibility of Establishing a Pharmacist-Only Medicine Category in Poland

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Abstract

Pharmacists are assuming a more prominent role, with a growing emphasis on direct patient care and expanded pharmaceutical services. This shift is evident in Poland as well. The present study therefore examined Polish pharmacists' views regarding the feasibility of establishing a new category of pharmacist-only medicines (POMs). Because the research was conducted during the COVID-19 pandemic, the anonymous questionnaire (10 questions for pharmacists) was distributed exclusively online. A total of 500 fully completed responses were gathered and analyzed. The great majority of pharmacists (91.8%) expressed readiness to broaden their professional responsibilities, and 88% considered the introduction of POMs important. When asked which substances should be reclassified from OTC to POM status, participants most frequently selected ketoprofen (26.2%), sildenafil (24.8%), and mometasone (24.4%). Regarding the financing of pharmaceutical services, 54.2% of respondents favored a shared-cost model involving both the patient and the payer. The findings indicate a strong need to adopt the POM category in Poland. Polish pharmacists are eager to advance pharmaceutical care, which they believe should be partially funded by patients and public payers alike.

Keywords: Pharmacist-only medicines, Access to medicines, Pharmaceutical market, Pharmacists

Introduction

For some time, international pharmaceutical markets have shown a tendency to expand pharmacists' professional authority [1]. The aim is to leverage their expertise better to improve access to healthcare and enhance patient care [1-3]. This development is also apparent in Poland, where recent legislative updates—including the "Pharmacy for the Pharmacists 2.0" Act, the Act on the Pharmacist Profession, and amendments to the Pharmaceutical Law—have reinforced this direction [2, 4, 5].

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Furthermore, the Ministry of Health's "State Drug Policy 2018–2022" document highlights key national objectives in pharmaceutical management, including "Achieving the best possible health outcomes through evidence-based and guideline-driven pharmacological treatment, proper oversight, and effective collaboration between physicians and pharmacists" [6]. Together with the Act on the Pharmacist Profession [4], initiatives such as the Medication Review Program, pharmacy-based vaccination, and broadened prescribing competencies are aligning Polish pharmacists' roles with practices established in the United States, Australia, and Western European nations [7, 8]. Consequently, the traditional sales-oriented model is gradually being replaced by a more advisory approach [2, 9-11].

Beyond the legislative changes noted earlier, several additional factors influence the pharmaceutical landscape. One significant global issue is medicine

shortages [12-16], which affect various therapeutic areas, including anticoagulants, antidiabetic agents, certain oncology drugs, and neurological medications [17-19]. Contributing causes include parallel trade, the COVID-19 pandemic, and the conflict in Ukraine [20]. Shortages often trigger heightened competition, price escalation, and reduced affordability [19]. Moreover, announcements of shortages frequently prompt over-prescribing and hoarding of both prescription and over-the-counter products [20]. In this context, appropriate medicine scheduling measures could help mitigate the public health impact of shortages and related problems such as medication misuse.

In Australia, medicines are classified into four schedules. Unscheduled items can be sold outside pharmacies. Pharmacy medicines are limited to pharmacy settings but can be supplied by non-pharmacist staff. Pharmacist-only medicines (POMs), however, require direct pharmacist involvement to ensure therapeutic appropriateness and correct use; they must be kept out of public reach and individually labeled [21, 22]. This category encompasses products such as emergency contraceptives, treatments for vaginal thrush, respiratory agents, various analgesics, and sexual health medications [21]. Prescription-only medicines form another distinct group. Similar classification systems exist in New Zealand and Canada, with minor variations in the United Kingdom and France [21]. In countries like Poland, which have witnessed numerous Rx-to-OTC switches (e.g., mometasone nasal spray, fenticonazole, tadalafil), adopting an Australian-style POM schedule could offer a valuable approach.

For these reasons, the current study sought to evaluate the potential for implementing POMs within the Polish pharmaceutical market. Additional objectives included gauging Polish pharmacists' readiness to deliver new pharmaceutical services and identifying their preferred remuneration models for such services.

Materials and Methods

The study was conducted between December 2020 and September 2022 using an anonymous, self-developed questionnaire comprising 10 questions (7 single-choice and 3 multiple-choice; see Supplementary Materials). The questionnaire was developed drawing on recent Polish pharmacy legislation, existing literature, and practical experience in community pharmacy. Before the main survey, the instrument was piloted with 10 pharmacists to evaluate clarity and consistency. Feedback from the pilot led to refinements, including a simplified explanation of POMs in the final version.

The survey targeted pharmacists exclusively; pharmacy technicians were excluded because they do not hold equivalent professional status to pharmacists in Poland and because the services under consideration (such as POM dispensing) necessitate pharmacist involvement. Participation was voluntary, with no incentives provided. Owing to the COVID-19 pandemic, the questionnaire was hosted on Google Forms and survio.com (accessed on 30 October 2019). The link was disseminated via closed Facebook groups for pharmacists and through emails sent to publicly available pharmacy addresses. Emails included numerical codes for anonymization to prevent the disclosure of pharmacy identities, in compliance with Polish advertising regulations. Non-respondents received one follow-up email after 2 weeks; the absence of a reply after the reminder was considered a refusal. The survey link was also posted on the websites of the Silesian and Greater Poland Regional Chambers of Pharmacists.

Once over 400 responses had been collected, the target was set at 500 completed questionnaires. Ultimately, 500 valid responses were included in the analysis. The local bioethics committee determined that the study did not constitute a medical experiment and therefore did not require formal approval from the Bioethics Committee at Poznan University of Medical Sciences. The research instrument is available from the corresponding author upon request.

Nominal variables were examined using the chi-square test of independence. Statistical significance was set at $p < 0.05$. Post-hoc tests of proportions were employed to identify significant differences between group percentages.

Results and Discussion

The majority of participants were female (n = 375; 75%). The mean age of respondents was 36 years, with the youngest participant being 24 and the oldest 81.

Only 6% of respondents worked in rural areas. Meanwhile, 28.6% practiced in towns with up to 50,000 residents, another 28.6% in cities with over 500,000 residents, and 36.8% in cities with 50,000–500,000 residents.

Most pharmacists were employed in chain pharmacies: 45.4% in large chains (> 15 outlets), 13% in medium-

sized chains (up to 15 outlets), 19.0% in small chains (2–5 outlets), and 22.6% in independent pharmacies.

A large proportion of participants (91.8%) indicated willingness to extend their professional competencies, which would be essential for implementing new drug categories and services. Because POMs represent a novel concept in Poland, the definition was provided in the questionnaire. When asked whether they had previously encountered this category, 54.2% reported they had not. Pharmacists in rural settings were more frequently (56.7%) familiar with the POM concept than those in other locations. Nevertheless, 88% of all respondents viewed the introduction of a POM category as a necessary measure that could serve as a safeguard amid ongoing Rx-to-OTC reclassifications.

In a multiple-choice question, participants identified substances they believed should be reclassified from OTC to POM status. Ketoprofen was selected most often (26.2% of responses), followed by sildenafil (24.8%) and mometasone (24.4%). Respondents also used the open option to suggest additional agents, most commonly codeine, pseudoephedrine, dextromethorphan, furazidine (furaginum), emergency contraception, and proton pump inhibitors.

When queried about their readiness to provide specific pharmaceutical services (multiple-choice), the highest support was for patient consultations involving medication use reviews (MUR) combined with POM management (26.3% and 26% of responses, respectively). Detailed response distributions are shown in **Figure 1**. Statistically significant differences were observed: willingness to offer MUR consultations and POM-related services was markedly higher than readiness to provide vaccinations ($P = 0.0001$), perform diagnostic tests ($P = 0.0016$ and $P = 0.0021$), or deliver home-delivery consultations ($P < 0.0001$).

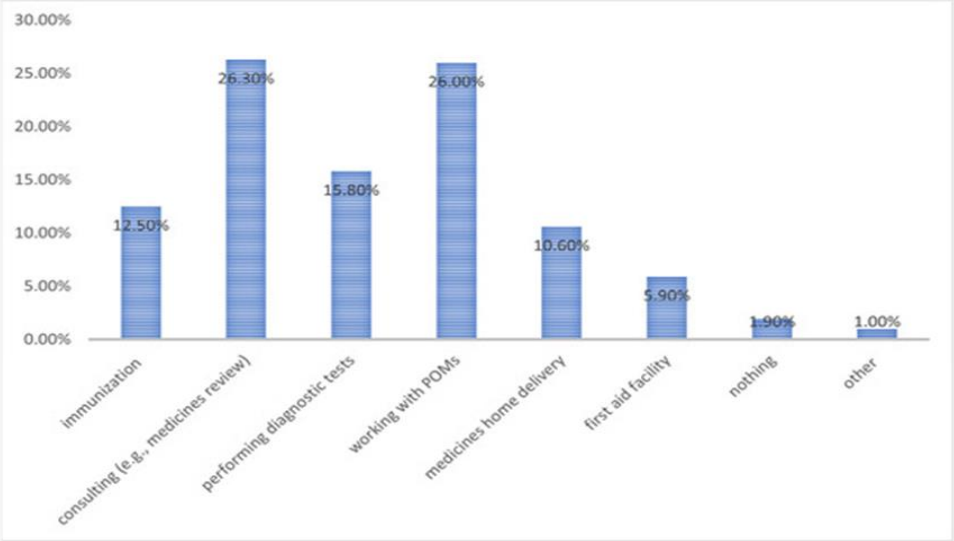


Figure 1. Pharmacists' readiness to deliver various selected pharmaceutical services. Source: authors' own research.

Among those who selected the "other" category, responses frequently referred to appliance use review (AUR) or the new medicine service (NMS). Additionally, the vast majority of participants (93.8%) expressed a willingness to attend further training and postgraduate courses to acquire the necessary competencies and formal qualifications to deliver pharmaceutical services.

Regarding financing pharmaceutical services, most respondents (54.2%) favored a mixed funding model in which costs would be shared between patients and payers. In comparison, 39% believed the public payer should fully cover these services, 6.4% indicated that patients should bear the full cost themselves, and only a very small proportion (0.4%) suggested that pharmacies should finance the implementation of such services.

Irrespective of the preferred funding approach, an overwhelming majority (92.2%) of pharmacists agreed that introducing POMs along with expanded pharmaceutical services would lead to a meaningful improvement in the overall quality of healthcare.

Participants also identified additional potential advantages, as shown in **Figure 2**.

Statistical analysis revealed a significant difference ($P < 0.05$) between the most frequently chosen benefits associated with incorporating POMs into pharmaceutical services and the option stating that no benefits would arise. The only exception was the comparison between "saved time for the patient" and "there are no benefits" ($P = 0.0765$), which did not reach statistical significance. Apart from a significant difference ($P = 0.0205$) between "better position at work" and "saved time for the patient," no other statistically significant differences ($P < 0.05$) were found when comparing the leading responses in this question.

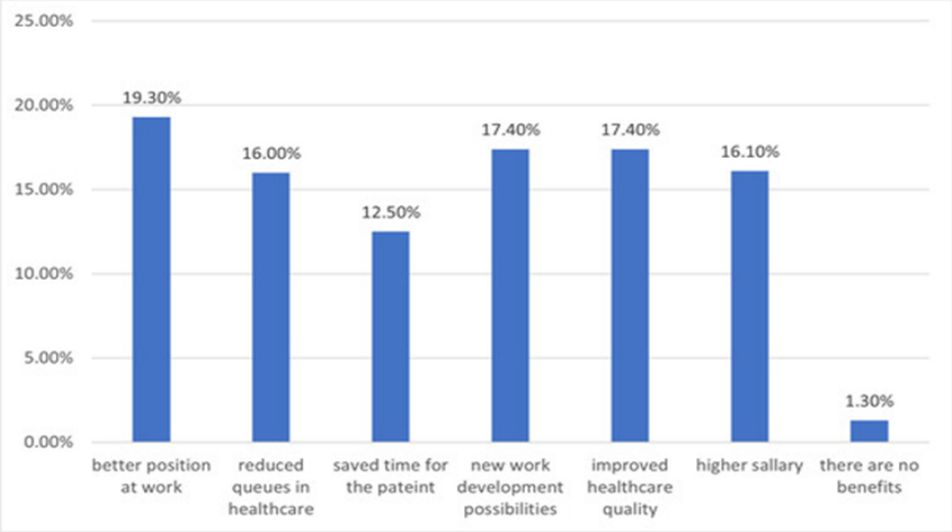


Figure 2. Potential advantages of integrating POMs into pharmaceutical services. Source: authors' own research.

The pharmacists surveyed in this research strongly supported the introduction of POMs, viewing it as a positive step that would address the ongoing trend of switching medicines from prescription-only (Rx) to over-the-counter (OTC) status. This perspective is consistent with the finding that most participants (91.8%) were eager to enhance their professional skills through the provision of pharmaceutical services. The POM category could serve as an important safeguard against unrestricted access to substances such as ketoprofen, sildenafil, and mometasone—products that respondents in the present study clearly identified as suitable candidates for this new classification rather than full OTC availability following Rx-to-OTC switches.

In the current environment of frequent Rx-to-OTC reclassifications, some medications hold dual registration status [23-25] or are readily obtainable through online channels [25, 26]. Furthermore, promotional activities for OTC products can drive inappropriate demand and consumption [23, 27]. In contrast, POMs demand a higher degree of professional oversight and can help prevent medication misuse [28-31]. They enable pharmacists to confirm the therapeutic necessity of the product, verify the buyer's identity, and offer guidance on appropriate pharmacotherapy [21]. These functions correspond closely with the current study's results, which demonstrate pharmacists' endorsement of the POM category and their preparedness to deliver a range of pharmaceutical care and medication management services. This aligns with findings reported by Emmerton [21], who noted that in Australia, medicines containing pseudoephedrine were progressively rescheduled from pharmacy medicines to POMs and subsequently to prescription-only status to reduce diversion for illicit use [21, 28, 31]. Beyond curbing non-medical use, the POM framework could improve oversight of medications already available without prescription (such as sildenafil, mometasone nasal spray, or furazidinum used for urinary tract infections) as well as those likely to be reclassified in the near future.

Pharmacists' expressed desire to broaden their competencies and offer pharmaceutical services reflects the worldwide evolution of the pharmacist's role within healthcare systems [32, 33]. Community pharmacy services have expanded considerably in recent years [34], a development accelerated by the COVID-19 pandemic,

during which pharmacies often served as the initial point of contact for medicine-related information and advice [34].

The pandemic also facilitated the rollout of COVID-19 vaccinations in community pharmacies. This is particularly significant given that pharmacists are among the most accessible healthcare professionals in community settings [7]. This observation is supported by Kirkdale *et al.* [35], who highlighted the value of influenza vaccination services delivered in pharmacies and their integration into healthcare systems in countries such as the United States, Canada, England, and Portugal [35]. Moreover, pharmacists' active involvement in patient care, alongside pharmaceutical services, has been shown to enhance health outcomes [33] and generate both clinical and economic benefits.

Consistent with the present findings, Merks *et al.* [33] reported that Polish pharmacists are keen to expand the range of services provided in community pharmacies [32, 36]. Most participants in the current study agreed that funding for these services should be split between the public payer (or private insurer) and the patient. Only a minority supported full patient payment. These views correspond with other research. Hohmeier *et al.* [37] found that patients were willing to pay out of pocket for point-of-care testing (POCT), albeit only modest amounts. Similarly, Brewer *et al.* [38] observed that patients were open to HCV screening in pharmacies but reluctant to cover the testing costs themselves. Healthcare policymakers will need to address this challenge by aligning funding mechanisms with the specific nature of services and national priorities.

A larger sample size would have been desirable. Nevertheless, responses were obtained from various regions across Poland, encompassing both urban and rural settings, which supports the representativeness of the findings. Even so, additional research is required to establish a precise definition of the POM category tailored to the Polish context. Due to the absence of a validated standardized instrument, the authors developed their own questionnaire, which was administered online. Given the circumstances of the COVID-19 pandemic, this was the only feasible method. Consequently, it was not possible to determine the exact number of pharmacists who received the invitation or to calculate a precise response rate. Although the survey was intended exclusively for pharmacists, it can only be assumed that the intended target group completed the questionnaires. The research team believes respondents answered honestly. With no incentives offered, there was little motivation for multiple submissions or participation by individuals outside the target group.

The authors also recognize that pharmacists' willingness to provide pharmaceutical services or support POM implementation may be affected by variables not captured in the questionnaire or discussed in this article. Factors such as pharmacy type (independent versus chain), local market conditions, employment status, and geographic location could influence outcomes. Future studies should therefore account for these variables to yield more nuanced insights and better evaluate the feasibility of introducing POMs in the Polish pharmaceutical market.

Conclusion

The introduction of a POM category in Poland is warranted. According to this study, ketoprofen, sildenafil, and mometasone should be classified as POMs rather than OTC products. This would allow healthcare professionals to review medications before any reclassification and ensure appropriate scheduling. Polish pharmacists are ready for the advancement of pharmaceutical services, which they believe should be funded jointly by patients and healthcare payers.

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References

1. McKnight AG, Thomason AR. Pharmacists' advancing roles in drug and disease management: a review of states' legislation. J Am Pharm Assoc. 2009;49(4):554-8. doi:10.1331/JAPhA.2009.08143
2. Merks P, Jakubowska M, Drelich E, Świeczkowski D, Bogusz J, Bilmin K, et al. The legal extension of the role of pharmacists in light of the COVID-19 global pandemic. Res Social Adm Pharm. 2021;17(10):1807-12. doi:10.1016/j.sapharm.2021.01.008
3. Dzionek J. Pharmaceutical Care in Ontario. J Med Sci. 2020;89(3):e458. doi:10.20883/medical.e458

4. Bochniarz M, Inglot-Brzęk E, Lewandowska A, Podgórska J. Directions of Changes in the Profession of Hospital Pharmacist in Poland. Int J Environ Res Public Health. 2022;19(22):14522. doi:10.3390/ijerph192214522
5. Wiśniewski M, Religioni U, Merks P. Community Pharmacies in Poland—The Journey from a Deregulated to a Strictly Regulated Market. Int J Environ Res Public Health. 2020;17(23):8751. doi:10.3390/ijerph17238751
6. Rada Ministrów Przyjęła Dokument "Polityka Lekowa Państwa 2018–2022" [Internet]. Ministerstwo Zdrowia – Portal Gov.pl; [cited 2023 Mar 10]. Available from: https://www.gov.pl/web/zdrowie/rada-ministrow-przyjela-dokument-polityka-lekowa-panstwa-20182022
7. Steltenpohl EA, Barry BK, Coley KC, McGivney MS, Olenak JL, Berenbrok LA. Point-of-Care Testing in Community Pharmacies: Keys to Success from Pennsylvania Pharmacists. J Pharm Pract. 2018;31(6):629-35. doi:10.1177/0897190017735242
8. Lowres N, Krass I, Neubeck L, Redfern J, McLachlan AJ, Bennett AA, et al. Atrial fibrillation screening in pharmacies using an iPhone ECG: a qualitative review of implementation. Int J Clin Pharm. 2015;37(6):1111-20. doi:10.1007/s11096-015-0175-1
9. Zaprutko T, Hromovyk B, Lesyk R, Lesyk L, Kremin Y, Kus K, et al. Pharmacies for the Pharmacists—Ukrainian Fears and Polish Experiences. Sci Pharm. 2020;88(1):7. doi:10.3390/scipharm88010007
10. Blouin RA, Adams ML. The Role of the Pharmacist in Health Care Expanding and Evolving. N C Med J. 2017;78(3):165-7. doi:10.18043/ncm.78.3.165
11. Świeczkowski D, Merks P, Cwalina N, Jaguszewski MJ. Development of Pharmacy Practice in European Countries—The Polish Perspective. Pharmacy (Basel). 2017;5(3):43. doi:10.3390/pharmacy5030043
12. De Weerdt E, Simoens S, Hombroeckx L, Casteels M, Huys I. Causes of drug shortages in the legal pharmaceutical framework. Regul Toxicol Pharmacol. 2015;71(2):251-8. doi:10.1016/j.yrtph.2015.01.005
13. De Weerdt E, Simoens S, Casteels M, Huys I. Toward a European definition for a drug shortage: a qualitative study. Front Pharmacol. 2015;6:253. doi:10.3389/fphar.2015.00253
14. Duong MH, Moles RJ, Chaar B, Chen TF. Stakeholder perspectives on the challenges surrounding management and supply of essential medicines. Int J Clin Pharm. 2019;41(5):1210-9. doi:10.1007/s11096-019-00880-y
15. Acosta A, Vanegas EP, Rovira J, Godman B, Bochenek T. Medicine Shortages: Gaps between Countries and Global Perspectives. Front Pharmacol. 2019;10:763. doi:10.3389/fphar.2019.00763
16. Pauwels K, Huys I, Casteels M, Simoens S. Drug shortages in European countries: a trade-off between market attractiveness and cost containment? BMC Health Serv Res. 2014;14:438. doi:10.1186/1472-6963-14-438
17. Deutsch J. Europe Comes Up Short on Drug Supplies [Internet]. POLITICO; 2019 [cited 2019 Sep 2]. Available from: https://www.politico.eu/article/europe-still-coming-up-short-on-drug-supplies/
18. Shukar S, Zahoor F, Hayat K, Saeed A, Gillani AH, Omer S, et al. Drug Shortage: Causes, Impact, and Mitigation Strategies. Front Pharmacol. 2021;12:693426. doi:10.3389/fphar.2021.693426
19. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Security of America's Medical Product Supply Chain; Shore C, Brown L, et al. Causes and Consequences of Medical Product Supply Chain Failures. In: Building Resilience into the Nation's Medical Product Supply Chains. Washington (DC): National Academies Press; 2022. PMID: 35512174.
20. Why Are There Medicine Shortages and What Is the Solution? [Internet]. World Economic Forum; 2023 [cited 2023 Nov 23]. Available from: https://www.weforum.org/agenda/2023/02/why-is-world-experiencing-medicine-shortages-and-how-can-the-generics-industry-address-supply-challenges/
21. Emmerton L. The "third class" of medications: sales and purchasing behavior are associated with pharmacist only and pharmacy medicine classifications in Australia. J Am Pharm Assoc. 2009;49(1):31-7. doi:10.1331/JAPhA.2009.08048
22. Medicines: Reclassify Your Product [Internet]. GOV.UK; 2023 [cited 2023 Nov 13].

Available from: https://www.gov.uk/guidance/medicines-reclassify-your-product
23. Gruchala K, Zimmermann A, Kawczak P. Rx-to-OTC Switch and Double Registration Occurrence in Poland—An Illuminative Case Study. Acta Pol Pharm. 2016;73(1):247-54.
24. Zaprutko T, Kopciuch D, Ratajczak P, Paczkowska A, Adamczak O, Kus K, et al. The Prescription to Over-the-Counter Switches and Double Registration of Medicines—The Perspective of Pharmacists from the Greater Poland. Acta Pol Pharm. 2019;76(5):907-12. doi:10.32383/appdr/109806
25. Aronson JK. From prescription-only to over-the-counter medicines ('PoM to P'): time for an intermediate category. Br Med Bull. 2009;90:63-9. doi:10.1093/bmb/ldp017
26. Zaprutko T, Kopciuch D, Paczkowska A, Sprawka J, Cynar J, Pogodzińska M, et al. Facebook as a source of access to medicines. PLoS One. 2022;17(10):e0275272. doi:10.1371/journal.pone.0275272
27. Bessell TL, Hiller JE, Sansom LN. "Pharmacist only" medicines. Aust N Z J Public Health. 1999;23(6):661-2. doi:10.1111/j.1467-842x.1999.tb01559.x
28. Casati A, Sedefov R, Pfeiffer-Gerschel T. Misuse of medicines in the European Union: a systematic review of the literature. Eur Addict Res. 2012;18(5):228-45. doi:10.1159/000337228
29. Emma Hammett Online Drug Addiction & Misuse: New Rules to Combat Misuse [Internet]. Online First Aid; 2019 [cited 2020 Jul 9]. Available from: https://onlinefirstaid.com/online-drug-addiction/
30. Chiappini S, Guirguis A, Corkery JM, Chiappini FS. Misuse of prescription and over-the-counter drugs to obtain illicit highs: how pharmacists can prevent abuse. Pharm J. 2020;305(7943). doi:10.1211/PJ.2020.20208574. [cited 2021 Apr 15]. Available from: https://pharmaceutical-journal.com/article/research/misuse-of-prescription-and-over-the-counter-drugs-to-obtain-illicit-highs-how-pharmacists-can-prevent-abuse
31. Zaprutko T, Koligat D, Michalak M, Wieczorek M, Józiak M, Ratajczak M, et al. Misuse of OTC drugs in Poland. Health Policy. 2016;120(8):875-81. doi:10.1016/j.healthpol.2016.06.008
32. Dulaney K, Hohmeier K, Fisher C, Cardosi L, Wasson M. Exploring pharmacists' perceptions regarding influenza and streptococcal testing within a chain pharmacy. J Am Pharm Assoc. 2018;58(4):438-41. doi:10.1016/j.japh.2018.04.031
33. Merks P, Religioni U, Waszyk-Nowaczyk M, Kaźmierczak J, Białoszewski A, Blicharska E, et al. Assessment of Pharmacists' Willingness to Conduct Medication Use Reviews in Poland. Int J Environ Res Public Health. 2022;19(3):1867. doi:10.3390/ijerph19031867
34. Rajiah K, Sivarasa S, Maharajan MK. Impact of Pharmacists' Interventions and Patients' Decision on Health Outcomes in Terms of Medication Adherence and Quality Use of Medicines among Patients Attending Community Pharmacies: A Systematic Review. Int J Environ Res Public Health. 2021;18(8):4392. doi:10.3390/ijerph18084392
35. Kirkdale CL, Nebout G, Megerlin F, Thornley T. Benefits of pharmacist-led flu vaccination services in community pharmacy. Ann Pharm Fr. 2017;75(1):3-8. doi:10.1016/j.pharma.2016.08.005
36. Gallimore CE, Porter AL, Barnett SG, Portillo E, Zorek JA. A state-level needs analysis of community pharmacy point-of-care testing. J Am Pharm Assoc. 2021;61(4):e93-8. doi:10.1016/j.japh.2021.02.008
37. Hohmeier KC, Loomis B, Gatwood J. Consumer perceptions of and willingness-to-pay for point-of-care testing services in the community pharmacy. Res Social Adm Pharm. 2018;14(4):360-6. doi:10.1016/j.sapharm.2017.04.003
38. Brewer A, Hanna C, Eckmann L, Schadler A, Divine H. Patient awareness, willingness, and barriers to point-of-care hepatitis C screening in community pharmacy. J Am Pharm Assoc. 2018;58(4S):S69-72. doi:10.1016/j.japh.2018.04.025