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# BEZPIECZEŃSTWO PUBLICZNE A DOSTĘP DO LEKÓW PSYCHOTROPOWYCH – NOWE WYMOGI PRAWNE I ICH SKUTKI

# PUBLIC SAFETY AND ACCESS TO PSYCHOTROPIC DRUGS – NEW LEGAL REQUIREMENTS AND THEIR IMPLICATIONS

**Streszczenie**
Od 2 sierpnia 2023 roku weszły w życie nowe przepisy dotyczące wystawiania recept na środki odurzające i psychotropowe. Zmiany te zostały wprowadzone z myślą o zapewnieniu większego bezpieczeństwa pacjentów i wynikają z rozporządzenia podpisanego przez ministra zdrowia 12 lipca 2023 roku, które zmienia rozporządzenie dotyczące środków odurzających, substancji psychotropowych, prekursorów kategorii 1 i preparatów zawierających te substancje. Od tej pory, aby otrzymać receptę na leki psychotropowe lub odurzające, pacjent musi przejść dodatkowe badanie i ocenę wpływu leku na jego stan zdrowia, które zostaną przeprowadzone przez jego lekarza. Głównym celem tych zmian jest ograniczenie możliwości wystawiania komercyjnych recept na tego rodzaju leki przez internet.

*Słowa kluczowe: polskie regulacje prawne, leki psychotropowe, zmiany w polskim prawie, legislacja, przeciwdziałanie narkomanii, e-recepty*

**Summary**
As of 2 August 2023, new regulations regarding the prescription of narcotic and psychotropic drugs came into force. These changes have been introduced to ensure greater patient safety and stem from a regulation signed by the Minister of Health on 12 July 2023, which amends the regulation on narcotic drugs, psychotropic substances, category 1 precursors, and preparations containing these substances. From that moment, to receive a prescription for psychotropic or narcotic drugs, the patient must undergo an additional examination and assessment of the effect of the drug on his or her health, which will be carried out by his or her doctor. The main aim of these changes is to limit the possibility of commercial prescriptions for such medicines over the internet.

*Keywords: Polish legal regulations, psychotropic drugs, changes in Polish law, legislation, drug abuse prevention, e-prescriptions*

## Introduction

The modern rule-of-law state is increasingly confronted with the complex challenge of maintaining a balance between the protection of public health and the safeguarding of civil liberties. One of the areas where this equilibrium proves particularly difficult to uphold is the regulation of access to substances with potentially addictive properties, including psychotropic medications and narcotic drugs. The widespread misuse of such pharmaceuticals—often prescribed without appropriate medical oversight, particularly through commercial services delivered via the Internet—has in recent years become a growing concern for both public authorities and the medical community.

In recent years, a marked increase has been observed in the phenomenon of commercially issued prescriptions, including those for substances with addictive potential, by entities providing remote services—commonly referred to as „prescription vending platforms" or "online prescription kiosks". While this practice may be formally lawful, it has raised serious ethical and legal doubts, as numerous instances have been documented where psychotropic drugs were prescribed without conducting a medical interview, without access to the patient's medical records, and without knowledge of the patient's pharmacotherapeutic history. Such practices not only violated the principles of medical professionalism and professional deontology but also posed a genuine threat to the health and lives of patients—both individually and collectively.

On 2 August 2023, amended executive regulations to the Act on Counteracting Drug Addiction came into force, pursuant to the Regulation of the Minister of Health dated 12 July 2023 r.[1] These amendments significantly tightened the formal requirements for the issuance of prescriptions for medicinal products containing psychotropic substances and narcotic drugs. The revision introduced a mandatory requirement for the verification of the patient's pharmacotherapeutic history and a documented medical examination—even in cases of remote prescription issuance—thus imposing a substantial limitation on the previously common and frequently abused model of „on-demand" e-prescriptions.

## THE LEGAL REGULATORY FRAMEWORK GOVERNING PSYCHOTROPIC SUBSTANCES AND NARCOTIC DRUGS

Psychotropic substances are classified into Groups I through IV, depending on the scope of their medical use and the associated risk of addiction.[2] The classification of these substances into specific groups is set forth in the Regulation of the Minister of Health concerning the list of psychotropic substances, narcotic drugs, and new psychoactive substances.[3] Pursuant to applicable regulations, every medicinal product containing a psychotropic substance is classified under a designated category of availability, determining the conditions for its prescription and dispensation.[4]

1 Rozporządzenie Ministra Zdrowia z dnia 12 lipca 2023 r. *zmieniające rozporządzenie w sprawie środków odurzających, substancji psychotropowych, prekursorów kategorii 1 i preparatów zawierających te środki* (Dz.U. 2023 poz. 1368) – weszło w życie 2 sierpnia 2023 r.

2 Jest to zapisane w Ustawie o przeciwdziałaniu narkomanii; Dz.U. 2023 poz. 1939. Art. 32. 1. Substancje psychotropowe dzieli się na grupy I-P, II-P, III-P i IV-P w zależności od stopnia ryzyka powstania uzależnienia w przypadku używania ich w celach innych niż medyczne oraz zakresu ich stosowania w celach medycznych.

3 Rozporządzenie Ministra Zdrowia z dnia 17 kwietnia 2023 r. *zmieniające rozporządzenie w sprawie wykazu substancji psychotropowych, środków odurzających oraz nowych substancji psychoaktywnych*; (Dz.U. 2023 poz. 744.)

4 Obwieszczenie Ministra Zdrowia z dnia 19 października 2016 r. *w sprawie ogłoszenia jednolitego tekstu rozporządzenia Ministra Zdrowia w sprawie kryteriów zaliczenia produktu leczniczego do poszczególnych kategorii dostępności.* (Dz.U. 2016 poz. 1769.)

In legal practice, this means that both the physician prescribing the medication and the pharmacist dispensing the prescription are required to comply with strictly defined regulations concerning documentation, patient identification, storage methods, and the reporting of the circulation of the given substance.Such classification is aimed at ensuring the safety of pharmacotherapy, limiting unauthorized access to psychoactive medications, and effectively counteracting addiction phenomena and the illicit trade in controlled medicinal products.[5]

The rules governing the issuance and dispensing of prescriptions for medicinal products containing psychotropic substances are set forth in the Act on Counteracting Drug Addiction,[6] The Pharmaceutical Law Act[7] and the regulations issued pursuant thereto, in particular the Regulation of the Minister of Health on narcotic drugs, psychotropic substances, category I precursors and preparations containing such substances or drugs, as well as the Regulation of the Minister of Health on prescriptions.[8]

Prescriptions are subject to a number of formal requirements. A paper prescription for psychotropic medications, regardless of the category to which the substances belong, must bear a unique identification number. As of 1 July 2021, this requirement also applies to prescriptions issued by veterinary practitioners.[9] As of the same date, all paper prescriptions for psychotropic drugs, including those issued at full cost, must include a barcode containing the personal data of the prescribing individual and the entity issuing the prescription, as well as the prescription number. Previously, it was permissible to use prescription forms compliant with templates provided under three successive regulations concerning prescriptions,[10] since July 2021, prescriptions may be issued exclusively using the most recent templates, as stipulated in § 19(2) of the Regulation on Prescriptions.[11]

Pursuant to the provisions of the Pharmaceutical Law Act, psychotropic substances may not be prescribed via cross-border prescriptions, which entails that such prescriptions are not valid for dispensing purposes under Polish law.[12] The same Act, in Article 86(5), provides for the possibility of dispensing medicinal products intended for human use by pharmacies for administration to animals, provided that the medicinal products obtained in this manner are administered to the animal either by its owner or by the veterinarian who issued the prescription, in the course of performing their veterinary medical practice.

All data required to appear on a prescription for any type of medicinal product are specified in Article 96a(1) of the Pharmaceutical Law Act. Additionally, in the case of prescriptions for psychotropic substances, it is mandatory to indicate the total quantity of the psychotropic substance or its amount expressed in the number of dosage units and the strength of

5 Regulacje dotyczące dokumentacji, identyfikacji, przechowywania i raportowania – art. 96a ustawy z dnia 6 września 2001 r. *Prawo farmaceutyczne*. (Dz. U. 2022 poz. 2301).

6 Ustawa z dnia 29 lipca 2005 r. *o przeciwdziałaniu narkomanii*. (Dz.U. 2005 nr 179 poz. 1485).

7 Ustawa z dnia 6 września 2001 r. *Prawo farmaceutyczne*. (Dz.U. 2001 nr 126 poz. 1381.)

8 Rozporządzenie Ministra Zdrowia z dnia 29 sierpnia 2023 r. *zmieniające rozporządzenie w sprawie recept*; Dz.U. 2023 poz. 1734.

9 Te wszystkie warianty są zapisane w Rozporządzeniu w sprawie recept.

10 Rozporządzenie Ministra Zdrowia z dnia 23 grudnia 2020 r. w sprawie recept; Dz.U. 2020 poz. 2424; Rozporządzenie Ministra Zdrowia z dnia 13 kwietnia 2018 r. w sprawie recept; Dz.U. 2018 poz. 745 oraz Rozporządzenie Ministra Zdrowia z dnia 8 marca 2012 r. w sprawie recept lekarskich; Dz.U. 2012 poz. 260.

11 § 19. 2. stanowi, że: Dopuszcza się stosowanie druków recept zgodnych ze wzorem obowiązującym przed dniem wejścia w życie:
1) niniejszego rozporządzenia,
2) rozporządzenia Ministra Zdrowia z dnia 13 kwietnia 2018 r. w sprawie recept (Dz. U. poz. 745, z późn. zm.3)) – jednak nie dłużej niż przez 6 miesięcy od dnia wejścia w życie niniejszego rozporządzenia.

12 Art. 96a. ust. 1b. stanowi, że: Na recepcie transgranicznej nie mogą być przepisane produkty lecznicze recepturowe, preparaty zawierające środki odurzające lub substancje psychotropowe oraz produkty lecznicze o kategorii dostępności „Rpz".

each dose. Furthermore, only one psychotropic medicinal product may be prescribed per prescription.

Psychotropic drugs classified under category II-P may be prescribed in quantities not exceeding the patient's therapeutic requirement for a period of 90 days. In contrast, prescriptions for medications containing psychotropic substances classified as III-P and IV-P are not subject to such limitations. It is legally permissible to prescribe such medications for a treatment period of up to 360 days, provided that in the case of paper prescriptions, the duration of use may not exceed 120 days,[13] one must nevertheless bear in mind that the validity period for the fulfilment of a prescription for psychotropic medicinal products expires 30 days from the date of issuance.

In the context of discussing the prescription and acquisition of psychotropic medications, it is also necessary to refer to the legal provisions governing the possession of narcotic drugs, i.e. narcotic substances or psychotropic substances. In Poland, such possession is permitted, but only under strictly defined circumstances. The Act on Counteracting Drug Addiction stipulates which entities are authorised to possess the aforementioned substances and under what specific conditions. Article 33 of the said Act provides that narcotic drugs classified under groups I-N and II-N as well as psychotropic substances classified under groups II-P, III-P, and IV-P may be used exclusively for medical, industrial, or research purposes. By contrast, psychotropic substances of group I-P may only be used for scientific research, whereas narcotic drugs of group IV-N may be used solely for research purposes and in veterinary medicine (Article 44f).

The unlawful possession of such substances is subject to criminal liability pursuant to Article 62 of the Act on Counteracting Drug Addiction. The verb ‚to possess', as used therein, is interpreted as actual control over the object, including temporary control, associated with its use or the intent to use it.[14] Within the meaning of the aforementioned provision, the possession of narcotic drugs shall include both holding them on one's person, at one's place of residence or any other location, regardless of their intended use, as well as temporary possession associated with the act of intoxication.[15]

Pursuant to Article 62(1) of the Act on Counteracting Drug Addiction, any person who, contrary to the provisions of the Act, is found in possession of narcotic drugs or psychotropic substances shall be subject to a penalty of imprisonment for up to 3 years. However, paragraph 3 of the same article provides that, in cases of lesser gravity, the perpetrator shall be subject to a fine, restriction of liberty, or imprisonment for up to 1 year. In determining whether a specific case qualifies as one of lesser gravity, the adjudicating authority must consider such factors as, inter alia, the quantity and type of the drug or substance, the purpose of possession (e.g., personal use, sharing, sale), and the ultimate intended use (e.g., recreational intoxication, alleviation of symptoms in an addicted individual, or relief of suffering in a medical context).

The term „possession" is interpreted broadly in Polish legal doctrine—it encompasses both actual control over a substance and temporary dominion over it, whether for the purpose of use or with the intention of using it. This interpretation was affirmed by the Supreme Court of Poland in its resolution of 27 January 2011 (case no. I KZP 24/10), wherein the Court held that any form of dominion over a substance—even of a temporary nature—constitu-

13 Wynika to z art. 96a, ust. 2 ustawy Prawo farmaceutyczne.
14 Zob. B. Kurzępa [w:] Ustawa o przeciwdziałaniu narkomanii. Komentarz, wyd. II, red. A. Ważny, Warszawa 2019, art. 62, LEX.
15 Zob. m.in. postanowienie SN z dnia 27.03.2013r., sygn. III KK 423/12.

tes statutory possession within the meaning of the applicable criminal provisions.[16] Case law, including that of the Courts of Appeal in Gliwice and Katowice, emphasizes the importance of circumstances such as the quantity and type of the substance, the purpose of possession (e.g., for personal use), and any potential intent to further distribute, as criteria for distinguishing a basic offense from one involving a *‚significant quantity'* or a case of *‚lesser gravity'*.[17]

The Regulation of the Minister of Health of 12 July 2023, published in the Journal of Laws of the Republic of Poland on 18 July 2023 (Dz.U. 2023, item 1374), introduced amendments to the legal framework regulating the issuance of prescriptions for narcotic drugs and psychotropic substances.[18] The amended regulation introduces new paragraphs (2a–2c) into § 7. The provisions restricting the remote issuance of prescriptions for such medicinal products entered into force on 2 August 2023. As of that date, a physician is required, during the course of the medical examination and prior to issuing a prescription for narcotic drugs, psychotropic substances, or Category 1 precursors, to verify which medicinal products have already been prescribed to the patient, what the patient is currently taking, and in what dosages.

The revised provisions clarify that a prescription for a preparation containing a narcotic drug, a psychotropic substance, or a Category 1 precursor may be issued only after the prescribing party has conducted a verification via the Electronic Platform for Collection, Analysis and Sharing of Digital Resources on Medical Events (P1 Platform), or after collecting a medical history from the patient which indicates that the quantity and type of medicinal products previously prescribed and dispensed are insufficient for the proper continuation of pharmacotherapy. To that end, the physician may request the patient to provide access to their prescription history.

A primary care physician (PCP), who provides ongoing medical care to the patient, has autonomous access to the patient's complete treatment history and is therefore exempt from the obligation to perform such verification each time. A medical specialist, however, only has access to the electronic prescriptions they themselves have issued and must therefore request the patient to share their full prescription record in order to perform the required verification.

The aforementioned examination may be conducted either in person or via teleconsultation. A prescription for narcotic or psychotropic substances may be issued without a new examination only if no more than three months have elapsed since the last medical evaluation related to the issuance of such a prescription. However, a relevant annotation confirming this fact must be recorded in the patient's medical documentation. The introduction of the amendment was driven by considerations of patient safety. Its objective is not to restrict access to medicinal products, but rather to limit the availability of potent pharmaceuticals in the absence of proper medical consultation. This regulatory measure is intended to restrict the commercial issuance of prescriptions via the internet. It constitutes a formal response by the Ministry of Health to practices publicly reported in the media, wherein certain entities offered clients the ability to obtain prescriptions rapidly, without a prior medical examination, in exchange for a fee. This mechanism was frequently exploited by individuals abusing or addicted to psychotropic and narcotic substances.

16 Uchwała SN I KZP 24/10 – wykładnia pojęcia „posiadanie" jako władztwa nad substancją.

17 Wyroki SA (Gliwice, Katowice) – ocena okoliczności i kryteriów rozróżniających typy czynów.

18 Nowe zasady przepisywania recept wynikają z podpisanego przez ministra zdrowia 12 lipca 2023 r. rozporządzenia zmieniającego rozporządzenie w sprawie środków odurzających, substancji psychotropowych, prekursorów kategorii 1 i preparatów zawierających te środki lub substancje (Dz.U. poz. 1368).

According to the 2021 report of the Supreme Audit Office of Poland (Najwyższa Izba Kontroli – NIK),[19] Prior to the recent amendments, the Ministry of Health and the National Health Fund (NFZ) lacked effective oversight mechanisms to detect irregularities in the prescription of addictive medications, which enabled the proliferation of such practices. It was only with the implementation of the obligations introduced by the amendment to the Regulation of the Minister of Health dated 12 July 2023 that meaningful restrictions on these practices became feasible. The reform introduced the mandatory verification of medical records prior to issuing prescriptions, the limitation of the validity period of e-prescriptions, and the establishment of minimum diagnostic standards, including for remote consultations. These legislative changes form part of a broader and long-advocated process aimed at strengthening the regulatory framework concerning the prescription and distribution of psychoactive medications—a need repeatedly emphasized by medical professionals and international bodies, including the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Accordingly, the introduction of these amendments should be regarded as a legitimate, proportionate, and constitutionally justified measure, consistent with the principle of public health protection enshrined in Article 68 of the Constitution of the Republic of Poland, as well as with the principle of proportionality in limiting the freedom of economic activity, as set out in Article 22 of the Constitution. The steps undertaken not only enhanced the integrity of the pharmaceutical care system, but also contributed to reducing the risk of addiction and curbing the scale of prescription drug abuse, thereby having a direct and positive impact on public safety.

Comparable mechanisms requiring verification of prescribed medications had already been implemented under the Act on Health Care Services Financed from Public Funds. The introduction of the recent amendment concerning psychotropic medications, as a legislative response to the problem outlined above, unquestionably constitutes a step towards improving the public health situation in Poland. The commercial issuance of prescriptions, particularly through online platforms, had become a widespread and increasingly prevalent threat to public health and safety.

## Conclusion

The introduction of new legal regulations concerning the issuance of prescriptions for psychotropic and narcotic drugs constitutes a significant step toward enhancing public safety and strengthening the standards of medical service delivery. The amendments in force since 2 August 2023, stemming from the revision of the Regulation of the Minister of Health dated 12 July 2023, represent a deliberate legislative response aimed at tightening control over the prescription of controlled substances and curbing practices that posed a growing threat to public health,[20] they constitute a response to the increasingly widespread and concerning practice of issuing commercial e-prescriptions, often without any direct contact between the physician and the patient, without taking a medical history, or having knowledge of the patient's pharmacotherapy background.

The amendment introduced a mandatory requirement for physicians to verify, on each occasion, the medical grounds justifying the prescription of controlled substances. It also imposed an obligation to document the medical examination or consultation — including

19 file:///C:/Users/pawlab/Downloads/K-21-001-LPO-01-01.pdf (dostęp: 01.07.2025)

20 Rozporządzenie Ministra Zdrowia z dnia 12 lipca 2023 r. *zmieniające rozporządzenie w sprawie środków odurzających, substancji psychotropowych, prekursorów kategorii 1 i preparatów zawierających te środki lub substancje* (Dz.U. 2023 poz. 1368).

those conducted via telemedicine — in the patient's medical records. An exception applies in cases where no more than 90 days have elapsed since the last examination related to the issuance of such a prescription. Importantly, the new regulations do not restrict authorized patients' access to pharmacotherapy but rather serve to tighten the system in order to prevent abuse and illegal distribution of addictive medicinal products. The legislative amendments introduced in 2023 form part of a broader governmental effort to combat drug addiction (Article 1(1) of the Act on Counteracting Drug Addiction), while also serving the constitutional objective of safeguarding public health (Article 68 of the Constitution of the Republic of Poland). The responsible management of psychotropic medicinal products —including their registration, monitoring, and access restricted solely to individuals with legitimate medical needs—constitutes a core component of a well-structured pharmaceutical regulatory system that effectively balances individual patient rights with the overarching public interest.

It is also worth emphasizing that the discussed regulations reinforce the professional liability of physicians and pharmacists, reaffirming the obligation to adhere to the principles of medical practice, professional ethics, and due diligence in the therapeutic process. A physician, as the entity authorized to issue prescriptions, bears responsibility not only for the efficacy of the treatment, but also for any legal consequences arising from the improper selection of pharmacotherapy. In conclusion, the amendment to the Regulation on Narcotic Drugs and Psychotropic Substances should be assessed positively. It constitutes an example of interventionist legislation that responds to tangible issues within medical practice and the healthcare services market in Poland. In addition to the benefit of curbing the phenomenon of psychotropic drug misuse, the amendment is also expected to contribute to the enhancement of healthcare service standards and the restoration of public trust in the institutions responsible for the protection of public health.

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**Judgments**

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