

Alarming increase in the number of prescriptions for medical marijuana and opioids in Poland and the activity of online platforms offering teleconsultations

Alarmujący wzrost liczby recept na medyczną marihuanę i opioidy w Polsce oraz aktywność platform internetowych oferujących telekonsultacje

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KEYWORDS:

- telemedicine
- opioid crisis
- ethics

ABSTRACT

Despite the change in regulations, portals providing teleconsultations and issuing electronic prescriptions continue to facilitate access to addictive drugs. Between 2019 and 2022, the number of prescriptions issued for medical marijuana in Poland increased sixfold. The number of prescriptions for opioid medications is also increasing. Over the last five years, the number of full-price prescriptions for strong opioid drugs has increased by one third. In 2019, 1.3 million full-price prescriptions for such drugs were issued, and in 2023 there will be half a million more.

There has been an opioid epidemic in the United States for twenty years. As early as 2008, the number of opioid overdose deaths exceeded the number of car accident victims. The epidemic in North America was started by OxyContin, a potent painkiller legally approved for sale in the treatment of pain. "Prescription factories" were established, i.e., clinics specializing in pain control run by doctors who prescribed opiates en masse.

In the era of telemedicine, it is no longer necessary to create clinics, just a portal with teleconsultations issuing e-prescriptions. The aim of the paper is to present statistical data on the number of prescriptions issued for medical marijuana and opioids in Poland against the background of the activity of on-line platforms offering teleconsultations allowing for the insertion of e-prescriptions.

The collected data shows that we are at a critical moment in Poland. There is an urgent need to amend the legislation and introduce a standard for teleconsultation in order to more effectively limit the activities of e-prescription platforms, otherwise they may become a gateway to uncontrolled prescriptions for addictive drugs.

SŁOWA KLUCZOWE:

- telemedycyna
- kryzys opioidowy
- etyka

STRESZCZENIE

Mimo zmiany przepisów, portale udzielające teleporad i wystawiające elektroniczne recepty nadal ułatwiają dostęp do leków uzależniających. W latach 2019-2022 sześciokrotnie wzrosła liczba recept wystawianych na medyczną marihuanę w Polsce. Rośnie także liczba recept wystawianych na leki opioidowe. W ciągu ostatnich pięciu lat liczba pełnopłatnych recept na silne leki opioidowe wzrosła o jedną trzecią. W 2019 r. wystawiono 1,3 mln recept pełnopłatnych na takie leki, a w 2023 r. już o pół miliona więcej.

W Stanach Zjednoczonych od dwudziestu lat trwa epidemia opioidowa. W 2008 r. liczba zgonów w wyniku przedawkowania opiatów przewyższała liczbę ofiar wypadków samochodowych.

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Epidemię w Ameryce Północnej zapoczątkował OxyContin, zsyntetyzowany silny lek przeciwbólowy legalnie dopuszczony do sprzedaży w leczeniu bólu. Powstały „fabryki recept”, czyli kliniki specjalizujące się w kontroli bólu prowadzone przez lekarzy, którzy masowo przepisywali recepty na opiaty.

W dobie telemedycyny nie trzeba tworzyć klinik, wystarczy portal z teleporadami wystawiający e-recepty. Celem pracy jest przedstawienie danych statystycznych dotyczących liczby wystawianych recept na medyczną marihuanę i opioidy w Polsce na tle działalności platform internetowych oferujących teleporady pozwalające na wstawianie e-recept. Ze zgromadzonych danych wynika, że znajdujemy się w krytycznym momencie w Polsce. Konieczna jest pilna zmiana przepisów i wprowadzenie standardu teleporady, by skuteczniej ograniczyć działalność platform wystawiających e-recepty, w przeciwnym razie mogą one stać się furką do niekontrolowanego przepisywania recept m.in. na środki uzależniające.

Introduction

The aim of the paper is to present statistical data on the number of prescriptions issued for medical marijuana and opioids in Poland against the background of the activity of online platforms offering teleconsultations allowing for the insertion of e-prescriptions. The data shows that the situation is critical, especially if we consider the opioid crisis that has been prevalent in the United States for more than 20 years.

Although in Poland we do not have a classic opioid crisis like in the United States, there are voices of experts that the leaky system of issuing e-prescriptions and the lack of tools enabling the doctor to verify whether the patient received a prescription for strong opioid drugs and filled it means that we are in a critical moment. In such a situation, it is easy to experience uncontrolled consumption of opioid drugs in doses exceeding medical indications.

The number of prescriptions for opioid drugs in Poland is systematically growing. Over the last five years, the number of full-price prescriptions for strong opioid drugs has increased by one third (1). In 2023, compared to the data from 2019, when the so-called prescription machines, by 4% the number of reimbursed prescriptions issued for strong opioid drugs decreased, by 32% the number of fully paid prescriptions for such drugs has increased. Current opioid drugs are reimbursed for all types of pain, so every patient who needs them can receive a reimbursed drug from the group of strong painkillers. Therefore, the question arises: why such a sudden, dynamic increase in full-price prescriptions for such drugs without medical indications?

By "opiates" I mean both drugs such as morphine and heroin obtained from opium poppies, but also synthetic drugs whose effects are similar to morphine. Derivatives are often referred to as "opioids". Opioids belong to the natural, semi-synthetic and synthetic substances that act agonistically (stimulant) on opioid receptors. Endogenous opioids are natural substances (produced in the human brain) that regulate the physiological neurotransmitter activity of the opioid system, e.g., prevent pain. These include endorphins, enkephalins, and dynorphins (2). Synthetic opioids are mainly painkillers, e.g., fentanyl, methadone, buprenorphine and tramadol. Using these drugs without medical indication can lead to addiction.

A side effect of opioid use is the sensation of bliss (euphoria) and this is a symptom highly desired by non-medical opioid users. Non-addicts can experience serious, life-threatening poisoning, called overdose. The main mechanism of opioid toxicity was thought to be the inhibitory effect on the respiratory center in the brain. Recently, attention has been drawn to the possibility of opioids (mainly synthetic)

influencing myocardial repolarization and severe cardiac arrhythmias. Increased drowsiness can be life-threatening, especially when combined with not feeling cold and prone to cold. Opioids are substances with a relatively high addictive potential, i.e. a significant percentage of those who have ever used them become addicted (2). However, opioids are also one of the main groups of drugs used in pain management (3). Properly selected and dosed, they allow for faster mobilization of the patient, reduce the frequency of complications and the likelihood of persistent pain after the procedure. Rational pharmacotherapy of pain, based on a good knowledge of the mechanisms of action of drugs, their pharmacokinetics, side effects and interactions with drugs from other groups, allows to effectively alleviate pain in the majority, i.e., in as many as 85-95% of patients.

The Opioid Crisis in North America

In North America, we have been dealing with an opioid epidemic for twenty years. In 2008, the number of opioid overdose deaths exceeded the number of car accident victims. Until then, the proportion was reversed (4). Most of the deaths were due to drug overdoses and were related to the use of opiates – prescription painkillers or heroin. Opiate painkillers became the vehicle through which heroin entered the mainstream of society. Football players and cheerleaders, soldiers returning from Afghanistan, but also young people became addicted. They all abused prescription pills issued by doctors for pain relief. They became addicted and died.

The epidemic in the U.S. began with the painkiller OxyContin, which was legally approved for sale in 1996 (4). It contains oxycodone, an analgesic synthesized for the first time in 1916 by the Germans from thebaïne, an opium derivative. Oxycodone is similar in its molecular structure to heroin (3). Oxycodone has an analgesic potency comparable to morphine. Compared to morphine, oxycodone is highly bioavailable when administered (42-87% oxycodone vs. 22-48% morphine).

The OxyContin tablet uses a formula of sustained release of the active substances of the medicine. The U.S. Food and Drug Administration (FDA) has approved the drug's unique warning formula. It allowed to maintain that, thanks to the controlled release mechanism of the active substance, which caused a delay in its absorption by the body, the risk of possible abuse of OxyContin was lower than in the case of other products containing oxycodone (4). This text and the warning on the packaging not to crush it, because in this way you can release a potentially toxic amount of the active ingredient has become a kind of invitation for addicts.

In the United States, "prescription factories" were established, that is clinics specializing in pain control run by doctors who prescribed opioids en masse. It was, in fact, a drug vending machine, as they used to write prescriptions for hundreds of people a day. A lot of goods ended up on the streets in this way, but they didn't come from dealers, but from doctors' offices.

Over the past two decades, the problem of opioid abuse in the United States has been increasing. The current opioid epidemic is one of the most serious public health crises in the history of the United States (5). 2020 was the deadliest year of the opioid epidemic in North America to date: there were more than 100,000 drug overdoses in the U.S., of which nearly 76,000 were attributed to opioids, an increase of about 30 percent from 2019 (6). In Canada, the number of deaths increased by 67 per cent in one year, to more than 6,200.

The vast majority of the nearly 80,000 deaths involved some form of opioid, including heroin, prescription painkillers, and, in recent years, synthetic opioids such as fentanyl (7). Fentanyl and related synthetic opioids alone accounted for about 71,000 drug overdose deaths in 2021 and are also involved in the majority of overdose deaths from methamphetamine, cocaine, and prescription opioids – the next most common substances associated with overdose deaths.

The European Drug Report "The Drug Situation in Europe to 2023 – Reviewing and Assessing Emerging Threats and New Developments" reports that drug problems in North America are an example of how changes in patterns of opioid availability and use can have important public health implications (8). In this region of the world, potent fentanyl derivatives have largely supplanted prescription opioids and heroin, becoming a major driver of the opioid death epidemic. New synthetic opioids are being reported in Europe and may be becoming more common. In 2021, EU Member States reported around 140 fentanyl-related deaths. However, fentanyl is believed to be responsible for a significant portion of this when it has been withdrawn from medical use. While this is likely an underestimate, this number in no way compares to the many thousands of fentanyl-related deaths recorded in the same period in North America.

A total of 74 new opioids were identified on the European drug market between 2009 and 2022, with the EU Rapid Alert System receiving notifications of one new synthetic opioid in 2022 and three in the first four months of 2023. Most of the new opioids detected in recent years do not belong to the fentanyl group, but rather to the very potent benzimidazole (nitazene) opioids. Because the new synthetic opioids are very potent, a small amount is enough to produce a large number of typical doses and may pose a greater risk of life-threatening poisoning. This means that even if the problems in this area are relatively not important at the moment, this group of substances poses a risk that could have a more significant impact on health and safety in Europe in the future (8).

Record increase in the number of prescriptions for medical marijuana and opiates in Poland

In the context of the opiate epidemic in the United States, the data on the record number of prescriptions issued for medical marijuana and opiates in Poland is alarming. In January and February 2023 Poles bought 270 kg of medicinal marijuana in pharmacies. This is more than in the whole

of 2021, when sales amounted to approx. 250 kg. Compared to 2020, this is already a twofold increase, and by 2019 as much as six times, according to data from the Ministry of Health (9). Data from the Ministry of Health show that in Poland we are dealing with a boom in medical marijuana issued on prescription in pharmacies. The number of patients who have filled prescriptions for medical marijuana has increased sixfold in the last three years: from 4,885 in 2020 to more than 30,000 in 2022.

One of the reasons for the increased interest in prescription marijuana is the increase in the number of companies offering the product. This is also influenced by the increased knowledge about the availability of prescription cannabis, but also by the possibility of issuing an e-prescription for such products on online portals offering teleconsultations. The possibility of legal sale of cannabis for medical purposes has existed in Poland since 2017 (10). In June 2018, the first distribution company submitted the preparation for registration. The demand for medical marijuana is so high that after the first two months of 2023, importers approached the annual limit for Poland with the number of permits. It amounts to 3 tonnes and is determined on the basis of the provisions of the Single Convention on Narcotic Drugs of 1961 (11).

Issuing an e-prescription via platforms is not always preceded by a real interview, during which it is verified whether it will actually be needed for medical purposes, e.g., for pain relief, epilepsy, HIV, MS or cancer. This is confirmed by the actions of the Ombudsman for Patients' Rights, who obliged the company issuing e-prescriptions during teleconsultations to refrain from using practices that violate the congregation's rights of patients. If the entity does not comply with this decision, the Ombudsman for Patients' Rights may impose a fine of up to PLN 500,000 (12). It was about issuing prescriptions for a fee only on the basis of a questionnaire, without medical consultation. The Ombudsman emphasized that the questionnaire cannot be the only document for a doctor on the basis of which he diagnoses and assesses the patient's health condition. On the occasion of imposing the penalty, the Ombudsman for Patients' Rights emphasized that the law obliges medical facilities to provide health services with due diligence. Only in exceptional cases can the examination of the patient be waived – in the case of prescriptions or orders for medical devices – which are necessary for the continuation of treatment. Even in such a situation, the doctor must have medical documentation to justify the issuance of a prescription or order.

According to the Ombudsman for Patients' Rights, the legal regulations in force in Poland are aimed at guaranteeing patients proper supervision over the effectiveness and safety of treatment. This supervision must not be illusory, especially in the field of pharmacotherapy, which is potentially fraught with the risk of interactions and adverse reactions. The Ombudsman stated that he was conducting several further proceedings in relation to other medical entities, the so-called prescription machines (in polish: receptomaty).

In Poland, there is also a growing interest in opioids, mainly strong analgesics, which are intended for patients suffering from oncology, post-traumatic and chronic pain. In order for a patient to receive a prescription with reimbursement, there must be a clear medical justification, as the preparations have a strong addictive effect. E-prescriptions issued by online platforms providing teleconsultations are fully paid. Maciej Miłkowski, Deputy Minister of Health, said that if a patient

has the right and is insured, he or she gets a reimbursed prescription. When there are no indications for reimbursement – in the case of this group of drugs – it means that there are no indications for treatment (13). According to data from the e-Health Centre, 100% of paid opioid prescriptions in 2023 were 1,825,203 (in 2019 – 1,384,149), and 5,611,040 were reimbursed (compared to 5,853,793 four years earlier).

Mass prescription issuance by platforms

Two record-breaking doctors when it comes to writing prescriptions (privately – a married couple) managed to issue over 700,000 e-prescriptions during the year: he – over 286,000 in 2022, she – over 429,000 (14). The rest of the top 10 doctors did not exceed 200,000 a year, and those in the last five record places put up little more than 100,000 a year. This is a lot, considering that doctors write prescriptions to about 60 patients on average per month. Medics who use the possibilities associated with teleconsultations earn millions of zlotys on it.

The data received by the Supreme Chamber of Physicians regarding a doctor issuing a record number of prescriptions shows that in March alone, he issued 21,433 electronic prescriptions (14). Assuming that a medic worked 24 hours a day, without a sleep break, he would have to write 691 prescriptions a day, or 29 prescriptions an hour. According to the data provided to the medical self-government, as many as 868 doctors exceeded the average number of prescriptions issued in March 2023, which is 60. The doctor who issued a record number of prescriptions prescribed them for: medical marijuana, emergency contraception, weight loss drugs, antibiotics and strong painkillers. This is yet another proof of the great threat to public health posed by platforms offering teleconsultations.

Urgent legislative changes needed

In February 2023, Dziennik Gazeta Prawna published an article by P. Nowosielska entitled: *Golden business on e-health* (15), in which, during a journalistic provocation, in just over an hour, without contact with a doctor, the journalist received a prescription for a strong anti-anxiety and antiepileptic drug and an e-prescription. She used one of the portals offering e-prescriptions and e-sick leave for a fee. To receive an e-prescription, all they had to do was fill out a virtual questionnaire with their name, surname, email address, information about allergies, past chronic diseases and a question about the reason for applying for a specific drug. The journalist typed in the laconic "mood disorders" and received an electronic prescription. No one contacted her and took her medical history. The article showed for the first time the disturbing phenomenon of commercial issuance of sick notes and on-demand online prescriptions. Officially, there is a teleconsultation before an e-prescription is issued. It is clear to people in the industry that the services are operated by bots using data provided by real doctors, e.g., the number of the license to practice.

After publicizing the pathological use of teleconsultations, the Ministry of Health changed the regulations to limit the issuance of e-prescriptions for psychotropic and narcotic drugs (16). From 2 August 2023, a doctor is required to check the patient's e-prescription history before prescribing narcotic or psychotropic drugs. Each time, before issuing

a prescription for narcotic or psychotropic drugs, the doctor, during the examination, is obliged to check what drugs have been prescribed to the patient and in what doses. The examination can be stationary or in the form of a teleconsultation. According to these rules, if the last test for a prescription for such drugs took place in less than three months, then the doctor may issue a prescription without the examination as part of the follow-up treatment.

Despite legislative changes, other products that may be addictive are still issued through platforms that enable teleconsultations and the issuance of electronic prescriptions. This is evidenced by the huge increases in the number of prescriptions issued for medical marijuana or opiates.

The Ombudsman for Patients' Rights has filed a complaint with the prosecutor's office regarding the death of two people who used prescriptions issued remotely by special websites (17). In both cases, he found that patients' rights had been violated. In the course of these proceedings, he also obtained specialist medical opinions, which pointed to irregularities. Both incidents involved two young women. In one case, it involved prescribing an e-prescription for the drug Xanax, which has psychotic, anxiolytic effects, and the very powerful painkiller OxyContin, which is an opioid drug.

The medical self-government emphasized that it is dangerous from the point of view of patient safety and public health to pathologically use teleconsultations to issue e-prescriptions and e-sick leaves on a mass scale for a fee. He added that in the face of the development of platforms that allow for remote, commercial issuance of prescriptions and e-sick leaves, it is necessary to clarify the standard of teleconsultation so that it cannot be a method that allows prescriptions to be issued without disregarding the standards of due diligence in patient care.

It is important to note that the decision to issue a prescription after a teleconsultation should always be based on medical considerations and not on expectations supported by the payment of a fee for the service. The Medical Ethics Committee of the Supreme Medical Council accents that it is the physician who should decide whether it is possible to conduct a teleconsultation in the established facts, and if it is undertaken, he or she should inform the patient to what extent the doctor can help him or her and what are the limitations related to remote consultation. The Commission emphasized that the decisive factor in the possibility of ICT advice is medical and not wishful or commercial criteria.

The Medical Ethics Committee of the NRL has prepared a proposal to amend the Code of Medical Ethics. According to the bill, Article 9, which sets out the most important rules for teleconsultations, would be amended (18). According to this proposal, personal contact between the doctor and the patient is the most appropriate form of doctor-patient relationship, and before providing the service in the form of a teleconsultation, the doctor is obliged to verify the patient's identity and ensure confidential conditions for the teleconsultation. The medical self-government emphasized that it is the doctor's duty to inform the patient about the limitations of teleconsultation compared to personal contact with the patient, and in particular to indicate the symptoms justifying a personal visit or, if necessary, to recommend contact with a medical facility. Teleconsultation would be provided, especially in the treatment of chronic conditions, in order to consult the ongoing treatment or to ensure continuity of treatment until the next possible personal visit. It is not recommended for patients who have not yet been treated by a given doctor or who report a new health problem. The Supreme Chamber

of Physicians emphasizes that it is unacceptable to conduct diagnostics and therapy of a patient only by means of teleconsultations.

Commercial e-prescriptions show the ethical problem associated with teleconsultations. The progressive commercialization of medicine means that today the patient is increasingly turning into a client and expects the doctor not only to provide care, but also to provide a certain service, which affects the entire doctor-patient relationship (19). The situation has been exacerbated by the operation of prescription machines using teleconsultations, as patients are prescribed many medications, including antibiotics, only after completing an online survey, which exacerbates the problem of antibiotic resistance (20).

Conclusions

Over the past two decades, opioid-related hospitalizations and deaths in North America have reached the level of a public health emergency. The epidemic of opioids was largely driven by pharmaceutical companies and initiated by their spread of misinformation, which led physicians to engage in overzealous prescribing behavior (21). Given the rapid pace at which the opioid epidemic has spread across the United States, Poland is at a critical moment. We do not have time to stand idly by while e-prescriptions for addictive substances are filled through portals offering teleconsultations for people without medical indications.

The medical self-government emphasizes that it wants to radically reduce the number of prescription machines and organize teleconsultation so that it is an actual consultation and not a purchase-sale transaction. This is the purpose of the proposed amendments to the Code of Medical Ethics. According to them, a doctor should undertake the care of a patient only after a prior assessment of the patient's condition. It is up to the doctor to choose the form of consultation (in-person visit, teleconsultation, etc.) that provides the patient with the highest available quality and continuity of medical care. It is the doctor who is responsible for the correct selection of the form of consultation. And most importantly, the doctor should make a decision about the patient's health condition after taking the patient's medical history, as well as after analysing the medical records. It is very important to note in the proposed regulations that not every health service can be provided in the form of telemedicine and it is not recommended to provide teleconsultations to patients who have not yet been treated by a given doctor or who report a new health problem.

Attention is drawn to the fact that restrictions on issuing documents remotely, without consultation, should first apply to situations when the patient reports to the doctor for the first time and the doctor does not know his or her medical history. There are voices that perhaps a catalogue of drugs should be created, the prescription of which should be prohibited or significantly limited during a teleconsultation. Such a list should include, m.in. antibiotics and opioid medications.

According to the US Food and Drug Administration, the 20-year rise in per-person opioid prescribing (from 44 prescriptions per 100 people in 1993 to 84 prescriptions per 100 people in 2012) was reversed in just 8 years (22). The Ministry of Health in Poland claims that it is planning to change the regulations on telemedicine, especially the provision of teleconsultations due to the operation of the so-called prescription machines, because in Poland

there are not only entities registered in the country, but also abroad (13).

Unfortunately, new, dangerous phenomena will appear. One company went a step further. A company operating a pharmacy belonging to it refers to the services of another company belonging to the same capital group. The latter company is a clinic that issues online prescriptions and introduces potential patients to the effects of opioid substances in articles (23). It is not only about the unethical nature of such actions, but above all about the huge threat from the point of view of public health. If the Polish government does not respond at the right time as it did in the US, the opioid epidemic may also reach us.

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