Opioid analgesics, particularly morphine, are fundamental in the pharmacotherapeutic management of severe pain. Morphine is enumerated in the World Health Organizations (WHO) 19th Model List of Essential Medicines (under ‘medicines for pain and palliative care’), which presents the most efficacious, safe and cost-effective medicines for priority conditions (1). Despite their valuable analgesic properties, the use of opioids commonly results in tolerance, dependence and addiction (2, 3). Consequently, these factors have necessitated the classification of opioids as controlled substances under national and international regulations (4). This, in turn, has created barriers to accessing opioids, which is an area that has attracted a growing interest from many organizations and associations.

These barriers are particularly evident in countries with low opioid consumption rates.

In Poland, the actual consumption of strong opioids (morphine equivalents in mg per capita) is 35.76 (the adequate should be 292) (5). Poland was a part of the Access to Opioid Medication in Europe (ATOME) project, which aimed to improve access to these medicines (6, 7). The Final report and Recommendations to the Ministers of Health indicated that, in Poland, policy barriers were the most common limiting factors to the availability of opioids. These barriers included, insufficient financing of pain clinics, palliative care and harm reduction initiatives, inadequate reimbursement of opioids for patients with pain conditions other than cancer, unsatisfactory knowledge about opioids as well as a
fear of opioids. In contrast to other countries, the Polish part of this report did not include an analysis of Polish legislation, as no legal documents were provided. However, it was highlighted (in the ‘voices for Poland ATOME participants’ section) that there were positive legal changes noticed that related to the availability of opioids (6).

Two important papers investigating barriers around the access of controlled substances have been published recently. The first study is related to the usage of opioids on a global scale. It indicated that the consumption rate of opioids was not satisfactory in the following regions: Africa, Asia, Central America, the Caribbean, South America, and eastern and southeastern Europe (8). The second paper presented results from 11 ATOME countries (all apart from Poland) and explored the reasoning behind the inadequate levels of access to controlled medicines in ATOME regions. According to the authors, the number of potential barriers ranged between 22 (Cyprus) to 128 (Lithuania). The most common barriers included: administrative requirements for prescribing and dispensing, limitations on the amount of controlled medicines allowed to be prescribed as well as the use of special prescription forms (9).

The aim of this study was to provide an insight into the current legal impediments that limit opioid access, subsequent to recent changes in Polish legislation.

**EXPERIMENTAL**

An analysis of Polish law relating to controlled medicines was undertaken in accordance with current WHO policy guidelines. First, legal acts associ-
RESULTS

In Poland, morphine, fentanyl, methadone, oxycodone, and pethidine in various drug formulations are considered controlled substances (group I-N, 'opioid analgesics'), and this study examines the regulations surrounding their use. Buprenorphine available in transdermal therapeutic systems (patches), in sublingual tablets (0.2 and 0.4 mg) and injections belongs to the psychotropic class of medicines, as are benzodiazepines, and therefore is not governed by very strict restrictions (10). Furthermore, tramadol and dihydrocodeine (II-N) are considered "common" medicines and their dispensing does not require any special procedures.

Every physician with a valid medical license is authorized to prescribe controlled medicines and, at present, the requirements concerning the prescribing of opioids are milder in light of recent legislative changes (Table 1). Opioids must be available in every registered pharmacy, apart from when a pharmacy does not wish to dispense opioids. In that case, the Regional Pharmaceutical Inspector must then issue a special exemption. The electronic survey showed that 10% of community pharmacies in Poland were exempted from dispensing controlled medicines (14 of 16 Regional Pharmaceutical Inspectors took part in the survey). Furthermore, health care settings and private medical practices may possess and use controlled medicines, provided that they have permission from the Regional Pharmaceutical Inspector. Controlled drugs should be stored in a safe, which every pharmacy and ward must be equipped with. These safes must be located in areas that are not visible or accessible to people other than pharmacy/medical staff. In the case of expired stock, the subsequent management procedures are formal and expensive, and require the involvement of a pharmacist.

The dispensing of controlled medicines by pharmacists is associated with several requirements. At both community and hospital pharmacies, licensed pharmacists must be involved in all procedures related to the distribution of these drugs, and each procedure should be annotated with their signature. In Poland a special record book (available from the Regional Pharmaceutical Inspector) is required to document all instances of opioid dispensing. At community pharmacies, the book must be completed immediately after dispensing the controlled medicines for the patient, whilst at a hospital or hospice pharmacy can be filled out after distribution within the ward. Each delivery of controlled medicines to the pharmacy must be also recorded in this book and the balance between these two amounts (delivery and dispensing) should be counted. When ordering controlled medicines from warehouses or other sources, a written request signed by the pharmacist and completed on a specific form is required.

According to Polish legal regulations, a person who violates laws surrounding the management of controlled medicines, commits a misdemeanor, and in the case of more serious offences, a crime.

DISCUSSION AND CONCLUSION

Poland is one of the largest countries in East-Central Europe (38.5 million inhabitants), and as such the inappropriate management of pain has the potential to affect a large number of patients. Within the ATOME project, the legal barriers acknowledged in other countries by Vranken and his colleagues were, to some extent, similar to those identified in Poland (9).

Our review of Polish legislation has shown, that the potential barriers do not significantly limit access to controlled medicines. A comparison of previous and current legislation has identified crucial changes in the management of opioid analgesics that should improve the availability of these restricted medicines. A new regulation allows physicians the opportunity to prescribe opioids, from one site using 3 separate prescriptions (each valid for 30 days). The introduction of this multiple prescription system, allows physicians to extend the duration of therapy, as well as limits patients’ to realizing only one prescription in one month, which protects them from an excess of opioids. It is observed that treatment period (90 days) is one of the longest among countries from the ATOME project. The volume of the controlled medicine in a single or daily dose is not limited and, as a new development, if the physician prescribes a higher dose than that recommended in the pharmacopeia, they are not required to justify it. This is especially desirable in patients with
severe chronic pain, who have developed a tolerance to opioids and still need very high doses. On the other hand, the physician must be mindful, that pharmacists who dispense these prescriptions, are unaware if doses have been exceeded deliberately or by mistake.

The study indicated, that the vast majority of pharmacies must distribute opioids. If the particular medicine is not available at the pharmacy, the pharmacist must order it from a pharmaceutical warehouse. In practice, ordering a drug on a special request is convenient for pharmacies, as it removes all concerns relating to expiration dates and the need for utilization, which surround the ordering of rarely prescribed medicines. All administrative procedures related to the documentation of controlled medicines are very strict and require the involvement of a licensed pharmacist who must take on the full responsibility for this process. On the one hand, this may make the pharmacist reluctant to dispense controlled medicines, however these administrative processes require the employment and presence of a registered pharmacist (not technician) in a pharmacy (community or hospital). As such from a broader perspective, this latter requirement is positive since it increases the need for professional pharmaceutical practice.

To sum up, the changes in Polish law for opioids have improved access to these exclusive medicines (11). The identified barriers, including strict documentation, requirements relating to prescribing and special conditions for the management of opioids may limit their usage. However, it is important to achieve an acceptable balance between restrictions on the usage of harmful opioids and their beneficial applications. Thus, the positive aspects of improving access to opioids should be considered in conjunction with their toxic effects.

REFERENCES


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