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The requirement to obtain the consent of a legal guardian for the provision of reproductive health pharmacist services to minors under the pilot program

Abstract

Emergency contraception in Poland is often referred to as the "morning-after pill". Its legal status has changed many times. In Poland, it has only been available on prescription since 2017. Attempts have been made to change the legal status in 2024. A draft amendment to the Pharmaceutical Act was then submitted to Parliament. However, the bill was vetoed by the President of the Republic of Poland. In response to the veto, the Minister of Health issued a decree on a pilot programme in the field of pharmacists' services related to reproductive health. In connection with this regulation, a question arose for pharmacists: whether it is necessary to obtain the consent of the legal guardian of minors who want to use the programme. Therefore, the aim of the work was a legal-comparative and dogmatic-legal analysis of legal acts in the field of reproductive health. A review of the data shows that while the pharmacist carries out the activities indicated in the pilot programme for pharmacist services about reproductive health, health services are provided to patients. Therefore, in the case of minor patients under 16 years of age, or who are over 16 but under 18 years of age, the consent of their legal representatives is required. It should also be noted that the term "pharmacist service" used in the title is not defined in any way in the law (unlike the term "pharmaceutical service") and does not constitute a definition that would allow the statement to be made that it is another unlisted activity that exempts the pharmacist from the obligation to obtain the consent of the legal guardian. It should therefore be assumed that this consent is necessary to provide the service.

Keywords: emergency contraception, pharmacist service, pharmaceutical service, legislation, morning-after pill.

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INTRODUCTION

Emergency contraception in Poland, often referred to as the "morning-after pill", has changed its legal and factual status many times. The changes were influenced by both external factors, such as changes in the European Union legislation, and internal social or political factors based on worldview or religion. According to data from PEX sp. z o. o. [1], in the period from January 2019 (date of introduction of e-prescription) to April 2024, a total of 532,152 packages of tablets containing 30 mg of ulipristal acetate were sold in Poland. The growing popularity of this medicinal product is illustrated by the quarterly sales chart. In addition, the trend line indicates a strong correlation (R2=0.9314) between the number of packages sold and the sales period, which also indicates an increasing demand for this medicinal product. Detailed data on the sales of ulipristal acetate tablets are presented in Figure 1.

A tablet containing ulipristal acetate as an active substance (registered in Poland under the name ellaOne® 30 mg) is registered in over 50 countries worldwide. Since 2010, it has been approved by the US Food and Drug Administration (FDA) with indications for use in emergency contraception [2]. Pursuant to the decision of the European Commission of 15 May 2009, ellaOne® was granted a marketing authorisation provided that it was dispensed only with a prescription issued by an authorised person. Subsequently, based on the European Commission's implementing decision dated 7 January 2015, these tablets could be purchased over-the-counter (OTC) at pharmacies without a prescription [3]. This decision became binding in all European Union member states. For the above reasons,

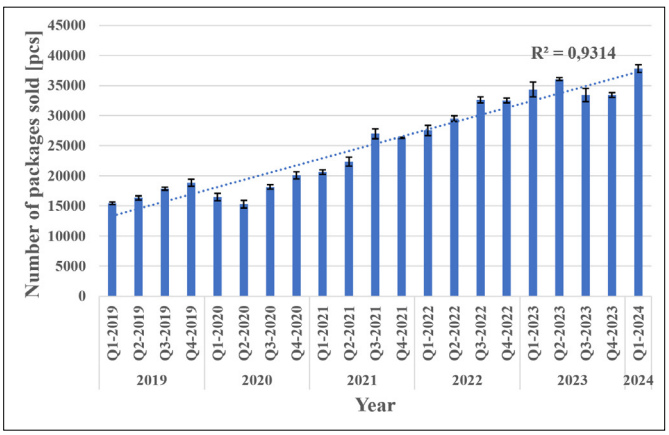

FIGURE 1. Quarterly breakdown of the number of ulipristal acetate tablets sold.

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in 2015, the Minister of Health indicated the possibility of purchasing this preparation OTC by a person who is at least 15 years old [4]. It is worth mentioning that in all European Union countries, except Poland and Hungary, emergency contraception is available in pharmacies without a doctor's prescription [5]. On July 23, 2017, regulations [6] came into force, once again changing the availability status of ulipristal acetate in Poland to prescription-only [7]. The next change was in 2024. At that time, a draft amendment to the Pharmaceutical Act [8] was submitted to the Parliament, aiming to repeal the regulations introduced in 2017 and to restore the OTC status for the tablet used in emergency contraception. While the text of the regulations did not specify the age from which patients could independently purchase emergency contraception, the justification for the draft clearly highlighted this possibility, adding the phrase "after reaching the age of 15". The proposed change in law sparked a profound social and political debate, which created extremely divergent positions regarding the use of emergency contraception. The main point of contention was the age of the patients, set at 15 years, and subsequently the requirement to obtain legal guardian consent for the use of the "morning-after pill". Despite the amendments passed by the Parliament, the President of the Republic of Poland vetoed the indicated amendment to the Pharmaceutical Act on March 29, 2024. He justified his decision by "respect for the constitutional rights and standards of health protection for children". In response to the veto and the need to increase patients' access to emergency contraception, the Minister of Health issued a Regulation on April 29, 2024, regarding a pilot program for pharmaceutical services related to reproductive health (Journal of Laws of 2024, item 662) [9]. The aim of the pilot program is to improve patient access to modern methods of emergency contraception and to ensure that pharmacies provide services related to patients' reproductive health, along with evaluating the effectiveness of these actions, particularly concerning patients aged between 15 and 18 years. The program includes conducting an interview and, if necessary, issuing a pharmaceutical prescription for the "morning-after pill".

Both during the drafting of the mentioned Regulation and after its entry into force, the issue of obtaining consent from a legal guardian in the case of a minor was raised. The Ministry of Health took the position that in the case of persons over 15 years of age covered by the pilot program, the consent of the legal guardian is not required [11], because the patient is not provided with health services, and therefore this activity is not subject to the regulations regarding patient rights. Contrarily, professional self-governing bodies of medical professions, including the Supreme Pharmaceutical Council and the Ombudsman, argued that regardless of the legal definitions used in the Regulation, we are dealing with the provision of healthcare services. Consequently, it is necessary to obtain the appropriate consent in the case of minors. It should be noted that improper (non-compliant with legal regulations) execution of the activities indicated in the pilot program may also lead to consequences in terms of professional liability. Its scope is widely discussed by Patryn and Drozd [13], especially in relation to the Code of Ethics of a Pharmacists (now the Code of Ethics of a Pharmacists of the Republic of Poland). Leaving aside social, political, or religious beliefs, the following research question was posed: is a patient participating in the pilot program for pharmaceutical services related to reproductive health receiving health service, and thus, if the patient is a woman aged 15 to 18, is the consent of a legal guardian required for the provision of this health service?

MATERIAL AND METHODS

The study was conducted using a legal-comparative and dogmatic-legal analysis of the following legal acts: The Regulation of the Minister of Health of April 29, 2024, regarding the pilot program for pharmaceutical services related to reproductive health [14], the Act of November 6, 2008 on Patient Rights and the Patient Ombudsman [15], the Act of September 6, 2001, on Pharmaceutical Law [16], and the Act of December 10, 2020, on the Profession of Pharmacist [17]. Additionally, the analysis included the Report from the public consultations and opinions on the draft regulation of the Minister of Health regarding the pilot program of pharmaceutical care for patients in the area of reproductive health [12].

RESULTS AND DISCUSSION

The role of pharmacists in increasing access to emergency contraception and sex education is a rational solution based not only on the knowledge and experience of this professional group, but also on the use of factors such as access to pharmacies in the context of opening hours or distance. DiPietro et al. point out the potential of the US in this area, noting that the provision of contraceptives by pharmacists by issuing, prescribing and/or administering according to the scope of practice in a given state helps planning reproductive life. In the European Union, among the 27 countries, only in Hungary and Poland the morning-after pill (registered under the name ellaOne® 30 mg) is available only on prescription [5]. In order to overcome the barrier in the availability of this medicine and at the same time use the potential of pharmacists, a pilot program was created prepared by the Minister of Health. In principle, the project's assumptions did not raise any doubts, but the rule for performing the activities specified in the regulation for patients under 18 years of age turned out to be a controversial issue. The Regulation of the Minister of Health of April 29, 2024 on the pilot program in the field of pharmacist services regarding reproductive health [14] does not directly refer to the issue of the requirement (or lack thereof) to obtain the consent of the legal guardian for actions involving a minor patient during the pilot program. The obligation to obtain such consent exists, however, in the case of the provision of health services to a patient under the age of 18. The Act on Patient Rights and the Patient Ombudsman [19] distinguishes minor patients who (1) are under 16 years of age and cannot make decisions for themselves; (2) are over 16 years of age but under 18 years of age and can make their own decisions within the indicated scope, under the supervision of statutory representatives – usually parents. The legal representative of a minor patient has the right to consent to conducting an examination or providing other health services [20]. Consequently, a patient who does not have full legal capacity is represented by a legal representative in the course of medical proceedings. It is therefore essential to answer the question as to the nature of the activities carried out in the context of pilot program. The Act on the Profession of Pharmacist [21] defines the concept of pharmaceutical care as a health service within the meaning of Article 5, point 40 of the Act of August 27, 2004, on health care services financed from public funds [22].

Of the five activities performed by a pharmacist providing this health service, pharmaceutical consultation is important to ensure patient safety in connection with the use of medicinal products, medical devices, accessories of medical devices, treatment systems and kits, (...) and medical devices for in vitro diagnostics and equipment for in vitro diagnostic medical devices, (…) [23]. Another concept included in the above-mentioned Act on the Profession of Pharmacist is a pharmaceutical service – pharmaceutical interview [24], which is not an element of pharmaceutical care and therefore not directly a health service. In the Report on the public consultation regarding the pilot program [12], the Ombudsman raised doubts about the nature of the activities carried out by the pharmacist, referring to the definitions indicated above. The Minister of Health emphasized that the project neither refers to pharmaceutical interviews as a pharmaceutical service nor to pharmaceutical consultations as an element of pharmaceutical care. Thus, he maintained the position that the activities performed in the pilot program are not health services. At the same time, he pointed out that in this case the pharmacist performs a different category of activities permitted in a generally accessible pharmacy [12]. Also, the authors of the project explicitly stated that the definitions of pharmaceutical care and pharmaceutical services were consciously omitted [12], emphasizing that this is a deliberate practice [12]. Taking into account that the term specified in the Act on the Profession of Pharmacists (pharmaceutical care) would necessitate obtaining the legal guardian's consent for the provision of services to a minor, the Ministry of Health intentionally uses terms that are unknown and undefined by Polish legal regulations, such as "pharmacist care" or "pharmacist service" (instead of "pharmaceutical care" or "pharmaceutical service"). This action may lead to bypassing the consent of the minor's guardian and the possibility of issuing emergency contraception available on prescription to a patient between 15 and 18 years of age. Despite the doubts raised by, among others, the Supreme Pharmaceutical Council, the Ombudsman, the Polish Pharmaceutical Society and business organisations, including Pradocawcy.pl, their comments were not taken into account at the design stage of the pilot program [12]. The leaders of medical professions' self-governments also expressed their opinion in the Position of April 17, 2024 of the Presidents of Medical Professions' Self-Governments [25], opposing circumvention of the law by defining the activities of a pharmacist in the pilot project differently than health services. The argument put forward by the Minister for Health to deny that the activities covered by the pilot project constitute healthcare services (consent of the guardian of a minor is required) is in contradiction with the very content of the Regulation in question. In the definition, a patient is defined as "a person seeking health services or using health services provided by a healthcare provider or a person performing a medical profession" [26]. This wording indirectly indicates the necessity of obtaining the legal guardian's consent to provide this health service to a minor. The fact of providing a health service is also confirmed by the very legal basis for creating the pilot program, which is based on regulations concerning health services financed from public funds [27].

At this point, it is worth mentioning the definition of health care services. According to the Act of April 15, 2011 on medical activities [28], health services are "activities aimed at maintaining, saving, restoring or improving health and other medical activities resulting from the treatment process or separate provisions regulating the principles of their implementation" [29]. This definition is fulfilled by the actual state of activities indicated in the pilot program, one of the goals of which is to issue "based on current medical knowledge, (...) and interview data, (...) – if it is justified by the state of risk to the patient's reproductive health, including the risk of unplanned pregnancy – pharmaceutical prescription referred to in Article 96 (4) of the Law of 6 September 2001 Pharmaceutical Law" [10]. Additionally, the drafter defined a state of threat to reproductive health as "a condition involving the sudden or expected appearance of symptoms of deterioration of reproductive health in a short period of time" [30]. This means that the activities carried out by the pharmacist are included in the catalogue of activities defined as health services ("activities to maintain, save, restore or improve health") [29]. Regardless, the pharmacist should assign a diagnosis code according to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) [31]. The next element is the place where the interview is to be conducted. The wording of the regulation states that "the activities, (...) shall be carried out in a place and in a manner which ensures respect for the rights of the patient and the security of the information provided by the patient, in a pharmaceutical care room, if a given pharmacy has one, or in an administration and training room, if it serves as the pharmaceutical care room" [32]. Such place marking is typical of rooms where pharmaceutical care, i.e. health services, are provided, and therefore, in the case of providing it to a minor, the consent of the legal guardian is also required. Another element indicating the fact that benefits are actually provided is the requirement to keep medical records as "recognized by the Fund as valid in connection with the settlement of benefits" [33]. At the same time, "for the purposes of conducting an interview, (...), the pharmacist is obliged to verify the patient's entitlement to health care services, in accordance with Article 50 of the Act of 27 August 2004 on publicly funded healthcare services" [34], which confirms that the activities indicated in the pilot program are in fact a healthcare service. This view is supported by the Supreme Pharmaceutical Council in its position, citing legal justification indicating the fact that health services are provided by a pharmacist. The Supreme Pharmaceutical Council also emphasizes that providing a minor patient with a medicinal product that is an emergency contraceptive requires the consent of the minor patient's legal representative [35].

The President of the National Health Fund also commented on this issue in his Communication [36], emphasizing that a pharmacist is independent and autonomous in making decisions about his professional activities. Additionally, he states that neither the request for the consent of the legal guardian nor the refusal to perform the activities listed in the pilot program if it is not obtained constitutes a basis for imposing any penalties on the part of the organizer of the pilot program. The communication was a response to the objections raised by the pharmacists participating in the pilot program, who, during its implementation, clearly indicated the need to obtain the consent of a legal guardian for the provision of services to a minor.

As part of monitoring the progress of implementing the pilot results, the E-Health Center confirmed as of June 21, 2024 a total of 1,307 consultations, including 197 that ended with a refusal to issue a pharmaceutical prescription for emergency contraception, without indicating the reason for the refusal [37].

CONCLUSIONS

The study result indicates that while the pharmacist performs the activities indicated in the pilot program in the field of pharmacist services regarding reproductive health, patients are provided with health services [14]. Thus, in the case of minor patients who are under 16 years of age and cannot make decisions for themselves, or are over 16 years of age but under 18 years of age and can make independent decisions within the indicated scope, under the supervision of statutory representatives – most often parents. This conclusion is confirmed by both the actual status of the activities performed, i.e. the determination of a health hazard, and the place where the activities are performed. Content analysis of the Regulation of the Minister of Health of April 29, 2024 on the pilot program for pharmacist services regarding reproductive health [14] also indicated direct references to health services, including by defining a patient as a person requesting or using health services from a health service provider or a person performing medical profession. At the same time, the obligation arising from the provisions of the Regulation itself to confirm the entitlement to health services, to define the disease entity or to keep medical records, literally confirms the fact of providing health services and, consequently, obtaining the consent of the guardian to provide them to a minor. The concept of a pharmacist services used in the title is not defined in any way by the law (unlike a pharmaceutical service) and does not constitute a definition authorizing the statement that it is another unspecified activity that releases the pharmacist from the obligation to request the consent of the minor patient's legal guardian.

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