SOŁTYSIŃSKI KAWECKI SZLĘZAK

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PHARMACIES

Basic conditions for operating a pharmacy

On 2 July 2025, a draft regulation of the Minister of Health amending the regulation on the basic conditions for operating a pharmacy was published on the website of the Government Legislation Centre ("RCL").

The draft envisages i.a.:

- introducing a procedure to monitor the storage conditions of medicinal products and dealing with any breaches of the procedure,
- **removing the requirement to provide pharmacies with equipment for round-the-clock monitoring of temperature and humidity**, and
- introducing the obligation to conduct and document risk analysis if there's a breach of the storage conditions for medicinal products (in particular, deviations from the acceptable temperature range.

You can read the entire draft **here**.

Amendments to applications for a licence to operate a pharmaceutical wholesale warehouse

On 2 July 2025, a draft regulation of the Minister of Health amending the regulation on the template for applications for a licence to operate a pharmaceutical wholesale warehouse was published on the RCL website.

The draft introduces **changes to the application form for a licence to operate a pharmaceutical wholesale warehouse** to bring it into line with the new guidelines of the European Medicines Agency, *Compilation of Community Procedures on inspections and exchange of information 15 September 2023 EMA/369583/2023 Rev 19.1,* and the Act on the health care information system.[1]

The proposed amendments include, in particular, introducing the possibility to declare in the application both the **wholesale trade in narcotic or psychotropic substances**, and **the temperature range** for products requiring storage at low temperatures, in accordance with the above guidelines.

You can read the entire draft **here**.

Changes to the ban on advertising pharmacies

On 22 August 2025, an announcement of a draft amendment to Pharmaceutical Law (UD291) was published in the List of Legislative and Program Works of the Council of Ministers.

According to the published assumptions of the draft, it aims **to repeal the total ban on advertising for pharmacies and pharmaceutical outlets to bring the law into line with the judgment of the Court of Justice of the European Union C-200/24**,[2] which found the ban to be contrary to EU law. The draft also aims to introduce restrictions on the content of advertising, preventing advertising that goes beyond the established standard of objectivity and neutrality of communication, and to triple the maximum financial penalty for violating the ban on advertising publicly accessible pharmacies, pharmacy outlets, as well as for their activities.

You can read the draft **here**.

[1] *Act of 28 April 2011 on the Healthcare Information System.*
[2] *Judgment of the Court of Justice of 19 June 2025, C-200/24, European Commission V Republic Of Poland.*

MEDICINAL PRODUCTS

Changes in the mail-order sale of medicinal products

On 16 July 2025, a regulation of the Minister of Health amending the regulation on the mail-order sale of medicinal products came into force. The regulation introduces another possibility to place orders for the **delivery of medicinal products**, i.e. placing an order using electronic means of communication other than those specified in the regulation (fax, e-mail, or online form) that enable the purchase of a medicinal product offered on an establishment's website.

In practice, the amendment creates new opportunities for the mail order sales of medicinal products by pharmacies which were not formally/directly permitted until now, e.g. via mobile applications. The catalogue of permissible means of electronic communication has been intentionally left open, as stated in the justification of the draft.

You can read the entire regulation **here.**

Draft regulation of the Minister of Health amending the regulation on detailed requirements for pharmacy premises

On 8 July 2025, a draft regulation of the Minister of Health amending the regulation on detailed requirements for pharmacy premises was published on the RCL website. The draft primarily introduces **terminological corrections** to the regulation, e.g. replacing the term 'health care facility' with '**medical facility of a medical entity**' and 'homeopathic products' with '**homeopathic medicinal products'**.

You can read the entire draft **here**.

Botulinum toxin – warning from the URPL President

After reports from the British regulator of cases of botulinum toxin poisoning after treatments using products that have not been approved for marketing

("unlicensed Botox-like products"), the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products ("**URPL President**") issued **a statement** on 14 August 2025, **reminding the rules for the safe use of medicinal products containing botulinum toxin**.

According to the announcement:

- in Poland, all products containing botulinum toxin authorised for marketing for human use are medicinal products that can be dispensed based on a doctor's prescription,
- patients planning to undergo treatment with botulinum toxin are advised to check whether it is listed in the register of medicinal products,
- **only physicians or dentists are permitted to inject products containing botulinum toxin**,
- products that do not have marketing authorisation in Poland pose a serious threat to health and life, and
- the marketing of medicinal products that do not have marketing authorisation is subject to criminal sanctions.

You can read the full text of the announcement **here**.

MEDICAL PROFESSIONS

Act on access to psychological services for persons under 13 years of age adopted by Parliament

On 21 July 2025, an Act amending the Act on patient rights and the Patient Ombudsman and certain other acts was submitted to the President for signature. The Act's primary objective is to improve the standard of mental health care for children and young people, and to prevent related crisis situations.

The amendment introduces, among other things, the right for minors **who have reached the age of 16** to receive the following as part of guaranteed services:

- **psychological counselling**,
- **individual psychotherapy sessions**, provided in the form of crisis intervention (psychosocial assistance), or
- **psychosocial support sessions**

without the consent of a legal representative. For **patients under the age of 16 but who are over 13 years of age, the number of sessions and psychological consultations has been limited to 3**.

According to media reports, the act was referred by the President to the Constitutional Tribunal for preventive review.

You can read the entire Act **here**.

Support of the Supreme Medical Council for the 'Lex charlatan'

On 4 July 2025, No. 4/25/IX of the Supreme Medical Council (**'NRL'**) of 4 July 2025 was published on the draft act amending the Act on patient rights and the Patient Ombudsman and the Act on the emergency notification system. The draft concerns pseudo-medical practices; we wrote about its assumptions in the latest **issue of Life Sciences Monitor** [**link**].

The NRL expressed its support for the draft act, emphasising the dangerous and harmful nature of pseudo-medical practices to human health. However, the NRL also raised some reservations about the draft.

The doubts expressed in the NRL's position concern, among other things:

- **providing only an administrative model for combating pseudo-medical practices** which may be ineffective in practice,
- **the definition of pseudo-medical practice** referring to a person who does not practice a medical profession, instead of a person who is not authorised to practice it, and
- the lack of a definition of the grounds on which the Patient Ombudsman should base its decision to impose or not impose a financial penalty.

The NRL's position can be found **here**.

HEALTHCARE ENTITIES

Supply of free samples of medicinal products – amendments

On 22 July 2025, an amendment to the Pharmaceutical Law[3] came into force. The amendment introduces the possibility for a person authorised to issue prescriptions to request a sales representative or medical representative **to provide a free sample of a medicinal product also in a document form** (in addition to the existing written form).

You can read the entire act **here**.

Deregulation of the Pharmaceutical Law

On 25 July 2025, the Act of 24 June 2025 amending the Pharmaceutical Law came into force. The Act provides for the **removal of the obligation for the Responsible Entity** to send **information on the planned place of delivery of medicinal products** to the Integrated System for Monitoring the Circulation of Medicinal Products.

You can read the entire act **here**.

Changes in electronic medical records

On 26 July 2025, the Regulation of the Minister of Health of 9 July 2025 amending the regulation on types of electronic medical records came into force. Under the regulation, the **emergency medical procedures card** and the **air ambulance medical card** were added to the list of documents constituting electronic medical records.

You can read the entire regulation **here**.

Changes in the tasks of AOTMiT - draft regulation

On 28 August 2025, a draft regulation of the Minister of Health amending the regulation on the manner and procedures for preparing a verification analysis by the Agency for Health Technology Assessment and Tariff System, and the fee for this analysis, was published on the RCL website. The draft aims to align the amended regulation with Regulation (EU) 2021/2282 of the European Parliament and of the Council,[4] and the so-called law implementing common HTA[5]. **The draft introduces amendments to §2 of the amended regulation specifying the tasks of the Agency for Health Technology Assessment and Tariff System (AOTMiT) with regard to reimbursement applications for products that have no equivalent reimbursed in a given indication**.

You can read the entire draft **here**.

[3] *2 Act of 4 June 2025 amending the Pharmaceutical Law (Journal of Laws 2025, item 905).*
[4] *Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.*
[5] *Act of 25 July, 2025, amending the Act on the reimbursement of medicines, foodstuffs intended for particular nutritional uses, and medical devices, and the Act on healthcare services financed from public funds.*

FOOD

Changes to the list of mushrooms authorised for marketing

On 11 August 2025, a draft regulation of the Minister of Health amending the regulation on mushrooms authorised for marketing or the production of mushroom products, foodstuffs containing mushrooms, and the powers of mushroom classifiers and mushroom experts was published on the RCL website. The draft proposes to **remove Cordyceps militaris (L.) Link from the list of mushrooms approved for marketing, or the production of mushroom products and foodstuffs containing mushrooms**.

You can read the full text of the draft **here**.

Changes to the list of substances prohibited in food production – draft regulation

On 11 August 2025, a draft regulation of the Minister of Health amending the regulation on food additives was published on the RCL website. The draft proposes adding **celandine, goldenseal, swallow wort, and greater celandine (Chelidonium majus L.)** to the list of substances other than vitamins and minerals prohibited in food production.

You can read the full text of the draft **here**.

Draft regulation of the Minister of Health on cooperation between the State Sanitary Inspection authorities and customs authorities with regard to border sanitary controls

On 4 August 2025, a draft regulation of the Ministry of Health on cooperation between the State Sanitary Inspection authorities and customs authorities with regard to border sanitary controls was published on the RCL website.

The draft specifies, among others, the manner of cooperation between the State Sanitary Inspection authorities and customs authorities, as well as the rules of conduct in specified cases concerning food of non-animal origin imported from third countries, and materials and products intended to come into contact with food.

You can read the full text of the draft **here**.

ALCOHOLIC BEVERAGES

Increase in excise duty on alcohol – Ministry plans

On 21 August 2025, an announcement of a draft law amending the Excise Duty Act and the Personal Income Tax Act (UD289) was published in the List of Legislative and Program Works of the Council of Ministers.

According to the published assumptions of the draft, the proposed changes include, among others, **changes to the current roadmap of excise duty rates on alcoholic beverages, i.e. an increase in rates**:

- **in 2026 – 15%** compared to the 2025 rates, and
- **in 2027 – 10%** compared to 2026 rates.

You can read the entire draft **here**.

TOBACCO PRODUCTS

Entry into force of regulations governing the market for nicotine pouches and nicotine - free e-cigarettes

On 5 July 2025, the Act of 21 May 2025 amending the Act on protection of health against the consequences of using tobacco and tobacco products came into force, introducing changes to the nicotine pouch and nicotine-free electronic cigarettes market.

We wrote about the provisions of the Act in the previous issue of the Life Sciences Monitor [**link**].

The Act can be found **here**.

Jacek Myszko
Partner, attorney-at-law
+48 660 617 009
✉ jacek.myszko@skslegal.pl

Martyna Jakubiak
Associate, attorney-at-law
+48 698 173 297
✉ martyna.jakubiak@skslegal.pl

Zuzanna Osiej
Associate
+48 538 156 787
✉ zuzanna.osiej@skslegal.pl

SOŁTYSIŃSKI KAWECKI SZLĘZAK

Warszawa
Jasna 26, 00-054 Warszawa
T +48 22 608 70 00
F +48 22 608 70 70
E office@skslegal.pl

Katowice
Korfantego 138a, 40-156 Katowice
T +48 32 731 59 86
F +48 32 731 59 90
E office.katowice@skslegal.pl

Poznań
Mickiewicza 35, 60-837 Poznań
T +48 61 856 04 20
F +48 61 856 05 67
E office.poznan@skslegal.pl

www.skslegal.pl