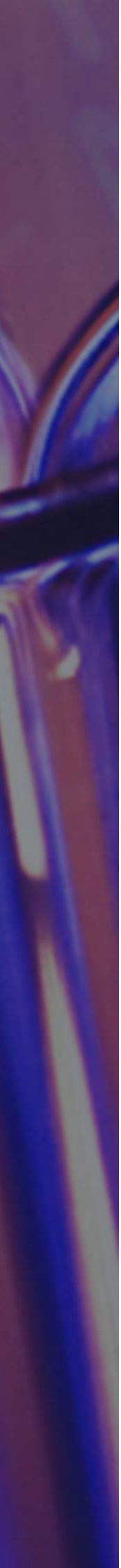
SOŁTYSIŃSKI KAWECKI SZLĘZAK

LIFE SCIENCES MONITOR

MAY AND JUNE 2025



MEDICAL PROFESSIONS

Qualified person - amendments to the Pharmaceutical Law

On 26 May 2025, a draft act amending Pharmaceutical Law was published on the website of the Government Legislation Centre ("**RCL**").

The draft act introduces **amendments to the provisions on a Qualified Person** (*PL:* "**Osoba Wykwalifikowana**" - *the person responsible for ensuring prior to marketing that each batch of a medicinal product has been manufactured and inspected in accordance with the provisions of the law and the requirements contained in the specifications and documents forming the basis for the issuance of marketing authorisation for that product*[1]).

The draft provides for simplifications in the educational requirements stipulated for a Qualified Person, to bring them in line with current regulations and eliminate practical restrictions on the ability to serve as a Qualified Person.

On 17 June 2025, the draft was submitted to the Polish Parliament. You can read the entire draft act here: **link**.

[1] *Art. 2 pkt. 21c ustawy z dnia 6 września 2001 r. Prawo farmaceutyczne.*

Practices violating collective patients' rights and pseudo-medical practices - draft act

On 16 June 2025, a draft act amending the Act on Patients' Rights and Patients' Rights Ombudsman and the Act on the Rescue Notification System was published on the RCL website.

The draft envisages, i.a. **amendments in proceedings concerning practices violating patients' collective rights**, for example, allowing the Ombudsman for Patients' Rights (**OPR**) to impose an obligation on an entity to eliminate the consequences of a violation of patients' collective rights, including where the entity refrains from such a violation.

The draft also provides for **an increase in the maximum amount of administrative fines** the OPR can impose - from **PLN 500,000** to **PLN 1,000,000** for a penalty imposed under Article 68 of the Act (i.e. failure of a healthcare provider or strike organiser to take action within a specified period of time, as specified in the decision declaring the practice to be in violation of patients' collective rights) and from **PLN 50,000** to **PLN 100,000** for a penalty referred to in Article 69 of the Act (i.e. failure to provide, at the request of the OPR, documents and information in proceedings on practices violating the collective patients' rights or in proceedings regarding compensation benefits).

The draft also provides for **provisions prohibiting so-called *pseudo-medical* practices**, introducing a definition of these practices, and the mechanisms that the OPR may apply when starting proceedings against them.

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

MEDICAL ENTITIES

National Cardiology Network

On 17 June 2025, the Act on the National Cardiology Network *(PL*: "**Krajowa Sieć Kardiologiczna**") ("**NCN**") was published in the Official Journal of Laws.

The NCN's establishment aims to, among other things:

- improve the organisation of cardiac care and improve the quality of treatment of cardiovascular diseases in Poland,
- ensure continuity of cardiac care, and
- create a new organisational structure and a new model for managing cardiac care and monitor its quality.

The Act sets out **the rules for the NCN's functioning and financing, monitoring the quality of cardiac care within the NCN, the functioning of the National Cardiology Council, and the management of cardiac care based on the electronic Cardiac Care Card**.

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

Draft act amending the Pharmaceutical Law

On 26 June 2025, yet another draft act amending the Pharmaceutical Law was forwarded for the President's signature.

The draft is an implementation of the government's deregulatory plans and envisages an amendment including **the exclusion of the obligation of the responsible entity to indicate to the Integrated System for Monitoring the Circulation of Medicinal Products** (*PL*: "**Zintegrowany System Monitorowania Obrotu Produktami Leczniczymi**") **information on the planned place of delivery of medicinal products intended for sale in the territory of Poland**.

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

Quality assurance system in tissue and cell banks - changes to the requirements

On 30 May 2025, a draft regulation amending the regulation on the requirements to be met by the quality assurance system in tissue and cell banks was published on the RCL website. The draft introduces changes regarding **the qualification of, among others, tissue donors with tattoos, piercings, or those having undergone procedures such as acupuncture or mesotherapy**.

The draft allows, among other things, the virological verification of donors with NAT or serological tests to exclude a HIV, HBV, or HCV infection. The purpose of the changes being introduced is, among other things, to improve the safety of recipients, in accordance with European guidelines.

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

Amendments to the Act on the Healthcare Information System

On 18 June 2025, a draft act amending the Act on the Healthcare Information System and certain other acts was published on the RCL website. The draft envisages the creation of **new information and communication domain systems: the e-Transplant System, the e-Hemophilia System, the System for Rare Diseases**, and the classification of the existing e-Blood System as a domain system, all of which constitute the Healthcare Information System.

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

MEDICINAL PRODUCTS

Ministry of Health draft regulation on the mail-order sales of medicinal products

On 13 June 2025, a draft regulation of the Minister of Health amending the regulation on the mail-order sales of medicinal products was published on the RCL website.

The draft aims to implement the Government's deregulation postulates and envisages changing and simplifying the catalogue of methods of placing orders for medicinal products offered by mail order by including the possibility of placing them "by means of electronic communication".

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

REIMBURSEMENT

Reimbursement - publication of the long-awaited draft act

On 22 May 2025, a draft act amending the Act on Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices, and certain other laws was published on the RCL website.

The draft act aims to improve the functioning of the reimbursement system by, among other things:

- **simplifying procedures related to the processing of reimbursement applications** (among other things, removing the obligation to provide evidence of the availability of a drug on the market at the time of submitting a reimbursement application),
- changing the definition of the responsible entity's representative (it no longer has to be a person with a residence or registered office in the Republic of Poland),
- simplifying and speeding up the reimbursement process for certain drugs in a foreign language packaging,
- allowing representatives of patient organisations to participate in price negotiations and coordinate team meetings in drug programs,
- modify and facilitate the reimbursement process for so-called orphan drugs,
- create a special IT functionality, **the Drug Policy Decision Support System** ("**SWDPL**").

You can read the entire draft act here: **link**.

PHARMACIES

Pharmacy advertising prohibition contrary to EU law - CJEU judgment

On 19 June 2025, the Court of Justice of the European Union ("CJEU") issued a judgment on Poland's prohibition on the advertising of pharmacies and pharmaceutical outlets under penalty of a fine (C-200/24), stating that the **introduction of the aforementioned prohibition is contrary to European Union law**.

The case concluded by the judgment was initiated by the European Commission and concerned Article 94a of the Act of 6 September 2001 Pharmaceutical Law prohibiting advertising of pharmacies and pharmaceutical outlets and their activities. Pursuant to the aforementioned regulation, information about the location and opening hours of a pharmacy or a pharmaceutical outlet does not constitute advertising. **The CJEU ruled that by introducing the aforementioned prohibition, the Republic of Poland had failed to fulfil its obligations under Article 8(1) of Directive 2000/31 and under Articles 49 TFEU (i.e. freedom of establishment) and 56 TFEU (i.e. freedom to provide services).** The introduction of the prohibition was also considered, among other things, to be **incompatible with the principle of proportionality**, as it "*goes beyond that which is necessary to attain the objective of protection of public health consisting in combating the overconsumption of medicinal products*".

You can read the entire CJEU judgement here: **link.**

FOOD

Changes in foodstuff labelling - draft regulation

On 7 May 2025, a draft regulation of the Minister of Agriculture and Rural Development amending the regulation on the labelling of different types of foodstuffs was published on the RCL website.

The draft is primarily aimed at ensuring compliance with EU law, and introduces amendments to the regulations on certain foodstuffs, including:

- **a clarification of the term "marmalade"** (PL: "**marmolada**") referring exclusively to a product made from citrus fruits, by adding the term "**from citrus fruits**" (PL: "**z owoców cytrusowych**"),
- for jams, jellies, and other products indicated in the regulation: **removing the obligation to indicate the sugar content of the ready-to-eat product** using the phrase "total sugar content .... g per 100 g of product" (PL: "**łączna zawartość cukru ... g na 100 g produktu**"),
- adding a new product category to the regulations: **reduced-sugar fruit juice, reduced-sugar fruit juice from concentrated fruit juice, concentrated reduced-sugar fruit juice**,
- introducing a requirement for the labelling of packaged honey from more than one country, **the names of the countries of origin with the percentage of honey originating from them, with a tolerance of ±5% for each share, placed in the main field of vision and listed in order of decreasing share of honey**.

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

Act on the commercial quality of agri-food products - further amendments

At the end of May, the RCL website updated the status of work on the draft act amending the Act on the commercial quality of agri-food products and certain other acts.

The amendment aims to **implement new EU regulations on the commercial quality of products in the fruit and vegetable sector, bananas and certain dried fruits**, as well as increase the effectiveness of supervision of agri-food products, particularly their commercial quality in production and marketing. The draft act also envisages clarifying the rules for inspections carried out in the relevant market by IJHARS.

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

FOOD

New Resolution of the Food Supplements Committee

On 7 May 2025, the Food Supplements Committee operating under the Sanitary and Epidemiological Council issued **an opinion on the requirements for the labelling of dietary supplements—as a method of use of the product—for the partitioning of tablets.**

You can read the opinion here: **link**.

Food for special medical purposes in CJEU case law - opinion of the Advocate General in the case C-315/24

The subject of the case was to determine whether:

i. **the product's energy value**, and

ii. **the amounts of the various nutrients**,

placed in addition to the mandatory nutrition declaration, can constitute an additional description of the properties and characteristics of a product within the meaning of Regulation 2016/128.

In an opinion submitted on 8 May 2025, the Advocate General concluded, among other things, that **energy and nutrient information provided in addition to the mandatory nutrition declaration cannot be qualified as an additional description of the properties and characteristics of a product.**

You can read the entire opinion here: **link**.

Products of animal origin – announcement on changes and a draft act

On 26 May 2025, an announcement about planned changes to the Act on products of animal origin was published. According to the announcement, the changes aim to allow uninterrupted business activity at animal food establishments supervised by the Veterinary Inspection authorities in the event of a change in the entity operating the establishment.

On 2 July 2025, a draft of the above-mentioned act was forwarded to the Parliament. The draft act provides for, among other things: **in the event that an establishment entered into the relevant register or list is sold or leased in its entirety to a specified entity, the rights and obligations arising from certain decisions related to it are transferred to that entity.**

You can read the announcement on the amendments here: **link**, the entire draft act here: **link**.

TOBACCO PRODUCTS

Amendment of the Tobacco Act regulating the nicotine pouches and nicotine-free e-cigarettes market published in the Journal of Laws

On 30 June 2025, the Act of May 21, 2025 amending the Act on Health Protection against the Consequences of Tobacco and Tobacco Products was published in the Official Journal of Laws.

Among other things, the act provides for the following regulations on nicotine pouches and nicotine-free e-cigarettes:

a) **prohibiting sales to persons under 18 years of age** and prohibiting distance sales (including online sales),

b) **prohibiting advertising and promotion,**

c) the obligation to report information to the President of the Bureau of Chemical Substances,

d) the need to **adapt the composition to the requirements of the Act** (e.g. prohibiting substances with CMR properties),

e) the requirement for **the appropriate labelling of product packaging**, including adding health warnings,

f) setting **the maximum nicotine content of nicotine pouches at 20 mg/g** and banning the use of ingredients in their production process that increase nicotine addictive properties.

The Act came into force on July 5, 2025. The act can be read here: **link**.

Further changes to the nicotine pouches and electronic cigarettes market

On 11 June 2025, another draft act amending the Act on Health Protection against the Consequences of Tobacco and Tobacco Products (UD 213) was published on the Government Legislation Centre's website.

The draft provides for, i.a.:

i. **prohibiting the marketing of single-use electronic cigarettes**;

ii. introducing, with certain exceptions, **a ban on the marketing of nicotine-containing products that are not tobacco products or related products** (*'wyroby powiązane'*)

iii. introducing **a ban on flavoured nicotine pouches; and**

iv. **amending the rules on the appearance of e-cigarette and nicotine pouches packaging** (i.a. the mandatory listing of all ingredients in the product, and a tobacco product identifier on the packaging of nicotine pouches. In addition, the packaging will not be allowed to contain any elements or have features that relate to taste, aroma, or flavourings).

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

[2] *Law of 9 November 1995 on health protection against the consequences of tobacco and tobacco products.*

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

Warsaw
Jasna 26, 00-054 Warsaw
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