SK&S Sołtysiński Kawecki Szlęzak

LIFE SCIENCES MONITOR

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Medicinal products / Clinical Trials / Medical Devices / Healthcare / Medical Professions / Biotechnology / Reimbursement / Pharmacies / Veterinary Medicine / Food Supplements / Cosmetics / Food / Alcoholic Beverages / Tobacco Products

HEALTHCARE ENTITIES AND MEDICAL PROFESSIONS

The 'Lex Charlatan' act - what's next?

On 20 August 2026, the President of Poland referred the Act of 31 July 2026 amending the Act on Patients' Rights and the Patients' Rights Ombudsman to the Constitutional Tribunal.

The Act aims to improve compliance with patients' rights and to counteract activities that are harmful and dangerous to human health and life. Above all, the Act introduces **a definition and a ban on pseudo-medical practices**, as well as the possibility of imposing a fine of up to PLN 1,000,000 on a healthcare provider or a natural person, a legal person, or an organizational unit without legal personality that engages in pseudo-medical practices.

The full text of the Act can be found here: link.

Changes to the remuneration and employment of healthcare workers - draft act

A draft act regulating the **rules for the employment and remuneration of medical staff providing healthcare services under contracts with the National Health Fund** ('**NFZ**') has been published on the RCL website. The draft aims to curb adverse trends in healthcare, primarily those linked to staff shortages, such as simultaneous employment with multiple healthcare providers or the uncontrolled rise in the cost of services. The changes proposed in the draft include, among others:

- introducing a limit on total working hours and a minimum working hours requirement for hospital and outpatient services;
- making the acceptance of further employment in the field of hospital care conditional upon the consent of the current manager of the healthcare provider, and
- introducing a maximum hourly rate of pay and a ban on linking remuneration to the amount received by the healthcare provider from the NFZ.

Once adopted, the draft is due to come into force 14 days after its publication.

The full text of the draft can be found here: link.

HEALTHCARE ENTITIES AND MEDICAL PROFESSIONS

Transparency in the procurement of healthcare services

A draft act amending the Act on Medical Practice concerning the provisions governing the award of contracts for healthcare services has been published on the RCL website. The draft act provides, among other things, for the introduction of an obligation to publish on a website and in a dedicated app:

- **the notice of a tender** and information on the entities whose tenders have been opened, as well as the prices or costs contained in the tenders, and
- **information about the entity awarded the contract** in cases where the contracting authority is not a public finance sector entity.

The full text of the draft can be found here: link.

Expansion of the scope of the central electronic registration - draft regulation

On 20 July 2026, a draft regulation amending the Regulation of the Minister of Health of 22 December 2025 on central electronic registration was published on the RCL website. The aim of the draft is to **extend the scope of healthcare services covered by the central electronic registration system to include further guaranteed services within the field of outpatient specialist care**.

It is planned **to gradually incorporate further types of services into the central electronic registration system**. The provisions introduced by the draft are to be implemented in stages; this is to allow for the changes to be announced sufficiently in advance and to ensure that healthcare providers, the NFZ, and the entity operating the ICT system have adequate time to make the necessary preparations to implement the new arrangements.

The full text of the draft can be found here: link.

Substitution Treatment - Ministry of Health Draft

On 17 July 2026, a draft regulation of the Minister of Health on substitution treatment was published on the RCL website. **The draft provides for the introduction of regulations concerning substitution treatment**, such as the procedures for dispensing, transport, storage, and documentation of the receipt and dispensing of medicinal products used in the substitution treatment program, as well as the conditions and methods for testing for the presence in urine or other bodily fluids of narcotic drugs or psychotropic substances other than those used in substitution treatment, or new psychoactive substances.

The full text of the draft can be found here: link.

MEDICINAL PRODUCTS AND MEDICAL DEVICES

A package of amendments to pharmaceutical legislation

On 23 July 2026, a draft act amending Pharmaceutical Law was published on the RCL website. The draft implements the government's deregulation proposals and introduces numerous changes to the regulations governing the pharmaceutical sector, including:

- standardizing the **rules for submitting and processing applications for the renewal of marketing authorizations for medicinal products** for human use, regardless of the procedure under which the medicinal product was granted a marketing authorization,
- introducing regulations under which an application for the renewal of a marketing authorization (excluding veterinary medicinal products) granted under the mutual recognition or decentralized procedure **is to be submitted using the electronic application form for renewal (eAF)**, available on the EMA website,
- clarifying the **educational requirements for candidates for the role of a 'Qualified Person'**, and
- amending the regulations allowing for the **revocation of a license to operate a public pharmacy**.

The full text of the draft can be found here: link.

Changes to the advertising of medicinal products directed at healthcare professionals

On 22 July 2026, amendments to the regulations concerning the **advertising of medicinal products to healthcare professionals** came into force. The amendments include the introduction, in the case of advertising directed at these professionals, of the possibility to provide certain information in two additional formats:

- in **electronic**, including on an electronic medium, and
- in the form of **a scannable code** (including a QR code or Data Matrix) containing a hyperlink or web address leading to a website or digital platform operated by the marketing authorization holder or an entity acting on its behalf, on which that entity has made the information available.

The full text of the draft can be found here: link.

FOOD AND ALCOHOLIC BEVERAGES

New regulations on the commercial quality of agri-food products

On 28 August 2026, the President of Poland signed the Act amending the Act on the commercial quality of agri-food products and certain other Acts.

The Act implements EU regulations with the aim of increasing the effectiveness of supervision over agri-food products. The Act introduces provisions clarifying the rules governing the conduct by the Agricultural and Foodstuffs Commercial Quality Inspectorate ('**IJHARS**') of commercial quality inspections of agricultural and foodstuffs, as well as proceedings conducted by IJHARS. The draft also significantly tightens the existing system of administrative penalties.

One of the most significant changes introduced by the Act is **the amendment to the definition of an adulterated agri-food product**. In addition to the existing cases (incorrect composition, false information on the label regarding the name, origin, use-by date, net content, or quality class), the new definition explicitly covers a product:

- **completely lacking the required labeling;**
- **incorrectly labeled with regard to variety or commercial type** (an expanded scope of false information).

The full text of the Act can be found here : link.

Geographical indications for agricultural products and beverages — draft amendment

On 8 July 2026, a draft act amending the Act on the registration and protection of designations of origin, geographical indications, and traditional specialties guaranteed for agricultural products and foodstuffs, wines, or spirit drinks, as well as on traditional products and certain other Acts, was published on the RCL website. The draft aims to bring national law into line with EU Regulation 2024/1143, which **harmonized the rules on registration, control, and protection for agricultural products, wines, and spirit drinks.**

The amended Act will enter into force 30 days after its publication.

The full text of the draft can be found here : link.

FOOD AND ALCOHOLIC BEVERAGES

New food labeling requirements

On 5 August 2026, a draft regulation by the Minister of Agriculture and Rural Development amending the Regulation on the labeling of specific types of foodstuffs was submitted for public consultation and feedback. The draft introduces significant changes for operators placing products on the market under their own brands.

The amendment aims to **establish a national obligation to indicate the actual manufacturer on food labeling**.

We reported on the changes being introduced to the regulation in SK&S Alert.

The full text of the draft can be found here : link.

New contaminant limits for hemp products

Under the Regulation of 28 July 2026, the European Commission introduced **new maximum levels of THC equivalent contamination in foodstuffs.**

In accordance with Regulation 2026/1828 amending Regulation (EU) 2023/915 with regard to the maximum permitted levels of delta-9-tetrahydrocannabinol (Δ9-THC):

- in hemp leaves intended for water infusion, the maximum permitted level will be **40 mg/kg,** and the product label will have to include additional information, and
- in ready-to-drink hemp leaves infusions, the maximum permitted level will be **0.02 mg/kg.**

The Regulation applies from 1 January 2027.

The full text of the Regulation can be found here: link.

Downsizing investigation - UOKiK checks how much chocolate is in chocolate

The President of the Office of Competition and Consumer Protection (‘**UOKiK**’) has launched an **investigation into the practices of chocolate manufacturers.**

Under Regulation 1169/2011, the entity responsible for food information is obliged to provide accurate information about products. Recently, a trend has been observed in the market whereby **the net weight of chocolate products has been reduced while the ‘old’ price has been retained.**

The President of UOKiK has decided to investigate whether companies are correctly communicating information about the reduction in the quantity of the products they offer, and whether their practices are misleading consumers.

More information can be found here: link.

SK&S Sołtysiński Kawecki Szlęzak

JACEK MYSZKO

Partner, attorney-at-law
jacek.myszko@skslegal.pl

KATARZYNA WÓJCIK-WELC

Associate, attorney-at-law
katarzyna.wojcik-welc@skslegal.pl

ZUZANNA OSIEJ

Associate
zuzanna.osiej@skslegal.pl