SOŁTYSIŃSKI KAWECKI SZLĘZAK

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HEALTHCARE ENTITIES AND MEDICAL PROFESSIONS

Changes to the procedure for accessing the records of an adopted child – draft regulation

On 12 March 2026, a draft regulation of the Minister of Health amending the Regulation on the types, scope, and formats of medical records and the manner of their processing was published on the Government Legislation Centre ("**RCL**") website.

The draft provides for, in the case of the full adoption of a newborn or a child, **the introduction of the possibility of issuing, at the request of the legal representative, an extract from the medical records indicating the newborn's or child's identification details resulting from the full adoption**. According to the explanatory memorandum to the draft, this change allows information regarding the child's former surname and the fact of their adoption to remain confidential, whilst safeguarding their health through access to archived medical records, constitutes a valuable source of information both about the patient and the healthcare services provided to them.

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

New organizational standards for teleradiology – amendments to the regulation

On 18 March 2026, a Regulation amending the Regulation on organizational standards for healthcare in the field of radiology and diagnostic imaging performed via ICT systems was published in the Journal of Laws. The regulation entered into force on 2 April 2026.

The amendment introduces a number of changes aimed at raising patient safety standards and improving teleradiology processes. Key changes include:

- **changes regarding safety when using contrast agents:** a radiological examination involving computed tomography or magnetic resonance imaging with the administration of a contrast agent must be carried out in a manner that ensures patient safety in the event of any complications arising after its administration. Furthermore, the assessment and description of the radiological examination must include information on complications following the administration of the contrast agent (if they occurred),
- **the expansion of the catalog of information provided with the referral:** the referring entity is obliged to send, via an ICT system, to the doctor performing the radiological service, the referral, information on the patient's state of health at the time the referral was sent, medical records, as well as information about any adverse events following the administration of a contrast agent, and
- **changes to the supervision of teleradiology services:** ongoing quality control of teleradiology services will also include supervision and monitoring of the service provider's compliance with the requirements set out in the regulations issued pursuant to Article 33zd(1) of the Atomic Energy Act, and the performance of operational tests on radiological equipment and ancillary equipment referred to in the regulations issued pursuant to that Act.

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

HEALTHCARE ENTITIES AND MEDICAL PROFESSIONS

Qualified Person and Competent Person - changes to the procedure for confirming requirements

On 25 March 2026, the Regulation of the Minister of Health of 6 March 2026 on the confirmation of the qualifications of a Qualified Person and a Competent Person came into force.

The Regulation specifies **the procedure for confirming compliance with the requirements referred to in the Pharmaceutical Law by a Qualified Person and a Competent Person**, as well as the documents confirming compliance with these requirements.

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

Flexible guaranteed services in the form of hospitalization care, elective hospitalization, and outpatient treatment – a draft regulation

On 24 March 2026, a draft regulation of the Minister of Health amending the Regulation on guaranteed services in the field of hospital treatment was published on the RCL website.

The draft stipulates that, in the case of guaranteed services in the form of hospitalization, planned hospitalization and day treatment**, these services may be provided through a flexible organization of service delivery if hospitalization, given the nature of the treatment, the patient will not remain in the hospital to receive this service for more than 12 hours from the time of admission**. However, the healthcare provider is obliged to ensure round-the-clock hospitalization in the event of complications or if it is required by the beneficiary's health condition. According to the explanatory memorandum to the draft, not all patients referred for hospitalization require a prolonged stay in hospital, but merely the assurance of access to equipment and medical staff whilst the healthcare service is being provided. The changes are intended to enable the effective and safe diagnosis and treatment of patients, whilst increasing cost-effectiveness and improving access to services.

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

MEDICINAL PRODUCTS

Mail-order sales of medicinal products – petition and GIF announcement

On 12 March 2026, **a statement regarding the obligation to comply with the rules governing the mail-order sale of medicinal products**, in which the authority restated the principles of the mail-order sale of OTC medicinal products, was published on the Chief Pharmaceutical Inspector ("**GIF**") website.

In the statement, GIF thus partially implemented the demands set out in a petition calling for supervisory action regarding the verification of transport standards for medicinal products in non-pharmacy and pharmacy trade conducted via mail-order sales, which was submitted to it in early 2026.

We wrote more about the petition and GIF's statement in our SK&S Legal Alert.

The full text of GIF's statement can be found here: link.

Psychotropic substances, narcotics, and new psychoactive substances

On 19 March 2026, a draft regulation by the Minister of Health amending the regulation on the list of psychotropic substances, narcotic drugs, and new psychoactive substances was published on the RCL website.

The draft proposes **amendments to the lists of psychotropic substances, narcotic drugs (including the addition of protonitazene, protonitazepine, and metonitazepine to Group I-N of the list of narcotic drugs), and new psychoactive substances (including the addition of Δ8-THCP and Δ9-THCP-O to the list).**

The changes are intended to address the rapid growth of the market for new psychoactive substances which pose a risk of poisoning, death, and the development of addiction.

The full draft can be found here: link.

MEDICAL DEVICES

Statement by the President of the URPL on the functionality of the EUDAMED database

On 6 March 2026, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("URPL") published a statement by the President of the URPL regarding the achievement of operational status by four modules of the European database on medical devices (EUDAMED) as of 27 November 2025, and the resulting obligations of economic operators.

In the announcement, the President of the URPL restated, amongst other things, that:

- On 27 November 2025, a decision was published in the Official Journal of the European Union **confirming the operational readiness and functionality of four modules of the EUDAMED database**, comprising: the electronic system for the registration of economic operators, the UDI database and the electronic system for the registration of devices, the electronic system for notified bodies and certificates, and the electronic system for market surveillance.
- **From 28 May 2026,** economic operators such as: medical device manufacturers, manufacturers of surgical systems and kits, authorized representatives and importers **are required to register in the EUDAMED database under the Actors module and obtain an SRN** (Single Registration Number). Until 27 May 2026, registration is possible but not mandatory.
- **Medical device manufacturers are required to enter information in the EUDAMED database in the UDI/Devices module: from 28 May 2026, to enter information on the medical devices they manufacture that comply with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, prior to their first placing on the EU market**, and by 27 November 2026, to publish information on the medical devices they manufacture which were placed on the EU market before 28 May 2026 and will remain on the EU market after 28 May 2026.

The full statement can be found here: link.

We also encourage you to read our SK&S Alert.

FOOD

Requirements for foodstuffs regarding residues of active substances in plant protection products – draft regulation

On 4 March 2026, **a draft regulation of the Minister of Health on the establishment of specific requirements for foodstuffs regarding residues of active substances in plant protection products** was published on the RCL website. The draft establishes specific requirements for foodstuffs regarding residues of active substances in plant protection products, as set out in the annex to the regulation. As an example, for products such as grapefruits, oranges and lemons: the maximum residue limit for carbendazim and benomyl (the sum of benomyl and carbendazim expressed as carbendazim) has been set at **0.01 mg/kg**.

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

New requirements regarding the commercial quality of potatoes

On 30 March 2026, the Regulation of the Minister of Agriculture and Rural Development of 23 March 2026 amending the Regulation on detailed requirements for the commercial quality of potatoes was published.

The amendment introduces a new quality category for potatoes, i.e., small early potatoes (small new potatoes) and small table potatoes. The changes to the regulation result from shifts in consumer preferences and an increase in demand for smaller-sized potatoes. The Regulation enters into force 30 days after its publication.

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

Update to the list of substances other than vitamins and minerals prohibited in food production

On 19 March 2026, the Regulation of the Minister of Health of 16 March 2026 amending the Regulation on fortifying substances added to food was published in the Journal of Laws.

The Regulation updates the list of substances other than vitamins and minerals prohibited in food production by adding **greater celandine, golden celandine, swallowwort, common celandine** (*Chelidonium majus L.*).

Foodstuffs containing greater celandine, golden celandine, swallowwort, common celandine (*Chelidonium majus L.*) placed on the market in the territory of the Republic of Poland prior to the date of entry into force of the Regulation may remain on the market for no longer than 30 days from the date of entry the Regulation.

The Regulation entered into force on 3 April 2026.

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

TOBACCO AND NICOTINE PRODUCTS

Draft Tobacco Act submitted to the Sejm

On 10 March 2026, **the Council of Ministers adopted a draft act amending the Act on the protection of health against the consequences of tobacco and tobacco products**. The draft was submitted to the Sejm on 11 March 2026, and on 18 March 2026 it was referred to the Parliamentary Committees for its first reading. The draft includes the following provisions: a ban on "flavored" nicotine pouches (allowing only pouches with ingredients that impart a tobacco smell or taste to remain on the market), changes to the labelling requirements for nicotine pouches, and a ban on the marketing of nicotine-containing products that are not: (i) tobacco products, or (ii) so-called "related products".

The draft also provides for a ban on single-use electronic cigarettes, both with and without nicotine.

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

(NON-)ALCOHOLIC BEVERAGES

Changes to the labelling of non-alcoholic beverages

On 18 March 2026, Regulation (EU) 2026/471 of the European Parliament and of the Council of 24 February 2026 amending Regulations (EU) No 1308/2013, (EU) No 251/2014 and (EU) 2021/2115 as regards certain market rules and sectoral support measures in the wine sector and for aromatized wine products and Regulation (EU) 2024/1143 as regards certain labelling rules for spirit drinks ("**Regulation**") formally came into force.

The Regulation introduces a number of changes in the area of wine sector products and aromatized wine sector products that have undergone total or partial dealcoholization treatment, including specifying the conditions for labelling and **designating these products as**:

a) ***alcohol-free*** - if the actual alcoholic strength of the product does not exceed 0.5% by volume; accompanied by the expression "0.0%", if the actual alcoholic strength of the product does not exceed 0.05% by volume or

b) ***reduced alcohol*** - if the actual alcohol content of the product is greater than 0.5% by volume and is at least 30% below the minimum actual alcohol content of products belonging to that category prior to dealcoholization.

You can read more about the changes in the non-alcoholic drinks market in our SK&S Legal Alert.

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

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This material has been prepared to inform SK&S' clients of certain significant changes in Polish law and does not constitute legal advice regarding the specific circumstances of any client and should not be treated by clients as such. If you have any questions regarding the legal issues outlined above and their potential impact on your business operations in Poland, please contact the lawyer handling your case.

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