

LIFE SCIENCES MONITOR

OCTOBER 2025

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HEALTHCARE ENTITIES

Draft act amending the Mental Health Protection Act and certain other acts

On 7 October 2025, a draft act amending the mental health protection act and certain other acts was published on the website of the Government Legislation Center ("RCL"). The draft provides for key changes to the Act of 19 August 1994 on Mental Health Protection including:

- **terminological changes**, i.a., replacing the term "mentally ill person" (showing psychotic disorders) with "person with psychotic disorders", and "mentally disabled person" with "person with intellectual disability",
- **changes in the provisions on the use of direct coercion**,
- the regulation of rules for subjecting people with mental disorders **to personal control**, and
- introducing provisions concerning the **installation of monitoring equipment in observation rooms**.

You can find the entire draft here: [link](#).

Draft act amending the Act on Medical Activity and certain other acts

On 9 October 2025, a draft act amending the Act on Medical Activity and certain other acts was published on the RCL website. The draft provides for the introduction of several organizational and administrative changes in the functioning of entities performing medical activities. The draft's main aim is to introduce regulations concerning procedures relating to births and deaths, as well as their proper documentation.

You can find the entire draft here: [link](#).

Changes in the healthcare organizational standard in the field of radiology and diagnostic imaging performed through ICT systems

On 7 October 2025, a draft regulation of the Minister of Health amending the regulation on healthcare organizational standards in the field of radiology and diagnostic imaging performed via ICT systems was published on the RCL website. The draft introduces changes to the current healthcare standards applicable in radiology and diagnostic imaging, including:

- changes in the **conditions necessary to perform teleradiology services**,
- introducing a **requirement for the presence of a physician and access to a rapid response team during the administration of a contrast agent to a patient**, and
- expanding the **list of cases in which teleradiology services are not performed**.

You can find the entire draft here: [link](#).



MEDICAL DEVICES

Changes to the regulation on medical records

On 29 October 2025, a draft regulation of the Minister of Health amending the regulation on the types, scope, and templates of medical records and the manner of their processing was published on the RCL website.

The draft aims to harmonize the current regulation's provisions regarding the information contained in medical documentation, such as referrals, in connection with the Act of 26 September 2025, amending the Act on healthcare services financed from public funds and certain other acts, recently passed by the Polish Parliament.

In addition, the draft addresses the issue of expanding the possibilities for storing digitized medical records, e.g., hospital treatment information cards.

You can find the entire draft here: [link](#).



URPL announcement on the advertising of medical devices

On 6 October 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("URPL") published a statement by the URPL President on the implementation of regulations concerning the advertising of medical devices. The announcement stated, as a reminder, that in accordance with the applicable regulations, the advertising of medical devices and products not intended for medical use, referred to in Regulation 2017/745,¹ addressed to the public, should:

- clearly state **who the manufacturer of the medical device is, and the authorized representative (if appointed)**,
- **specify the entity conducting the advertising**, and
- include the relevant **warning**.

This information should also ensure identification is available, i.e., clearly indicating the manufacturer, authorized representative, or advertising entity and their role. The URPL President also emphasized that **it is not sufficient to indicate only the name and surname or name of the entities without clearly specifying their role**.

You can find the entire announcement here: [link](#).

¹ Article 1(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002, and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

FOOD

Changes to harmonized standards for clothing and surgical dressings, medical masks, and sterilizers for medical purposes

On 20 October 2025, Commission Implementing Decision (EU) 2025/2078 of 17 October 2025 amending Implementing Decision (EU) 2021/1182 as regards harmonized standards for surgical clothing and drapes, medical face masks, and sterilizers for medical purposes came into force.

Based on the decision, **four new items have been added to the annex to Implementing Decision (EU) 2021/1182 - harmonized standards:**

- **EN 13795-1:2025**, surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns,
- **EN 13795-2:2025**, surgical clothing and drapes – Requirements and test methods – Part 2: Clean air suits,
- **EN 14683:2025**, medical face masks – Requirements and test methods, and
- **EN 14180:2025**, sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing.

You can find the entire decision here: [link](#).



Changes in permissible levels of inorganic arsenic

On 8 October 2025, Commission Regulation (EU) 2025/1891 of 17 September 2025 amending Regulation (EU) 2023/915 as regards maximum levels of inorganic arsenic in fish and other seafood, came into force.

Under the regulation, changes to the maximum levels of inorganic arsenic in various food products came into force, including in:

- muscle meat of the following fish: anglerfish, monkfish, and *Kathetostoma* (*Lophius species*; *Kathetostoma giganteum*), flatfish (*Pleuronectiformes species*), haddock (*Melanogrammus aeglefinus*), Atlantic herring (*Clupea species*), skates and rays (*Rajidae species*), and shark (all species) – **0.50 mg/kg**,
- crabs and crab-like crustaceans (*Brachyura* and *Anomura*), prawn, and shrimps (all species) – **0.10 mg/kg**,
- bivalve molluscs: scallops – **0.10 mg/kg**, other bivalves – **0.50 mg/kg**, and
- cephalopods – **0.050 mg/kg**.

You can find the entire regulation here: [link](#).

Ban on the use of animal product names for vegan products supported by the European Parliament

On 8 October 2025, the European Parliament voted in favor of changes to the existing food labeling rules and to introduce a ban on the use of animal product names for plant-based products. According to the planned changes, names such as "steak", "escalope", and "burger" are to be reserved exclusively for meat products. For the above-mentioned ban to come into force, it must undergo a legislative procedure in the European Union.

You can find the entire proposal here: [link](#).

ALCOHOLIC BEVERAGES

Amendments to the Act on Upbringing in Sobriety

In October 2025, the Ministry of Health published a **new version of the draft act amending the Act on Upbringing in Sobriety and Counteracting Alcoholism** and the Act on Healthcare Services Financed from Public Funds. Several key changes have been introduced to the existing draft, including:

- **changing the definition of an alcoholic beverage to *a liquid intended for human consumption containing ethyl alcohol of agricultural origin with an alcohol content exceeding 0.5% by volume*,**
- **introducing a total ban on the advertising and promotion of alcoholic beverages** (including beer),
- **banning the sale, serving, and consumption of alcoholic beverages at gas stations and medical facilities**, and in the premises of other facilities where health services are provided,
- **introducing a ban on the retail sale of alcoholic beverages intended for consumption outside the place of sale at a price not exceeding the amount of excise duty and goods and services tax due on them,**
- **changing the regulations concerning the distance sale of alcoholic beverages** (including the obligation to label beverages in a manner that allows them to be identified and to indicate the name and surname of the purchaser, or the requirement for the purchaser to collect the beverages), and
- **expanding the list of advertising and promotional activities subject to sanctions.**

You can read the entire draft here: [link](#).

PRODUCT SAFETY

European Parliament recommendations on the New Legislative Framework

On 21 October 2025, the European Parliament published its recommendations on upcoming changes to the New Legislative Framework ("NLF") regulating the product market in the European Union. The Parliament's recommendations include, i.a:

- **gradual implementation of the Digital Product Passport (DPP)** for all relevant products,
- **encouraging sustainable consumption** (so that changes to the NFR are consistent with other EU initiatives),
- **standardizing the definitions of "remanufacturers", "refurbishers", "repairers" and other emerging social and economic actors** to prevent their erroneous classification as manufacturers or importers, and to remove the risk of sanctions for non-compliance, and
- **enhancing the operational capacity and coordination of national and EU authorities.** The Parliament also calls on the Commission to consider introducing a mandatory "responsible person" in the EU for non-EU traders, to improve consumers' redress rights, as well as **establishing an EU market surveillance authority.**

You can read the recommendations here: [link](#).



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