SOŁTYSIŃSKI KAWECKI SZLĘZAK

LIFE SCIENCES MONITOR

NOVEMBER 2025

MEDICAL PROFESSIONS

Confirmation of the qualifications of Qualified Persons and Competent Persons – draft regulation

On 5 November 2025, a draft regulation on the confirmation of the qualifications of Qualified Persons and Competent Persons was published on the website of the Government Legislation Center (**RCL**). The regulation specifies **the manner in which Qualified Persons and Competent Persons confirm their compliance with the requirements referred to in Pharmaceutical Law.**

You can read the entire draft here: link.

PRODUCT SAFETY

Act on the supervision of general product safety

On 28 November 2025, the Act of 7 November 2025 on the Supervision of General Product Safety was submitted to the President for his signature. The Act implements Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety and introduces the rules and procedures for supervising general product safety.

The Act specifies, among other things, **the tasks of the President of the Office of Competition and Consumer Protection, the rules for conducting product inspections in terms of their compliance with general safety requirements at business entities, and the inspection of products offered for distance selling.**

You can read the entire Act here: link.

Guidelines on the regulation on general safety published

On 21 November 2025, the European Commission **published guidelines on the application of the EU general product safety legislative framework by businesses** (Regulation 2023/988 on general product safety, **GPSR**).

The guidelines answer many questions about the GPSR, including: (a) Which businesses are subject to the obligations under the GPSR? (b) What is a safe product? (c) What types of products and sales channels are covered by the GPSR and which are excluded?

The guidelines also clarify issues concerning economic operators such as manufacturers or importers.

You can read the guidelines here: link.

HEALTHCARE ENTITIES

Changes to the healthcare services financed from public funds

On 3 November 2025, a draft bill amending the Act on Healthcare Services Financed from Public Funds and certain other acts was published on the RCL website. The draft introduces changes to, among others, the Act on Healthcare Services Financed from Public Funds, the Act on the Social Insurance System, and the Act on Laboratory Medicine.

The amendments proposed in the draft include, among others, **replacing cross-border prescriptions with prescriptions entitling the holder to reimbursement**, and adapting the provisions to the judgment of the Court of Justice of the European Union C-777/18[1] **in the form of introducing the impossibility of refusing reimbursement of cross-border healthcare costs in a situation where the applicant did not submit an application to the President of the National Health Fund before going for treatment to another EEA or EU country, if this was justified by his or her state of health**, i.e., it resulted from the need for immediate treatment. The draft also introduces changes adapting the provisions to EU law regarding **consent to treatment in another EU or EFTA member state**.

You can read the entire draft here: link.

Draft regulation of the Minister of Health amending the regulation on the organizational standard of healthcare in the field of anesthesiology and intensive care – extension of the deadline

On 21 November 2025, a draft regulation of the Minister of Health amending the regulation on the organizational standard of healthcare in the field of anesthesiology and intensive care was published on the RCL website. The draft proposes **extending the deadline for compliance with the requirements set out in the regulation concerning the separation of anesthesiology and intensive care wards for adults and children by one year, i.e., from 31 December 2025 to 31 December 2026.**

You can read the entire draft here: link.

MEDICAL DEVICES

European Commission decision on the functionality of the EUDAMED database

On 27 November 2025, a decision on the functionality of the electronic systems belonging to the European database on medical devices (**EUDAMED**) was published in the Official Journal of the European Union.

We wrote about the changes related to the publication of the decision in more detail, which you can find in our SKS Legal Alert.

[1] *Judgment of the Court of Justice of the European Union of 23 September 2020, in case C-777/18.*

FOOD SUPPLEMENTS

Changes to the list of vitamins and minerals used in supplements

On 26 November 2025, an amendment to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002, on the approximation of the laws of Member States relating to food supplements, came into force. The amendment consists in adding **magnesium L-threonate** and **monosodium salt of L-5-methyltetrahydrofolic acid** to the list of vitamins and minerals that may be used in the manufacture of food supplements.

You can read the entire text of the regulations amending the Directive here: link, link.

FOOD

Labeling of certain groups and types of packaged agri-food products or agri-food products without packaging not intended directly for the final consumer – draft regulation

On 12 November 2025, a draft regulation of the Minister of Agriculture and Rural Development amending the regulation on the detailed scope and method of labeling certain groups and types of packaged agri-food products or unpackaged agri-food products not intended directly for the final consumer was published on the RCL website. The draft adapts the provisions to European Union law, in particular, Directive (EU) 2024/1438 of the European Parliament and of the Council of 14 May 2024 and **excludes the possibility of placing the term "filtered honey" on containers for transporting honey in bulk, packaging, or commercial documents**.

You can read the entire draft here: link.

Amendments to the regulation on specific requirements for the commercial quality of honey

On 12 November 2025, a draft regulation of the Minister of Agriculture and Rural Development amending the regulation on specific requirements for the commercial quality of honey was published on the RCL website. The draft adapts provisions to European Union law, in particular, Directive (EU) 2024/1438 of the European Parliament and of the Council of 14 May 2024, and **provides for the exclusion of filtered honey from the main types of honey, depending on the method of extraction or packaging.**

You can read the entire draft here: link.

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

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