SOŁTYSIŃSKI KAWECKI SZLĘZAK

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MEDICAL DEVICES

Changes to the MDR and IVDR

On 6 December 2025, the European Commission published **a** comprehensive **draft amendment to Regulation 2017/745** ("**MDR**") and **Regulation 2017/746** ("**IVDR**").

The draft provides for several significant changes, which are primarily intended to simplify the current regulations governing the medical device market. The changes proposed in the draft include adapting the regulations to the developing market **of AI medical devices** and **supporting the digitization process**, for example, by allowing electronic instructions for use.

You can read the entire draft here: link.

BIOTECHNOLOGY

Draft Biotechnology Act

On 16 December 2025, the European Commission published the **draft European Biotech Act**. The draft aims to establish a framework to strengthen the competitiveness of the medical biotechnology sector and to create conditions for the development of biotechnology while maintaining high standards in the areas of human health, animal health, patient and consumer protection, the environment, ethics, quality, food and feed safety, and biosafety. The draft introduces provisions on **the implementation and use of AI in the life cycle of a medicinal product**.

You can read the entire draft here: link.

PHARMACIES

Changes to the ban on advertising pharmacies – draft act

On 12 December 2025, **a draft act amending Pharmaceutical Law** was published on the website of the Government Legislation Center ("**RCL**"). The draft is intended to bring Polish regulations into line with the requirements of the CJEU ruling, according to which a **total ban on advertising pharmacies violates European Union law**, and therefore an amendment to Article 94a of the Pharmaceutical Law is required. The draft introduces **of restrictions on the advertising of pharmacies**, including that advertising may not:

i. consist of **offering, directly or indirectly, any benefit** in exchange for the purchase of a product available in a pharmacy;

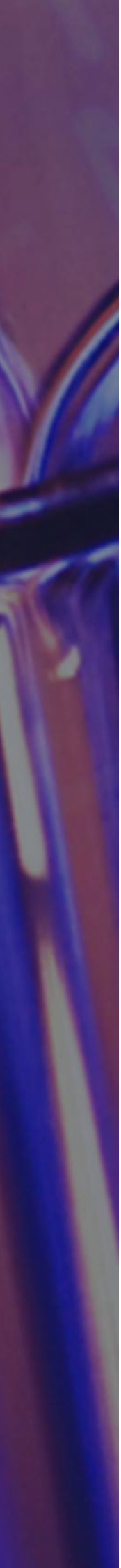
ii. constitute **comparative advertising**;

iii. be **directed at children or young people** under the age of 18;

iv. be **misleading,** or;

v. violate **professional secrecy or the rules of** professional **ethics** and deontology binding on pharmacists.

You can read the entire draft here: link.



MEDICAL ENTITIES

Medical documentation

On 23 December 2025, a regulation amending **the regulation on the types, scope, and templates of medical documentation and the manner of its processing** was published in the Journal of Laws.

The regulation is intended **to harmonize the provisions of the current 2020 regulation 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, passed by the Sejm. In addition, the draft addresses the issue **of expanding the possibilities for storing digitized medical records, such as hospital treatment information cards**.

You can read the entire regulation here: link.

PRODUCT SAFETY

Act on the Supervision of General Product Safety comes into force

On 19 December 2025, **the Act of 7 November 2025, on the Supervision of General Product Safety** was published in the Journal of Laws. 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 compliance with general safety requirements** at business entities, and **the inspection of products offered for distance sales.**

You can read the entire act here: link.

New regulation on toy safety

On 12 December 2025, **Regulation (EU) 2025/2509 of the European Parliament and of the Council of 26 November, 2025, on Toy Safety** was published in the EU Official Journal. The regulation lays down essential safety requirements for toys, these are intended to ensure a high level of protection of the health and safety of children when playing with toys, as well as to ensure the free movement of toys within the EU.

The Regulation will, in principle, apply **from 1 August 2030,** with certain exceptions, including the notification of conformity assessment bodies, which will apply from 1 January 2026.

You can read the entire regulation here: link.

TOBACCO PRODUCTS

Changes to the excise duty on e-cigarettes – draft act

On 22 December 2025, **a draft act amending the Excise Duty Act** was published on the RCL website.

The draft is intended to take into account the specific nature of **e-cigarettes operating based on electromagnetic induction** and extands the definition of disposable and reusable e-cigarettes in this respect.

You can read the entire draft here: link.

FOOD

Changes to the list of mushrooms approved for sale

On 17 December 2025, a regulation of the Minister of Health amending the regulation on mushrooms approved for marketing or production of mushroom products, foodstuffs containing mushrooms, and the qualifications of mushroom classifiers and mushroom experts was published in the Journal of Laws. The draft provides for the removal of **Cordyceps militaris** from the list of mushrooms approved for marketing or production of mushroom products and foodstuffs containing mushrooms.

You can read the entire regulation here: link.

Conditions of use in dietary supplements of preparations from the plant Artemisia absinthium L.

The Dietary Supplements Group (PL: Zespół ds. Suplementów Diety) has established the **conditions for the use of preparations from the herb *Artemisia absinthium*** in dietary supplements, including:

a) **quantity** - less than 2 g of powdered Artemisia absinthium herb in the recommended daily dose of the product; or its equivalent in several single doses throughout the day, and the thujone content in the daily dose should be less than 1.5 mg,

b) **warnings on the packaging**, including: *„not for use by children, pregnant women, or during lactation„ and "do not use for more than 2 weeks."*

You can read the entire text 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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