SOŁTYSIŃSKI KAWECKI SZLĘZAK

LIFE SCIENCES MONITOR

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MEDICINAL PRODUCTS

Joint clinical assessment - new rules for health technology assessment under the HTA Regulation

On 12 January 2025, the first of the transitional periods of Regulation 2021/2282 of 15 December 2021 on health technology assessment ("**HTA Regulation**")[1] ended. Health technology assessment is to be divided into clinical (so-called joint clinical assessment) and non-clinical aspects.

The first products for which the new health technology assessment rules started to apply from 12 January are:

- **medicinal products** to be placed on the market **containing a new active substance with an indication for the treatment of cancer**; and
- *advanced therapy medicinal products* (ATMP), **consisting of cell therapy, gene therapy and tissue engineering products**.

With further transitional periods, the application of the HTA Regulation will be extended to further product groups: certain medical devices, orphan drugs and other medical technologies.

The changes aim to unify the ongoing health technology assessment procedures across the EU, reduce the costs incurred by manufacturers of innovative health technologies in bringing them to the market, speed up the processes of making them available on the market, and, as a consequence, increase the patients' access to new medical technologies.

The full text of the HTA Regulation can be accessed at the following: **link**.

[1] *Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.*

Generating of QR codes for educational material on medicinal products

On 28 January 2025, a notice was published on the website of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (PL: *Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*, "**the President of the Office**") regarding the introduction of a new function in the Register of Medicinal Products in the area of educational materials.

According to the information - a new option is to enable generating QR codes directly using the URL provided in the system source file. The generated QR codes are to lead directly to official leaflets, brochures of medicines made available in the Register of Medicinal Products. This amendment is intended to provide quick and verified access to official drug information for patients as well as for the medical staff.

The information of the President of the Office can be accessed at the following: **link**.

MEDICAL DEVICES

The commencement of the application of obligation to notify the anticipated interruption or suspension of the supply of medical devices

On 10 January 2025, the **obligation to provide information on interruptions or suspensions of medical devices** introduced by Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746[2] started to apply.

According to the regulation, the obligations arise when **it is reasonably foreseeable that an interruption or suspension of supply could cause serious harm or a risk of serious harm to patients or public health** in one or more member states.

Information on interruption or suspension:

- **the manufacturer** must provide at least **six months'** notice of any anticipated interruption of supply or anticipated suspension of supply. The manufacturer must also specify the reasons for the interruption of supply;
- **other economic operators** who have received information from the manufacturer or from another economic operator are obliged to notify, **without undue delay**, all other economic operators, public health institutions and health professionals to whom they directly supply the product of an anticipated interruption or suspension of supply.

The full text of the regulation can be accessed at the following: **link**.

[2]*Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 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 and Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards the phased implementation of the Eudamed database, the information obligation in case of interruption or suspension of supply and the transitional provisions for certain in vitro diagnostic medical devices. Text with EEA relevance (OJ EU. L. 2024, item 1860).*

Amendments to the IT systems collecting data on operators and products

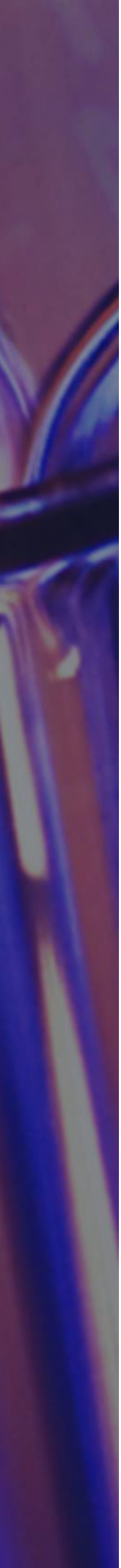
On 1 January 2025, new functionalities were implemented in the following IT systems:

- system constituting a list of distributors of products, systems or treatment kits [**link**],
- system that collects information on devices, systems and treatment kits brought into the territory of the Republic of Poland by entities and persons carrying out therapeutic activity and other entities that use the devices in the course of their economic or professional activity [**link**].

Functionalities introduced include:

1. **downloading confirmation of the data entered into the system;**
2. **creation of accounts for additional users**.

The Information of the President of the Office can be accessed at the following: **link**.



PHARMACIES

Information on processing of personal data of pharmacy customers selling medicinal products over the internet

On 30 January 2025, the website of the Chief Pharmaceutical Inspectorate (PL*: Główny Inspektor Farmaceutyczny*) published an *Information on the processing of customers' personal data by entrepreneurs running pharmacies selling medicinal products via websites in connection with the CJEU judgment in the case C-21/23 Lindenapotheke*.

According to the Information, as a consequence of the above-mentioned CJEU judgment, which 'broadened the definition' of data concerning health by including certain information entered by pharmacy customers when placing an online order, **new obligations may arise on the part of businesses selling medicinal products online**, including: (**i**) the content of information clauses to be displayed on websites when placing orders, (**ii**) obtaining the explicit consent of customers ordering medicines to the processing of personal data, or (**iii**) personal data protection documentation.

The full Information can be accessed at the following: **link**.

CLINICAL TRIALS

Clinical Trials Information System

On 31 January 2025, the full implementation of the use of the Clinical *Trial Information* System (**CTIS**) started. Under the Regulation 536/2014, the use of the system for the registration of new clinical trial applications in the EU and EEA area was mandatory from 31 January 2023.

Currently, all clinical trials that are currently ongoing must be registered in CTIS. This also means that clinical trials in progress must be transferred/registered in CTIS.

The CTIS database can be accessed via the following: **link**.

New Guideline on Good Clinical Practice

On 27 January 2025, a new version of the Guideline for good clinical practice (ICH E6 R3) was published on the European Medicines Agency's website, setting the standard for conducting clinical trials involving human participants.

Amongst other things, the Guideline aim to ensure the safety, respect for the rights and welfare of participants. Changes introduced by the new Guideline include the development of Good Clinical Practice principles or the introduction of rules for data management by the investigator and sponsor.

The Guideline will enter into force on 23 July and can already be accessed at the following: **link**.

MEDICAL PROFESSIONS AND MEDICAL ENTITIES

Amendments to the Code of Medical Ethics - Artificial intelligence, advertising rules, social media activity

On 1 January 2025, the amended Code of Medical Ethics (PL: *Kodeks Etyki Lekarskiej*, KEL) entered into force. This is the first time in more than 20 years that the codified rules of professional ethics for doctors and dentists have undergone such significant modifications.

The amendment introduced a wide range of changes, some of which include:

- specifying the conditions for **the use of artificial intelligence (AI) by doctors -** such as: (i) the patient is adequately informed and informed consent is obtained for the use of AI; (ii) AI algorithms are approved for medical use and certified; (iii) the doctor makes the final diagnostic and therapeutic decision each time,
- amendments to **the rules on advertising of medical activities** - as of 1 January, doctors may, provided that they comply with the principles of medical ethics, provide information regarding the services offered, i.e. any form of communication aimed at disseminating the image of the doctor or services related to the exercise of the profession. However, it is not permissible to use the doctor's authority to promote services unrelated to his or her profession,
- the introduction of other regulations, such as those concerning: **doctors' activity on the internet and social media**, the possibility for a doctor to express **substantive criticism**, **patient consent** or the introduction of the concepts of ‚**online consultation**' and '**futile therapy**' into the new regulation.

The full text of the amendment to the Code of Medical Ethics can be accessed at the following: **link**.

Amendment of the Act on healthcare services financed from public funds

On 28 January 2025 The President of the Republic of Poland signed an amendment to the Act on healthcare services financed from public funds.

The amendment to the Act expands the circle of entities authorised to issue prescriptions for the free supply of medicines, foodstuffs for special nutritional purposes and medical devices to which children and seniors are entitled to include any *'authorised person'*[3] including those with the right to practice a profession, who has ceased to do so (e.g. retired doctors) and issues a prescription for themselves or their family. This means that **doctors in private practice will also be authorised to issue prescriptions for the above products.**

The Act will enter into force on 14 February 2025 and can be accessed at the following: **link**.

Medical Centre with Data Protection Authority fine - hidden monitoring in the neonatology department

17 January 2025. The President of the Office for the Protection of Personal Data (PL: *Prezes Urzędu Ochrony Danych Osobowych*) has issued a decision imposing **two administrative fines on one of Kraków's healthcare entities**.

In two rooms of the fined entity's neonatology department**, hidden video monitoring** was installed **in wall clocks** in contravention of the regulations. The authority further indicated that technical and organisational measures corresponding to the risk for the data processed on the memory cards that were in the above-mentioned monitoring devices had not been applied. A total fine of **PLN1,145,891** was imposed on the medical entity.

The decision can be accessed at the following: **link**.

[3] *I.e. a person holding a licence to practise a medical profession who, on the basis of the regulations governing the practice of the medical profession concerned, is authorised to issue prescriptions in accordance with the Act and the Act of 6 September 2001. - Pharmaceutical Law and orders for the supply of medical devices.*

ALCOHOLIC BEVERAGES

Amendments to packaging of spirit drinks up to 200 millilitres

On 30 January 2025, the Regulation of the Minister of Agriculture and Rural Development of 28 January 2025 on specific requirements for the commercial quality of packaging of certain spirit drinks entered into force, which **introduces requirements for unit packaging of spirit drinks with a nominal volume of up to 200ml** (hereinafter: '**spirit drinks**').

According to the regulation, spirit drinks can be placed on the market **either in bottles or in cans** and their labelling:

- **must not be questionable or misleading** in terms of identification;
- **makes it possible to distinguish spirit drinks from other foodstuffs**, in particular from foodstuffs intended for children.

Spirit drinks placed on the market in accordance with the provisions in force in another EU Member State, Turkey or originating in and placed on the market in accordance with the provisions in force in an EFTA Member State which is a party to the Agreement on the European Economic Area, **shall be deemed to meet the requirements of the Regulation insofar as they comply with the labelling requirements therein.**

Spirits in packaging up to 200ml other than bottles or cans placed on the market before the Regulation entered into force **may remain on the market for 30 days after the Regulation entered into force.**

You can read the full regulation at the following: **link**.

TOBACCO PRODUCTS

Pending changes in the tobacco and nicotine industry: nicotine-free e-cigarettes, nicotine pouches and a flavour ban

On 31 January 2025, two government **draft acts on amending the Act on health protection against the consequences of tobacco and tobacco products** were referred to the Parliamentary Health Committee for the first reading**.**

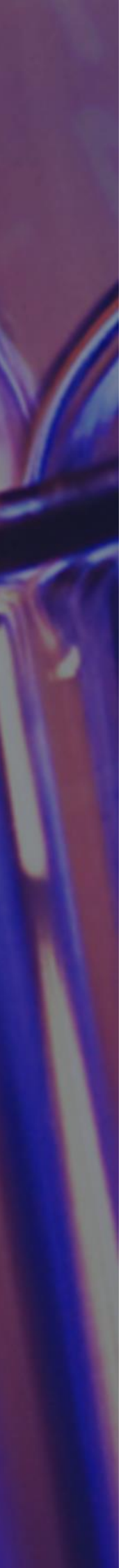
1. **The first of the drafts** (print **983**) [**link**] envisages the introduction of, among other things, the following regulations for nicotine-free e-cigarettes and nicotine pouches:

a) a ban on sales to persons 18 years of age and a ban on distance selling (including online);
b) a ban on advertising and promotion;
c) obligation to report information to the President of the Bureau for Chemical Substance;
d) the need to adapt the composition to the requirements of the Act (e.g. prohibition of substances with CMR properties);
e) a requirement for product packaging to be appropriately labelled, including appropriate health warnings.

For nicotine pouches, the draft also proposes the introduction of a maximum nicotine content of **20 mg/g** and a ban on the use of ingredients in the manufacturing process that increase the addictive properties of nicotine[4]

2. **The second draft** (print **982**) [**link**] envisages the establishment of regulations **prohibiting the marketing of heated tobacco products with characterising flavour**. It is worth recalling that the draft is the result of the obligation to implement European Union law, i.e.: Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.

[4] The draft amendment to the Act was notified to the European Commission on 27 January 2025, due to the obligation under Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and rules on information society services.



FOOD

Ban on the use of Bisphenol A in certain materials and articles intended to come into contact with food

On 20 January 2025, Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A and other bisphenols and bisphenol derivatives with a harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food entered into force.

The regulation introduces, among other things:

- **prohibition of the use of Bisphenol A (BPA)** and its salts and other hazardous bisphenols and their derivatives in the manufacture of food contact materials and articles,
- **prohibition of placing on the EU market of food contact materials and articles manufactured using BPA** and and the placing on the market of food contact materials and articles manufactured using hazardous bisphenols other than BPA or hazardous bisphenol derivatives.

The regulation also provides for exceptions to the aforementioned prohibitions.

The full text of the regulation can be accessed at the following: **link**.

Upcoming regulations on packaging

On 22 January 2025, the Official Journal of the European Union published Regulation (EU) 2025/40 of the European Parliament and of the Council on packaging and packaging waste (the so-called '**PPWR Regulation**')[5].

The new regulations will cover most (with some exceptions) of the packaging on the market. Among the regulations introduced by the PPWR are:

- new requirements to manufacture packaging placed on the market in a way that minimises the presence and concentration of substances of concern as components of packaging materials or any packaging components;
- the introduction of a minimum content of recycled material in plastic packaging;
- labelling requirements for packaging (including environmental claims);
- obligations of economic operators to reduce packaging and packaging waste (including ensuring a maximum void ratio in packaging).

The regulation will enter into force on 11 February, but the application of most of the regulations established will begin in 2026.

The full text of the regulation can be accessed at the following: **link**.

[5] Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repealing Directive 94/62/EC.

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