SOŁTYSIŃSKI KAWECKI SZLĘZAK

# LIFE SCIENCES MONITOR

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# MEDICINAL PRODUCTS

## European Platform for Monitoring Shortages

On February 2, 2025, **the mandatory use of the European *Shortages Monitoring Platform*** "**ESMP**"), which was launched by the European Medicines "**EMA**"), **came into** force[1]. One of the main goals of establishing the platform is to attempt to address drug shortages (resolve the problem of medicine shortages) in the European Union ("**EU**").

According to EMA announcements, the first full version of the platform was made available on 29 January 2025, changes effective as of February 2, 2025 include, among others: the introduction of an obligation for responsible entities to use the platform to report data on shortages of authorized medicinal products based on a central authorization under regular circumstances, as well as the obligation to report data on the supply and availability of medicinal products in specific situations.

Authorities' announcements on the functioning of ESMP can be found at following: **link**, **link**. **ESMP** is available here: **link**.

## Advertising campaigns for prescription drugs – the latest CJEU ruling C-517/23

In February 2025, the Court of Justice of the European Union ("**CJEU**") ruled in the case of a Dutch mail-order pharmacy concerning it's discount campaigns for German customers related to the sale of prescription drugs.

Among the activities the pharmacy conducted were:

- offering a **reduction of prices and payments of an exact amount** for unspecified prescription drugs,
- offering gratuities ranging from **€2.50 to €20**, which involved payment, but the exact amount was not known in advance, and
- offering **vouchers for the future purchase of other products** (including OTC drugs and health and care products), in connection with the purchase of prescription drug products.

According to the CJEU, the "**Medicines Directive**"[2] does not preclude the prohibition under German national law of advertising campaigns in the form of offering vouchers for the future purchase of other products (OTC medicines as well as health and care products).

The CJEU held that since the consumer can choose between purchasing OTC medicinal products and purchasing other products, such as health and care products, **shopping vouchers equalize OTC medicinal products with the aforementioned other products, thus dissuading the consumer from objectively assessing the need to take these medicinal products.**

More information on the case can be found here: **link**.

*[1] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.*

*[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.*

# MEDICAL DEVICES

## Update of the EMA Q&A on medical devices

On February 5, 2025, a new version of the Q&A on medical devices was published on the EMA website[4]. The updated document answers further questions related to the practical implementation of Regulation 2017/745 and 2017/746 ("**MDR Regulation**"[5], "**IVDR Regulation**"[6]).

The amendments in the published document cover, among other things, selected issues related to medicinal products that contain an iDDC medical device as an integral part, including issues related to marketing authorization applications, opinions of notified bodies or declarations of conformity.

The full content of the updated Q&A can be found here: **link**.

*[4] Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746).*
*[5] 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*
*[6] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance).*

# HEALTHCARE

## Draft act to amend the Act on the Healthcare Information System

On February 10, 2025, in the Council of Ministers' List of Legislative and Programme Works, an announcement of **a draft act amending the Act on the Health Care Information System** was published**.**

The aim of the amendment is to introduce a system of **Provider Potential Records** (PL: **System Ewidencji Potencjału Świadczeniodawcy** ,**EPS**'), enabling real-time monitoring of the potential of providers performing hospital services treatment activities.

The EPS is also to eventually collect data on, among other things: a total or partial inability to provide health care services due to force majeure or reasons on the service provider's part. **This information is to be automatically distributed to all entities performing tasks of overseeing the operation of the health care and crisis management systems.**

The EPS is to enable authorities to monitor on an ongoing basis, among other things: the infrastructure of facilities related to the provision of health care services, medical gas resources, or the accessibility of:

1) medical workers,
2) hospital beds,
3) medical devices (key medical equipment, e.g., CT, MRI, X-ray, ultrasound, ventilators), and
4) personal protective equipment.

The Council of Ministers is planned to accept the draft in the second quarter of 2025. The objectives of the project and information on the reasons and need for the solutions it sets out can be found here: **link**.

# MEDICAL PROFESSIONS AND MEDICAL ENTITIES

## Position of the Supreme Pharmaceutical Council regarding amendments to the Act on health care services financed from public funds

On February 14, 2025, an amendment on the Act on health care services financed from public funds went into effect. You can read more about the amendment in the last issue of **Life Sciences Monitor** [link].

The amendment expands the catalog of entities (among others by physicians in private practice) authorized to issue prescriptions for the free supply of drugs, foodstuffs for particular nutritional uses and medical devices which children and seniors are entitled to. The draft also introduces amendments to pharmaceutical prescriptions.

In connection with the entry into force of the new regulations, the Supreme Pharmacy Council (PL: **Naczelna Rada Aptekarska**, **‚NRA'**) has issued it's position on charging fees for issuing a pharmaceutical prescription for a reimbursable immunological product necessary for a recommended vaccination in a pharmacy.

The NRA is of the opinion that if **pharmacies charge for issuing a pharmaceutical prescription for a reimbursable immunological product necessary for publicly funded vaccinations at the pharmacy,** this activity is very likely to be **challenged by the National Health Fund** (**‚NHF'**).

At the same time, in the position, NRA pointed out that in **the case of vaccinations that are not publicly funded and are not covered by contracts with the NHF, there are no clear regulations that could exclude the possibility of charging such fees**.

The content of the Act can be read here: **link**, the content of the NRA communiqué is available here: **link**.

## ‚Receptomat' vs. suspension of the right to practice - final decisions of the Supreme Medical Court

This February, an information regarding the publication of two final rulings by the Supreme Medical Court (PL: **Naczelny Sąd Lekarski**, **‚NSL'**) **in connection with the activities of *‚receptomaty'*** (systems for online e-prescription dispensing without the need for physical medical consultation) was published.

In each of the cases, the NSL found that the doctors' behavior fulfilled the prerequisites for professional misconduct under Article 53 of the Law on Medical Chambers[7].

The first case involved allegations of prescribing an opioid painkiller without first examining and analyzing patients' medical records. The NSL imposed **a penalty of suspension of the right to practice medicine for two years**.

The second case involved a doctor who was charged with issuing a significant number of prescriptions via teleinformatic systems during a period that made it impossible to review patients' reported ailments or medical records. The NSL concluded that the case also involved professional misconduct, and consequently imposed a penalty of suspension of the right to practice **medicine for two years and a fine of more than PLN 30,000. The fine is to be donated to the hospice.**

More information on the rulings can be found here: **link**.

[7] *Article 53 of the Act of December 2, 2009 on Medical Chambers - Members of medical chambers are subject to professional liability for violations of the rules of medical ethics and regulations related to the practice of the medical profession,"professional misconduct."*

# CLINICAL TRIALS

## Draft regulations on the profession of psychotherapist

On February 11, 2025, a parliamentary draft act on the profession of a psychotherapist and professional self-government was submitted, which provides, among other things:

- introducing of definitions of the terms ***psychotherapist*** and ***trainee psychotherapist***,
- **granting the psychotherapist profession the status of a profession of public trust**,
- introducing of regulations on the **professional secrecy of psychotherapists**,
- establishing **a professional self-government of psychotherapists**,
- defining **the rules for the practice of the profession of psychotherapist** with the establishment of rules for their **disciplinary responsibility**,
- creating of an appropriate **system to regulate and standardize the accreditation process of** training entities and examination centers for psychotherapists.

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

## New EMA Q&A - clinical trials clinical trials of medicinal products advanced therapy

On February 6, 2025, the EMA website published a new Guideline[8] for Clinical Trials of Advanced Therapy *Medicinal* Products (ENG: *Advanced Therapy Medicinal Products* "**ATMP**").

Under Regulation 1394/2007[9] , the group of ATMP products primarily consists of: **(i)** gene therapy medicinal products, **(ii)** somatic cell therapy medicinal products**, (iii)** tissue engineering products.

The guidelines are multidisciplinary in nature and address, among other things: development, manufacturing and quality control of investigational ATMPs. They include, among other things, guidance on the structure and data requirements for a clinical trial application for investigational ATMP products.

The guidelines will come into effect on July 1, 2025, the full content of which can be read here: **link**.

*[8] Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials.*
*[9] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.*

# ALCOHOLIC BEVERAGES

## WHO appeal on warnings on alcohol packaging

February 14, 2025. The World Health Organization (**WHO**) published a report ***‚Alcohol health warning labels: a public health perspective for Europe'*** in which, among other things:

- the latest data on alcohol consumption and alcohol-related harm in the European Union was presented,
- the role of labeling and health warnings from the perspective of consumer protection and public health was described, and
- new evidence presented on the impact of alcohol health warnings in the European Union was presented.

The WHO is also calling for national regulations mandating health warnings on alcoholic beverage packaging.

The full WHO report can be read here: **link**.

# TOBACCO PRODUCTS

## Excise law - President's signature

On February 28, 2025, the draft act amending the Excise Duty Act, the Public Health Act and certain other acts was submitted to the President for signature[10].

The aim of the act is to subject new categories of products to excise duty, including vaporization devices (reusable *electronic cigarettes, heaters, multi-function devices*), nicotine pouches, as well as raising excise duty on disposable electronic cigarettes.

The text of the act can be read here: **link**.

## Law on flavors - passed by the Sejm, forwarded to the Senate for works

On February 21, 2025, the Parliament (PL: **Sejm**) passed the draft act on amending the Act on protection of health against the consequences of the consumption of tobacco and tobacco products[11].

The act, also known as the ‚**Flavor Act**' aims to implement the EU Delegated Directive 2022/2100[12] into the Polish law.

The implementation of the directive is expected to lead to a ban on the marketing of products with a distinctive flavor in Member States.

The catalog of products the flavor ban covers consists of:

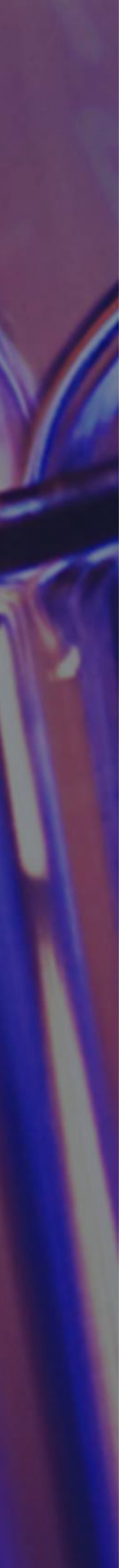
**(i) cigarettes,**

**(ii) tobacco for self-rolling cigarettes,**

**(iii) heated tobacco products.**

The text of the law passed by the Sejm and the course of legislative works can be followed here: **link**.

[10] *Print 981.*
[11] *Print 982.*
[12] *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.*



## FOOD

### Food labeling in the EU - Court of Auditors report Court of Auditors of the EU

A special report by the Court of Auditors ("**the Court**") was published in February this year, on food labeling in the EU.

In the report, the Court emphasized the practical and helpful nature of food labels for consumers, and pointed out serious shortcomings in the legislation in this area.

According to the Court, loopholes in the law, ineffective controls and complicated labeling often make consumers feel lost when confronted with food labels.

The Court also made several recommendations, according to which it is necessary to - among other things:

- **close loopholes in the EU's food labeling framework,**
- **intensify efforts to analyze food labeling practices and**
- **take steps to make consumers better understand the information on food labels.**

The full report can be found here: **link**.

## COSMETICS

### Inspections of establishments manufacturing cosmetic products

On February 26, 2025, the website of the General Inspectorate of Sanitation ("**GIS**") published information on inspections of cosmetic product manufacturing facilities. According to the announcement, the GIS in 2024, as a part of it's activities related to the supervision of cosmetic products, carried out, among other things, an action related to the inspection of cosmetic product manufacturing conditions.

In particular, the GIS inspection covered **small manufacturing plants, focusing on so-called "home" production, newly reported plants, as well as those that haven't been inspected for some time.**

As part of the action, **387** cosmetic product manufacturing plants were inspected, resulting in **35** decisions for irregularities.

GIS information can be found here: **link**.

### Microbiological testing of cosmetic products - GIS activities

On February 26, 2025, information appeared on the GIS website that an action had been carried out in 2024 as part of cosmetic product surveillance activities related to microbiological purity analysis of cosmetic products. The inspection focused on the verification of products that are intended for use around the eyes (**including eye creams and makeup remover products**).

According to the reported results, 434 samples were taken for testing, 3 were found to be non-compliant.

GIS information on the results of the testing can be found here: **link**.

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