

LIFE SCIENCES MONITOR

SEPTEMBER 2025

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MEDICINAL PRODUCTS

EMA and GIF warnings regarding the risk of counterfeit diabetes medicines and obesity

At the beginning of September, the European Medicines Agency (EMA) and the Chief Pharmaceutical Inspector (GIF) issued warnings about counterfeit medicines for diabetes and weight loss.

In their announcements, the authorities emphasised that the main risk is associated with medicines used for weight loss and diabetes, which mainly consist of **semaglutide, liraglutide, and tirzepatide**, marketed as GLP-1 receptor agonists.

These medicines **are only available on prescription - this means that they cannot be purchased online.** The announcement highlighted the risks and dangers that these products may pose to health and even life.

You can read full text of the EMA's announcement here: [link](#), and the information published by the Polish GIF here: [link](#).



MEDICAL DEVICES

Medical devices in aesthetic medicine - announcement by the President of URPL

On 4 September 2025, the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL) published a statement in relation to the improper use of medical devices intended for use in facial skin or other skin or mucous membrane filling by subcutaneous, submucosal, or intradermal injection, or other introduction intended for so-called "aesthetic medicine" procedures ("**medical devices**").

In the announcement, the URPL President indicated, among other things, that:

- i. medical devices such as hyaluronic acid injections or lifting threads require a conformity assessment with the participation of a notified body
- ii. medical devices should be accompanied by appropriate instructions for use
- iii. the instructions for the use of medical devices in the possession of the URPL President clearly **indicate that they are intended for use by professionals only**
- iv. persons intending to undergo aesthetic medicine procedures using medical devices are advised **to ensure that the qualifications of the person administering the medical device and the conditions of its use comply with the device's instructions**
- v. **the use of medical devices in a manner inconsistent with their instructions for use, e.g. by persons without medical training or in premises that do not meet the requirements specified by the manufacturer, is associated with "unacceptable risk" and constitutes a violation of Article 63 of the Medical Devices Act.**

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

FOOD AND FOOD SUPPLEMENTS

Changes to the list of chemical forms of vitamins and minerals which may be used in the production of food supplements

On 11 September 2025, the Regulation of the Minister of Health of 25 August 2025 amending the regulation on the composition and labelling of food supplements came into force.

Among the changes introduced by the amendment to the regulation, the most notable is the introduction of new forms of vitamin D and iron to the list of chemical forms of vitamins and minerals that may be used in the production of dietary supplements: **calcidiol monohydrate and iron hydroxide (nano) tartrate and iron caseinate from milk.**

It is worth noting that, from the regulation's date of entry into force, the introduction of new forms of the above-mentioned ingredients may only take place in accordance with the new requirements.

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

Phytosanitary inspections of wooden packaging - changes to the regulation

On 5 September 2025, the Government Legislation Centre published a draft regulation of the Minister of Agriculture and Rural Development amending the regulation on the obligation to submit wooden packaging material to border phytosanitary control.

The draft provides for a reduction in the minimum average frequency of border phytosanitary inspections from 5 to 1 consignment per 100 consignments transported using wooden packaging material introduced into the territory of the Republic of Poland from third countries where Bursaphelenchus xylophilus has not been found.

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

E-Sanepid

On 17 September 2025, a statement was published on the website of the Chief Sanitary Inspectorate (GIS) regarding the expansion of the SEPIS system used by the authority.

As part of the expansion, **work has begun on two platforms: one for Inspection employees (the SEPIS client application) and the other for citizens, entrepreneurs and institutions (e-Sanepid).**

The e-Sanepid module is intended to enable online transactions in the form of e-services (i.e. applications for entry in registers and records, and submission of notifications and forms), as well as communication with Inspection employees and checking the status of submitted applications.

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

VETERINARY PRODUCTS

Statistics on veterinary border inspections of products of animal origin

On 17 September 2025, the Chief Veterinary Inspectorate (GIW) published **statistics on veterinary border inspections of products of animal origin** for the period from 1 January to 31 August 2025.

According to the GIW, the inspections revealed irregularities resulting in the refusal of consignments containing products of animal origin to enter the EU in **54 cases.**

35% of the cases of non-compliance resulting in the rejection of consignments occurred at the documentation inspection stage, **37%** of which was due to the lack of a health certificate. The vast majority (**78%**) of irregularities found during the identification inspection concerned discrepancies between the information in the documents and on the labels. In the case of direct inspections, **50%** of the irregularities found concerned signs of a break in the cold chain.

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

ALCOHOL

Draft acts on upbringing in sobriety

On 22 and 23 September 2025, two parliamentary acts amending the Act on upbringing in sobriety and counteracting alcoholism were submitted by the Lewica and Polska 2050 – Trzecia Droga parliamentary parties. The drafts propose a number of changes to the current regulations, including:

- i. **a change in the definition of the promotion of alcoholic beverages**
- ii. **an introduction of a total ban on the advertising and promotion of all alcoholic beverages**
- iii. **the introduction of regulations on verifying the age of purchasers of alcoholic beverages.**

In addition:

- i. Lewica's draft also provides for, among other things, changes to the regulations on **the distance sales of alcoholic beverages, a ban on the sale of alcohol at gas stations, and an increase in penalties for violating certain provisions of the Act** (up to PLN 1 million), while
- ii. the draft by Polska 2050 – Trzecia Droga provides for **the introduction of a definition of a non-alcoholic beverage and the inclusion of such beverages in the ban on advertising and promotion, as well as regulations concerning the appearance of containers** in which the nominal quantity of alcoholic beverage does not exceed 300 ml.

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



PNRL calls for the introduction of a ban on the night-time sale of alcoholic beverages

On 30 September 2025, **two appeals by the Presidium of the Supreme Medical Council (PNRL)** were published on the Supreme Medical Council's website.

The first concerns **the introduction of a ban on the night-time sale of alcoholic beverages intended for consumption outside the place of sale**. As arguments for taking appropriate legislative action in this direction, the PNRL points to, among other things, measures to reduce the health and social harm resulting from alcohol consumption. The PNRL proposes introducing a nationwide ban.

The second appeal was addressed to **representatives of the world of culture and sport, asking them not to participate in alcohol advertising**. In its appeal, the PNRL points out the harmful effects of alcohol and the fact that alcohol prices in Poland are among the lowest in the EU.

You can read the entire text of the appeals here: [link](#).

TOBACCO AND NICOTINE PRODUCTS

Soldiers oppose ban on flavoured nicotine pouches

On 16 September 2025, as a part of the comments submitted during public consultations on the currently proceeded act amending the Act on the protection of health against the consequences of tobacco and tobacco products, the SPRZYMIERZENI z GROM Foundation published a statement **calling for the removal from the draft of provisions the prohibition of the sale of nicotine pouches with flavours other than tobacco**.

The appeal emphasised that the entry into force of the above-mentioned provisions would result, among other things, in soldiers and other uniformed services personnel resorting to less safe nicotine products, as they are easier to detect by the enemy and more difficult to consume quickly.

You can read the foundation's full position here: [link](#).



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