Draft name: Regulation of the Minister for Health amending the Regulation on the list of psychotropic substances, narcotic drugs and new psychoactive substances **Lead ministry and co-operating ministries:** Chief Sanitary Inspectorate **Person responsible for the draft: Minister, Secretary of State or Undersecretary of State:** Paweł Grzesiowski — Chief Sanitary Inspector **Contact details for the draft supervisor:** Agnieszka Miazga — Department of Chemicals Supervision, Chief Sanitary Inspectorate tel.: (22) 345 35 10; e-mail: agnieszka.miazga@sanepid.gov.pl	**Date of preparation** 17.3.2025 **Source:** Article 44f of the Act of 29 July 2005 on combating drug addiction (Journal of Laws [Dziennik Ustaw] 2023, item 1939) **Number on the list of legislative works of the Minister for Health:** **MZ1718**

REGULATORY IMPACT ASSESSMENT

1. What issue is being addressed?

In view of the rapid rate of emergence on the market of new drugs, which are increasingly acutely toxic substances, and taking into account the availability of these substances, including through various online distribution channels, it is necessary to amend the Regulation of the Minister for Health of 17 August 2018 on the list of psychotropic substances, narcotic drugs and new psychoactive substances (Journal of Laws of 2024, item 1139). These amendments reflect the provisions of the United Nations Drug Control Convention, including Decision 67 taken during the meeting of the UN Commission on Narcotic Drugs (CND) held in Vienna between 14 and 22 March 2022, and the recommendations of the working group for the assessment of risks to human health or life associated with the use of new psychoactive substances.

The draft Regulation extends: the 'List of psychotropic substances divided in groups referred to in Article 32 of the Act of 29 July 2005 on combating drug addiction', contained in Annex 1, part '2. Group II-P psychotropic substances' to include four additional chemical compounds: 3-CMC, DIPENTYLONE, 2-FDCK and lisdexamfetamine, and in part '4. Group IV-P psychotropic substances' to include one additional chemical compound: BROMAZOLAM. In addition, the 'List of narcotic drugs divided in groups referred to in Article 31 of the Act of 29 July 2005 on combating drug addiction and indicating the group IV-N drugs authorised for use in the treatment of animals in accordance with Article 33(2) of that act', contained in Annex 2, part '1. Group I-N narcotic drugs' to include one additional chemical compound: BUTONITAZENE. The amendment also alters the 'List of new psychoactive substances' contained in Annex 3, by adding eight chemical compounds: Δ^9-THCP, HHCP, GIDAZEPAM, MDMB-5Br-INACA, ADB-INACA, ADB-5Br-INACA, ibotenic acid and muscimol, adding a group of new psychoactive substances: 'Benzimidazole derivatives — group VIII-NPS', extending group III-NPS — synthetic cannabinoids (cannabinomimetics), and clarifying the general formula for group IV-NPS — fentanyl derivatives.

The draft Regulation also adds a different chemical name for the substance a-PHiP listed in Annex 1, part '2. Group II-P psychotropic substances' in the table item 76.

The draft Regulation removes the substances dextrometorphan and dextrorphan listed in Annex 2, part '1. Group I-N psychotropic substances' as isomers of levomethorphan (item 115) and levorphanol (item 117).

These substances have an effect on the central nervous system, can pose a potential threat to human health and life and cause social harm, and given the lack of public awareness of the risks of new psychoactive substances, it is essential to limit their availability without delay. These substances have not only been identified on the territory of the Republic of Poland, but are also present in other European Union countries. The risks associated with new psychoactive substances affect vulnerable groups, especially young people. A failure to prohibit the use of a substance may give rise to an erroneous impression of its harmlessness. Unauthorised possession of new psychoactive substances is subject to criminal liability. The State Sanitary Inspection authorities, in co-operation with the President of the Office for Chemical Substances, are obliged to supervise the legal use of new psychoactive substances.

2. The recommended solution, including planned intervention tools and expected impact

The expected effect of the draft Regulation will be a further reduction of public health risks, reflected as a reduced number of cases of poisoning by new drugs. The regular occurrence and spread of new chemical variants of psychoactive substances poses a threat to human health or life. In order to increase the impact, the recommended solution is to include further substances in the drug lists. In the draft Regulation, based on the resolutions of the working group for the

assessment of the risks to human health or life associated with the use of new psychoactive substances, the list of new psychoactive substances has been expanded to include one additional chemical compound and a new group of chemical substances. The draft Regulation accelerates the listing of substances (as in other European countries). Due to the current dynamics of the new drugs market, which poses one of the biggest challenges to public health and safety, restricting the availability of these substances as a result of their inclusion in criminal law, enables more effective and faster protection of the society against dangerous substances.

3. How has this problem been solved in other countries, in particular OECD/EU Member States?

Other countries, in particular OECD/EU Member States, as is the case in the Republic of Poland, have been taking actions to effectively reduce the availability of psychoactive substances posing serious risks to public health and, in certain cases, serious social risks, and to stop trade in these substances.

4. Entities affected by the draft

Group	Size	Data source	Impact
State Sanitary Inspection Police Public Prosecutor's Office National Revenue Administration Office for Chemical Substances	5	Act of 14 March 1985 on the State Sanitary Inspection (Journal of Laws of 2024, item 416) Act of 6 April 1990 on the Police (Journal of Laws of 2024, item 145, as amended) Act of 28 January 2016 on the Public Prosecutor's Office (Journal of Laws of 2024, item 390) Act of 16 November 2016 on the National Revenue Administration (Journal of Laws of 2023, item 615) Act of 25 February 2011 on chemical substances and their mixtures (Journal of Laws of 2022, item 1816)	Increased effectiveness of supervision by the State Sanitary Inspection and other state authorities, including the Police, operating in the field of combating drug addiction
Testing laboratories authorised to carry out tests to determine whether a product consists of a substitute compound	18	Ministry of Health toxicological laboratories research institutes	conducting research on substances posing a risk to human life or health
National Centre for the Prevention of Addiction State Sanitary Inspection Police Public Prosecutor's Office National Revenue Administration	5	National Centre for the Prevention of Addiction	increased efficiency of the combat against drug addiction, through cooperation of the State Sanitary Inspection and other entities within the European Information Network on Drugs and Drug Addiction (fr. REITOX) with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).
National Consultant on Clinical Toxicology	1	Ministry of Health healthcare entities	flow of information on poisoning cases

5. Information on the scope, duration, and summary of consultation results

No pre-consultations on the draft Regulation have been carried out.

The draft Regulation was submitted for public consultation and opinion seeking, with a 7-day deadline for submitting comments, to the following entities:

1) President of the Office for Competition and Consumer Protection;
2) President of the Personal Data Protection Office;
3) President of General Attorney's Office of the Republic of Poland;
4) Naczelna Rada Lekarska [Supreme Medical Council];
5) Naczelna Rada Pielęgniarek i Położnych [Supreme Council of Nurses and Midwives];
6) Naczelna Rada Aptekarska [Supreme Pharmacy Council];
7) Krajowa Rada Fizjoterapeutów [National Council of Physiotherapists];
8) Krajowa Rada Diagnostów Laboratoryjnych [National Council of Laboratory Analysts];
9) Instytut Psychiatrii i Neurologii [Institute of Psychiatry and Neurology] in Warsaw;
10) Krajowe Centrum Przeciwdziałania Uzależnieniom [National Centre for the Prevention of Addiction];
11) Helsińska Fundacja Praw Człowieka [Helsinki Foundation for Human Rights];
12) Fundacja Batorego [the 'Batory' Foundation];
13) Stowarzyszenie Monar [the 'Monar' Association];
14) Polska Sieć Polityki Narkotykowej [Polish Drug Policy Network];
15) Polskie Towarzystwo Zapobiegania Narkomanii [Polish Society for the Prevention of Drug Addiction];
16) National Consultant for Psychiatry;
17) National Consultant for Clinical Toxicology;
18) Gdański Uniwersytet Medyczny [Medical University of Gdańsk];
19) Polska Izba Przemysłu Chemicznego [Polish Chamber of the Chemical Industry];
20) Polskie Stowarzyszenie Przemysłu Kosmetycznego i Detergentowego [Polish Association of Cosmetic and Detergent Industry];
21) Stowarzyszenie Inżynierów i Techników Przemysłu Chemicznego [Association of Chemical Industry Engineers and Technicians];
22) Polski Związek Przetwórców Tworzyw Sztucznych [Polish Plastic Processors Association];
23) Sieć Badawcza Łukasiewicz – Instytut Chemii Przemysłowej im. prof. Ignacego Mościckiego [Łukasiewicz Research Network — Prof. Ignacy Mościcki Institute of Industrial Chemistry];
24) Sieć Badawcza Łukasiewicz – Instytut Przemysłu Organicznego [Łukasiewicz Research Network — Institute of Industrial Organic Chemistry];
25) Narodowy Instytut Leków [National Medicines Institute];
26) Instytut Włókien Naturalnych i Roślin Zielarskich [Institute of Natural Fibres and Herbal Plants];
27) Polska Izba Lnu i Konopi [Polish Flax and Hemp Chamber];
28) Instytut Ekspertyz Sądowych w Krakowie [Institute of Forensic Experts in Cracow];
29) Warszawski Uniwersytet Medyczny [Medical University of Warsaw];
30) Federacja Związków Pracodawców Ochrony Zdrowia „Porozumienie Zielonogórskie" ['Porozumienie Zielonogórskie' Healthcare Employers' Unions Federation];
31) Ogólnopolski Związek Zawodowy Lekarzy [National Union of Physicians];
32) Ogólnopolski Związek Zawodowy Pielęgniarek i Położnych [National Trade Union of Nurses and Midwives];
33) Niezależny Samorządny Związek Zawodowy „Solidarność" [Independent Self-governing Trade Union 'Solidarity'];
34) KK NSZZ „Solidarność 80" [National Commission of the Independent Labour Union 'Solidarity 80'];
35) Ogólnopolskie Porozumienie Związków Zawodowych [All-Poland Alliance of Trade Unions];
36) Forum Związków Zawodowych [Forum of Trade Unions];
37) Federacja Związków Zawodowych Pracowników Ochrony Zdrowia i Pomocy Społecznej [Federation of Healthcare and Social Welfare Employees' Trade Unions];
38) Business Centre Club;
39) Konfederacja Lewiatan ['Lewiatan' Confederation];
40) Pracodawcy Rzeczypospolitej Polskiej [Polish Employers];
41) Związek Przedsiębiorców i Pracodawców [Union of Entrepreneurs and Employers];
42) Rada Dialogu Społecznego [Council of Social Dialogue];
43) Związek Rzemiosła Polskiego [Polish Union of Craftsmen];
44) Federacja Przedsiębiorców Polskich [Federation of Polish Entrepreneurs];
45) Izba Gospodarcza „Apteka Polska" [Chamber of Commerce 'Apteka Polska'];
46) Izba Gospodarcza Właścicieli Punktów Aptecznych i Aptek [Chamber of Commerce of Dispensary and Pharmacy Owners];
47) Izba Gospodarcza „Farmacja Polska" [Chamber of Commerce 'Farmacja Polska'];

48) Polska Izba Zielarsko-Medyczna [Polish Chamber of Herbal Healing];
49) Polski Związek Pracodawców Przemysłu Farmaceutycznego [Polish Association of Pharmaceutical Employers];
50) Polski Związek Producentów Leków bez Recepty [Polish Association of Self-Medication Industry] PASMI;
51) Stowarzyszenie Farmaceutów Szpitalnych i Klinicznych [Association of Hospital and Clinical Pharmacists];
52) Stowarzyszenie Importerów Równoległych Produktów Leczniczych [Association of Parallel Importers of Medicinal Products];
53) Związek Pracodawców Innowacyjnych Firm Farmaceutycznych „INFARMA" [Association of Employers of Innovative Pharmaceutical Companies 'INFARMA'];
54) Narodowy Fundusz Zdrowia [National Health Fund];
55) Central Forensic Laboratory of the Police;
56) Polskie Towarzystwo Prawa Medycznego [Polish Society of Medical Law];
57) Polskie Towarzystwo Gospodarcze [Polish Economic Society].

The draft Regulation was submitted for public consultation and opinion seeking again pursuant to § 48(2) of the Cabinet Resolution No 190 of 29 October 2013 — Regulations on the work of the Council of Ministers (Polish Official Gazette [Monitor Polski] of 2024, item 806).
The draft Regulation was made available in the Public Information Bulletin on the page of the Government Legislation Centre on the Government Legislative Process website, in accordance with § 52(1) of the Cabinet Resolution No. 190 of 29 October 2013 — Regulations on the work of the Council of Ministers and on the page of the office of the Minister for Health, in accordance with Article 5 of the Act of 7 July 2005 on lobbying activities in the lawmaking process (Journal of Laws of 2017, item 248; 2024, item 1535).
The results of the public consultation and opinion seeking can be found in the consultation and opinion report attached to the Impact Assessment.

6. Impact on the public finance sector

(fixed prices for … [year])	Impact over 10 years from implementing the amendments [PLN million]											
	0	1	2	3	4	5	6	7	8	9	10	Total (0–10)
Total revenue	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.3256–0.3696
state budget	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.0296 – 0.0336	0.3256–0.3696
local government units	0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)	0	0	0	0	0	0	0	0	0	0	0	0
Total expenditure	0	0	0	0	0	0	0	0	0	0	0	0
state budget	0	0	0	0	0	0	0	0	0	0	0	0
local government units	0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)	0	0	0	0	0	0	0	0	0	0	0	0
Total balance	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.3256–0.3696
state budget	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.0296 – 0.0336	+0.3256–0.3696
local government units	0	0	0	0	0	0	0	0	0	0	0	0
other units (separately)	0	0	0	0	0	0	0	0	0	0	0	0

Sources of financing	The entry into force of the Regulation will have an impact on the public finance sector through its impact on the state budget, in particular in terms of revenue. The draft Regulation will have no impact on the budgets of local government units. The proceeds from the fees paid by entrepreneurs and the proceeds of the fines imposed, as specified in the Act of 29 July 2005 on combating drug addiction, constitute State budget revenue. The amount of state budget revenue depends on the number of applications for issuing the licenses provided for in the above-mentioned Act of 29 July 2005 on combating drug addiction. It is not possible to determine the number of substances that, due to the chemical structure of the molecule, will structurally belong to the new VIII-NPS group and III-NPS group after the change in the general formula for this group. In addition, it is difficult to estimate the entrepreneurs' future interest in obtaining an authorisation to conduct business using the following compounds: Δ^9-THCP, HHCP, gidazepam, MDMB-5Br-INACA, ADB-INACA, ADB-5Br-INACA, ibotenic acid, muscimol or substances belonging to the VIII-NPS group and the revised III-NPS group. Based on the revenues obtained for the previously added new psychoactive substances with the names 1cP-LSD and 1V-LSD, and groups VI-NPS and VII-NPS, it can be assumed that the estimated revenue to the state budget from the submission of the applications concerning the substances from the new group VIII-NPS, extended group III-NPS and new psychoactive substances with the names THC-P, HHC-P, gidazepam, MDMB-5Br-INACA, ADB-INACA, ADB-5Br-INACA, ibotenic acid and muscimol, will amount to PLN 3 600 per year. It can be estimated that the budget revenue from the issue of import, export, intra-Community acquisition and intra-Community supply licences, pursuant to Article 37 of the Act of 29 July 2005 on combating drug addiction, for each case of transport to/from the territory of the Republic of Poland of products containing lisdexamfetamine by authorised operators may reach approximately PLN 26 000 to PLN 30 000 per year.
Additional information, including the identification of data sources and assumptions made in the calculation	1. The position of the President of the Office for Chemical Substances of 17 July 2024, reference no.: BSCH-DSN.070.1.2024.MG. 2. The position of the President of the Office for Chemical Substances of 3 December 2024, reference no.: BSCH-DSN.451.43.2024.JK. 3. The position of the Chief Pharmaceutical Inspector of 4 December 2024, reference no.: NFKS.070.78.2024.KPO.1. 4. Public consultation and opinion report. 5. Report on public re-consultations and opinion seeking.

7. Impact on the competitiveness of the economy and entrepreneurship, including the functioning of enterprises and impact on families, citizens and households

Impact								
Time in years since entry into force of the amendments		0	1	2	3	5	10	Total (0–10)
In monetary terms (PLN million, fixed prices for … [year])	large enterprises	0	0	0	0	0	0	0
	micro-, small- and medium-sized enterprises	0	0	0	0	0	0	0
	families, citizens and households	0	0	0	0	0	0	0
In non-monetary terms	large enterprises	The draft Regulation allows for the operation of the market in terms of legal uses of psychoactive substances both in industry and in scientific research.						
	micro-, small- and medium-sized enterprises							
	families, citizens and	The draft Regulation has an impact on the protection of the life and health of						

	households	citizens by restricting access and consequently restricting the use of psychoactive substances posing a risk to health and life. The draft Regulation will not affect the economic and social situation of families citizens and households.
	the elderly and persons with disabilities	The draft Regulation has an impact on the protection of the life and health of the elderly and persons with disabilities by restricting access and consequently restricting the use of psychoactive substances posing a risk to health and life. The draft Regulation will not affect the economic and social situation of the elderly and persons with disabilities.
Unmeasurable		
Additional information, including the identification of data sources and assumptions made in the calculation		

8. Change in the regulatory burdens (including disclosure obligations) resulting from the draft

☐ not applicable

Burdens are placed outside those strictly required by the EU (see the inverted compatibility table for details).	☐ yes ☒ no ☐ not applicable
☐ reduction in the number of documents ☐ reduction in the number of procedures ☐ shortening of the time to settle the matter ☐ other:	☐ increase in the number of documents ☐ increase in the number of procedures ☐ extension of the time to settle the matter ☐ other:
The introduced burdens are suitable for digitisation.	☐ yes ☐ no ☒ not applicable

Comment:

9. Impact on the labour market

The implementation of the draft Regulation has no impact on the labour market.

10. Impact on other aspects

☐ natural environment ☐ regional standing and development ☐ ordinary, administrative or military courts	☐ demography ☐ state property ☐ other:	☐ computerisation ☒ health

Discussion of the impact	The draft Regulation will contribute to reducing health damage (reduction of poisoning cases due to the reduction of the number of psychoactive substances placed on the market).

11. Planned implementation of the provisions of the act

It is planned that the draft Regulation come into force 14 days after its publication.

12. How and when will the impact of the draft be assessed, and what measures will be applied?

The draft Regulation will reduce the placing on the market of psychoactive substances and reduce the number of cases of poisoning. The evaluation of the effects will show a reduction in the number of psychoactive substances placed on the market and a reduction in the number of poisoning cases associated with these substances.

13. Annexes (important source documents, research, analyses, etc.)

1. The position of the President of the Office for Chemical Substances of 17 July 2024, reference no.: BSCH-DSN.070.1.2024.MG.
2. The position of the President of the Office for Chemical Substances of 3 December 2024, reference no.: BSCH-DSN.451.43.2024.JK.
3. The position of the Chief Pharmaceutical Inspector of 4 December 2024, reference no.: NFKS.070.78.2024.KPO.1.

4. Public consultation and opinion report — draft version of 12 November 2024
5. Public re-consultation and opinion report — draft version of 26 January 2025