1. Need to draft the legislative act

Title of the annotation (ex ante)

Preliminary (*ex ante*) impact assessment report (annotation) for the draft legal act ‘Amendments to the Law On the Procedures for the Coming into Force and Application of the Criminal Law’

1.1. Legal basis

Rationale for drafting

Ministry / Institutional Initiative

Description

The draft law aims to subject to control synthetic cannabinoids ADB-5Br-INACA and MDMB-5Br-INACA, to subject to control a number of fentanyl-related substances and opioids not related to fentanyl, as well as new psychoactive substances recommended by the International Drug Control Board; to allow a control exemption for mastinib mesilate used in veterinary medicine; to allow an exemption for etorphine used during veterinary procedures; to allow lisdexamfetamine for medical purposes; to allow tiletamine for use in veterinary medicine; and to include individual substances flubromazepam, bromazolam, zolazepam, thiopental, primidone, and esketamine already controlled in the lists of controlled narcotic and psychotrophic substances in Latvia; to clarify the control of butorphanol, etc. The draft law also aims to determine the scope of illegal trade at the national level for a number of precursors subjected to control by the EU regulations. On 29 November 2023, the temporary ban of the Centre for Disease Prevention and Control (hereinafter, the SPKC) entered into force for the substance: 2-amino-1-(4-bromo-2,5-dimethoxy-phenyl-ethanol) or BOH-2C-B (hereinafter, BOH-2C-B) and articles containing it.

1.2. Objective

Description of the objective

To control synthetic cannabinoids, a number of fentanyl-related substances and opioids not related to fentanyl, new psychoactive substances, BOH-2C-B; to allow a control exemption for mastinib mesilate used in veterinary medicine and an exemption for etorphine used during veterinary procedures; to allow to use lisdecamphetamine in medicine; to include as individual substances, the substances already controlled under Annex 2 to the law; to determine the extent of illegal trade of several precursors, etc.

Date of entry into force

Next day after promulgation (for the draft law)

Legal basis

As the draft law includes essential aspects to protect the public health and safety by protecting the public interests and hindering the increase in the supply and demand of narcotic and psychotropic substances in Latvia, it would be important to examine the draft law according to the shortened procedure.
As of 29 November 2023, the temporary ban on BOH-2C-B and any products containing it imposed by the Centre for Disease Prevention and Control (hereinafter, the SPKC) is in force. In view of the fact that a substance, which is the subject of a decision of the SPKC to ban the manufacture, acquisition, storage, transport, transfer or distribution of the new psychoactive substance in question or of any products containing it, undermines the public health and safety, no later than in 12 months from the date of entry into force of the decision the substance must be subjected to continuous control in Annex 2 to the law to prevent the substance from returning to uncontrolled circulation.
A faster review is also related to the change of classification of lisdexamfetamine, which is currently subject to control under list I of Annex 2 to the law, by including it in list II of Annex 2 to the law (very dangerous narcotic substances and similar psychotropic substances, which may be used for medical and scientific purposes) as an individual substance, thus allowing it to be used in medicine. The State Agency of Medicines has received questions from several individuals and medical practitioners on the availability of medicinal products containing lisdexamfetamine in Latvia. Interest has been expressed both by nationals of other countries who wish to import the above medicinal product for personal use to treat a specific disease and not to discontinue the use of the medicinal product when they enter Latvia, as well as by the Latvian nationals who need medicinal products for the treatment of attention deficit/hyperactivity disorders (UDHS). As medicinal products containing lisdexamfetamine are used as part of a comprehensive treatment programme for the attention deficit/hyperactivity disorder (UDHS) in children aged 6 years and above, if the response to a previous methylphenidate therapy is considered clinically insufficient, the availability of these medicinal products is very important.

1.3. Current situation, problems and solutions

Current situation

The lists of narcotic and psychotropic substances controlled in Latvia (hereinafter, list I, list II, list III, and list IV) are laid down in Annex 2 to the law drafted according to the UN Single Convention on Narcotic Drugs of 30 March 1961 and its amendments made pursuant to the 1972 Protocol amending the Single Convention on Narcotic Drugs of 30 March 1961, the Convention on Psychotropic Substances of 21 February 1971, and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988 (hereinafter, the UN Convention on Narcotic Drugs). Annex 2 to the law also lays down the maximum amounts of controlled narcotic and psychotropic substances that are considered small, and the minimum amounts that are considered large. Depending on these values, penalties for the illicit trade in narcotic and psychotropic substances are imposed[1].

Article 39 of the Single Convention on Narcotic Drugs of 30 March 1961, Article 23 of the Convention on Psychotropic Substances of 21 February 1971, and Article 24 of the Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988 stipulate that states may adopt stricter measures than those in these conventions if they consider such measures desirable or necessary to prevent or eliminate illicit trade in such narcotic and psychotropic substances and to protect the public health and welfare. Thus, the lists of controlled narcotic and psychotropic substances are regularly updated by including non-listed circulating substances.
As of 23 February 2013, narcotic and psychotropic substances are controlled in Latvia according to the principle of a generic system, i.e. basic formulas of chemical groups of substances with descriptions that identify substances included in the group are subjected to control. At the same time, the law also gives a possibility to subject individual substances to control, if needed.
As of 14 November 2013, amendments to the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors are in force (Section 4(2)), which stipulates that by a decision of the Centre for Disease Prevention and Control (hereinafter, the Centre), the manufacture, acquisition, storage, transport, transfer or distribution of such new psychoactive substances or products containing such substances, which are not included in the lists of narcotic and psychotropic substances controlled in Latvia, as well as lists of precursors, and on which information has been received from the European Rapid Alert System or an opinion of a forensic examination body on new psychoactive substances, may be banned or limited for up to 12 months from the date of entry into force of the decision. As the substance, which is the subject of a decision of the Centre to ban the manufacture, acquisition, storage, transport, transfer or distribution of the new psychoactive substance in question or any products containing it, undermines the public health and safety, the substance must be subjected to continuous control under Annex 2 to the law no later than in 12 months from the date of entry into force of the decision to prevent the substance from returning to circulation.

[1] Criminal law: https://likumi.lv/ta/id/88966-kriminallikums
Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors: https://likumi.lv/ta/id/40283-narkotisko-un-psihotropo-vielu-un-zalu-ka-ari-prekursoru-likumigas-aprites-likums
Law on Administrative Liability: https://likumi.lv/ta/id/303007-administrativas-atbildibas-likums

Problems and solutions

Description of the problem

In practice, there are cases, when due to its chemical composition a substance such as methohexital is found to comply with lists II and III of Annex 2 to the law, which means that the substance can be controlled both as the structural analogue (list II) of pentobarbital, secobarbital, etc. and as a barbital derivative (list III). At the same

time, the law governing the circulation of narcotic and psychotropic substances and medicinal products does not require that the requirements of the lists of narcotic, psychotropic substances and precursors subject to control in Latvia are applied in such situations.

Description of the solution

To find a solution in the specific situation and as Paragraph 4 of Annex 2 to the Law On the Procedures for the Coming into Force and Application of the Criminal Law stipulates that should due to its chemical composition any substance included in list II, III or IV also comply with list I, the provisions of list I shall not apply to this substance, the draft law is supplemented by an equivalent Paragraph 4.[1]: 'If due to its chemical composition any substance of list III also complies with list II, that substance shall not be made subject to the requirements of list II.' This allows to ensure the continuity and certainty of application of the current legal framework by eliminating any possibility to interpret the law and by ensuring clarity to those who apply the law. At the same time, it should be noted that currently there is no indication that such cases could be frequent in the future (i.e. that one substance would comply with several lists, in particular, with lists II and III). Together with experts, the Centre for Disease Prevention and Control has studied the lists of narcotic and psychotropic substances in human and veterinary medicinal products to minimise this risk as far as possible. The draft law stipulates that each time such cases are identified, the responsible authorities, in particular, the Centre for Disease Prevention and Control, depending on their competences and by involving experts, shall assess the hazards of the respective substance and, if needed, prepare draft amendments to the Law On the Procedures for the Coming into Force and Application of the Criminal Law to regulate the inclusion of such substances in list II (or even list I if there are very serious hazards).
Together with sectoral and law enforcement experts, the Ministry of Health has been proactive in assessing the control of new psychoactive substances, as well as known narcotic and psychotropic substances, to try to minimise possible risks and threats to the public health by preventing legal circulation of these substances. Thus, for more than ten years, the country has controlled such substances according to the basic principles of the generic system (the system allows to control groups of substances rather than individual substances), and has operated a system of temporary bans on substances that allow to rapidly react by prohibiting substances that are not controlled individually or under the generic system.
So far there have been no precedents, when the control status of any controlled substances would have been downgraded/eased after an evaluation by experts. Moreover, in this particular situation it is believed that there are no risks to the public health, and the law enforcement that would require the inclusion of such substances in list II or list III, while the proposed principle ensures legal continuity and more uniform interpretation (i.e., the legal norm can be interpreted literally), as well as legal certainty.

Description of the problem

The Ministry of Health has received a letter from the International Drug Control Board (INCB)[1] with an annex listing opioids not related to fentanyl and the related new psychoactive substances (hereinafter, the INCB list)[2] that have no known legal use. The INCB asks governments (presumably, governments of countries that have ratified the UN Convention on Drugs) to take the necessary measures with regards to the circulation and control of these substances. The INCB list also includes bromadol[3], faxeladol and thiobromadol that are not individually controlled in Latvia.

[1] The Board of Governors of INCB is an independent quasi-judicial organisation of experts established according to the 1961 UN Convention.

[2] https://www.incb.org/documents/Global_Projects_OPIOIDS/INCB.GRIDS.OPIOIDS.NoFOs_list.pdf

[3] https://www.caymanchem.com/product/15608

Description of the solution

As these substances are not suitable for medical or other purposes of public interest, such as research, but may be used for intoxication purposes, the draft law provides for the inclusion of these substances in list I of Annex 2 to the law (very dangerous prohibited substances and plants, whose illegal trade and abuse endangers health). As due to their structure and properties these substances are synthetic opioids, they are included in Paragraph 5 ‘Synthetic opioid analgesics’ of list I, Annex 2. According to information provided by the Forensics Board of the State Police, bromadol, faxeladol and thiobromadol have not yet been found in Latvia, but have been found and removed from circulation in several European countries. For bromadol or BDPC, faxeladol and thiobromadol, the maximum amount for the quantities to be considered small is 0.001 g, while the minimum amount for the quantities to be considered large is 1 g. Bromadol or BDPC is a compound equivalent to the generic formula 1-arylcyclohexylamines and (1-arylcyclohexyl)methaneamines, thus, the imposed quantities are equivalent. Irrespective of the equivalence with the generic formula 1-arylcyclohexylamines and (1-arylcyclohexyl)methaneamine the quantities differ from those of tramadol, as tramadol is the only compound of this generic group that is used in medicine and is registered for use in Latvia with the Latvian Register of Medicinal Products that confirms its safety if used as a medicinal product. Paragraph 5 of Chapter II, Annex 2 to the law is reworded (in sub-paragraphs (2), (4), and (8)).

Description of the problem

Medicinal products that contain etorphine are not registered with the Register of Veterinary Medicinal Products of the Food and Veterinary Service; they are imported in Latvia as unauthorized medicinal products. Etorphine is a semi-synthetic opioid

analgesic that is approximately 1000 to 3000 times more potent than morphine. Etorphine is often used to immobilise large animals such as elephants. The dose used in veterinary medicine is fatal to humans. In animals, diprenorphine mitigates the effects of etorphine. As an antidote, naloxone is most often used in humans. It should always be available should accidental exposure (skin or dermal contact, eye contact, inhalation or oral intake) to etorphine takes place. As the authority responsible for issuing import and export permits for controlled substances in Latvia, the State Agency of Medicines has repeatedly received requests (approx. once every three years) from Riga National Zoo regarding the need to use medicinal products containing etorphine for immobilisation/anaesthesia of large animals for scientific research purposes, veterinary procedures, as well as should any animals escape. According to information provided by the Forensic Board of the State Police, no cases of removal of etorphine from illegal trade have taken place in Latvia. Likewise, there are no data on illegal circulation of etorphine in the European Rapid Alert System. Etorphine is important for veterinary procedures, and the Ministry of Agriculture has informed both the Ministry of Health and the State Agency of Medicines of the need to apply exemption what concerns the use of this substance for veterinary procedures.
According to information available in Estonia, etorphine is classified as a controlled substance (narcotic substance) included in list II. [1] As a result, this substance may be used for medical and scientific purposes. In Estonia, Captivon solution for injection 9.8 mg/ml 5 ml N1 is imported and distributed at the request of a veterinarian as an unauthorised medicinal product. In Lithuania, etorphine is included in list I of controlled substances ‘Narcotic and psychotropic substances that may not be used for medical purposes, unless list I substances are authorised medicinal products’. According to the available information, neither the Lithuanian register of medicinal products, nor the Community register of medicinal products contains medicinal products with etorphine as an active substance, thus, such medicinal products cannot be supplied to the Lithuanian market. Likewise, no requests for authorisations of re-export of such medicinal products have been received. No medicinal products containing etorphine as the active substance have been registered with the Lithuanian register of veterinary medicinal products, an no applications on such medicinal products have been received.

[1] https://www.riigiteataja.ee/akt/129102022013

Description of the solution

As etorphine is required for veterinary procedures, this substance shall be exempt if used for veterinary procedures (Paragraph 6(3) of Chapter II, Annex 2). The above substance will be controlled as a list I substance, and shall be exempt if used for veterinary procedures. The competences of the Food and Veterinary Service and the State Agency of Medicines shall be set out in the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors, and by delegation the Cabinet shall determine the requirements, conditions and procedures

for handling medicinal products that contain list I substances at veterinary practices, if they are exempt for the purposes of veterinary procedures. The medicinal product will be imported by a licensed veterinary wholesaler that has received a special permit (licence) for handling narcotic substances, and on the basis of a one-time import permit of the State Agency of Medicines that will be issued in accordance with a decision of the Food and Veterinary Service on the right of a veterinary practice to use medicinal products containing etorphine for veterinary procedures. Pursuant to the law, the pharmaceutical wholesalers shall submit quarterly and annual reports on their circulation of narcotic medicinal products. While veterinary practices shall submit a report on their use of controlled narcotic medicinal products to the State Agency of Medicines. The Food and Veterinary Service shall control the veterinary practices.
The amendment in the draft law shall come into force concurrently with related amendments to the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors, and the binding normative acts that set out the procedure for circulation, control and monitoring of etorphine. Thus, transitional Paragraph 9 is included in the draft law.

Description of the problem

During one case of removal from illegal circulation, the Forensic Board of the State Police found a powder containing synthetic cannabinoids ADB-5Br-INACA and MDMB-5Br-INACA[1]. Due to their impact on health, both substances belong to the generic group ‘indole, azaindoles and indazol-3-carbonl derivatives’, but the current law does not provide for a situation, when there is no substitute in the molecules of substances at position 1 of indole, azaindol or indazol cycle nitrogen atom.

[1] https://www.caymanchem.com/product/36757/mdmb-5br-inaca

Description of the solution

These substances are not for human or veterinary use. To control these substances, the description of the generic group ‘indole, azaindoles and indazol-3-carbon derivatives’ (Article 8(1) of Chapter II, Annex 2) is updated. The description of the generic group is supplemented with a condition that nitrogen atom in position 1 of the indole, azaindol or indazole cycle may be unsubstituted. This update expands the range of synthetic cannabinoids that are hazardous to human health. The maximum amounts established for the generic group for the quantities to be considered small and the minimum amounts for the quantities to be considered large remain unchanged.

Description of the problem

The Ministry of Health has received a letter from the INCB with an annex listing the substances related to fentanyl[1]. The letter asks governments (i.e. the governments of states that have ratified the UN Convention on Drugs) to examine the annexed list and to subject to control substances not yet controlled[2]. After the review of INCB

list, it was established that fentanyl carbamate[3] is not yet controlled in Latvia. The effects of fentanyl carbamate are similar to those of the generic formula of acetyl-fentanyl.

[1] https://www.incb.org/documents/Global_Projects_OPIOIDS/INCB.GRIDS.OPIOIDS.Fentanyl-Rel_Subs_list.pdf

[2] The INCB initiative is implemented in the framework of project ‘Operational Partnerships to Interdict Opioids' Illicit Distribution and Sales’ (OPIOIDS). The project is a global initiative to support national governments and international organisations in their efforts to prevent the spread of illegal synthetic opioids. The project is also part of the INCB programme ‘Global Rapid Interdiction of Dangerous Substances’ (GRIDS).

[3] https://www.caymanchem.com/search?q=fentanyl%20carbamate

Description of the solution

The above substance is not for human or veterinary use. As the chemical composition and properties of this substance match the acetylfentanyl group, the description of the generic group of acetylfentanyls (Paragraph 8(2)(d) of Chapter II, Annex 2) is updated to subject the above substance to control by including a condition that the acetyl group may be substituted with an esther group. The maximum amounts established for the generic group for the quantities to be considered small and the minimum amounts for the quantities to be considered large remain unchanged. According to information provided by the Forensic Board of the State Police, fentanyl carbamate has never been found in Latvia. However, to protect the public health, narcotic substances should be controlled before they appear or enter the illegal trade for the law enforcement authorities to have the required legal basis for action.

Description of the problem

The INCB list includes substances AP-238, para-methyl-AP-237 and 2-methyl-AP-237[1] which are not controlled in Latvia.

[1] On 10–14 October 2022, a meeting of the WHO Expert Committee on Drug Addiction took place. As a result, the Committee recommended to subject several narcotic and psychotropic substances, including 2-methyl-AP-237, to international control by including it in list I of the UN Single Convention on Narcotic Drugs of 30 March 1961. 2-methyl-AP-237 is not used in medicine. As the EU Member States, which are members of the UN Commission on Narcotic Drugs, vote on international drug control according to a Council decision, during 7 and 8 February 2023

horizontal meeting of the Narcotics Working Party an agreement was adopted on a draft Council Decision on the position that has to be taken on behalf of the European Union at the 66th session of the Commission on Narcotic Drugs with regards to including substances in lists annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 Convention on Psychotropic Substances. The above Council Decision stipulates that the EU Member States shall support inclusion of 2-methyl-AP-237 in list I of the UN Single Convention on Narcotic Drugs of 30 March 1961.

Description of the solution

These substances are not for medical use. To control these substances, the draft law provides for the creation of a new generic group 4-cinamilpiperazine-1-carbaldehydes (Paragraph 8(4) of Chapter II, Annex 2 is added). The maximum amount for the quantities to be considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g. These quantities are the same as for acetyl-fentanyl group as these substances are related to fentanyls. According to information provided by the Forensic Board of the State Police, P-238, para-methyl-AP-237 and 2-methyl-AP-237 have never been found in Latvia. However, to protect the public health, narcotic substances should be controlled before they appear or enter the illegal trade for the law enforcement authorities to have the required legal basis for action.

Description of the problem

The INCB list contains substances W-15, W-18 and W-19 that are not controlled in Latvia.

Description of the solution

To control these substances, the draft law provides for the creation of a new generic group N-[1-(2-phenylethyl)-2-piperidilidene]benzenesulfonamides (Paragraph 8(5) of Chapter II, Annex 2 is added). For substances of the generic group, the maximum amount for the quantities to be considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g. For this group, these quantities are the same as for acetyl-fentanyl group as the included opioids are similar to fentanyls. Moreover, it has been reported that substances of this generic formula are used to replace (counterfeit) fentanyl in illicit trade[1], while their preliminary study is related to the fact that they have the same opioid properties as fentanyl (https://insight.jci.org/articles/view/97222). According to publications, substances covered by the generic formula such as W-18 are 100 times more potent than fentanyl and thousands of times more potent than morphine. As a result, the generic formula falls under list I (very dangerous prohibited narcotic substances, equivalent psychotropic substances and plants whose illegal trade and abuse pose a health risk). According to information provided by the Forensic Board of the State Police, W-15, W-18 and W-19 have never been found in Latvia. However, to protect the public health, narcotic substances should be controlled before they appear or enter the illegal trade for the law enforcement authorities to have the required legal basis for action.

[1] https://www.vice.com/en/article/qbx55w/everything-we-know-so-far-about-w-18-the-drug-thats-100-times-more-powerful-than-fentanyl

Description of the problem

The draft law provides for the creation of a new generic group N-(2-aminocyclohexyl) benzamides and N-(2-aminocyclohexyl)-2-phenylacetamides (Paragraph 8(6) of Chapter II, Annex 2 is added), which will include substances already controlled in Latvia such as U-47700, U-51754 and 3,4-methylenedioxy-U-47700 (Paragraphs 5(5), (6), and (7) of Annex 2), as well as several derivatives and structural analogues of these substances (structural analogues of U-47700: 2-naphthyl U-47700, U04, 4-TFM U-47700, U10, 1-naphthyl U-47700, U-48800, U-49900, U-50488, 3,4-difluoro U-47700, N-methyl U-47931E (as well as its methylated amide U-47931E or bromadolin[1]), N-ethyl-U-47700, cyclopropyl U-47700, and methoxy c); U-4700 derivative: isopropyl-U-47700; structural analogue of U-51754: U-69593). The maximum amount for the quantities to be considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g. What concerns the above substances that so far were included individually in Annex 2 to the law, the draft law includes them in a new generic group with the respective quantities of 0.1 g and 1 g.

[1] https://www.caymanchem.com/product/20530/u-47931e

Description of the solution

The draft law reduces the level of small quantities of some synthetic opioid analgesics from 0.1 g to 0.001 g, as the number of newly synthesised and illicit substances of this generic group for which there is no hazard research data has rapidly increased at the time, when there is a large number of reported deaths worldwide. A relatively high number of deaths has also been reported in Europe due to overdose of U-47700[1] and substances covered by the proposed generic formula. Known deaths caused by the mixture of U-47700 and fentanyl[2] or fentanyl and flubromazepam[3], etc. In view of the above, experts from the Chemistry Expert Groups of the Centre (hereinafter, the Chemistry Expert Working Group) is of the opinion that there is a high risk of unknown hazards posed by these opioids. Individual inclusion of these substances in the list of controlled substances is no longer efficient as various new substances rapidly appear in the illegal trade. As a result, to protect the public health, a decision was made to reduce the maximum amount for the quantity to be considered small. As, judging by their composition and properties, U-47700, U-51754 and 3,4-methylenedioxy-U-47700 belong to a new generic group, there is no longer any need to keep these individual substances in the lists of Annex 2 to the law. Thus, the draft law provides for their removal from list I

of Annex 2 to the law (Paragraphs 5(5), (6), and (7) of Annex 2 to the law) by rewording Paragraph 5 of Chapter II of Annex 2 to the law.

[1] Case in Italy: https://www.lastampa.it/torino/2017/10/24/news/torino-ucciso-dalla-droga-comprata-online-la-prima-vittima-italiana-dell-u47700-1.34405641/

[2] https://www.sciencedirect.com/science/article/abs/pii/S0379073816302006?via%3Dihub

[3] https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/10.1002/dta.2391

Description of the problem

The lists of Annex 2 to the law (Paragraph 5(4) of Annex 2) include AH-7921, whose quantities so far have been 0.1 g and 1 g respectively. As the Working Group of Chemistry Experts is of the opinion that substances related to AH-7921 may appear in illegal trade in the future, it is recommended to create a new generic group.

Description of the solution

In light of the above, the draft law provides for the inclusion of a new generic group N-[(1-aminocyclohexyl)methyl] benzamides in the lists of Annex 2 to the law (Paragraph 8(7) of Chapter II, Annex 2 is added). The maximum amount for the quantities to be considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g (so far, the respective values for the individual substance AH-7921 in Annex 2 to the law were 0.1 g and 1 g). It was decided to reduce the maximum limit for the quantities to be considered small from 0.1 g to 0.001 g due to a sharp increase in the number of newly synthesised and illicit substances of this generic group on which there is no research data. According to the Working Group of Chemistry Experts, these opioids have a high risk of unknown hazards. As AH-7921 belongs to a new generic group, the draft law provides for its deletion as an individually controlled substance (Paragraph 5(4) of Chapter II, Annex 2) by rewording Paragraph 5 of Chapter II of Annex 2.

Description of the problem

Annex 2 contains furanil UF-17 (Paragraph 5(8) of Annex 2 to the law). So far, in Annex 2 the respective amounts for furanil UF-17 have been 0.1 g and 1 g. And the INCB list includes the structural analogue of furanil UF-17 already controlled in Latvia. As the Working Group of Chemistry Experts is of the opinion that other substances related to furanil UF-17 may also appear in the illegal trade, the Centre recommends to create a new generic group.

Description of the solution

Accordingly, the draft law provides for the inclusion of a new generic group N-(2-aminocyclohexyl)-N-phenylformamides in the lists of Annex 2 to the law (Paragraph 8(8) of Chapter II, Annex 2 is added). The maximum amount for the quantities to be

considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g (so far, the respective values for furanil UF-17 in Annex 2 have been 0.1 g and 1 g). Like for the above two groups of synthetic opioids, for this substance and the group to which this substance and the related substances belong, it was decided to reduce the maximum amount for the quantity to be considered small from 0.1 g to 0.001 g as the number of newly synthesised and circulating substances belonging to this generic group for which there is no research data has rapidly increased. Considering the above, the Working Group of Chemistry Experts is of the opinion that this group has a high risk of unknown hazards. As, judging by its composition and properties, furanil UF-17 belongs to a newly created generic group, the draft law removes furanil UF-17 as an individual substance from the lists of Annex 2 to the law (Paragraph 5(8) of Chapter II is removed) by rewording Paragraph 5 of Chapter II of Annex 2.

Description of the problem

After the review of INCB list[1], it was established that Carbonyl-Bromadol is not yet controlled in Latvia.

[1]
https://www.incb.org/documents/Global_Projects_OPIOIDS/INCB.GRIDS.OPIOIDS.NoFOs_list.pdf

Description of the solution

The above substance is not for human or veterinary use. To subject these substances to control, the description of the generic group ‘cathinons’ (Paragraph 11(6) of Chapter II, Annex 2) is updated. The amounts set for the group remain unchanged. According to information provided by the Forensic Board of the State Police, Carbonyl-Bromadol has never been found in Latvia. However, to protect the public health, narcotic substances should be controlled before they appear or enter the illegal trade for the law enforcement authorities to have the required legal basis for action.

Description of the problem

Masitinib mesilate is the active substance of a number of veterinary medicinal products, which is used to treat inoperable mast cell tumours in animals, in particular, dogs. The register of veterinary medicinal products contains masitinib mesilate product Masivet[1]. Masitinib mesilate is a benzamide, a derivative of the benzoic acid amide. Though masitinib mesilate affects the function of the central nervous system and can be used to treat multiple sclerosis, there are no indications for the use of masitinib mesilate for intoxication purposes. According to its composition, masitinib mesilate belongs to the group of piperazines included in list I of Annex 2 to the law. According to information provided by the Forensic Board of the State Police, no cases of removal of masitinib mesilate from illegal trade have taken place in Latvia.

[1] https://registri.pvd.gov.lv/vz/dati?i_n=Masitinib

Description of the solution

To allow legal circulation of medicinal products containing masitinib mesilate in Latvia, it is necessary to lay down an exemption for masitinib mesilate in the piperazines group (Paragraph 11(7) of Chapter II). Medicinal products containing masitinib mesilate will continue to be prescription-only products in Latvia; they can only be prescribed by a doctor or a veterinarian. Medicinal products containing masitinib mesilate are included in the register of veterinary medicinal products with a specific dispensation procedure: veterinary medicinal products subject to prescription. The Food and Veterinary Service is the competent authority responsible for the distribution of veterinary medicinal products. The exception is justified as masitinib is an inhibitor of tyrosine kinase and has not been shown to have psychoactive effects.

Description of the problem

4-anilinepiperidine was included in Category 1 of Annex I to Regulation (EC) No 273/2004 and Category 1 of the Annex to Regulation (EC) No 111/2005 pursuant to the Delegated Regulation (EU) 2023/196 of the European Commission. This substance was included in these regulations as N-phenylpiperidin-4-amine (4-AP).

Description of the solution

The draft law provides for the removal of 4-anilinepiperidine from Paragraph 13 of Chapter III of Annex 2 to the law (Sub-paragraph (1)). 4-anilinepiperidine remains a substance controlled in Latvia, but will be controlled as a Category I precursor N-phenylpiperidin-4-amine (4-AP) (Paragraph 18(18) of list IV, Annex 2 to the law). For 4-anilinepiperidine, the maximum amount for quantities to be considered small shall be 0.6 g, whereas the minimum amount for the quantities to be considered large shall be 10 g. For the new substance 4-anilinepiperidine, which will henceforth be listed in Annex 2 to the law as a precursor to N-phenylpiperidine-4-amine, the maximum amount for quantities to be considered small shall be 10 g, whereas the minimum amount for the quantities to be considered large shall be 100 g. These quantities are similar to those of other precursors of fentanyl compounds of this group.

Description of the problem

After the assessment of its chemical composition, the active substance lisdexamfetamine of Lisdexamfetamine dimesylate STADA hard capsules shall be classified as a derivative of amphetamine. The generic group of amphetamines is listed in list I of Annex 2 to the law (Paragraph 11(3), Chapter II of Annex 2 to the law). As a result, the circulation of Lisdexamfetamine dimesylate STADA in Latvia is currently prohibited. Pursuant to Section 17 of the Pharmaceutical Law, it is allowed to distribute only medicinal products that are authorised in Latvia and included in the Latvian register of medicinal products. Due to this reason and

pursuant to Paragraph 100 of Cabinet Regulation No 376 ‘Procedures for the Registration of Medicinal Products’ of 9 May 2006, the State Agency of Medicines cannot conclude the authorisation of the above medicinal products in Latvia and make a decision on the authorisation of medicinal products in Latvia, as it is not possible to assign a classification group to these medicinal products and, consequently, to establish the dispensation procedure, as the circulation of such medicinal products is currently prohibited in Latvia pursuant to Annex 2 to the law. Lisdexamfetamine dimesylate STADA hard capsules are used as part of a comprehensive treatment programme for the attention deficit/hyperactivity disorder (UDHS) in children aged 6 years and above, if the response to a previous methylphenidate therapy is considered clinically insufficient. The State Agency of Medicines has received questions from several individuals on the availability of medicinal products containing lisdexamfetamine in Latvia. Interest has been expressed both by nationals of other countries who wish to import the above medicinal product for personal use to treat a specific disease and not to discontinue the use of the medicinal product when they enter Latvia, as well as by the Latvian nationals who need medicinal products for the treatment of attention deficit/hyperactivity disorders (UDHS). According to information provided by the Forensic Board of the State Police, no cases of removal from illegal circulation have taken place in Latvia. However, to protect the public health, narcotic substances should be controlled before they appear or enter the illegal trade for the law enforcement authorities to have the required legal basis for action.

Description of the solution

To allow the circulation of medicinal products containing lisdexamfetamine and to ensure their availability for the treatment of patients with attention deficit/hyperactivity disorders (UDHS) in Latvia, as well as taking into account the high intoxication and addiction potential of this substance, lisdexamfetamine is included in list II of Annex 2 to the law as an individual substance (Paragraph 13 of Chapter III, Annex 2, is supplemented by sub-paragraph 591). In the draft law, the maximum amount of lisdexamfetamine for the quantities to be considered small is 0.6 g, while the minimum amount for the quantities to be considered large is 10 g. These amounts are the same as for lisdexamfetamine-like compounds, such as benzfetamine and lefetamine, which are also amphetamine stimulants.

Description of the problem

Medicinal products containing naloxone are widely used as an emergency treatment for opioid overdose, when emergency therapy is administered in cases of known or suspected opioids overdose (e.g. heroin or morphine). Naloxone temporarily eliminates the effects of opioid drugs. Opioids act by attaching to and activating opioid receptors in the body. Naloxone quickly blocks these receptors, thereby stopping the effects of opioids such as slower breathing. Studies have demonstrated that naloxone is effective in treating opioid overdose either by injecting it (which is the standard treatment for opioid overdose) and by spraying it into the nose[1]. If

naloxone is administered on time, human life can be saved. Many European countries have successfully introduced a naloxone programme: Austria, Czech Republic, Denmark, Estonia, France, Germany, Ireland, Italy, Great Britain, Lithuania, Norway, Slovenia, Spain, and Sweden[2]. The program includes injection of naloxone hydrochloride or free distribution of a spray to individuals addicted to opioids or their relatives for use during opioid intoxication to provide the first aid until the arrival of the emergency medical services.
Pursuant to the law, medical facilities and social care facilities may purchase medicinal products containing naloxone that they require for treatment from wholesalers of medicinal products (pursuant to Cabinet Regulation No 220 ‘Procedures for the Acquisition, Storage, Use, Registration and Disposal of Medicinal Products in Medical Treatment Institutions and Social Care Institutions’).
According to the assessment provided by the Centre for Disease Prevention and Control, naloxone should be considered a derivative of oxymorphone included in list II of narcotic and psychotropic substances, and precursors to be controlled in Latvia, Annex 2 to the law ‘On the Procedures for the Coming into Force and Application of the Criminal Law’. Thus, pursuant to Section 3(3)(5) of the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors, it is subject to control as a substance included in list II of narcotic and psychotropic substances, and precursors controlled in Latvia (very dangerous narcotic substances and equivalent psychotropic substances that may be used for medical and scientific purposes). However, considering the purpose and the pharmacological mechanism of action of naloxone (prevents adverse effects caused by opioids by reducing life-threatening suppression of the central nervous system and the respiratory system), it should be made exempt in Annex 2 to the law ‘On the Procedures for the Coming into Force and Application of the Criminal Law’, as the benefits of naloxone availability (availability of a life-saving therapy) significantly exceed the risk of not subjecting the substance to stricter controls. The risk of abuse for intoxication purposes is low, it does not present notable addiction-forming symptoms, and does not have any addictive properties. The effects of the substance are limited to individuals who already have a sufficient concentration of opiates in their body.
The following medicinal products containing the active substance naloxone are included in the Latvian Register of Medicinal Products (excluding combination medicinal products in which naloxone is used in combination with other active substances and which have other indications): Nyxoid 1.8 mg nasal spray, solution in a single-dose packing (marketing authorisation number EU/1/17/1238/001) and Forvel 0.4 mg/ml solution for injection/infusion (marketing authorisation number 17-0156).

[1] https://www.ema.europa.eu/en/documents/overview/nyxoid-epar-summary-public_lv.pdf

[2] https://www.emcdda.europa.eu/publications/topic-overviews/take-home-naloxone_en#section4

Description of the solution

As availability of naloxone is of critical importance to save human lives after an opioid overdose and having established that the risk of abuse for intoxication purposes is small, and as this substance usually does not cause distinct addiction symptoms or have addictive properties, the draft law allows an exemption for naloxone (Paragraph 13(82), Chapter III, Annex 2). Medicinal products containing naloxone (excluding combination products) are listed as prescription medicinal products in the register of products. While combined medicinal products that contain naloxone (naloxone in combination with a substance from list II of narcotic and psychotropic substances to be controlled in Latvia) have already been included in the register as medicinal products subject to control, and their issuance procedure is imposed.

Description of the problem

Thiopental is controlled in Latvia as a structural analogue of pentobarbital included in list II (Paragraph 14(17), Chapter III of Annex 2). Thiophenal sodium salt is an active ingredient in several medicinal products registered with the Latvian Register of Medicinal Products: Thiopental Panpharma 1 g powder for solution for injection (auth. No 18-0016), and Thiopental Panpharma 500 mg powder for solution for injection (auth. No 18-0015). Pursuant to Paragraph 7 of Cabinet Regulation No 885 on ‘Procedure for the Classification of Medicinal Products’ of 22 November 2005 and pursuant to Paragraph 8.1 of this regulation, the State Agency for Medicines has decided that the above medicinal product requires a special prescription from a doctor (issuance procedure: Pr.I, Pr.II stac.). This medicinal product temporary suppresses the activity of all activated tissue. Thiopental sodium salt acts via the central nervous system, in particular, by affecting the reticular activation system of the midbrain. Thiopental may cause addiction.

Description of the solution

For distributors of medicinal products that contain the active substance thiopental sodium salt, and for medical facilities to clearly know that the medicinal product is controlled, thiopental should be included in list II as an individual substance (Paragraph 13 of Chapter III, Annex 2 to the law, is supplemented by sub-paragraph 101^{1}). The maximum amount of thiopental for the quantities to be considered small is 0.2 g, while the minimum amount of quantities to be considered large is 10 g. In view of the fact that thiopental is a structural analogue of pentobarbital, the respective amounts were determined like for pentobarbital, for which the maximum amount for the quantities to considered low was 0.1 g, while the minimum amount for the quantities to be considered high was 10 g. However, unlike pentobarbital, the maximum amount of thiopental for the quantities to be considered small was higher, i.e. 0.2 g, as thiopental is a medicinal product.

Description of the problem

Gammahydroxybutyric acid (GHB) is currently included in Paragraph 14(10), Chapter III of Annex 2 to the law. After a consultation with the experts of the Latvian Academy of Sciences, it was found that the substances should be listed by indicating the supplementary part at the end and by separating it with a comma. On the other hand, when the name of the substance is used in the text, the supplementary part should be indicated at the beginning of the name (e.g. 1 tablet contains X g of gamma hydroxybutyric acid).

Description of the solution

In view of the above and to comply with the above spelling rules, the draft law provides for an editorial change in the spelling of the substance from "gammahydroxybutyric acid (GHB)" to "Hydroxybutyric acid, gamma (GHB)". The name of the substance was also updated on the website of the State Agency of Medicines[1].

[1] https://www.zva.gov.lv/lv/industrijai/registracijas-apliecibu-ipasnieki/pirms-registracijas/vielu-saraksts?q=Hidroksibutirsk%C4%81be%2C+gamma

Description of the problem

On 10–14 October 2022, a meeting of the Expert Committee on Drug Addiction of the World Health Organisation took place. As a result, the Committee recommended to subject several narcotic and psychotropic substances, including bromazolam, to international control by including them in the UN Convention on Psychotropic Substances of 21 February 1971[1]. Bromazolam is not used in medicine. As the EU Member States, which are members of the UN Commission on Narcotic Drugs, vote on international drug control according to a Council decision, during 7 and 8 February 2023 horizontal meeting of the Narcotics Working Party an agreement was adopted on a draft Council Decision on the position that has to be taken on behalf of the European Union at the 66th session of the Commission on Narcotic Drugs with regards to inclusion of substances in lists annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 Convention on Psychotropic Substances[2], [3]. The Council Decision establishes that the EU Member States shall support the inclusion of bromazolam in the UN Convention on Psychotropic Substances of 21 February 1971. Bromazolam is currently controlled in Latvia as a structural analogue of alprazolam included in list III of Annex 2 to the law. The Forensic Board of the State Police has reported 21 case of removal of bromazolam from illegal trade in Latvia. In 12 of these cases, it was found in mixtures with metonitazene and protonitazene, in 2 cases in the form of counterfeit "Xanax" tablets, and in 1 case in a mixture with flubromazepam.

[1] https://cdn.who.int/media/docs/default-source/controlled-substances/45th-ecdd/bromazolam_draft.pdf?sfvrsn=f1bc761e_1

[2] https://eur-lex.europa.eu/resource.html?uri=cellar:651ce326-8b5b-11ed-999b-01aa75ed71a1.0010.02/DOC_1&format=PDF

[3] https://eur-lex.europa.eu/resource.html?uri=cellar:651ce326-8b5b-11ed-999b-01aa75ed71a1.0010.02/DOC_2&format=PDF

Description of the solution

In view of the above, the draft law provides for the inclusion of bromazolam in list III of Annex 2 to the law as an individual substance (Paragraph 16 of Chapter IV, Annex 2 to the law, is supplemented by sub-paragraph 8^1). The maximum amount for the quantities to be considered small shall be 0.001 g, and the minimum amount for the quantities to be considered large shall be 1 g. As bromazolam is a structural analogue of alprozam, it has the same amounts as alaprozam. The substance is controlled individually, as it has been found by the Forensic Board of the State Police, and a request has been received to control it individually to ensure that the application of the law is unambiguous and simple. Bromazolam is currently controlled as structural analogues of several benzodiazepines.

Description of the problem

Butorphanol used in veterinary medicine in Latvia is controlled as a derivative and a structural analogue of levorfanol included in Paragraph 13(59) of list II of Annex 2 to the law (very dangerous narcotic substances and equivalent psychotropic substances, which may be used for medical and scientific purposes). Butorphanol is a morphine-like synthetic agonist-antagonist opioid analgesic. It is available in an injectable form, as tablets and as an intra-nasal spray. Though butorphanol is a structural analoge of levorfanol, their differing pharmacological properties and the mechanism of action should be taken into account. Levorfanol is a long-acting substance with a high binding affinity (with a stimulating effect) to all opioid receptors (μ, δ and κ). Butorphanol, on the other hand, is a short-acting substance with a stimulating effect on kappa (κ) receptors (pain relief) and sigma (δ) receptors (cough suppression), and an antagonistic effect on mu (μ) receptors (pain reduction, euphoria, sedation, nausea, respiratory depression, constipation). Butorphanol has strong analgesic and soothing properties, and it does not suppress respiration. The main therapeutic effect of butorphanol is the relief of mild to moderate pain, while of levorfanol — the relief of moderate and severe pain.
Several medicinal products for dogs, cats and horses[1] containing the active substance butorphanol are included in the Register of Veterinary Medicinal Products of the Food and Veterinary Service: Alvegesic vet., Nalgosed, Butomidor, Torphadine vet., Morphasol. Medicinal products containing butorphanol for animals are used as analgesic, calming and anaesthetic agents. Their use is essential in “mobile” clinics that visit animals, as well as in providing the first aid to animals in critical cases such as severe pulmonary oedema, when combinations of other medicines may endanger the life of the animal due to changing blood pressure.

Butorphanol is one of the most suitable medicinal products for short and painless diagnostic examinations in aggressive and very mobile animals, as its effects are short-term, mild and at the same time safe to the animal. Pursuant to the current legal framework, medicinal products with butorphanol may be distributed only to practising veterinarians, ensuring the traceability of distribution and use of these medicinal products. Human medicinal products containing butorphanol are not included in the Latvian register of medicinal products. Medicinal products containing butorphanol are used only in veterinary practices (for the treatment of animals). In humans, butorphanol can cause drowsiness, nausea and dizziness. If overdosed in humans, the main sign is respiratory suppression. An opioid antagonist (e.g. naloxone) can be used as an antidote to mitigate a potentially lethal suppression of the central nervous system and the respiratory system. Long-term use of butorphanol may cause addiction. Like other opioid analgesics, butorphanol affects the central nervous system.
At the same time, there are no statistical data on the registered illegal trade and abuse of the active substance butorphanol for intoxication purposes, and there is no information that this veterinary medicinal product has entered the illegal trade and has been abused. The European Database on New Drugs (EDND) of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) does not contain any information on deaths caused by butorphanol, nor is it monitored by the EMCDDA.

[1] https://registri.pvd.gov.lv/vz/dati?i_n=Butorphanol

Description of the solution

Having assessed the above information, and to ensure that veterinary operators and employees clearly understand that butorphanol is controlled in Latvia, the draft law provides for the individual inclusion of butorphanol in list III of Annex 2 to the law (hazardous psychotropic substances that may be abused) (Paragraph 16 of Chapter IV, Annex 2 to the law, is supplemented by sub-paragraph 10^{1}). In the draft law, the maximum amount of butorphanol for the quantities to be considered small shall be 0.2 g, and the minimum amount for the quantities to be considered large shall be 10 g. As butorphanol is a derivative and a structural analogue of levorfanol, it has the same amounts as levorfanol.

Description of the problem

Esketamine is already controlled in Latvia as an enantiomer of ketamine included in list III of Annex 2 to the Law. Esketamine is an active ingredient in several medicinal products registered with the Latvian Register of Medicinal Products: Esketamine Kalceks 5 mg/ml solution for injection/infusion (auth. No 19-0152), Esketamine Kalceks 25 mg/ml solution for injection/infusion (auth. No 19-0153), Spravato 28 mg nasal spray, solution (auth. No EU/1/19/1410/004, EU/1/19/1410/001, EU/1/19/1410/003, EU/1/19/1410/002).

Description of the solution

For distributors of medicinal products that contain the active substance esketamine that is the enantiomer of ketamine S(+)[1], and for medical facilities to clearly know that the medicinal product is controlled, esketamine should be included in list III of Annex 2 to the law as an individual substance (Paragraph 16 of Chapter IV, Annex 2 to the law, is supplemented by sub-paragraph 15^{1})[2]. This would clearly regulate the presence of this substance in list III. The maximum amount of esketamine for the quantities to be considered small shall be 0.6 g, and the minimum amount of esketamine for the quantities to be considered large shall be 10 g. As esketamine is an enantiomer of ketamine, it has the same amounts as ketamine.

[1] An enantiomer is one of two stereoisomers that are mirrored; structurally, they are the same molecules that are not identical, as spatial layout differs.

[2] Currently, the interpretation of the law may lead to an inaccurate conclusion that the substance belongs to the generic group: 1-Arylcyclohexylamines and (1-arylcyclohexyl)methanamines

Description of the problem

What concerns benzodiazepine substance flubromazepam[1], the Forensic Board of the State Police has indicated that there has been 1 case of removal in liquid form and 1 case with a mixture together with bromazolam. Flubromazepam is not used in medicine. The European Rapid Alert System indicates that this substance was first identified in Germany in 2013, and that 15 other EU Member States have alerted about this substance since then.

[1] https://www.caymanchem.com/product/15157/flubromazepam

Description of the solution

Considering the above, flubromazepam is made subject to control by including it in list III of narcotic and psychotropic substances controlled in Latvia (Paragraph 16 of Chapter IV, Annex 2 to the law, is supplemented by sub-paragraph 25^{2}). Like with other controlled benzodiazepines, the maximum amount for the quantities to be considered small is 0.05 g, and the minimum amount for the quantities are to be considered large is 10 g. The substance is controlled individually, as it has been found by the Forensic Board of the State Police, and a request has been received to control it individually to ensure that the application of the law is unambiguous and simple. Flubromazepam is currently controlled as structural analogues of several benzodiazepines included in list III.

Description of the problem

Primidone is already controlled in Latvia as a structural analogue of phenobarbital under list III of Annex 2 of the law (hazardous psychotropic substances that may be abused). According to the Latvian Register of Medicinal Products, no human medicinal products containing primidone are authorised in Latvia. In Latvia, unauthorised medicinal products containing primidone[1] are distributed to patients

pursuant to Section 10(7) (a) and (b) of the Pharmaceutical Law. According to the information in the SPCs, primidone is deoxybarbiturate with an anticonvulsant effect (like two of its metabolites: phenobarbital and phenylethylmaloneamide (PEMA)). Primidone strongly suppresses the central nervous system and is partially metabolised into phenobarbital. Sustained use of primidone may cause addiction, and abrupt discontinuation of treatment may lead to withdrawal symptoms.

[1] If a medicinal product is required to treat a particular patient, and is not authorised in Latvia, and if medicinal products included in the Latvian register of medicinal products may not be used for the treatment of that particular patient due to medical indications, it is possible to receive a distribution permit for unauthorised medicinal products, medicinal products authorised and used in other countries on the basis of a prescription or a request issued pursuant to the law.

Description of the solution

For distributors of medicinal products that contain the active substance primidon (i.e. barbiturate) and for medical facilities to clearly know that the medicinal product is controlled, primidone, like other barbiturates, should be included in list III of Annex 2 to the law as an individual substance (Paragraph 16 of Chapter IV, Annex 2 to the law, is supplemented by sub-paragraph 61^2). The maximum amount of primidone for the quantities to be considered small shall be 0.6 g, and the minimum amount for the quantities to be considered large shall be 10 g. As primidone is a structural analogue of phenobarbital, it has the same amounts as phenobarbital. The amounts are determined by taking into account the fact that both substances are used in medicine.

Description of the problem

The veterinary medicinal product Zoletil contains psychoactive substances tiletamine and zolazepam. The veterinary medicinal product Zoletil has been authorised in Latvia under the national authorisation procedure since 2007[1]. Zoletil is an anaesthetic for diagnostic and short surgical procedures.
Tiletamine is pharmacologically similar to ketamine. Zolazepam is a benzodiazepine and is pharmacologically similar to diazepam. It has a sedative, tranquillising and muscle-relaxing effects. Ketamine and diazepam are currently controlled as substances included in list III of Annex 2 to the law. Tiletamine is currently controlled according to list I (Paragraphs 11(9) of Chapter II of Annex 2 to the law ‘1-arylcyclohexylamines and (1-arylcyclohexyl) methaneaminemfetamines’), and Zolazepam is controlled according to list III (Paragraphs 16(26) of Chapter IV of Annex 2 to the law ‘fludiazepam’).
The use of tiletamine in combination with Zolazepam is essential in cases when inhaled anaesthesia such as anaesthesia beyond the veterinary clinic, cannot be used. This combination is also essential if the duration of anaesthesia provided by ketamine combinations is insufficient. In the Latvian register of veterinary medicinal products, Zoletil is the only veterinary medicinal product that contains these active substances.

Pursuant to Paragraph 8.4 of Cabinet Regulation No 600 ‘Procedures for the Authorisation of Veterinary Medicinal Products’ of 18 July 2006, the conditions of supply and use of medicinal product Zoletil are to be classified as ‘for distribution only to veterinary practitioners’. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) monitors tiletamine and zolazepam. According to the European Rapid Alert System, tiletamine was first identified in illicit trade in Spain in 2016 and later in 2017 in Slovenia. Subsequently, it was never found in illicit trade. There is no information on Zolazepam in the European Rapid Alert System. In the literature collected by the EMCDDA — in the reports, there is information on at least 4 deaths and multiple poisonings after an injection of the medicinal product. According to information provided by the Forensic Board of the State Police, no cases of removal of tiletamime or zolazepam from illegal trade have been found in Latvia. According to the information provided by the Food and Veterinary Service, the veterinary medicinal product Zoletil is not subject to control in the EU Member States, except Zoletil in France that is subject to control as a medicinal product included in the lists of controlled narcotic and psychotropic substances.

[1] https://registri.pvd.gov.lv/vz/dati?o_n=zoletil

Description of the solution

As in veterinary medicine tiletamine is used in combination with zolazepam and as no cases of removal of tiletamine and zolazepam from illegal circulation have been found in Latvia, both substances are individually added to list III (Paragraph 16 of Chapter IV, Annex 2 is supplemented with Sub-paragraphs 66^{1}) and 71^{1}). Tiletamine is transferred from list I to list III and will be made subject to control under list III by requesting the required permits and ensuring the use of this medicinal product in veterinary medicine. The medicinal product may be distributed by wholesalers of veterinary medicinal products that have received an appropriate licence. The Food and Veterinary Service shall grant the right to handle the list III medicinal products to veterinary practices. Both the whole seller of the veterinary medicinal products and the veterinary practices shall submit reports on the circulation and use of medicinal products. The medicinal products may be imported or exported only according to one-time permit issued by the agency. Zolazepam is included as an individual substance for economic operators, veterinarians and other involved parties to clearly understand that this substance is subject to control. The maximum amount for the quantities to be considered small is 0.6 g, and the minimum amount for the quantities to be considered large is 10 g, considering the fact that tiletamine and zolazepam are used in veterinary medicine. In light of the above, the amounts are similar to those of other list III compounds used in human and veterinary medicine.

Description of the problem

Pursuant to Delegated Regulation (EU) 2022/1518 of the European Commission of 29 March 2022 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 with regards to the

inclusion of precursors of specific narcotic substances in the list of classified substances (entered into force on 4 October 2022)[1], substances ethyl-alpha-phenylacetate (EAPA) and methyl 3-oxo-2-(3,4-methylenedioxyphenyl)butanoate (MAMDPA) are controlled at the European Union level and included in Category 1 of Annex I to Regulation (EC) No 273/2004 and Category 1 of the Annex to Regulation (EC) No 111/2005. EAPA is used to produce 1-phenyl-2-propanone (P-2-P), also known as benzyl methyl ketone (BMK), MAMDPA is used to produce 3,4-methylenedioxy-phenyl-propan-2-one (PMK).

[1] https://eur-lex.europa.eu/legal-content/LV/TXT/PDF/?uri=CELEX:32022R1518&from=LV

Description of the solution

To determine the extent of the above precursors in illegal trade, which is the national competence of each EU Member State, the draft law supplements Paragraphs 18 of list IV of Annex 2 to the law (substances that may be used for the illicit manufacture of narcotic or psychotropic substances or precursors) by including category 1 precursors of ethyl-alpha-phenylacetoacetate (EAPA) (7) and methyl 3-oxo-2-(3,4-methylenedioxyphenyl)butanoate (MAMDPA) (11), establishing that the maximum amount for the quantities of those substances to be considered small is 10 g, and the minimum amount for the quantities to be considered small is 100 g. These quantities are the same as those for other compounds that are precursors to amphetamine and methamphetamine.

Description of the problem

Likewise, pursuant to Commission Delegated Regulation (EU) 2023/196 of 25 November 2022 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances (entered into force on 20 February 2023)[1] (hereinafter, Commission Delegated Regulation (EU) 2023/196) substances: diethyl (phenylacetyl) propanedioate (DEPAPD), ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate), N-phenylpiperidin-4-amine (4-AP), terc-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP), N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl) are subjected to controls at European Union level by including them in Category 1 of Annex I to Regulation (EC) No 273/2004 and Category 1 of the Annex to Regulation (EC) No 111/2005.

[1] https://eur-lex.europa.eu/legal-content/LV/TXT/PDF/?uri=CELEX:32023R0196&from=LV

Description of the solution

To determine the extent of the above precursors in illegal trade, which is the national competence of each EU Member State, the draft law supplements Paragraph 18 of

list IV of Annex 2 to the law (substances that may be used for the illicit manufacture of narcotic or psychotropic substances or precursors) by including category 1 precursors diethyl (phenylacetyl) propanedioate (DEPAPD) (Sub-paragraph (3)), ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate) (Sub-paragraph (8)), N-phenylpiperidin-4-amine (4-AP) (Sub-paragraph (18)), terc-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP) (Sub-paragraph (23)), N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl) (Sub-paragraph (17)), establishing that the maximum amount for the quantities of those substances to be considered small is 10 g, and the minimum amount for the quantities to be considered small is 100 g. These quantities are the same as those for other compounds that are precursors to the group of fentanyl compounds.

Description of the problem

Pursuant to Article 18 of Commission Delegated Regulation (EU) 2023/196 '[t]he Commission Implementing Regulation (EU) 2021/1832 of 12 October 2021 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (4) reclassified ANPP and NPP'. Paragraphs 18(21) of Chapter V, Annex 2 of the law contains the name 4-aniline-N-phenethyldiperidine (ANPP), while Article 18(12) contains the name 1-(2-phenylethyl)piperidine-4-one (NPP).

Description of the solution

As a result the name '4-aniline-N-phenethyldiperidine (ANPP)' in Paragraphs 18(21) of Chapter V, Annex 2 to the law should be changed to 'N-phenyl-1-(2-phenylethyl)piperidine-4-amine (ANPP)' (new wording: Paragraph18(16)). The name indicated in Paragraph 18(12) 'N-phenethyl-4-piperidone (NPP)' should be changed to '1-(2-phenylethyl)piperidin-4-one (NPP)' (new wording: Paragraph18(24)). 4-aniline-N-phenethyldiperidine (ANPP) and N-phenethyl-4-piperidone (NPP) are listed in Regulations No 273/2004 and No 111/2005 as the Combined Nomenclature (CN) names.
As Paragraph 18, Chapter V of Annex 2 should be reworded to maintain the enumeration and alphabetical order, it is reworded.

Description of the problem

BOH-2C-B is a derivative of 2C-B of the internationally controlled phenethylamine group. The use of the substance BOH-2C-B and any products containing it may cause serious harm to health and life, and undermine the public safety in general. The Rapid Alert System has received information on the identification of the substance BOH-2C-B in 12 EU Member States. This substance has also been identified in Latvia. [1] Substance BOH-2C-B (2-amino-1-(4-bromo-2,5-dimethoxy-phenyl-ethanol) currently is not made subject to control under the generic formula of 2,5-dimethoxyphenylethaneamines, as condition b of the generic formula requires (b) replacement of the hydrogen atom(s) in the ethylene group with one or more alkyl groups. In this case, replaced by a hydroxyl group.

[1] https://www.spkc.gov.lv/lv/jaunums/spkc-nosaka-pagaidu-aizliegumu-vielai-boh-2c-b-un-tas-saturosiem-izstradajumiem

Description of the solution

As it is easy to separate the hydroxyl group by chemical synthesis, 2,5-dimethoxyphenylethaneamine can be easily derived from BOH-2C-B. As a result, there is a high risk that it will be used to produce 2,5-dimethoxyphenylethanamines. As of 29 November 2023, the temporary ban of the SPKC on 2-amino-1-(4-bromo-2,5-dimethoxy-phenyl-ethanol) or BOH-2C-B (hereinafter, BOH-2C-B) and any products containing it has been in force. Accordingly, amendments are made to Paragraph 11(1)(b) of Chapter II of the law, subjecting the above substance to control. In view of the fact that a substance, which is the subject of a decision of the SPKC to ban the manufacture, acquisition, storage, transport, transfer or distribution of the new psychoactive substance in question or of any products containing it, undermines the public health and safety, no later than in 12 months from the date of entry into force of the decision the substance must be subjected to continuous control in Annex 2 to the law to prevent the substance from returning to uncontrolled circulation.

Have alternative options been assessed?

No

Have the proportionality of the requirements and the costs and benefits been assessed?

No

1.4. Evaluations/studies justifying the need for the LA

1.5. Ex post evaluation

Will be performed?

No

1.6. Other information

-

2. Societal groups impacted by the draft regulation, impact on the economic development and administrative burden

Does the draft affect this area?

No

3. Impact of the draft law on the national and local government budgets

Does the draft affect this area?

No

Other information

-

4. Impact of the draft on the current legal framework

Does the draft affect this area?

Yes

4.1. Related regulatory drafts

4.1.1. 1) Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors (in conjunction with Paragraph 6(3), Part II of Annex 2).

2) Cabinet Regulation No 175 ‘Regulations Regarding Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions’ of 8 March 2005 (in conjunction with Paragraph 13 and Paragraph 59[1], Chapter III, Annex 2).

Justification and description

1) As etorphine is required for veterinary procedures, at the request of Riga National Zoo, an exemption for the use of this substance during veterinary procedures should be imposed. To establish a system for the circulation, control and monitoring of etorphine, the above amendment shall enter into force on 1 December 2025 together with the related amendments to the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors, as well as other statutory acts. Statutory amendments take time.
Initially, amendments to the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors should be prepared by defining the following competences:
- The Food and Veterinary Service shall have the right to make a decision on granting to veterinary practices the right to handle medicinal products containing substances included in list I that are exempt for use in veterinary medicinal procedures, as well as to monitor and control veterinary practices and practicing veterinarians that handle medicinal products containing substances included in list I that are exempt for use in veterinary medicinal procedures.
- The State Agency for Medicines shall have the right to issue an authorisation for the import of medicinal products containing substances included in list I, if they have an exemption for use during veterinary medical procedures, and if the Food and Veterinary Service has granted the veterinary practice the right to handle medicinal products containing substances included in list I that are exempt for use during veterinary procedures.

The mandate included in the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors should be updated by the mandate of the Cabinet of Ministers to impose requirements on veterinary practices to receive the right to handle medicinal products containing substances included in list I, if they are exempt for use during veterinary medicinal procedures: incl. requirements for veterinary practices for them to be granted the right to handle medicinal products containing substances included in list I that are exempt for use during veterinary medicinal procedures. The conditions and procedures for veterinary practices to be granted, refused, suspended or cancelled the right to handle medicinal products containing substances included in list I that are exempt for use during veterinary medicinal procedures. The conditions and procedures for veterinary practices to purchase, store, record and destroy medicinal products containing substances included in list I that are exempt for use during veterinary medicinal procedures. To ensure compliance with the above requirements, amendments to the related regulatory enactments, including the following, shall be considered: Cabinet Regulation No 405 ‘Regulations Regarding Activities with Narcotic and Psychotropic Substances and Medicinal Products at Veterinary Medical Practice Institutions’ of 22 June 2021; Regulation No 441 ‘Procedures for the Purchase, Receipt, Storage, Distribution, Dispensation, Accounting and Destruction of Narcotic and Psychotropic Substances and Medicinal Products in Manufacturing of Medicinal Products and Veterinary Medicinal Products, at Drug and Veterinary Drug Wholesalers and Pharmacies’ of 17 June 2008; Cabinet Regulation No 35 ‘Procedure for the issue, suspension, re-registration and revocation of special permits (licences) for veterinary activities’ of 11 January 2011.

2) As lisdexamfetamine is included in list II of Annex 2 to the law as an individual substance (Paragraph 13, Chapter II, Annex 2, is supplemented by Section 59^{1}) to dispense medicinal products to patients by means of prescriptions, amendments to the following legal act is required: Cabinet Regulation No 175 ‘Regulations Regarding Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions’ of 8 March 2005. Thus, the interim provisions of the law stipulate that the above paragraph shall become effective on 1 January 2025, as lisdexamfetamine included in Annex 5, Cabinet Regulation No 175 requires amendments taking note of the fact that it is a narcotic substance, and the maximum limit that can be included in one prescription shall be established. Amendments to Cabinet regulations take time.

Responsible body

The Ministry of Health of the Republic of Latvia

4.2. Other information

The Ministry of Agriculture shall be the responsible body for drafting a veterinary legal act. Cooperation with the State Agency of Medicines, the Food and Veterinary Service, the Centre for Disease Prevention and Control is required.

5. Compliance of the draft with international obligations of the Republic of Latvia

Does the draft affect this area?

No

5.3. Other information

Description

Pursuant to Paragraphs 2.3 and 2.4 of the Cabinet Instruction No 1 of 23 February 2010 ‘Procedures on provision of information by the public administration on draft technical regulations”, the draft law shall be agreed with the European Commission.

6. Institutions involved in preparing the draft and the public participation process

Public participation is not required for this draft

Yes

Explanation

Public engagement in drafting the law was not ensured, as subjection of narcotic and psychotropic substances to control, the change of control classification, and use for medical or scientific purposes, imposition of the amounts of illicitly circulating substances is a specific issue that is addressed by sectoral experts.

6.4. Other information

Other information

-

7. Implementation of the draft and its impact on institutions

Does the draft affect this area?

Yes

7.1. Institutions involved in implementing the draft

Institutions

State Police
State Revenue Service
National Forensic Examination Office
National Centre for Forensic Medical Examinations

State Limited Liability Company ‘Rīgas psihiatrijas un narkoloģijas centrs’ (Riga Psychiatric and Narcology Centre)
Municipal police, Tax and Customs Police Board of the State Revenue Service, bodies that have the right to perform expert examinations (Forensic Board of the State Police, Customs Laboratory of the Customs Board, the State Revenue Service). The draft law will affect: 1) Law enforcement institutions (the State Police, the Municipal Police and the Tax and Customs Police Board of the State Revenue Service). 2) Bodies that have the right to perform expert examinations. 3) Medical facilities that may receive patients that have used such substances. 4) Natural persons, who use the above substances. 5) Medical and veterinary practices that should more thoroughly control controllable substances for medical use. 6) Natural persons affected by the users of such substances. 7) Persons involved in the circulation of illegal substances.

7.2. Monetary assessment of administrative costs

Does the draft affect this area?

No

7.3. Monetary assessment of compliance costs

Does the draft affect this area?

No

7.4. Impact of the draft on administrative functions and institutional structures

Impact	Yes/No	Explanation
1. A new institution will be created	No	-
2. An institution will be dissolved	No	-
3. A current institution will be reorganised	No	-
4. Functions and tasks of an institution will change (will be expanded or narrowed)	Yes	The draft law could affect expert examinations.
5. Efficiency of internal processes will be improved in an institution	No	-
6. Internal processes of an institution will be digitized	No	-
7. Internal processes of an institution will be optimized	No	-
8. Other information	No	-

7.5. Other information

Other information

-

8. Horizontal impacts

8.1. Impact of the draft on legal framework

8.1.1. On the development of public services

Does the draft affect this area?

No

8.1.2. On the development of national and local government information and communication technologies

Does the draft affect this area?

No

8.1.3. On the implementation of information society policy

Does the draft affect this area?

No

8.1.4. On the indicators of the National Development Plan

Does the draft affect this area?

No

8.1.5. On territorial development

Does the draft affect this area?

No

8.1.6. On environment

Does the draft affect this area?

No

8.1.7 On climate neutrality

Does the draft affect this area?

No

8.1.8. On the social situation of the population

Does the draft affect this area?

No

8.1.9. On equal opportunities and rights of persons with disabilities

Does the draft affect this area?

No

8.1.10. On gender equality

Does the draft affect this area?

No

8.1.11. On health

Does the draft affect this area?

Yes

Description

The draft law has a positive impact on public health; by limiting the increase in the supply and demand of narcotic substances and psychotropic substances in Latvia, the public’s interest at large will be protected.

8.1.12. On human rights, democratic values and the development of civil society

Does the draft affect this area?

No

8.1.13 On data protection

Does the draft affect this area?

No

8.1.14. On diaspora

Does the draft affect this area?

No

8.1.15. On regulation of professions

Does the draft affect this area?

No

8.1.16. On the best interests of the child

Does the draft affect this area?

Yes

Description

As the draft law is protecting the public health and safety, it also protects the interests of children by hindering the increase of supply and demand of narcotic and psychotropic substances in Latvia.

8.2. Other information

Other information

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