Amendment 1: Inclusion in the List of Narcotic Drugs and Psychotropic Substances

The main expected impact of the changes is to restrict the availability of these substances and curb their distribution, thereby reducing the risk of misuse and damage to health. Clarification of the regulation provides a clearer basis for monitoring and supports preventive action.

The significance of the impacts under evaluation is based on their scope, frequency of occurrence, size of the affected target group and risk of undesirable impacts. The analysis is based on the content of the draft Act and its practical implementation, and draws on data of the State Agency of Medicines, the Ministry of the Interior and the National Institute for Health Development.

The impact analysis addresses the social and economic impact of the draft Act as well as its impact on public governance. The impacts have been analysed by target groups. The main target groups affected are the general public, including users of narcotic drugs, psychotropic substances and medicinal products, the health sector, pharmacies, the Police and Border Guard Board, the Tax and Customs Board and the State Agency of Medicines. The amendments have no direct impact on regional development, national defence and foreign relations, information technology and the information society, the environment, education, culture or sports, and therefore no separate assessment of their impact on these areas has been carried out.

Impact target group 1: users of narcotic drugs and psychotropic substances

The draft Act affects persons who use or may potentially start using narcotic substances or psychotropic medicinal products without a doctor's prescription. The target group includes both occasional and regular users, including individuals who use new narcotic or psychotropic substances or misuse prescription drugs.

The number of people who have used drugs in their lifetime has increased over the last ten years. According to the 2023 Estonian adult population survey on drug use, 31 % of people aged 16–64 had used a narcotic substance at least once in their lifetime. According to data from 2023, the proportion of people aged 16–34 who had used drugs in the past 12 months was 16.5 %. In 2018, the relevant figure was 25 %. Drugs are often offered free of charge, and more frequently to younger people.

Nearly one-third (31 %) of young people aged 14–18 have used or tried some narcotic substance in their lifetime, and 75 % of them have done so on several occasions. Compared to 2015 and 2021, the share of young people who have used drugs repeatedly has increased significantly. Among young people, Estonia stands out in the European Union by a higher than average prevalence of drug use among schoolchildren aged 15–16. This indicates an early development of risk behaviour and increases the risk of long-term health damage. Drug users who use several substances simultaneously constitute a particularly high-risk subgroup.

The substances to be included in the list have been repeatedly found in mixtures with other psychoactive substances in Estonia: for example, MDMB-PINACA and EDMB-4en-PINACA have been found in combination with tetrahydrocannabinol and other cannabinoids, while promethazine has been found in combination with synthetic opioids and cocaine. A single postal consignment was found to contain harmine together with DMT, which is already a psychotropic substance included in List I in Estonia – it is therefore possible that these substances are being deliberately combined to achieve stronger psychoactive effects. Furthermore, these substances appear to be distributed rapidly in Estonia in various forms –

MDMB-PINACA has been detected in both cannabis buds and e-cigarette liquid in a quantity of 47.94 g, whilst EDMB-4en-PINACA was found in quantities of 75.69 g (2025), a figure which had already risen to 102.7 g by May 2026 alone. Semi-synthetic cannabinoids have been found both in the possession of private individuals and in postal consignments, and are distributed in various forms, including confectionery such as gummy and chocolate sweets, which may increase the risk of accidental consumption, particularly among children.

Although there is virtually no legitimate use of medicinal products containing promethazine in Estonia (according to data from the State Agency of Medicines, 12 packs of unauthorised medicinal products were dispensed on a doctor's request in 2024, and none in 2025), the substance is present on the illicit market – according to the data from the Estonian Forensic Science Institute, it was detected on three occasions in 2025, and according to the data from the National Institute for Health Development, promethazine was identified in syringe residues on 14 occasions. One fatality has been reported in which promethazine was taken in combination with other substances. Such combination of substances significantly increases the risk of unpredictable and life-threatening poisoning, as the interactions between the substances are often unknown.

Based on the surveys, the size of the target group is estimated to be average for both adults and young people. In particular, the draft Act will have the effect of restricting the availability of new and rapidly distributed psychoactive substances, which will help reduce risky behaviour and the associated health damage. Given the rapid distribution of these substances in Estonia, the health risks associated with their use, and the trend of simultaneous use of several substances, the draft Act will have a significant impact on this target group.

Impact target group 2: patients

The draft Act will affect patients who use promethazine for medical reasons, including the treatment of allergic conditions, nausea, vomiting and travel sickness, as well as sleep disorders and anxiety. Promethazine does not have a marketing authorisation in Estonia, and a doctor will request the medicinal product on behalf of the patient if necessary.

The use of medicinal products containing promethazine is virtually non-existent in Estonia. According to the data from the State Agency of Medicines, 12 packs of an unauthorised medicinal product were dispensed in 2024 as requested by a doctor. In 2025, medicinal products containing promethazine have not been used in Estonia.

The inclusion of an active substance in List IV of Narcotic Drugs and Psychotropic Substances restricts the prescription and handling conditions of medicinal products, but does not affect the conditions for reimbursement of medicinal products and does not restrict the ability of a doctor to prescribe prometazine for special medical purposes. Compared with the present use and prescription of unauthorised medicinal product, inclusion in List IV will introduce several changes: a prescription can be issued for up to 30 days' treatment (currently, a repeat prescription allows medicinal products to be ordered for up to nine months at a time), the medicinal product may not be sent by post or dispensed via an online pharmacy15, dispensing based on a cross-border digital prescription is not permitted, and a Schengen certificate is required when travelling to a Schengen country. Consequently, patients must consult

their doctor more frequently than before to obtain a new prescription, and the administrative process starts anew every time – in the case of an unauthorised medicinal product, the State Agency of Medicines handles the case and usually reaches a decision within 14 days, although this may take up to a maximum of 30 days.15 Negative impacts on the availability of medicinal products can be avoided if patients and healthcare professionals are aware of the procedure and the potential lead time for the supply of the medicinal product.

For certain conditions, such as allergies and travel sickness, there are alternative medicinal products with a marketing authorisation, which are available in pharmacies in Estonia (e.g. loratadine, dimenhydrinate). In contrast, for indications where the action of promethazine is medically necessary, alternatives may not be equivalent. Whilst this does somewhat mitigate the negative impact of inclusion in List IV on patients' treatment options, it does not eliminate it entirely.

The risk of adverse effects for patients is low, as the target group is small and the use of promethazine in Estonia is minimal. Although this change does restrict access to medicinal products compared with before, continued treatment under a doctor's supervision is guaranteed. Overall, the impact of the draft Act on this target group is limited.

Impact target group 3: healthcare sector and veterinary sector

The draft Act will affect the healthcare sector, in particular healthcare professionals who prescribe promethazine for medical purposes. The inclusion of the active substance in List IV of Narcotic Drugs and Psychotropic Substances Act does not impose any direct restrictions on treatment or alter existing treatment guidelines, but it does entail a number of specific changes to the conditions under which the medicinal product may be prescribed.

As promethazine is an unauthorised medicinal product in Estonia, prescribing it already requires a doctor to issue a digital prescription, together with a justification, and a prior decision of the State Agency of Medicines for each patient individually. Inclusion in List IV entails additional restrictions: a prescription may be issued for up to 30 days' treatment – whilst the medicinal product currently has unauthorised status, a repeat prescription allows for up to nine months' supply to be ordered at a time – dispensing on the basis of a cross-border digital prescription is not permitted, and a Schengen certificate is required when travelling to a Schengen country. The amendment requires increased attention from physicians to explain these requirements to patients16 and more frequent requests to the State Agency of Medicines for the continuation of treatment of the same patient15.

Although some veterinary medicinal products containing promethazine are authorised in the European Union, according to the State Agency of Medicines, none have been imported into Estonia and there is virtually no veterinary use of these medicines. In theory, a veterinarian has the opportunity to order promethazine via the cascade system, but in such cases the requirement for an import licence already applies, so inclusion in List IV would not change anything in this respect.

Given that the use of promethazine in Estonia is virtually non-existent, the target group is small – in 2024, only 12 packs were dispensed on the basis of a doctor's request, and in 2025, none at all. Thus, the impact of the draft Act on the health sector is minimal. The

amendment does not restrict the continuity of care for patients or the clinical discretion of the physician and does not entail any significant additional administrative burden.

The risk of adverse effects on the provision of health and veterinary services is low, as the amendment does not limit the availability of medicinal products on medical grounds.

Impact target group 4: drug handlers and pharmacies

The draft Act will affect wholesale distributors of medicinal products and pharmacies dispensing promethazine as prescription-only medicinal products. The inclusion of active substances in List IV of narcotic drugs and psychotropic substances will result in stricter regulation of the handling and dispensing of medicinal products and increased supervision.

Since promethazine is an unauthorised medicinal product in Estonia, handling it already requires additional procedures from pharmacies compared to standard prescription-only medicinal products – the medicinal product must be ordered separately from the wholesaler and patients must be informed of the arrival of the medicinal product15. Inclusion in List IV entails additional requirements: the medicinal product may not be sent by post or dispensed via an online pharmacy; it may be necessary to issue Schengen certificates to patients for travel purposes.17 Starting from 1 September 2024, pharmacies can already issue Schengen certificates, so this will not entail a significant additional burden; furthermore, given the frequency with which promethazine is dispensed, the impact on the target group will be minor.

The risk of adverse effects on pharmacies is low, as the use of promethazine in Estonia is minimal and the amendment does not restrict the lawful dispensing of the medicinal product on medical grounds. Overall, the draft Act will have a minor impact on those handling medicinal products and on pharmacies.

Impact target group 5: State Agency of Medicines

The draft Act will affect the State Agency of Medicines as the authority responsible for the regulation and supervision of narcotic drugs and psychotropic substances. The amendment is based on a proposal made by the State Agency of Medicines in connection with the distribution of new substances with an increased risk of misuse and the need to protect public health. Therefore, the draft Act does not represent a new or additional task for the State Agency of Medicines, but is part of the agency's normal regulatory role.

The inclusion of substances in the lists of narcotic drugs and psychotropic substances requires the State Agency of Medicines to update the existing lists, to refine guidance materials and to inform the relevant target groups. The amendment may also require the improvement of monitoring and reporting procedures and the continuation of cooperation with other supervisory authorities, including the Police and Border Guard Board and the Tax and Customs Board.

The draft Act contains a significant regulatory innovation – the inclusion of the group of semi-synthetic cannabinoids in List VI represents a departure from the previous approach, as until now only individual substances have been included in the lists. The inclusion of a group of substances will allow the State Agency of Medicines to respond more efficiently and flexibly to the continuous distribution of new substances without handling each substance separately. Given that 35 semi-synthetic cannabinoids are currently monitored by EUDA, and that new substances such as delta-9-THCV, delta-8-THCV and delta-9-THCH had already been

detected in Estonia in 2025, such a flexible regulatory tool is an important instrument for the State Agency of Medicines on the rapidly changing narcotics market. The semi-synthetic cannabinoids currently included in List I will remain there, but in the future new semi-synthetic cannabinoids will be added directly to the group of substances in List VI without the need for a separate procedure for each substance.

The impact of the draft Act on the State Agency of Medicines is primarily organisational. The inclusion of the class of semi-synthetic cannabinoids in List VI is a significant regulatory development that will enhance the capacity of the State Agency of Medicines on the rapidly changing narcotics market. The amendment remains within the scope of the current tasks and competences of the State Agency of Medicines and does not entail the need for structural changes, additional fixed costs or the creation of new administrative functions. Overall, the impact of the draft Act on the State Agency of Medicines is positive and significant.

Impact target group 6: the Police and Border Guard Board and the Tax and Customs Board

The draft Act will affect the Police and Border Guard Board and the Tax and Customs Board, which are responsible for combating and supervision of the illegal handling of narcotic drugs and psychotropic substances. The amendment clarifies the applicable rules, bringing previously unregulated substances under clear regulation, and creates a clearer basis for carrying out supervisory and procedural activities.

The amendment will enable the Police and Border Guard Board and the Tax and Customs Board to respond more effectively to the illegal handling of narcotic drugs and psychotropic substances, including the identification and confiscation of substances and the conduct of misdemeanour and criminal proceedings. Clearer regulation will also support cross-border cooperation and exchange of information, in particular with regard to the import and export of substances and the control of international trade.

The impact of the draft Act on the Police and Border Guard Board and the Tax and Customs Board is mainly organisational and the risk of undesirable effects is small. The amendment does not introduce any new supervisory tasks, but clarifies the existing procedural framework and improves legal clarity with regard to new substances that are being distributed illegally. The impact is revealed in everyday operations, but remains within the normal operational framework of the institutions and does not require the creation of additional structures or permanent costs.

Overall, the draft Act will have a minor impact on the Police and Boarder Guard Board and the Tax and Customs Board, whilst supporting the capacity of law enforcement agencies to prevent and combat illicit drug trafficking and to protect public health and internal security.