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

The main expected impact of the changes is to restrict the availability of these substances and curb their spread, 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 and its practical implementation, and uses data from the Police and Border Guard Board, the Ministry of the Interior, the National Institute for Health Development, and international studies.

The impact analysis addresses the social and economic impact of the Bill as well as its impact on public governance. The impacts have been analysed across target groups. The main target groups affected are the population, the health sector, pharmacies, the Police and Border Guard Board, the Tax and Customs Board and the Medicines Agency. 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 sport, 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 affects persons who use narcotic substances or psychotropic medicines without a doctor's prescription. The target group includes both occasional and regular users, including individuals who use new psychoactive 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. For comparison: In 2015, the Public Opinion and Risk Behaviour Survey of the Police and Border Guard Board showed that the same figure was around 20%.

The proportion of people who have used drugs in the last month and year has fallen in recent years. Based on the 2024 Health Behaviour in the Adult Population Survey of the National Institute of Health Development, 4.4% of respondents aged 16–64 had used narcotic drugs or prescription drugs with a narcotic effect without a doctor’s prescription in the last 12 months and 5.1% in the last 30 days. In 2020, the corresponding figures were 7.1% and 5.8%. In the last 12 months, the prevalence of drug use is highest among men aged 16–34 (over 16%) and women aged 25–34 (7.1%).

Nearly a third (31%) of young people aged between 14–18 have used or experimented with 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. Since 2022, the spread of synthetic opioids has become a significant negative

trend, accompanied by disproportionately high damage to public health. Approximately half of the deaths caused by overdose (117 people died from overdose in 2023) have been linked to the use of synthetic opioids, often in combination with other substances. The simultaneous use of several substances significantly increases the risk of overdose and death.

Based on studies, the size of the target group is estimated to be average among both adults and young people, but considering the increase in repeated use among young people, the impact of the Bill on this target group is significant. In particular, the draft act will have the effect of restricting the availability of new substances with an increased risk of misuse, which will help reduce risky behaviour and the associated health damage and premature deaths.

Impact target group 2: patients

The draft affects patients taking pregabalin and gabapentin for medical purposes, including the treatment of epilepsy, neuropathic pain and generalised anxiety disorder (see pages 9-10). These are patients whose treatment is long-term and for whom the continued availability of medicinal products is important.

According to statistics on the use of medicinal products, the use of pregabalin and gabapentin in Estonia has increased in recent years: In 2024, the use of gabapentin was 2.91 and the use of pregabalin was 4.19 DPD per 1,000 inhabitants per day, compared to 1.87 and 2.61 DPD in 2020, respectively. This means that these active substances are used daily by around 0.3-0.4% of the population, or several thousand patients, and by tens of thousands of people every year. The indicators refer to the persistent use of the active substances and to a significant patient population.

The addition of active substances to Schedule IV of narcotic and psychotropic substances does not restrict the prescription of medicines or the continuation of treatment, but makes the conditions for handling and dispensing medicines more stringent. The amendment does not entail any further restrictions on the patient’s treatment options and does not affect the conditions for reimbursement of medicinal products.

The impact of the Bill on this target group consists mainly in increased control of the use and dispensing of medicinal products, the purpose of which is to reduce the misuse and unlawful spread of medicinal products. From the patient's perspective, the impact is estimated to be minor and rarely apparent, primarily through the clarification of formal requirements related to the dispensing of medicines and travel.

Inclusion in Schedule IV entails additional administrative requirements for patients, including a restriction on cross-border ePrescription and postal distribution of medicinal products and the obligation to hold a Schengen certificate when travelling in Schengen States. In implementing the amendment, it is important to note that the range of medicinal products available at pharmacies may vary from one region to another and it is necessary to ensure that patients have access to such medicinal products in all regions of Estonia. The specified requirements are consistent with the other rules applicable to Schedule IV medicinal products and do not restrict access to treatment for special medical purposes.

The risk of adverse effects on patients is low, as the change does not limit the availability of treatment, and continued treatment under the guidance of a physician is ensured. Overall, the impact of the draft on this target group is limited.

Impact target group 3: health sector

The Bill will affect the health care sector, in particular neurologists, family physicians and psychiatrists who prescribe pregabalin and gabapentin for medical purposes. The addition of active substances to Schedule IV of narcotic and psychotropic substances does not impose direct treatment restrictions on doctors or change the current treatment guidelines, but it does lead to a stricter regulatory framework for the prescription and use of medicines and greater supervision.

The amendment requires doctors to justify the indication more thoroughly than before, to document it and to pay more attention to the prevention of the risks of misuse of medicinal products. This may be reflected in greater transparency about the prescription regime for medicinal products, as well as in increased attention paid by the supervisory authorities to the issue of prescriptions for medicinal products.

The impact of the Bill on the healthcare sector is primarily organisational and estimated to be minor. The impact is more permanent than frequent, as it relates to normal prescription practices and does not entail any significant additional administrative burden. The amendment does not restrict the continuity of care for patients or the clinical discretion of the physician but strengthens the responsible dispensing and use of medicinal products.

The risk of undesirable effects on the provision of healthcare is low, as treatment continues under medical guidance and the change does not affect the availability of medicinal products for special medical purposes. Overall, the impact of the Bill on the health sector is small and proportionate, supporting the protection of public health and the prevention of the misuse of medicinal products. The amendment also requires health care professionals to provide better-informed counselling and monitoring of patients, including the assessment of mental state and potential risk behaviours, which is in line with the current principles of good medical practice and patient safety.

The amendment requires healthcare professionals to be more attentive in counselling and monitoring patients, including assessing their mental health and possible risk behaviours, in line with standard treatment practices and patient safety principles. The Bill supports the protection of public health and the prevention of the misuse of medicinal products.

The risk of undesirable effects on the provision of health services is low, as treatment continues under the guidance of a doctor and the amendment does not restrict the use of medicines for special medical purposes.

Impact target group 4: drug handlers and pharmacies

The Bill will affect pharmaceutical operators and pharmacies dispensing pregabalin and gabapentin as prescription medicines. The inclusion of active substances in Schedule IV of narcotic drugs and psychotropic substances will result in stricter regulation of the handling and dispensing of medicinal products and increased supervision.

The amendment will require more detailed compliance by pharmacies with requirements relating to the dispensing of medicinal products, including the verification and documentation of prescriptions, and the specification of procedures relating to the handover of medicinal

products. There is also an increased need to pay attention to potential risks of misuse and to cooperate with monitoring bodies.

The inclusion in Schedule IV of new medicinal products will increase the number of medicinal products for which a Schengen certificate is required when travelling to the Schengen States. From 1 September 2024, pharmacies will be able to issue Schengen certificates for medicines, which will increase their role in advising patients and checking documents. Since pharmacies already perform these tasks, and the amendment only concerns the inclusion of two additional medicinal products in Schedule IV, this does not entail any significant additional burden.

The impact of the Bill on handlers of medicinal products and pharmacies will be permanently manifested in the framework of the usual handling of prescription medicinal products, including in the counselling of patients and in the control of documents in connection with the use of medicinal products in the Schengen States. The amendment will not entail any significant additional administrative burden or require any substantive changes to the organisation of work in pharmacies.

The risk of adverse effects on pharmacies is low, as the change does not restrict the legal dispensing of medicinal products and does not affect the availability of medicinal products to patients for medical purposes. Overall, the amendment will help reduce the misuse of medicines without imposing an unreasonable additional burden on pharmacies.

Impact target group 5: State Agency of Medicines

The Bill 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 spread of new substances with an increased risk of misuse and the need to protect public health. Therefore, the Bill 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 active substances in the Schedules of narcotic drugs and psychotropic substances requires the State Agency of Medicines to update the existing Schedules, to refine guidance material 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 impact of the Bill on the State Agency of Medicines is mainly organisational and estimated to be minor. 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. On the contrary, the amendment supports the current activities of the State Agency of Medicines in more effectively controlling narcotic and psychotropic substances and preventing their misuse.

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

The Bill will affect the Police and Border Guard Board and the Tax and Customs Board, which are responsible for the prevention and supervision of the illegal handling of narcotic drugs and psychotropic substances. The amendment clarifies the existing 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 Bill 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 new supervisory tasks, but clarifies existing procedural grounds and improves legal clarity. The impact is permanent, but remains within the normal operational framework of the institutions and does not require the creation of additional structures or permanent costs. In conclusion, the Bill strengthens the capacity of law enforcement agencies to prevent and combat illicit drug trafficking and supports the protection of public health and internal security.