

## **Impact assessment**

### **The problem at hand and what is to be achieved**

Rilmazafone is an ingredient in medicinal products approved in Japan. Since these medicinal products have not been approved in Sweden, they are only available under what is known as prescription under licence. However, the Swedish Medical Products Agency has not granted any such licences to date. After ingestion, the substance rilmazafone is converted into the substance rilmazolam, which has psychoactive properties. The Swedish National Board of Forensic Medicine reported four deaths linked to the ingestion of rilmazafone in 2022 and 2023. In all cases, rilmazolam was deemed to have caused or contributed to the deaths. The Swedish National Forensic Centre also had cases concerning rilmazafone in 2022 and 2023. Furthermore, rilmazafone is available for sale in several online outlets for recreational users. Thus, there is misuse of that substance in Sweden.

By including the substances rilmazafone and rilmazolam in Annex 1 to the Narcotic Drugs Control Ordinance (1992:1554), illegal handling and access to the illegal market should be reduced.

### **Impact on the State**

The classification of these substances as narcotic drugs gives the Swedish Customs and the Swedish Police Authority the power to seize these substances under the narcotic drugs legislation. The courts will be able to prosecute persons illegally handling rilmazafone and rilmazolam. The impact is otherwise considered to be limited.

### **Impact on businesses**

The classification of these substances as narcotic drugs means that any businesses handling rilmazafone and/or rilmazolam for medical, scientific or special socially beneficial purposes will need to have a narcotic drugs authorisation for the manufacture, possession, import and export, and trade in these substances. The authorisation requirements entail application fees and administrative costs, but at a negligible level in this context.

### **Impact on individuals**

The classification of these substances as narcotic drugs imposes stricter restrictions on individuals concerning the quantities that may be carried for medical purposes when travelling to Sweden. As medicinal products containing rilmazafone are only authorised in Japan, this will mainly concern travellers from Japan.