5. Amendment of Minister for Human Capacities Decree No 55/2014 of 30 December 2014 on substances or groups of compounds classified as new psychoactive substances (hereinafter: the ‘Decree’)

6. On the proposal of the Lifestyle and HIV/AIDS Focal Points Department, Health Promotion and Screening Coordination Division, Ministry of State for Healthcare, Ministry of Human Capacities, one new unique psychoactive substance susceptible to abuse (CUMYL-PeGaClone) will be listed in the schedule of Annex 1 to the Decree.

7. -

8. The one new unique psychoactive substance to be listed in the schedule of Annex 1 to the Decree (CUMYL-PeGaClone) will not be permitted to be freely marketed in Hungary.

In view of this, health risks will be reduced, as it will be made more difficult for substance users to gain access to this substance.

9. The Criminal Investigation General Directorate of the Hungarian National Police Headquarters indicate that in the first quarter of the year the National Expert and Research Centre identified the synthetic cannabinoid CUMYL-PeGaClone among a growing number of substances suspected to be drugs seized by police forces. Police forces also have information that several circles of perpetrators are trafficking in the substance, thereby making a profit of tens of millions or even hundreds of millions. This is the only substance on the illegal market whose marketing is not subject to criminal sanctions.

The Lifestyle and HIV/AIDS Focal Points Department of the Health Promotion and Screening Coordination Division recommended that CUMYL-PeGaClone be listed in the schedule of Annex 1 to the Decree in order to limit the free circulation of the said substance.

With regard to characterisation of the substance, based on the uniform opinions during a peer review, the Lifestyle and HIV/AIDS Focal Points Department of the Health Promotion and Screening Coordination Division concluded that the provisions in § 15/B(3) of Act XCV of 2005 on medicinal products for human use and the amendment of other acts regulating the market of medicinal products (the ‘Act’) apply to the aforementioned assumed new psychoactive substance, i.e.:

a) no such information is known which would indicate the pharmaceutical use of the above compound, and

b) no such information is known which rules out the possibility that the aforementioned compound poses a public health threat similar to the narcotic drugs specified in § 1(4) of the Act or the substances listed in Schedules I-II to Legislative Decree No 25 of 1979 announcing the Convention on Psychotropic Substances signed in Vienna on 21 February 1971 and in Schedules A and B of Annex 2 to the Act.

The status of the substances listed in the schedule of Annex 1 to the Decree shall remain provisional until the relevant risk assessments have been conducted. Following expiration of the deadline determined by the Act for conducting a risk assessment, substances posing a serious health risk can be included in the criminal law schedule (which is the factual basis for drug abuse), or moved to another schedule of substances which are deemed to be harmless but not permitted to be marketed freely.

10. Restrictions on the placement on the market or use of chemical substances, preparations or products.

Reference(s) to basic text(s): Minister for Human Capacities Decree No 55/2014 of 30 December 2014 on substances or groups of compounds classified as new psychoactive substances

Latest amendment: Notification 2017/156/HU

The basic texts were forwarded with an earlier notification: 2012/0137/HU: 2015/0062/HU

11. Yes

12. In the interests of reducing the marketing of new psychoactive substances and thus effectively preventing deaths, it is justified to expand the schedule of new psychoactive substances of Annex 1 to the Decree to include the new compound, on the risks of which the authorities have been informed.

Little concrete data on the new psychoactive substance to be listed, CUMYL-PeGaClone, is available from literature and reported health-care cases, but its chemical structure is nevertheless similar to the known cannabinoid agonist JWH-018, which has been proven to have a similar effect to marijuana (cannabis). The substance JWH-018 has been listed in the schedule of psychotropic substances equivalent to drugs in Hungary since 2012.

Notifying the amendments to Annex 1 to the Decree as a matter of urgency is justified because the market of new compounds which pose a health risk and are susceptible to be used for mind-altering purposes is expanding rapidly.

13. No

14. No

15. Yes

16. TBT aspect

No - the draft is neither a technical provision nor a conformity assessment procedure.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

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