New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 24/10/2017 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 609 votes to 19, with 29 abstentions, a resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Improving monitoring: given the rapidly growing market for these new products, which remains challenging, the amended text stressed the need to **enhance monitoring and early warning systems** and to assess their health and social risks.

Vulnerable groups, especially young people, are particularly exposed to the health and social risks associated with new psychoactive substances.

Exchange of information, early warning system and risk assessment: the European Monitoring Center for Drugs and Drug Addiction (EMCDDA) in cooperation with Europol shall collect, collate, analyse and assess the information and **communicate it in a timely manner to the national focal points and the Europol national units** as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report.

Initial report: an initial report shall be drawn up on a new psychoactive substance where information provided by the Member States on that new psychoactive substance gives rise to concerns that it might pose health or social risks at Union level. The initial report shall allow the Commission to **make an informed decision** regarding the launch of the risk assessment procedure. The risk assessment procedure at Union level should be undertaken rapidly.

Where the a **majority of the Member States** considers that information shared on a new psychoactive substance gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.

The amended text stated that the initial report shall contain a first indication of the nature, number and scale of **incidents showing health and social problems** in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance.

The initial report shall also contain information:

- on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;
- on the **commercial and industrial use** of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes.

The **Scientific Committee** may be extended as deemed necessary by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance.

Following the risk assessment procedure, the Commission shall determine whether the new psychoactive substance in question **should be included in the definition of 'drug'** in accordance with the procedure provided for in Council Framework Decision 2004/757/JHA.

Exclusion from risk assessment: in principle, no risk assessment shall be carried out on a new psychoactive substance if it is subject to an assessment **under international law**, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report. In addition, no risk assessment shall be carried out on a new psychoactive substance if it is an active substance in a **medicinal product for human use** or in a veterinary medicinal product.