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COVER NOTE

From:	Matthias RUETE
date of receipt:	28 August 2015
To:	Ambassador Christian BRAUN
Subject:	Request for risk assessment on a new psychoactive substance: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α-PVP)

Delegations will find attached a request from the Commission for a risk assessment on a new psychoactive substance 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α-PVP).

EUROPEAN COMMISSION
DIRECTORATE-GENERAL MIGRATION AND HOME AFFAIRS

Director-General

Brussels, 26 AOUT 2015
DG HOME/D4/MR/md(2015)

Your Excellency,

On 3 August 2015, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol presented to the Council, the Commission and the European Medicines Agency (EMA) a Joint Report on the new psychoactive substance 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α-PVP).

This Joint Report, drawn up in accordance with the Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances[1], points out that α-PVP has been available on the Union's drugs market since at least February 2011 and has been detected in all 28 Member States, Turkey and Norway. A considerable number of acute intoxications and deaths related to α-PVP were reported in several Member States. Information has also been provided on the involvement of organised crime in the mixing and the distribution of this substance. Although the Joint Report points out that there is limited data on the pharmacology and toxicology of this substance, non-clinical studies suggest that α-PVP is likely to be a potent psychostimulant in humans, with abuse liability and dependence potential.

Moreover, α-PVP is subject to control measures under drug control, medicines and other legislation in twenty Member States, in Turkey and in Norway. It is not subjected to control measures in eight Member States.

I therefore consider that the health and social risks posed by the manufacture, trafficking and use of α-PVP, as well as the involvement of organised crime and possible consequences of control measures, should be assessed through a risk assessment, as foreseen by Article 6 of Decision 2005/387/JHA.

His Excellency Mr Christian BRAUN
Permanent Representative of Luxembourg to the European Union
Avenue de Cortenbergh 75
1000 Bruxelles
Belgique

[1] OJ L 127, 20.5.2005, p.32.

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I should be grateful if you would notify this request to conduct a risk assessments of α-PVP to the Members of the Council.

Yours faithfully,

Matthias RUETE

Annex 1: Findings of the Joint Report and summary of the procedure under Council Decision 2005/387/JHA

Annex 2: EMCDDA-Europol Joint Report on 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α-PVP)

cc: Mrs Christine ROGER - Director-General, Secretariat General of the Council
Mr Luigi SORECA – Director, DG HOME, Directorate D
Ms Catherine DELACOUR, Mr Julian SIEGL – DG HOME Assistants
Ms Floriana SIPALA, Mr Marius RASCANU – DG HOME, Unit D4

ANNEX 1 - FINDINGS OF THE JOINT REPORT AND SUMMARY OF THE PROCEDURE

1.1 THE FINDINGS ON 1-PHENYL-2-(1-PYRROLIDINYL)-1-PENTANONE (α-PVP)

- α-PVP is a synthetic cathinone derivative closely related to pyrovalerone and MDPV, both of which are synthetic stimulants that are controlled under the 1971 United Nations Convention on Psychotropic Substances. Pyrovalerone is listed in Schedule IV and MDPV is listed in Schedule II. The systematic IUPAC name for α-PVP is (*RS*)-1-phenyl-2-(1-pyrrolidinyl)-1-pentanone and it has been reported under street names as: grind', 'flakka', 'gravel', 'crystal love', 'Pure NRG', 'Snow Blow' and 'vanilla sky';

- α-PVP has been available on the Union's drugs market since at least February 2011 and has been detected in 28 Member States, Turkey and Norway. In most cases, it has been seized as a powder, but also under other forms as tablets, in multi-kilogram quantities originated from China. In about 35% of the detections, α-PVP was found in combination with other substances, as cathinones, synthetic cannabinoids and a range of other new psychoactive substances;

- One Member State has reported the involvement of organised crime in the mixing and posterior distribution of this substance with plant material; Two Member States reported the seizure of illicit production and tableting sites;

- A total of 106 deaths associated with the use of α-PVP were reported by seven Member States, in a period of time between 2012 and 2015. Case-level data for 34 acute intoxications associated with this substance were reported by six Member States;

- The adverse symptoms and signs recorded for non-fatal intoxications associated with the use of α-PVP include tachycardia, mydriasis, hallucinations, agitation, tremor and hypertension;

- There is limited data on the pharmacology and toxicology of this substance; there are no clinical studies. Nevertheless, non-clinical studies suggest that α-PVP is likely to be a potent psychostimulant in humans, with abuse liability and dependence potential. There are no prevalence surveys assessing the use of α-PVP in the general population;

- Information from seizures and users websites suggest that α-PVP has been sold as a 'research chemical' online and is available in wholesale and consumer amounts. Data reported by the Member States suggests that α-PVP is used by recreational and high risk drug users, including those who inject drugs, in a range of settings including at home and in party contexts. The routes of administration include nasal insufflation, injection and oral administration;

- α-PVP is subject to control measures under drug control, medicines and other legislation in twenty Member States, in Turkey and in Norway. It is not subjected to control measures in 8 Member States.

1.2 SUMMARY OF THE PROCEDURE AS LAID DOWN IN COUNCIL DECISION 2005/387/JHA

Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances, hereafter referred to as the 'Council Decision', establishes a mechanism for subjecting substances to control across the Union.

Joint Report

The Council Decision (Article 5) provides that when a new substance has been notified by a Member State, Europol and EMCDDA consider - on the basis of a set of predefined criteria - whether the gathering of further information is necessary. If so, a Joint Report on the specific substance is drawn up by the agencies in consultation with the European Medicines Agency (EMA) and based on information from the Member States. The Joint Report is submitted to the Council, the Commission and the EMA within **ten weeks.**

A Joint Report on α-PVP was submitted by EMCDDA and Europol on 3 August 2015.

Risk Assessment

Within **four weeks** from receipt of the Joint Report, the Commission or at least one quarter of the Member States may submit a written request to the Council asking for a Risk Assessment to be conducted (Article 5(5)). The Council decides by a majority of its Members (Article 6(1)) whether to request the Scientific Committee of the EMCDDA to conduct a risk assessment.

If a risk assessment is requested, the EMCDDA must submit the risk assessment reports within **12 weeks**.

In line with the deadlines set by the Council Decision, the Commission is transmitting this request to conduct a Risk Assessment **within four weeks** from the presentation of the Joint Report.

Grounds for not carrying out a Risk Assessment

Article 7 of the Council Decision describes a number of circumstances under which a Risk Assessment of a new psychoactive substance is not to be carried out – in particular if the substance is under an advance stage of assessment within the United Nations system and if it is a medicine.

According to the Joint Report (page 29), on 27 June 2015, the World Health Organization informed the EMCDDA that α-PVP is currently not under assessment and has not been under assessment by the UN system.

Furthermore, the Joint Report (page 33) informs that α-PVP has no known medical use (human or veterinary) in the EU and there is no marketing authorisations granted (existing, on-going or suspended) in the Member States which responded to the EMA. It is understood that the collection of such information is a challenge in the absence of a EU database on the synthetic routes of all medicinal products.

Therefore, there are no grounds for excluding α-PVP from Risk Assessment.

Procedure for bringing specific new psychoactive substances under control

Within **six weeks** from the date of submission of the risk assessment report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures or to present a report explaining it is not necessary to do so. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

In accordance with Article 8(3) of the Council Decision, the Council shall decide, by qualified majority and acting on an initiative presented to paragraph 1 or 2 of this Article, whether to submit the new psychoactive substance to control measures.