European Monitoring Centre
for Drugs and Drug Addiction

New drugs

Medicines in the context of the Early Warning System

Legal requirements under the Council Decision and Pharmacovigilance system

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Psychoactive medicines may actually be classed as new drugs!

- Council Decision 2005/387/JHA is a legal framework that provides a three-step approach to responding to new psychoactive substances in the EU: *information exchange (Early Warning System), risk assessment, EU-wide control*

- Under the EU legal framework of Council Decision 2005/387/JHA a *new psychoactive substance ('new drug')*:

    - new narcotic or psychotropic drug, in pure form or in preparation, that is not controlled by the 1961 or the 1971 UN Conventions, but which may pose a public health threat comparable to that posed by substances listed in Schedule I or II or IV of the former and in Schedule I or II or III or IV of the latter convention

- The definition of new psychoactive substances in the Council Decision may include human and veterinary medicinal products

Psychoactive medicines may be new drugs!

- No deterioration of either human or veterinary health care as a result of the Council Decision will be permitted
- Substances of established and acknowledged medical value are therefore excluded from control measures based on the Council Decision (medicines that in the EU and/or Member States are authorised or an application has been made for authorisation or has been suspended)
- Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused (European Commission and EMA with support from the EMCDDA)
- Medicines authorised in the EU and in Third countries are likely to be of growing importance, as are medicines and derivatives sold as ‘legal highs’ or ‘food supplements’

New drugs in Europe

Four broad and overlapping groups. Most are synthetic substances

- **Designer drugs:** sold on illicit market as ‘ecstasy’ (PMAA) or ‘speed’ (4-methylamphetamine) or heroin (fentanyls). Users mostly unaware that they are taking them
- **Legal highs:** sold openly, often as branded products in sophisticated packaging. Sold on the Internet, in head shops and by street-level drug dealers. Also called research chemicals, herbal highs, party pills, bath salts, plant food, incense
- **Food supplements:** aimed at lifestyle users, sold on Amazon and eBay (phenibut and DMAA)
- **Medicines (human and veterinary):** diverted within EU (pregabalin) or imported from Third countries (phenazepam)
    - designer medicines (such as O-desmethyltramadol); derivatives of medicines; pharmaceuticals that were never commercialised (AH-7921)

Broad classification of medicines encountered

- **Authorised** in the European Union or Member States (central, national)
    - Pregabalin, gabapentin, GHB, ketamine
- **Unauthorised**
    - **Illegal** (although they may be authorised in a Third country)
        - Phenibut a GABA derivative which is an anxiolytic that is sold (illegally) as a ‘dietary supplement’ in the EU
    - Legal (e.g. named patient basis)

Examples of medicines notified under the Council Decision

- Ketamine (signals of ulcerative cystitis only in 2007; EU risk assessment in 2001)
- GHB
- Etizolam (IT, JP, but sold as a 'research chemical')
- Carfentanyl (veterinary medicinal product, at least 4,000 more potent than heroin)
- Phenibut (derivative of GABA, sold as a 'food supplement')
- Dextromethorphan
- Benzydamine ('Tantum Rosa', NSAID, hallucinations)
- Pregabalin (early warning of misuse)
- Etaqualone
- Pyrazolam
- Phenazepam (LV, but sold as a 'research chemical')
- Zopiclone ('z-drug' used for insomnia)
- Glaucine
- Amyl-nitrite
- Tropicamide (anti-cholinergic injected IV by heroin users)
- Gabapentin
- *O-Desmethyltramadol (active metabolite of tramadol; found in 'Krypton' products)*
- *Derivatives of medicines or never commercialised medicines*

Why is the Council Decision useful?

A system for detecting, monitoring and acting on the misuse of medicines not under international control

- National early warning systems are often uniquely positioned to identify early signals of misuse and abuse of a medicine, for example:
    - information from health and care system (hospitals' emergency rooms, poisoning centres, psychiatric departments, outreach and street-work agencies, drug prevention and harm reduction establishments, low threshold services)
    - supported by information from samples analysed by forensic science and toxicology laboratories
    - links with relevant national competent authorities (such as national medicine agencies; national pharmacovigilance systems; government departments responsible for enacting drugs legislation)

Why is the Council Decision useful?

A system for detecting, monitoring and acting on the misuse of medicines not under international control

- At the EU-level there is close cooperation, including regular information exchange, with the European Medicines Agency (EMA), other competent bodies (Europol, European Commission)
    - **Council Decision 2005/387/JHA**
    - **Article 28c (2) of Regulation (EU) No 1235/2010**
        - The EMA and the European Monitoring Centre for Drugs and Drug Addiction shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs
    - **Amended Working arrangement** between EMCDDA and EMA signed in 2012 enhances and strengthens cooperation while avoiding duplication of efforts and overlaps in their respective activities and ensuring the best use of available resources

Are medicines under reported to the Early Warning System?

- Yes, it appears that there is under-reporting of medicines that are being misused
- Possible reasons for this include:
    - a lack of awareness in forensic laboratories that medicines are within the scope of the Council Decision (focus on substances sold for the ‘recreational’ market?) so they are not reported to national early warning systems and/or because the medicines are controlled at a national-level
    - a belief that medicines are excluded from the scope of the Council Decision (source of confusion may be Article 7, ‘Circumstances where no risk assessment is carried out’)
    - not reported as viewed as ‘everybody knows it is being misused‘ — but this excludes it from monitoring
- How could/should we improve reporting and monitoring of the misuse of medicines?

Psychoactive medicines not under international control can be included under the Council Decision

This allows earlier detection and monitoring of signals of misuse and abuse, and, where necessary, appropriate action to protect public health

If in doubt, report it