Risk Assessment of Psychoactive Substances: Potentialities and Limitations

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ReDUse Conference, Vienna, 16 November 2012
Overview

- Why and how risk assessments on psychoactive substances are carried out
- Examples of WHO, EMCDDA and UK/NL methods
- Scoring systems in the UK/NL
- Main conclusions of assessments in the UK/NL
- Scientific and political limitations of risk assessments
Why do a risk-assessment?

1. To determine if a substance should be controlled under drugs legislation

2. If control is decided, then need to determine control status, i.e. specific schedule and penalties
The elements of risk assessment

- Basic principle of all drugs legislation is to limit the use of harmful substances – it should not be concerned with moral judgements

- Risk assessment is therefore about determining the physical and psychological harms of substances to individuals and to society
Examples of risk assessment: The WHO method

- A list of factors is discussed by ECDD committee (e.g. pharmacology, toxicology, dependence potential). The ECDD makes a recommendation to UN.

- The UN CND makes a decision to control under the 1961 or 1971 Conventions
Examples of risk assessment: The WHO method

The last meeting of ECDD took place a few months ago. Among the substances discussed for possible control under the 1961/1971 Conventions were:

- Dextromethorphan
- GBL
- Ketamine
- Khat
- Tapentadol
- Piperazine derivatives
Examples of risk assessment: EMCDDA

In the EU, a ‘Joint Action on new synthetic drugs’ was set up in 1997. It was replaced by a Council Decision in 2005, but continued to have three elements:

1. Information collection by Member States
2. Risk assessment of suitable substances
3. Mechanisms for control throughout the EU
Examples of risk assessment:
EMCDDA


- Pharmacology
- Health risks
- Social risks
- Organised crime involvement
- Consider relative risks
- Analogy with related substances
- Use a semi-quantitative method
- Evaluate the evidence

EMCDDA

Twelve substances assessed since 1997

<table>
<thead>
<tr>
<th>Substance</th>
<th>Risk-assessment report by EMCDDA</th>
<th>Proposed for control in EU</th>
<th>Subsequent Schedule in UN1971</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBDB</td>
<td>1999</td>
<td>No</td>
<td>Not listed</td>
</tr>
<tr>
<td>4-MTA</td>
<td>1999</td>
<td>Yes</td>
<td>I</td>
</tr>
<tr>
<td>GHB</td>
<td>2002</td>
<td>No</td>
<td>IV</td>
</tr>
<tr>
<td>Ketamine</td>
<td>2002</td>
<td>No</td>
<td>Not listed</td>
</tr>
<tr>
<td>PMMA</td>
<td>2003</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>TMA-2</td>
<td>2004</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>2C-I</td>
<td>2004</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>2C-T-2</td>
<td>2004</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>2C-T-7</td>
<td>2004</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>BZP</td>
<td>2007</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>Mephedrone</td>
<td>2011</td>
<td>Yes</td>
<td>Not listed</td>
</tr>
<tr>
<td>4-Methylenedamine</td>
<td>2012</td>
<td>?</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

- Starting in 2000, the Advisory Council on the Misuse of Drugs (ACMD) carried out risk assessments on 22 substances.

- It used a committee of ~ 16 drug experts to assess 9 criteria of harm on a scale of 0 (no harm) to 3 (high harm).

- It was a subjective process and scores were unweighted, i.e. all criteria of harm treated equally.
Each parameter scored by ACMD on a scale from 0 (no harm) to 3 (high harm)

<table>
<thead>
<tr>
<th>Category of harm</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL HARM</td>
<td>1  Acute</td>
</tr>
<tr>
<td></td>
<td>2  Chronic</td>
</tr>
<tr>
<td></td>
<td>3  i.v. harm</td>
</tr>
<tr>
<td>DEPENDENCE</td>
<td>4  Intensity of pleasure</td>
</tr>
<tr>
<td></td>
<td>5  Psychological dependence</td>
</tr>
<tr>
<td></td>
<td>6  Physical dependence</td>
</tr>
<tr>
<td>SOCIAL HARSMS</td>
<td>7  Intoxication</td>
</tr>
<tr>
<td></td>
<td>8  Other social harms</td>
</tr>
<tr>
<td></td>
<td>9  Healthcare costs</td>
</tr>
</tbody>
</table>
Mean harm scores of twenty-two substances. The respective classification (A, B or C) under the Misuse of Drugs Act (X = unclassified) is shown against each bar.

Key: 1 = heroin; 2 = cocaine; 3 = alcohol; 4 = barbiturates; 5 = amphetamine; 6 = methadone; 7 = benzodiazepines; 8 = solvents; 9 = buprenorphine; 10 = tobacco; 11 = ecstasy; 12 = cannabis; 13 = LSD; 14 = steroids.

Examples of risk assessment: United Kingdom (2009-2010)

- Using an expert group, Multicriteria Decision Analysis (MCDA) was used to assess the harms of 20 substances

- This used more parameters of harm and included a system for weighting the different elements harm

- But it was still largely a subjective process; many harms cannot be readily quantified
Multicriteria decision analysis: elements of harm

OVERALL HARM
  └── TO USERS
      ├── PHYSICAL1
      │   └── DRUG SPEC MORT
      │       └── DRUG REL MORT
      │           └── DRUG SPEC DAMAGE
      │               └── DRUG REL DAMAGE
      │                   └── DEPENDENCE
      │                           └── SPEC IMPAIR MENT FUN
      │                               └── REL IMPAIR MENT FUNC
      │                                   └── LOSS OF TANGIBLES
      │                                       └── LOSS OF RELAT
      │                                           └── SOCIAL1
      │                                               └── PHYSICAL_PSYCHOL2
      │                                                   └── INJURY
      │                                                       └── CRIME
      │                                                               └── ENVIRONM DAMAGE
      │                                                                 └── FAMILY ADVERSITIES
      │                                                                        └── INTERNATIONAL DAMAGE
      │                                                                                   └── SOCIAL2
      │                                                                                       └── ECONOMIC COST
      │                                                                                                         └── COMMUNITY
  └── TO OTHERS
Examples of risk assessment: Netherlands (2008-2010)

- Following the initial UK work published in 2007, the Dutch Government requested the CAM committee to carry out a similar exercise.

- This used a different set of criteria of harm, but the results showed a high correlation with the UK study.
Ranking of drug harm - Comparison of two data sets

Correlation coefficient = 0.81

\[ y = 0.6472x + 0.6176 \]

What do UK drug users think of relative harms?

- Online survey of (1506 respondents) in 2010 asked about mephedrone use, availability etc.

- We also asked the users to rank the harmfulness of mephedrone and 12 other substances
The ranking of overall harm of thirteen substances by respondents to an online survey

Key: 1 = alcohol; 2 = heroin; 3 = tobacco; 4 = cocaine; 5 = amphetamines; 6 = GHB; 7 = benzodiazepines; 8 = mephedrone; 9 = ketamine; 10 = MDMA; 11 = LSD; 12 = cannabis; 13 = magic mushrooms

Other estimates of drug harm from online surveys of drug users


Both studies came to a similar conclusion to the earlier work.
Risk assessment – summary findings

- Despite their largely subjective nature, and despite different approaches to determining harm, there is wide agreement about the relative harms of well-known substances...
Risk assessment – summary findings

- All surveys show that the most harmful substances include Heroin, cocaine, tobacco and alcohol.

- All surveys show that the least harmful substances include MDMA, khat, ‘magic mushrooms’ and LSD.
Risk assessment – summary findings

- There is no correlation between harm and current classifications of substances in the UK Misuse of Drugs Act or the Schedules of the US Controlled Substances Act.
Risk assessment – limitations

- New psychoactive substances cannot be risk-assessed using the methods described. There is often no information in the literature on their pharmacology, toxicology, potential for dependence etc.

- Proposals to recalibrate the UK classification of MDMA were rejected by politicians

- Legislation often ignores evidence, but is guided instead by moral principles. Thus the preamble to the UN 1961 Convention refers to the “evil of drug addiction”
Risk-assessment - Conclusions

- A valuable tool for determining the legal status of well-known substances

- Not suitable for new substances

- Hence, new substances are not suitable for inclusion in normal drug legislation

- Other methods of regulation are needed for new substances