REVIEW ARTICLE

# Evaluating potential hazards of new trends in psychoactive substance use – literature review of "risk assessment" procedures

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**BACKGROUND: In the last decade new trends in the manufacture and retail of new psychoactive substances (NPS) can be observed as a result of the rapid expansion of the Internet and technological developments. Evidence-based drug policy demands an elaborate assessment of the risks that could be caused by the new trends before control measures and other interventions are applied. AIMS: A systematic conceptual literature review was conducted, with the aims being to: (i) describe currently applied models of risk assessment in practice, (ii) specify the shortcomings of current models that are facing the challenges of new trends in psychoactive substance use, and (iii) propose adaptations of current models to meet these challenges. METHODS: 17 databases of peer-reviewed sources and grey literature were searched with specific search terms in January 2014. 56 relevant documents were further analysed with the use of qualitative content analysis by means of the NVIVO software. FINDINGS: Risk assessment (RA) procedures consist of three main parts – data collection, data evaluation, and data interpretation based on the consensus of experts. RA procedures take a long time and demand high-level scientific data in order to be reliable. The large numbers of newly emerging NPS and the lack of information have led to changes in the RA procedures. First, their duration is shortened. Second, data that has lower scientific reliability but high relevance is being assessed as well, i.e. consumer reports, online discussion forums, drug checking service data, or RAR (risk assessment and response) methods. Further RA procedures could evolve into a continuous process of evaluation and re-evaluation of NPS risks. Local-level risk assessment should be more involved. CONCLUSIONS: The outcomes of RA should include a greater variety of interventions than a suggestion for control (e.g. prevention, treatment, harm reduction measures, or other control instruments than the simple scheduling of the risky NPS).**

**KEY WORDS:** RISK ASSESSMENT – RAPID ASSESSMENT AND RESPONSE – NEW TRENDS IN PSYCHOACTIVE SUBSTANCE USE – CONCEPTUAL LITERATURE REVIEW – NEW PSYCHOACTIVE SUBSTANCES

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## 1 INTRODUCTION

In the past decade, patterns in global drug trafficking have changed considerably with the emergence of the phenomenon of New Psychoactive Substances (NPS). Decision 2005/387/JHA of the Council of the European Union defines NPS as "substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat" (Council of the European Union, 2005; Martinotti et al., 2015; UNODC, 2013). The EU Council Decision furthermore stipulates the exchange of information about NPS and the risk assessment and control of these substances.

While the above definition of NPS focuses on their legal status, the definition of a substance as an NPS is rather based on its individual history and the context of its marketing. These substances are popularly referred to as "legal highs" or "designer drugs" (Corazza et al., 2013b). They can be sold as "research chemicals" (RC) or under different fanciful names or brands (e.g. K2, Funky, Cocolino, etc.) (Corazza et al., 2014b). In order to circumvent the legislation and regulations, retailers sell NPS as "bath salts", "incense", or "goods not intended for human consumption (collector goods)" (Measham, 2011). NPS mimic the effects of "classic" illegal drugs such as cocaine, cannabis, heroin, or even ketamine. NPS are commonly marketed online, but different countries have seen them in retail shops or on a street-level market (also as adulterants to illegal drugs). They come in the form of powder, pills, capsules, herbal mixtures, resin, and others. What characterises them as a group, despite their diverse chemical structure, is a relative lack of research on these substances compared to drugs that are already controlled (Schifano et al., 2011). This complicates the decision about how and whether to regulate particular compounds; prohibition by means of the criminal law is technically difficult given the diversity and speed of development of NPS, and neither is it desirable, given that many of them can be used for industrial purposes or in pharmaceutical development (Measham, 2011; Winstock & Ramsey, 2010). The risk assessment (RA) of NPS evaluates the potential health and social harms that may be caused to societies, and it has become a priority of drug policy bodies at multiple levels (Dargan & Wood, 2013). The main characteristic of the NPS phenomenon and increasingly of drug markets in general is their unpredictable character. With 101 NPS newly registered in the EU in 2014 (EMCDDA, 2015), the creativity of 'designer drug cooks' seems boundless. NPS and the accelerated epidemiological cycle of new drug trends create a need to speed up the 'drug policymaking cycle'. In order to develop effective policies and, when indicated, interventions, policymakers and drug services require objective, factual information before new drug trends turn problematic. Regular monitoring of (online) drug markets and drug-using communities and expedited risk assessment procedures can serve to inform the development of more effective policy responses to the increasingly changing landscape of drug consumption. In this paper we report the results of a systematic literature review that aimed to describe the current status quo of risk assessment procedures in Europe and internationally. The specific aims of this review were to:

(i) describe currently applied models of risk assessment in practice (which organisations are responsible for RA, what the tools used in RA are, and what its implications for drug policy are), and (ii) outline the shortcomings of current models that are facing the challenges of new trends in psychoactive substance use and specify adaptations of current models to these challenges (how the RA system deals with the rapid emergence of NPS and the information, or lack thereof, about them).

## 2 METHODS

A systematic conceptual review of the RA of new trends in psychoactive substance use was conducted. A conceptual approach allows published material to be sorted through in a focused manner and is guided by a basic understanding of the research issues rather than by specific or expert knowledge of research methodology (Findley, 1989). On the topic of how to conduct a systematic literature review, see the Cochrane manual (Higgins & Green, 2006).

English-language peer-reviewed articles, publications, and grey literature (informally published written material, e.g. organisations' reports) were used as the sources of data. Selected scientific databases and electronic databases of grey literature (*Table 1*) were searched for specific descriptors pertaining to the research questions. Risk assessment-specific terms ("risk assessment", "assessment tool", "rapid assessment", "quick scan", and "assessing risks") and general terms ("substance abuse", "drug use", "patterns of drug use", "patterns of substance abuse", and "new trend") were reciprocally combined using Boolean connectors (i.e. „OR", „AND", and „NOT") and used as keyword strings for searching each database.

The search resulted in 91 potentially relevant articles or publications. Out of this sample, 50 publications were available in full text versions and were relevant to the topic under research. Six more publications that were referenced in the primarily searched literature were added to the sample. In total, 56 publications were subjected to content analysis using the NVivo 10 software. Out of the 56, 48 publications were peer-reviewed (four monographs, 44 journal articles) and nine were grey literature (six reports, two sets of guidelines, and one dissertation). 38 sources were theoretical articles, nine described RAR methods, four concerned the British RA approach, three the Dutch approach, and

**Table 1 / Tabulka 1**
List of databases searched for the purpose of this review
*Seznam databází použitých pro vyhledávaní zdrojů*

| | Database | URL |
|---|---|---|
| Peer-reviewed literature databases | Google Scholar | scholar.google.com |
| | ProQuest | www.proquest.com |
| | EBSCO | www.ebsco.com |
| | SAGE | online.sagepub.com |
| | Scopus | www.scopus.com |
| | Web of Knowledge | apps.webofknowledge.com |
| | Ingenta Online and Ariel | www.ingentaconnect.com/ |
| | JSTOR | www.jstor.com |
| | PsycINFO | www.apa.org/pubs/databases/psycinfo/index.aspx |
| | Pub Med/Index Medicus | www.ncbi.nlm.nih.gov/pubmed/ |
| | ERIC | www.eric.ed.gov/ERICWebPortal/journalList/journalList.jsp |
| | Cochrane Library | www.thecochranelibrary.com/view/0/index.html |
| Grey literature databases | OpenSIGLE | www.opengrey.eu/ |
| | National Criminal Justice Reference Service | www.ncjrs.gov/App/QA/SearchQA.aspx |
| | European Legal Database on Drugs | eldd.emcdda.europa.eu/ |
| | Interventie-database | www.loketgezondleven.nl/interventies/i-database/ |
| | NARCIS | www.narcis.info/ |

two the approach of the WHO. Basic coding of text areas relevant to each specific research question was performed. Other relevant topics were coded using open coding. The coding structure helped to categorise the findings and divide them into thematic segments according to the research questions.

## 3 FINDINGS

Our literature review identified several RA procedures that are conducted on the international, national, and local levels. A description of them and the challenges and subsequent responses are presented below, organised as responses to the research questions outlined in the Introduction.

### 3 / 1 Organisations responsible for conducting risk assessments

RA procedures are conducted on the international, European, and national levels. On the local level, related Rapid Assessment and Response (RAR) methods are employed.

On the international level, RA procedures are coordinated by the *World Health Organisation (WHO)* and performed by the *WHO's Expert Committee on Drug Dependence (ECDD)*, composed of various international experts. The ECDD recommends certain substances for scheduling or other regulatory action. Subsequent to an ECDD recommendation, the *Commission on Narcotic Drugs* adopts the recommendation. The RA process is conducted in accordance with *Guidance on the WHO review of psychoactive substances for international control* (WHO, 2010).

On the level of the European Union, RAs are coordinated by the EMCDDA. The decision of the Council of the European Union from 2005 (no. 2005/387/JHA) on the exchange of information on NPS and their risk assessment and control empowers the Scientific Committee of the EMCDDA with a central role in the assessment of risks associated with NPS. The Scientific Committee cooperates closely with Europol (the European police agency) and the European Medicines Agency (EMEA). The RA process team consists of experts in the fields of criminology, pharmacology, psychology, medicine, and the mental health field from key institutions and universities all over Europe (EMCDDA, 2009b).

While more or less structured expert RA procedures are specified by legislation in several EU member states, namely Denmark, Germany, Estonia, France, the Netherlands, and the United Kingdom (Hughes & Blidaru, 2009), the scheduling of NPS in the law is mostly decided on a political level in these countries. Only two of these six EU member states (the Netherlands and the United Kingdom) conduct elaborate national-level assessments of NPS that have an impact on the further control of the compounds that are assessed.

Much like in the international examples, in the Netherlands the Minister of Health and in the UK the Home Secretary request an RA from an independent body of various

experts; in the Netherlands it is the *Coordination Centre for the Assessment and Monitoring of New Drugs (CAM)* and in the UK the *Advisory Council on the Misuse of Drugs (ACMD)*. The results of the RA are summarised in a report that directly recommends an appropriate intervention (Bossong et al., 2005; Reuter, 2011).

The implementation of a Rapid Assessment and Response method (RAR) can be observed in some localities and regions. An RAR aims to assess a problem or situation in a short period of time, using all possible sources of data, and to design suitable interventions (in contrast to the national or international level, an intervention on a local level is a programme or service, rather than a regulatory option). An example RAR on the local level would be the Bergen Early Warning System (BEWS) in Norway, which successfully implemented a series of RARs performed by an outreach service (Mounteney, 2009). RAR studies can be conducted on the national or regional level as well (Ogborne, 2006).

## 3 / 2 Tools of risk assessment

Risk assessment uses three main tools in order to fulfil its function. First, a set of risk factors is established and then the data that has been collected is evaluated while using quantifying scales and considering the validity and relevance of the data. Third, an outcome that represents the opinion of each assessor needs to be reached.

### 3 / 2 / 1 Risk factors

In the literature, an important distinction is made between the often interchanged terms "harm" and "risk". Harm is defined as the amount and type of harm and risk as the likelihood that harm will occur (Steadman et al., 1994, p. 297). The British Medical Association defines risk as the probability that something unpleasant will happen (Jones, 1988). Harm does not occur alone and is enabled by the presence of a risk environment (Rhodes, 2002, 2009). This concept enables harm and risk to be perceived as a consequence of various biological, psychological, and social factors (Miovský et al., 2015). Equally, Steadman et al. (1994) emphasised the importance of a multidimensional perception of risk and introduced the concept of risk factors that are used by institutions during the RA process.

The risk factors differ from institution to institution (*Table 2*) but in general they concern biomedical, pharmaceutical, economic, and legal risks concerning individuals, social groups, and society, but not all these categories can be represented equally. For instance, the WHO's Expert Committee on Drug Dependence (ECDD) relies primarily on biomedical data and legal considerations. Social indicators are limited and lumped into the "other" category. On the other hand, the Dutch and UK procedures allow for quite an extensive input of social indicators and expertise.

Institutions performing RA are often criticised for not considering the possible benefits (e.g. replacement of a more harmful illegal substance or treatment purposes) (Reuter, 2011). For example, the risk assessment of the emerging head shops in Ireland mostly considered the benefits of their restriction, without taking into account any potential negatives except for the high costs. RA procedures in other research areas (e.g. environmental research) have a more elaborate system of weighing costs and benefits (Reuter, 2011). In any case, RA should aim to evaluate the effect of banning what is being examined and the negative effects that may be associated with such legislative action (Spruit, 2001).

Additionally, the potential harm caused by a change in the legal status of an NPS is not always sufficiently considered and it is hard to predict (Caulkins et al., 2011; Reuter, 2011). The tools for the prediction of the consequences of a ban are simply missing. For instance, the EMCDDA considers the involvement of organised crime resulting from the banning of a substance as an important issue, but their risk assessment guidelines (EMCDDA, 2009b) do not provide any guidance on how to assess the potential for criminal involvement once a substance is banned. Therefore a review of the current risk categories and the introduction of more comprehensive "harm matrices" that would put individual risks into a broader social context could be a solution to the current inefficiencies of RA (Caulkins et al., 2011).

### 3 / 2 / 2 Evaluation of data from multiple sources

The data concerning each specific risk factor that have been collected need to be evaluated further. Data quality and its relevance need to be considered. Then all the information on each risk factor is quantified.

Bodies performing RA have to assess data of very different origins: pharmacological data, toxicological analyses, and population studies combined with case studies, emergency reports, etc. The validity and relevance of the data need to be assessed, compared, and evaluated.

Considering the validity of the collected data, the EMCDDA divides the available sources of data for an RA into five categories, ordered from the most valid to the least valid: peer-reviewed scientific publications, official reports of international organisations and governmental institutions, other reports and/or scientific publications, unpublished data from forensic and clinical laboratories, and other sources (EU databases, media, individual reports, unofficial publications, and the Internet) (EMCDDA, 2009b).

Unpublished data, despite its lower ranking in the evidence hierarchy, can, however, still be very relevant (EMCDDA, 2009b). Additionally, very recent data is not likely to be published quickly, but the actual data can have very high importance for the assessment of a new psychoactive drug. The quality of these various sources

**Table 2 / Tabulka 2**

List of risk factors and criteria considered in the RA process according to various institutions

*Seznam rizikových faktoru a kritérií, které jsou posuzovány při procesu RA různými institucemi*

| WHO Criteria | EMCDDA Criteria | CAM Criteria (The Netherlands) | ACMD Criteria (UK) |
|---|---|---|---|
| 1. Chemistry | **1. Dependence and abuse potential** | **1. Individual health** | 1. Drug-specific mortality |
| 2. Ease of convertibility into controlled substances | – animal in vitro data, human data | – Physical dependence | 2. Drug-related mortality |
| 3. General pharmacology, pharmacokinetics, pharmacodynamics | **2. Prevalence of use** | – Psychological dependence | 3. Drug-specific damage |
| 4. Toxicology | **3. Health risks** | – Acute toxicity | 4. Drug-related damage |
| 5. Adverse reactions in humans | – acute, chronic, public health risks | – Chronic toxicity | 5. Dependence |
| 6. Dependence potential | **4. Social risks** | **2. Public health** | 6. Specific impairment function |
| 7. Abuse potential | – individual social risks | – Extent and frequency of use | 7. Relative impairment function |
| 8. Therapeutic applications, (therapeutic use, epidemiology of medical use) | – risks for direct social environment | – Vulnerability of the user | 8. Loss of tangibles |
| 9. Listing on the WHO model list of essential medicines | – society as a whole | – Availability of information on possible e?ects of the drug | 9. Loss of relationships |
| 10. Marketing authorisations (as a medicine) | – economic costs | – Availability of the drug | 10. Injury |
| 11. Industrial use | – effects related to cultural context | – Reliability of the drug's pharmaceutical quality | 11. Crime |
| 12. Non-medical use, abuse, and dependence | – appeal to specific subpopulations | – Reliability of the drug's distribution and sale | 12. Environmental damage |
| 13. Public health problems related to abuse and dependence | **5. Involvement of organised crime** | – Reported nature and extent of incidents | 13. Family adversities |
| 14. Licit production, consumption, and international trade | – systematic involvement of groups for financial gain | **3. Violation of civil order** | 14. International damage |
| 15. Illicit manufacture and trafficking and related information | – impact on production of other substances | – Annoyance to the general population | 15. Economic cost |
| 16. Current international controls and their impact | – involvement of the same group in different kinds of crime, violence | – Increased resort to use violence | 16. Community |
| 17. Current and past national controls | – impact on society | – Impaired reaction time (tra?c, labour) | |
| 18. Other medical and scientific matters relevant for a recommendation on the scheduling of the substance | – evidence of money laundering or impact of organised crime on other socio-economic factors in society | **4. Criminal involvement** | |
| | – economic costs of consequences | – Criminality with respect to the final product | |
| | – violence between crime groups | – Criminality with respect to raw products | |
| | – corruption | | |

Sources: (Bossong et al., 2005; Caulkins et al., 2011; EMCDDA, 2009; Reuter, 2011; WHO, 2010)

*Zdroje: (Bossong et al., 2005; Caulkins et al., 2011; EMCDDA, 2009; Reuter, 2011; WHO, 2010)*

needs to be weighed, as do the various types of harms (to individual health, public health, or to society) that the data predict.

An RA procedure assesses the harmfulness of the substances being examined objectively and quantitatively (Caulkins et al., 2011). While the ECDD (WHO) do not closely describe the data evaluation process in their guidelines (WHO, 2010), the ADMC (UK) (Nutt et al., 2007) and CAM (The Netherlands) (van Amsterdam & van den Brink, 2010) have developed tools for risk factor quantification, some of which were adopted by the EMCDDA. The EMCDDA uses a semi-quantitative assessment procedure for its RA process. Experts judge each subgroup and assign it a score, which is referred to as a risk level. The scores are represented by numbers on a scale from 0 (no risk) to 4 (severe risk).

### 3 / 2 / 3 Deciding the final outcome of RA

Once the members of the body performing an RA quantify the risk factors, a final decision must be made. The RA outcome needs to represent the opinion of each of the members of the scientific committee. For instance, the head of the EMCDDA Scientific Committee collects the risk level values and average risk values from each member of the committee and the overall summary is then sent back to the members before the final meeting of the group. The group meets to discuss the findings and review the risk scores (EMCDDA, 2009b).

The discussion is led in consensus with the Delphi approach. That is a technique designed for obtaining a consensus in opinion within a group of experts which includes tools ranging from structured questionnaires to controlled opinion feedback (Dalkey & Helmer, 1963). Members of the EMCDDA Scientific Committee are allowed to re-evaluate their scores after discussion guided by the Delphi approach is finished. The new scores are gathered and the Scientific Committee creates an RA report and draws conclusions based on the second version of the scores.

According to van Amsterdam et al. (2004), the Dutch CAM does not base its final judgment on written scores only, but preferably on the outcomes of discussions between the experts. Expert discussion after primary judgments has been confirmed as a suitable tool for finding overall consensus on an issue that has been presented (van Amsterdam et al., 2004).

## ● 3 / 3 Implications of RA outcomes for drug policy

The outcomes of the risk assessments serve as background for interventions concerning the substance or trend being assessed, mostly as a legal response or preventive, treatment, and harm reduction intervention. The response of the authorities is, however, aimed at the scheduling of emerging substances in most cases. Council Decision 2005/387/JHA provides a framework for assessing the risks associated with NPS so that control measures for narcotic and psychotropic substances can be applied accordingly.

### 3 / 3 / 1 Is the outcome of RA binding for policymakers?

RA represents an evidence-based approach towards drug policymaking but from practice we can see that policymakers often do not take scientific knowledge into consideration in classifying and scheduling psychoactive substances (Caulkins et al., 2011; Nutt et al., 2007). The outcomes of more elaborate RA methods often clash with the approach of the authorities. For instance, the United States Drug Enforcement Agency (DEA) accepted that marijuana has a lower level of toxicity compared to other illegal substances, but did not approve the re-classification of marijuana to a lower-risk group because of other pharmacological and behavioural risks (Gable, 2004). Likewise, banning mephedrone in North Dakota was based on individual reports from emergency rooms.

"*We had a couple of teenage girls in the hospital here after injecting "bath salts" intravenously, presumed to contain mephedrone. The news reports and general research were enough for the Board and the Attorney General. When the lab report came back it was actually 3,4-methylenedioxypyrovalerone (MDPV) so we scheduled that one as well*." (Reuter, 2011)

Especially when facing the rapid growth of newly-emerged substances, drug policymakers often speed up the legislative process, which leads to even less informed decisions about the scheduling of the substance (Hughes & Blidaru, 2009). The Precautionary Principle, which has become an important part of the approach towards risk and harm in environmental policy and public health since the 1990s, could explain the regulation of NPS with minimal information about their risks. The principle states that a lack of scientific evidence should not be an obstacle to postponing possible regulatory measures when there is a possibility that the phenomenon being examined might pose a danger to public health (Reuter, 2011).

## ● 3 / 4 Challenges in risk assessment of new trends in psychoactive substance use and RA responses

The rationale and mechanisms of risk assessment on the national and international levels have been described above; the major limitations and challenges of these processes are presented below.

### 3 / 4 / 1 Rapid emergence of NPS vs. time-demanding risk assessment procedures

Since 2012, eight NPS have been assessed by the EMCDDA (EMCDDA, 2014, 2015). If one looks at the high numbers of newly-emerged NPS in Europe, which are reaching new records every consequent year, i.e. 81 NPS notified by the European Early Warning System in 2013 (EMCDDA, 2014) and 101 NPS notified in 2014 (EMCDDA, 2015), it cannot be assumed that all newly- emerged substances can be assessed before being scheduled. The reason for this is that the RA procedure is time- consuming and places heavy demands on resources. The challenges for risk assessment are such that it has to be completed in a timely manner and upon the basis of a limited amount of scientific information, and it has to compromise on formal data quality in favour of data relevance.

Conducting and publishing epidemiological or toxicological research may take years (Stimson et al., 1999). Conclusive biomedical evidence is mostly lacking when the

need for an assessment arises, as toxicological and pharmacological studies take substantial amounts of time (EMCDDA, 2009b, 2015).

The time between an RA being requested and an advisory report being delivered can vary across the institutions that perform them. The ECDD (WHO) assesses a limited number of substances every two years, while the ACMD in the UK is able to deliver an advisory letter in 3-6 months (Reuter, 2011). France, Austria, and Norway are able to shorten the RA procedure in cases of emergency. In the Netherlands the duration of RA is directly self-driven by the amount of perceived harm to deliver outcomes as fast as needed (Hughes & Blidaru, 2009). The number of RAs performed per year by the EMCDDA is rising (two RAs in 2013, six RAs in 2014 (EMCDDA, 2014, 2015)), but compared to the numbers of newly identified NPS it is still insufficient. Therefore faster substance scheduling processes have recently been introduced in some European countries (Hughes & Blidaru, 2009).

The use of various available data for assessment of risks is used in the RAR methodology. According to Stimson et al. (1999), RAR generates data gathered by multiple methods and from multiple sources in a cost-effective manner. Research questions are addressed at different levels of society (individual, community, cultural, and economic perspectives), and the overall risk environment is taken into account (Rhodes, 2002). In RAR various sources of data, such as policy documents, statistical data, research, and media reports, are collected in a short period of time, evaluated, and directly transformed into recommendations for appropriate interventions (Ogborne, 2006). A best practice example of the use of RAR in local settings is presented by the Early Warning System in Bergen (Norway). Using the routine collection of both quantitative and qualitative data, monitoring of media content, and information from key informants, the local outreach organisation running the RAR has been successful in identifying several new trends in the area, including an increase in heroin use among young people. The RAR was concluded in six months (from the start of the data collection until the end of the assessment) (Mounteney, 2009). Recently the RAR method has proved useful in providing a comprehensive overview of the use of NPS by PDUs in the Czech Republic, Greece, Poland, Portugal, and Romania (Grund et al., 2015).

**3 / 4 / 2 Lack of information vs. new sources of data**

The lack of information about NPS is determined not only by their novelty and rapid cycle but also by the incentive to market them under false pretences, with the information on content and effect lacking (Winstock & Ramsey, 2010). The lack of information affects both users and researchers.

Both the EMCDDA and the ACMD acknowledge the fact that reliable and valid scientific information will be very limited for RA purposes (Corkery et al., 2011; EMCDDA, 2009b). As Winstock and Ramsey (2010) note, clinical and toxicological data is generally limited or completely lacking; this makes the RA procedures rather vague compared to the standard in pharmaceutical safety studies. Therefore, alternative sources of relevant information are seen as valuable (Corkery et al., 2011). While the scientific validity of this data may not be optimal, its relevance, as outlined in Chapter 2.2.2.1, is high and it offers important information on adverse effects and other harms that may be associated with new substances.

In the light of toxicological/pharmacological data being lacking, data from Internet forums, grey literature, and unpublished surveys is becoming crucial for RA procedures. As we can see through the example of the EMCDDA RA procedure for mephedrone (4-methylmethcathinone), apart from data collected from surveys and toxicological analysis, less valid data coming from Internet forum reports and grey literature was also taken into consideration (EMCDDA, 2011). The RA of benzylpiperazine (BZP) included data from online consumer reports and clinical observation of intoxicated patients (EMCDDA, 2009a).

Analysis of online user reports and discussion forums where people actively discuss their experiences – both positive and negative – and efforts to counter these (harm reduction) provides valuable data on the effects of NPS and the harms they cause, along with focus groups with consumers and case reports (Bersani et al., 2014; Corazza et al., 2014a; Corazza et al., 2013a; Schifano et al., 2011; Schifano et al., 2009; Schifano et al., 2005; Soussan & Kjellgren, 2014; Winstock et al., 2011; Winstock et al., 2010). These forums represent an important source of information and such 'consumer reports' are increasingly taken into account by official authorities such as the EMCDDA. The Psychonaut, REDNET, iTrend, and other EU NPS activities have made valuable contributions to RAs, informing authorities such as the British ACMD (Corkery et al., 2011; Schifano et al., 2003).

Other important sources of information are Emergency Drug Medical Care and harm reduction projects or drug checking services at festivals and at nightlife venues or at prevention organisations. In the Netherlands, Portugal, and several other EU countries these projects contribute important data to the monitoring and RA of NPS and feed into national and the EU Early Warning Systems. The Dutch drug-checking service DIMS monitors the quality and purity of recreational drugs, focusing on identifying newly emerging threats and new trends on the scene (Spruit, 2001). The DIMS results are regularly referred to in national and international RAs (Brunt & Niesink, 2011).

## 4 DISCUSSION AND CONCLUSIONS

RA is a structural and coordinated, evidence-based, and transparent activity to collect relevant information on the potential risks (and, less conventionally, benefits) of NPS, aimed at informing both a transparent decision-making process of policymakers and regulatory bodies and stakeholders in prevention and harm reduction approaches. RA procedures are generally conducted at the international (European), and on a limited basis, on the national level. On the local level, methods of risk assessment are conducted that generally show the features of RAR. RA procedures aim to collect the most reliable information about the risks posed by NPS, which does indeed take a considerable amount of time. The challenges posed by NPS create a demand for interim, less time-consuming, RA that considers the best evidence available at the time of assessment (EMCDDA, 2009b). More timely or *real-time* data sources are required. Alternative sources such as online drug forums, data from drug testing services, consumer reports, etc. are increasingly used in risk assessments. The data available at the time of first assessment may not be reliable enough to support definite decisions about the potential risks and benefits of the substance being assessed (Reuter, 2011). Data from higher ranks of the hierarchy will still be demanded. Therefore the design of shorter assessments followed by longer thorough assessments, as described in the Netherlands, could be more suitable. According to Winstock and Ramsey (2010), there will also be a need for constant reviewing of substances that have already been assessed, because the environment in which the substances cause harm will be changing all the time (the legal status of the substance may cause other kinds of risks, more dangerous alternatives will appear on the market, and the overall risk posed by the substance will change).

RA is intended to feed into a transparent decision-making process. Policymakers and regulatory bodies mostly apply it in designing legal responses resulting in the substance that is assessed being banned. This commonly happens despite the fact that the bare scheduling of NPS is not going to solve the problem, because banned substances are going to be replaced immediately by other analogues about whose effects and toxicity even less information is available (Winstock & Ramsey, 2010). Banning popular substances may also create a black market, with the involvement of organised crime. Winstock and Ramsey call for a more diverse approach towards substances that are not assessed as dangerous and they suggest other interventions that would allow the retailing of NPS and would oblige the retailers to provide evidence of the safety of their product, as is the case with medical products. This approach was applied in New Zealand with benzylpiperazines (Sheridan et al., 2007) and recently it has also been introduced for other NPS. The effectiveness of these new approaches should be examined further and compared to the prohibition approaches applied in Europe.

At the same time, the use of RA in order to support the decision to ban a substance or not is a very narrow view of the purpose of RA itself (Cameron, 2006). As we can learn from the RAR method, a variety of recommendations for appropriate interventions ranging from prevention, treatment, and harm reduction to policy measures should be designed by policymakers. RAR methods seem to be well suited to the early identification of new drug trends at the local level, but could also be adapted to the national level. As emphasised by the LOCAL PASS project (http://www.localpass.eu/), localities often have to deal with the immediate consequences of a new trend and demand tailored interventions that could prevent the further spread of the trend. In this sense, an advantage of the up-to-date use of RAR outcomes compared to RA outcomes is that it creates commitment among the key stakeholders and it involves policymakers in the assessment (Caulkins et al., 2011; Fitch et al., 2003; Mounteney, 2009; Rhodes et al., 1999).

While the RAR approach has proven useful in many HIV prevention projects and was applied in a local Early Warning System in Bergen, Norway (Mounteney, 2009), the literature review did not bring specific evidence about RAR methods being applied to the NPS problem. It is interesting to question why this has been the case – whether the NPS phenomenon attracted relatively more attention on the national and international level, where policymakers are "biased" towards scheduling, or whether it has been assumed that the already-existing preventive, treatment, and harm reduction programmes should absorb non-legal responses to the phenomenon.

To conclude, RA procedures are challenged by the high number of NPS and Internet drug markets. Changes leading to shorter RA procedures and the use of alternative sources of data are already being implemented. The introduction of brief initial assessments with recommendations for the development of an initial response may benefit effective drug policing. These should be followed by more in-depth assessments when indicated or when the data is inconclusive, with the aim being to confirm or refute initial conclusions and recommendations.

Our data suggests that public policymaking is best served when risk assessments of emerging drug trends are situated within a cyclic and systematic process of monitoring and evaluation in which national and local-level efforts are included and the perspectives of (online) communities of people involved in NPS consumption and outreach workers are represented.

Beyond merely formulating legal responses to NPS (e.g. scheduling), the outcomes of risk assessments should inform other potential regulatory instruments, as well as prevention, harm reduction, and treatment responses.

**The roles of the authors:** Eva Drápalová, Jean-Paul Grund, and Vendula Běláčková conceived the study and drew up its design. Eva Drápalová performed the review, collected and analysed the data, and compiled the results. Jean-Paul Grund and Vendula Běláčková participated in the analysis of the data and the preparation of the paper for publication.
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***Role autorů:*** *Eva Drápalová, Jean-Paul Grund a Vendula Běláčková navrhli tuto studii a její design. Eva Drápalová provedla rešerši, analyzovala sebraná data a shrnula výsledky. Jean-Paul Grund a Vendula Běláčková se spolupodíleli na analýze dat a přípravě této publikace.*
***Konflikt zájmů:*** *V uvedené studii nedošlo ke střetu zájmů.*

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# Community Based Research Informing Planning & Implementation of Interventions

## Results from a 5-Country RAR of New Psychoactive Drugs (NPS)

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## Abstract

**Background.** The EC-DPIP **NPSinEurope.eu** project is piloting harm reduction interventions, targeting NPS consumption in communities of people who use drugs heavily (PUDH). The Department of Addictology, Charles University in Prague (DoA) conducted a RAR study of NPS use together with the local project partners.

**Methods.** Partners reviewed new drug trends in their countries, an Internet Snapshot and focus groups with key stakeholders. DoA developed al research materials and conducted the 5-country data analysis.

**Results.** NPS are available from a variety of sources. Smart shops boosted the popularity of NPS, but after legislative action most were closed or severely restricted their assortment. A variety of NPS are available via websites; synthetic cannabinoids and synthetic stimulants prevail. Injecting of mephedrone, MDPV or other synthetic stimulants among PUDH is reported in the Czech Republic, Poland and Romania, but to varying degrees. In Portugal and Greece, NPS are of less concern. In Greece the RAR was focussed on the use of Sisha (smoked methamphetamine).

**Conclusions.** Trends in NPS use vary greatly across Europe. Emerging drug trends are increasingly unpredictable, subject to (offline/online) availability, legal status/action, local preferences, access to traditional substances, such as cannabis, MDMA or heroin, and economic variables.

Local NGOs successfully conducted an assessment of the NPS situation in their communities and countries, informing the implementation of pilot harm reduction interventions.

## Introduction

**Scope and Objectives**

This project (NPSinEurope.eu) aims to contribute to the development of innovative and effective health promotion interventions targeting emerging NPS use in Europe, in particular in response to more hazardous patterns of use and in vulnerable populations.

**Aims of RAR study:**

Identify and document the emergent use of NPS among People Who Use Drugs Heavily (PUDH) in the five EU member states and map the developing response in these countries.

**Countries & Implementing Partners**

Czech Republic – Sananim, Prague
Greece – Praksis, Athens
Poland – Monar, Krakov
Portugal – APDES, Porto
Romania – Carusel, Bucharest

**Main Applicant**

APDES, Porto, PT

**Intervention Development**

FRG, Amsterdam, NL


## Methods and Materials

The local RAR consisted of three parts:

**1) A desk review on the national NPS situation;**

Each partner organisation collected and reviewed published and unpublished information pertaining to the key RAR questions concerning on NPS consumption: peer reviewed and "grey" scientific literature; government publications; statistics and estimates; local media reports; and information online.

**2) An assessment of NPS availability in offline and online drug markets;**

Offline availability of NPS was determined by literature review, inspection of data from early warning systems, drug testing programs (where available) , law enforcement or other relevant data sources, as well as in the separate focus group discussions. Online availability was assessed using the EMCDDA Snapshot Methodology.

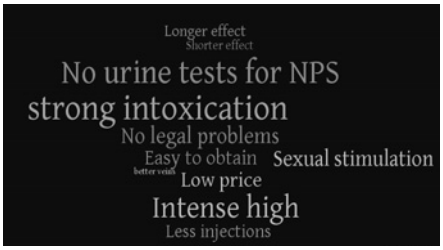
**3) Focus groups with stakeholders in NPS use that explored specific questions more in-depth.**

In each country focus groups were organised in two different cities/regions with evident NPS use with (i) knowledgeable professionals; and, (ii) with PUDH involved in NPS consumption. In total, 19 focus groups were conducted in 8 cities; ten with professionals and nine with PUDH and 111 participants in total.

The 5-country RAR data were subsequently subjected to a stepwise content analysis in order to describe the national situation, cultural interpretations and meanings of NPS use across user populations and national borders. The analysis aimed to describe the various viewpoints and the needs of the affected communities and other stakeholders that need to be addressed in service development.

## Results

**Positive and negative effects of NPS use (Focus Groups, all countries)**





*Availability*

In the *Czech Republic*, *Poland*, *Portugal* and *Romania*, NPS availability increased sharply with the introduction of brick & mortar outlets (2007-2009) and decreased again after their closure (2001-2013). In *Greece*, NPS emerged in 2010 but gained only minor attention. But since 2010-2011, Greek PUDH have turned to "Sisa" (homemade methamphetamine). Although the closure of physical outlets resulted in important reductions in (novice) NPS consumption, websites targeting the studied countries mail NPS to anybody with a credit card. Importantly, (once bought in bulk online) NPS are increasingly retailed in traditional drug dealing structures.

*Extent and nature of NPS use among PUDH*

Use of NPS among PUDH concerns primarily *synthetic cathinones* and varies widely between the countries, from (nearly) absent in Portugal, to almost one and two thirds in cities in respectively the Czech Republic and Romania, to unmeasured, but clearly present, in Poland. Many Greek PUDH have either replaced or combine heroin with *Sisa*, which is smoked (±80%) or injected (20%). A regional trend in the Czech Republic concerns injection of *diverted opioid pain killers* (fentanyl & Vendal-Retard® (extended release morphine). In 2014 5.1% of Czech PWID had injected pharmaceutical opioids (23.6% in the Pilsen region). Opioid substitution treatment (OST) coverage in these regions is considered low.


## Conclusions

- NPS are available to residents of the studied countries online, in black market structures and in peer networks, in which bulk online purchases are further distributed.
- The NPS most frequently consumed among PUDH across the 5 countries are synthetic cathinones.
- Among Greek PUDH, Sisa – cheap homemade methamphetamine – has largely substituted (expensive) heroin and cocaine.
- The legal status of NPS is viewed as a benefit by PUDH, but their constant purity, strong intoxication effects, low price and availability seem at least equally important. Legal status is less of a factor when NPS are bought in black market structures. .
- In the Czech Republic many PUDH in the region have turned to diverted pharmaceutical opioids, reportedly due to the unstable quality and availability of heroin, in a situation of low OST coverage.
- Heavy of cathinones or Sisa may lead to a range of serious physical and (mental) health problems, often similar to those of scheduled stimulants.
- Mental health problems and loss of control among PUDH are often heralded by fatigue, sleep deprivation and exhaustion and may be associated with either the pharmacology (drug) or alien status (setting) of the recently introduced substances.
- Short acting cathinones are associated with high injecting frequencies. Collective consumption, e.g. at the point of sale, stimulant related sexual and other risk behaviours may increase the burden of infectious diseases in studied countries.

## Curious 4 More?

Today 14:00-15:30 Taming Sari 3: Parallel 53:

***Internet, Unternet and harm reduction.***



**Or come to Lisbon, 26-11-2015!**

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