Early warning systems in Europe

An evidence brief

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Introduction

Drug markets are unpredictable with new substances emerging sporadically and established drugs varying in potency and quality. This unpredictability can result in people who use drugs being at increased risk of experiencing drug-related health harms. To counteract this, early warning systems (EWS) have been established in a number of regions and countries including the European Union (EU), United States (US), New Zealand, Netherlands, Scotland and Sweden. An EWS can identify changes in the drug market, such as new drug use patterns and substances in circulation that are contaminated, adulterated, or missold. They can enable effective and early dissemination of information and encourage harm reduction behaviour, thus protecting public health. Ireland's National Drug and Alcohol Strategy: 'Reducing Harm, Supporting Recovery: A health-led response to drug and alcohol use in Ireland 2017–25' acknowledges the need to develop analytical capacity, data collection and public warning mechanisms. Strategic Action 3.3.38 of the strategy aims to strengthen the response to the illegal drug market, including the changing nature of new psychoactive substances. This evidence brief, comprising three descriptive country case studies, has been prepared by the Health Research Board (HRB) Evidence Centre with the aim of informing any future work that may be undertaken regarding the establishment of an EWS in Ireland.

Research questions

The following research questions were agreed with the Department of Health:

For each of the countries under study (Scotland, Sweden, the Netherlands):

1. Describe the management and administration of the EWS in the three countries using the following parameters: objectives; terms of reference; organisation of system; staffing and costs; data protection; and network membership and roles/responsibilities.
2. Describe the data collection, validation, and management of each EWS using the following parameters: sources of data; data collection tools; access to system; monitoring; and validation.
3. Describe how communication with stakeholders is managed and information disseminated using the following parameters: assessment of signals; decision making around risk communication; information exchange with institutional stakeholders; dissemination of outputs; and facilitation of research and analytical work undertaken by third parties such as universities.

Methods

Given the nature of the research questions for this evidence brief, it was considered unlikely that relevant source documents would be found primarily in traditional bibliographic database sources or that a traditional approach to searching would yield relevant results. Consequently, this evidence brief relied primarily on grey literature published by health systems, government agencies, and independent organisations and on interviews undertaken with the managers of the EWS in each country under study. The search was conducted in two phases:

- **Grey literature search:** Broad searches were undertaken using search engines (e.g. Google and Google Scholar). Relevant documents were retained for inclusion and relevant organisations were identified for additional targeted searching.
- **Database search:** In addition to the grey literature search, a systematic scoping search was performed in bibliographic databases (Ovid MEDLINE, Ovid Embase, and Ovid Social Policy and Practice).

Relevant material was imported into Zotero reference management software, and full texts were obtained for the purpose of data extraction.

After completing a search of both the grey literature and bibliographic databases it was apparent that there was insufficient published literature to adequately answer the questions. The managers of each system were contacted and were requested to provide unpublished documents/protocols on their EWS if available. In addition, online interviews were conducted with the managers of the Scottish and Dutch systems, while the manager of the Swedish system provided answers via email.

Findings

Scotland

RADAR (Rapid Action Drug Alerts and Responses) is the Scottish EWS and was established in 2022 as a direct result of an increase in drug-related deaths. It is coordinated by Public Health Scotland and is a single platform that provides a structured way to collect, assess and communicate information about drugs. The objectives of RADAR are to:

- Identify trends, risks and clusters of overdose and intoxication
- Respond to new and emerging substances, changing harms and other relevant scenarios
- Advise on and implement immediate harm prevention and control measures
- Provide high-quality current public health information
- Inform decision-making about resource allocation, prevention and service design and delivery

Management and administration of EWS

Within RADAR's structure there are two PHS groups and four multi-agency groups.

- The RADAR **PHS Programme Team** has seven members and provides internal project management. Its key roles are to: manage progress of the programme; be accountable for actions; keep key partners updated; manage partnerships; data collation and validation, and providing a quarterly update.
- The RADAR **PHS Advisory Group** has 27 members and provides internal project advisory and development. Its key roles are to: analyse presenting data; ensure that interventions reflect a public health approach to drugs; advise on how RADAR intersects with wider determinants of health; comment on guidance before it goes to the Development Group; advise on how RADAR communicates with relevant networks; and ensures information is accessible.
- The **Development Group** has 41 members and is formed of communication, data and intervention subgroups that support system design and development, including the creation of a communication and response toolkit.
- The **Network** is a large multi-agency national group currently comprising of 193 members and it supports the operation of the system. Its key roles are to: monitor markets, collect information, and detect trends; collect and share drugs information, using email, forms, and surveys; strengthen local information sharing and communication networks; help to validate information and reports; and communicate outputs from the Assessment Group
- The **Assessment Group** is a specialist technical team comprising 15 members. The aim of the group is to regularly assess validated information on drug trends and incidents of drug harm, consider the level of risk and decide on the threat level and action needed.
- The **Toxicology and Pathology Group** is a specialist technical group of 15 members that provides expertise on toxicology and ensures consistency of reporting of data providers.

Data collection, validation, and management

Services and local communities are actively encouraged to share information such as drug-related adverse health effects or changes to the drug markets by using RADAR reporting forms, regular monitoring surveys, and the RADAR mailbox. This is combined with data from PHS systems and information from healthcare providers, prisons, police, and toxicology services. Data is extracted from LimeSurvey or from Network meetings and stored in a protected space with controlled access in SharePoint for analysis and processing. The data is added to the main database, analysed for trends or changes and the results summarised. To understand the accuracy and importance of the information received, PHS checks the context, source, other reports (including from the Network). If this information warrants a rapid or specific response then the validated information is sent from the PHS Programme Team to the Assessment Group using a validation and assessment form. If information cannot be validated, PHS will continue to monitor and may investigate further through targeted requests or enhanced surveys.

Communication with stakeholders and information dissemination

The Assessment Group considers the validated information and agrees on the level of potential risk and the threat level, action needed, and type of response. The action and response agreed by the Assessment Group is shared widely, including to the Network. As the Network is a community that links RADAR with the people most at risk of drug harm, its members can share information quickly to those that need it. Communications may take the form of warnings or alerts, information summaries, risk assessments, educational resources, or reports. If the information does not warrant a rapid or specific response the summarised data is shared on the RADAR webpage and newsletters disseminated through the RADAR network. Eighteen reports were validated by RADAR between September 2022 and January 2023. To date, RADAR has issued one alert about nitazene-type drugs, which was published in January 2023. PHS compiles a quarterly report of drug-related indicators which includes data from the RADAR system; the first quarterly report was published in October 2022.

Sweden

In response to high drug mortality, the Public Health Agency (PHA) of Sweden were commissioned to develop an alert system for increased and improved information exchange between authorities, and health and social services through an early warning system. Between 2019 and 2021, the PHA undertook a pilot project whereby a network was established and a web portal was developed and tested – Warning System Drugs (VSN), which was then extended in 2022 to a system that is part of the PHA's system management.

Management and administration of EWS

The main objective of VSN is to detect at an early stage, new and dangerous substances or changing patterns of use that increase the risk of drug-related health harms or deaths. The VSN network has more than 500 members who are professionals within authorities, regions and municipalities and either work directly with people who use drugs or have a strategic or analytical or investigative role in the drugs field. Members don't have to share information; some will rarely or perhaps never share their own information but may benefit from getting access to information shared by others in VSN that is important.

Data collection, validation, and management

The exchange of information in the portal starts when a member reports an incident. Members of the VSN network then receive an e-mail notification that a new event has been reported in the system. In the portal members can also comment on events, read other people's events and search for past events. Any information submitted by a member of VSN is reviewed by the PHA before the new information is

published. The review primarily involves ensuring that no confidential information or information that makes it possible to identify individuals is present. All information uploaded into the system comes from the members or from the Swedish Public Health Agency. There are no routine monitoring systems. The information in the VSN can be either quality reviewed (verified) or unverified. Verifying information can take time so being able to share even unverified information can increase the ability to quickly disseminate information that may be of importance for the network to act on. The urgency of the information in VSN is marked by the person reporting an event who grades the information as red, yellow, or green.

Communication with stakeholders and information dissemination

Every VSN member can post information and warnings in the portal, concerning, for example, observations of new harmful substances, contaminated substances, or new (local or national) drug use trends. When reporting an observation, the information is tagged as green, yellow or red, depending on the level of urgency of the information. Examples of 'red' information may be observations of very potent, or contaminated, substances that may increase the risk of drug-related deaths. Examples of 'green' information may be new research results or epidemiological data.

Netherlands

There is no official early warning system in the Netherlands, however, many of the activities that would normally be associated with such a system are undertaken by the Trimbos Institute which houses the Drugs Information and Monitoring System (DIMS) and was established in 1992.

Management and administration of EWS

DIMS co-ordinate and manage the drug checking service, the Monitor Drug-related Incidents (MDI), and the Reporting Desk for New Drugs:

- ***DIMS' drug checking service*** is a large network (32 organisations that provide drug addiction and/or prevention services) of testing facilities that provide a simple drug testing service to people who wish to gather information about the content of their drugs. Drug consumers hand in their drugs and receive the laboratory results approximately one week later.
- The ***MDI*** is a drug monitoring system that collects data on drug-related adverse health incidents from emergency departments, forensic doctors, first aid services, and ambulance services. This includes both physical and psychological effects as well as bodily injuries sustained while under the influence of drugs.
- The ***Reporting Desk for New Drugs*** assembles, analyses, and reports on data collected about the production, trade, and consumption of NPS. The Customs Laboratory of the Netherlands and the Netherlands Forensic Institute provide data about seized NPS. DIMS drug checking service provides data about NPS that have been detected in consumer samples at a drug checking service. The MDI and the Dutch Poisons Information Centre share data about adverse NPS health-related events. Additional information about NPS being used in the Netherlands is also collected from pre-selected online discussion boards about drugs.

If there is a situation whereby it may be appropriate to issue a warning due to increased health risks with a substance, the Coordination point Assessment and Monitoring (CAM) may be requested by the Ministry of Health, Welfare and Sport to undertake a risk assessment. Based on the outcome of this risk assessment, the CAM advises the Minister of Health, Welfare and Sport on applicable measures.

Data collection, validation, and management

If there are strong signals about the use of new drugs or new trends in the use of existing drugs, the Ministry of Health, Welfare and Sport may request the CAM to start a risk assessment procedure. The risk assessment utilises the Delphi method. It is not anonymous, but it does have the iterative and expertise character of Delphi. Before the start of the risk assessment, the committee members first undertake an individual risk assessment on the basis of the information report prepared by CAM. The risk assessment consists of arguing (qualitatively) and numerically scoring (quantitatively) a number of criteria, according to a fixed format. There are 16 risk assessment criteria covering four areas: individual health, public health, public order and crime. The various possible policy measures and their consequences are also discussed. The outcome of the risk assessment and the impact of the discussion is recorded in the risk assessment report, which is submitted to the State Secretary for Health, Welfare and Sport. Following interdepartmental consultation, a policy recommendation is submitted to the Minister of Health, Welfare and Sport who is responsible for the final decision on whether to take measures. Possible follow-up steps include, but are not limited to:

- Monitoring or investigation must take place.
- An information or warning campaign should be held.
- Measures must be taken that hinder production and trade: the legislator ensures an adequate legal regulation to import, export and/or prohibit trade (Opium Act, Commodities Act or other legislation).
- A total ban be imposed: the legislator ensures adequate regulations (Opium Act, Commodities Act or other legislation).
- A report must be made to the EMCDDA or Europol through the National Focal Point and the Europol National Unit.

Communication with stakeholders and information dissemination

There is a ‘Red Alert’ protocol in place for these situations whereby public health is threatened by the appearance of a worrying substance on the drug market. Red alerts are only issued for targeted or national warnings. In these situations DIMS informs its participants (via drug checking services, institutions providing drug treatment or prevention services, internet platforms and social media, posters at parties or other locations where the target group is, and via intermediaries who are in direct contact with the target group), the relevant health authorities via its MDI network, relevant teams in the Trimbos institute (communication, drug information line and drug prevention), and other relevant stakeholders (Netherlands Forensic Institute, National Poisons Information Centre). Trimbos also creates a media post and generates a push message for the Red Alert app.

Conclusion

Drug markets continue to evolve worldwide with new substances continually emerging and changes being observed in the potency and quality of established drugs. It is increasingly being acknowledged that it is important from a public health perspective to develop systems to identify and respond to these threats in a timely fashion to minimise drug-related health harms. The three early warning systems described in this evidence brief all have the following attributes – multiple indicators that measure use, harms, and market characteristics; regular data collection that is accessible and available in a timely manner; triangulation and cross-verification of data to increase certainty in emerging trends; and communication of trends to policy makers, healthcare workers and people who use drugs.

3 Introduction

An early warning system (EWS) on drugs can be described as a multidisciplinary, inter-institutional network which enables information exchange among key actors who are involved in the drugs area. An EWS aims to identify emerging drugs that pose a potential threat to public health at an early stage. It assesses the risks such drugs may pose and provides information to enable the design of effective responses. An EWS can also help identify changes on the drug market, such as new use patterns and unusual concentrations or contents such as toxic adulterants and can enable effective and early dissemination of information. Scientific evidence-based information of the changing drug market is essential in making informed policy decisions to address any changes and protect public health from possible health threats and drug-related criminality [1].

A number of regions and countries have established an EWS, including the European Union (EU), United States (US), New Zealand, Netherlands, Scotland and Sweden. This evidence brief aims to describe the operation of three existing early warning systems in Scotland, Sweden and the Netherlands.

3.1 European Union Early Warning System

The EU EWS was established in 1997 as part of Joint Action 96/699/JHA concerning the information exchange, risk assessment and control of new synthetic drugs (ref) and was the first regional early warning system. It is operated by the European Monitoring Centre for Drug and Drug Addiction (EMCDDA) in close cooperation with Europol. The system is composed of a multi-sectoral, multidisciplinary, and multiagency network, which includes the EMCDDA, 29 national early warning systems (27 Member States, Turkey, and Norway), Europol and its law enforcement networks, the European Medicine Agency, the European Commission, and other partners. The EMCDDA is responsible for collecting, collating, analysing, assessing, and communicating the information reported by the Network. It was set up due to concerns that the emergence of ecstasy (MDMA) had revealed a lack of capacity in Europe to identify and respond to the appearance of uncontrolled substances that could be used for their psychoactive properties and cause harm. Since then, the drug market has undergone significant changes including the emergence of the new psychoactive substance (NPS) market. From 1997–2007, a relatively small number of NPS were identified, but from 2008–2015 there was a rapid increase in the number, type and availability of NPS in Europe. In both 2014 and 2015, over 100 NPS were identified. Since 2016 there has been a drop in the number of substances appearing each year to around 50. However, more highly potent substances have emerged that are associated to more problematic patterns of use or among chronic and long-term drug-using populations. These include new opioids, such as fentanyl derivatives that are often linked to outbreaks of poisonings or deaths. By 31 December 2021, the EMCDDA was monitoring 884 NPS that had appeared on Europe's drug market since monitoring began in 1997; this includes 52 substances that were notified for the first time in 2021 [2].

3.1.1 Operation of the EU EWS

The EU EWS is based on the foundation that 'good decisions begin with good data'. Critical information is shared in a timely manner through the EWS to raise awareness and support preparedness and response activities. Data reported by the national early warning systems can be used to:

- Identify the appearance of an NPS on the drug market for the first time.
- Identify other substances of interest, in particular toxic agents, related to adulteration, contamination, or dilution.
- Describe, analyse, and assess the distribution, use, and spread of NPS.

- Identify and estimate the magnitude of a public health or social threat caused by an NPS, including outbreaks.
- Monitor changes in the NPS market.
- Identify research needs and facilitate epidemiologic and laboratory research.
- Facilitate planning.
- Detect changes in use and patterns of use.
- Evaluate response measures, including restrictive measures.

When a Member State identifies an NPS, its national EWS reports this to the EMCDDA. This includes chemical and analytical information, as well as the circumstances of the event. If confirmed as an NPS, then a formal notification is issued to the Member States. At this stage, the EMCDDA begins to formally monitor the substance. Early detection of an NPS allows potential threats to be identified and analysed, and for forensic and toxicology laboratories to include the substance in their analytical screening [3].

The EU EWS also responds to public health threats that may not be directly caused by NPS, but due to other hazards associated with their use. Examples include harmful adulterants, diluents, synthesis-related impurities and contaminants, the biological contamination of substances, and the transmission of infectious diseases. The EWS may also exchange information on new trends in the use of existing substances and/or new combinations of substances which pose a potential risk to public health.

It is a task of the Member States to ensure that its Reitox national focal point and Europol National Unit provides the EMCDDA with the available information (e.g. detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks) on NPS in a timely manner. The organisation and functioning of the national early warning systems are a national responsibility. The EMCDDA recommends that national early warning systems have a clear mandate, strategic aim and supporting objectives, and use a multi-sectoral, multiagency, and multidisciplinary approach. Regular liaison should be maintained with forensic science and toxicology laboratories, poison centres, government departments responsible for implementing drugs policy, national medicines regulatory authorities, and other drugs agencies as appropriate.

In response to the ever-changing nature of the NPS market and the large number of substances that need to be monitored, the EMCDDA has developed a toxicovigilance system, a signal management system, an open source information monitoring system, and a risk communication system better detect, assess, and respond to public health threats associated with NPS.

Toxicovigilance

This has harmonised data collection on acute non-fatal and fatal poisonings involving NPS. A serious adverse event in a human associated with the use of an NPS or other substance of interest is one that meets any of the following criteria:

- Results in death.
- Is life-threatening.
- Requires intensive treatment in an emergency room and/or requires hospitalisation.
- Results in persistent or significant disability or incapacity, or in substance dependency or substance abuse.
- Consists of a congenital anomaly or birth defect.
- Is an important medical event that may not be immediately life-threatening or result in hospitalisation or death but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above.

Serious adverse events may or may not be subject to analytical confirmation through analysis of a biological sample and/or a seizure and/or a collected sample. The likelihood of exposure to the substance is assessed and classed according to the Drug Exposure Classification System [4].

Signal management

The EMCDDA defines a signal as '*the information arising from one or more sources that suggests a potential public health or social threat of European relevance associated with a new psychoactive substance or other substance of interest and is judged to be of sufficient likelihood to justify verification, and, where necessary, a response'*. Signal management is a central component of the EU EWS. They may be detected through data reported by Member States, or data identified from monitoring open source information, or any other data at the disposal of the EMCDDA. Signals are analysed, characterised, assessed, prioritised, and responded to according to the type of threat, the seriousness of the threat, and the urgency of the threat [4]. Events that are classed as signals include:

- First identification of a substance judged by the Member States to be an NPS. If the EMCDDA determines it is an NPS, a formal notification is issued to the Network.
- First identification in country of an NPS.
- Cases of severe acute poisoning, severe chronic poisoning, and deaths subject to medico-legal investigation.
- Events that are unusual or unexpected for the given time and place.
- Outbreaks (including clusters), such as poisonings or infectious disease.
- Events or situations that have a potential for cross-border (international) spread.
- Large seizures or other seizures of concern.
- Mis-selling (mislabeling, substitution), adulteration, contamination, or dilution events that could have a high public health impact such as fake opioid analgesics or benzodiazepine medicines containing fentanyl, heroin adulterated with fentanyl or synthetic cannabinoids, or PMMA sold as MDMA tablets.
- Detection of high strength/dose products.
- Infectious diseases and biological contamination of substances.
- Events involving criminal groups.

Signal management consists of the following steps:

1. Detection.
2. Validation – if the signal is invalid then it is refuted and no further action is taken; if the signal is valid it is confirmed and the process continues.
3. Analysis and characterisation of the signal.
4. Assessment – involves making an evaluation/judgement about the signal.
5. Prioritisation –involves prioritising the signal as relevant to other validated signals.
6. Recommendation for what actions the EMCDDA will take in order to respond to the signal. The response actions are: awareness/no further action required; monitoring; issuance of a risk communication; intensive monitoring; or any other action within the competencies of the EMCDDA. The EMCDDA may issue a request for information to one or more members of the Network and/or other partners.

As new information becomes available, a signal may be assessed repeatedly during an event or over time.

Monitoring open source information

The EMCDDA has developed a multi-lingual monitoring system that includes the medical information system (MedISys), which was developed by the European Commission's Joint Research Centre, Google Alerts, Twitter, and other sources. The system monitors events from thousands of sources of information,

such as the media, health agencies, and law enforcement. Important types of events detected through open source monitoring include an outbreak in Russia when MDMB-FUBINACA was involved in 600 poisonings over a two week period and a multi-state outbreak in the United States involving ADB-CHMINACA [4].

3.1.2 Risk communication

The EMCDDA issues four types of risk communications for the purposes of early warning: alerts, formal notifications, advisories, and briefings which vary by the importance and time sensitivity of the information.

- An alert provides vital, time-sensitive information for a specific event or situation associated with an NPS or other substance of interest that may pose a serious public health or social risk within Europe. Alerts convey the highest level of importance and require immediate attention by the Network.
- A formal notification is issued the first time there is an analytically confirmed identification of an NPS in Europe; it may not require immediate attention.
- An advisory provides important information for a specific event or situation associated with an NPS or other substance of interest but may not require immediate attention.
- A briefing provides important background information for a specific event and does not require immediate action by the Network.

Risk communications also request the Network to report to the EMCDDA any additional information they may have that could increase understanding of the risks posed by the event, situation, NPS or other substance of interest.

3.2 Irish Early Warning and Emerging Trends Committee

Ireland's National Drug and Alcohol Strategy: 'Reducing Harm, Supporting Recovery: A health-led response to drug and alcohol use in Ireland 2017–25' acknowledges the challenges around monitoring NPS and states that there is a need to develop analytical capacity, data collection and public warning mechanisms. Strategic Action 3.3.38 of the strategy aims to strengthen the response to the illegal drug market, including the changing nature of new psychoactive substances **[5]**. The strategy states that this action will be delivered by:

- Continuing to develop systems to monitor changing drug trends in line with the EU Early Warning System.
- Completing the development of the HSE public alert system for adverse events due to drugs and commencing implementation.
- Supporting government funded laboratories, tasked with analysis of drugs of abuse, to engage in novel analytical development work, in relation to psychoactive drugs but especially new psychoactive substances (licit or illicit), while continuing to fulfil their core functions.
- Providing funding in the capital expenditure programme for the construction of a purpose built new laboratory for Forensic Science Ireland with €6m prioritised to commence the project immediately.
- Strengthening the legal robustness of Presumptive Drug Testing (PDT) to contribute to the timely prosecution of Section (3) drug-related offences.

The Irish Early Warning Emerging Trends (EWET) Committee is a sub-committee of the National Oversight Committee of the strategy. It was established in September 1997 on an administrative basis by the Department of Health to consider national issues arising from the 1997 Joint Action on New Synthetic Drugs by the Council of the European Union around information exchange, risk assessment and control of new synthetic drugs. Under this Joint Action, each member state was required to set up a system of early warning to monitor the emergence of such substances. The 1997 joint action was replaced in 2005 by Council Decision of 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances. In 2001, the EWET committee was placed on a formal basis within the National Advisory Committee on Drugs (NACD) and its remit extended to include the monitoring of emerging trends. It remained within the NACD until 2017 and is now under the remit of the Department of Health. The committee's terms of reference are in the process of being updated, but the most recent terms are as follow:

- To receive, share and monitor on behalf of the Department of Health, information from National and EU sources on New Psychoactive Substances of concern in the context of the Council Decision of 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances.
- To receive, share and monitor on behalf of the Department of Health, information on emerging trends and patterns in drug use particularly poly drug use and associated risks.
- To monitor the work on emerging trends being developed at EU level (EMCDDA responsibility), to consider its implementation in Ireland.
- To monitor the reports to the Early Warning System on a quarterly basis about emerging trends and New Psychoactive Substances, but more frequently if circumstances warrant it.
- To examine new ways of getting sensitive information on changing patterns of drug use and trends.
- To consider the implications of changing drug markets and distribution networks which can impact on the popularity of certain psychoactive substances.
- To review the risk assessment reports provided by the EMCDDA and determine their relevance to the Irish situation and advise Government accordingly.

Responsibility for the committee lies with the Department of Health. The committee meets each quarter and members report on trends in drug use or consequences of drug use noted during the preceding quarter. Meetings are chaired by the Department of Health who provides a report of each meeting to the National Oversight Committee. The members of the EWET committee cover a wide range of government departments, professional disciplines and services which include: police and customs, human, chemical and forensic toxicology, pharmacology and pharmaceutical science, emergency medicine, drug treatment, harm reduction, prison service, voluntary drug sector, and research (including the EMCDDA's focal point). Each member of the committee represents a wider body from whom they receive information and to whom they disseminate information. There are no fulltime staff allocated to the EWET committee and all staff incorporate this function into their other work.

3.2.1 EMCDDA requirements

Under Article 5a of Regulation (EC) No 1920/2006 it is a requirement of EU member states, including Ireland, to ensure that its Reitox national focal point provides the EMCDDA with information on NPS in a timely manner and without undue delay. As national focal point, the Health Research Board performs this role in Ireland which involves:

- Reporting the first incidence of a new psychoactive drug in Ireland when it occurs and completing the associated form in conjunction with the Irish laboratories.

- Participating in joint reports and risk assessments as legally required by the EMCDDA and responding to suggested control measures.
- Completing an annual national report for the EMCDDA [3].

3.2.2 Risk communication and alert channels in Ireland

In Ireland, risk communication and the issuing of alerts is undertaken by the Health Service Executive (HSE) if a substance of concern has been identified through existing structures or if drug emergencies or overdose cases are been investigated and thought to have involved substances of concern. The HSE National Clinical Lead for Addiction Services, the HSE National Social Inclusion Manager and the HSE Public Health Department discuss situations that arise with An Garda Siochana and other relevant stakeholders. Following the review of local, national, and international evidence, it is the responsibility of the National Clinical Lead to decide and sign off on the appropriate response for each situation that arises. The five levels of alerts are outlined in Table 1. The decision to issue an alert will be made based on cases where there is an extra threat to life. The HSE Press Office and HSE Communications team are involved in the dissemination of any warnings/alerts to the national media and through HSE social media channels including Drugs.ie. Information is also disseminated to relevant stakeholders such as addiction services and emergency departments.

Table 1 Five levels of alerts issued in Ireland by HSE

Alert not warranted	Information to support staff	HSE Advisory Notice	Targeted Alert	Public /National Alert
- Information reviewed - Trend or issue noted. - Consideration for developing new information based on evidence.	- Information shared with professionals to support their work. - Possible tailored message shared on drugs.ie and HSE channels as information. - Situation monitored.	- Information for professionals or targeted audience to advise them of a trend. - May include details and harm reduction information. - May be internal within services or shared with media. - Situation monitored in relation to prevalence, hospital presentations and deaths.	- Alerts for an increased threat to life within a certain using cohort (area, festival or specific cohort).	- The highest level of concern. - Alert for an increased threat to life among the public.

3.3 Questions

For each of the countries under study (Scotland, Sweden, the Netherlands):

1. Describe the management and administration of the EWS in the three countries using the following parameters: objectives; terms of reference; organisation of system; staffing and costs; data protection; and network membership and roles/responsibilities.
2. Describe the data collection, validation, and management of each EWS using the following parameters: sources of data; data collection tools; access to system; monitoring; and validation.
3. Describe how communication with stakeholders is managed and information disseminated using the following parameters: assessment of signals; decision making around risk communication; information exchange with institutional stakeholders; dissemination of outputs; and facilitation of research and analytical work undertaken by third parties such as universities.

4 Method

4.1 Search strategy

Given the nature of the research questions for this evidence brief, it was considered unlikely that relevant source documents would be found primarily in traditional bibliographic database sources or that a traditional approach to searching would yield relevant results. Consequently, this evidence brief relied primarily on grey literature published by health systems, government agencies, and independent organisations. The search was conducted in two phases:

- **Grey literature search:** Broad searches were undertaken using search engines (e.g. Google and Google Scholar). Search results were screened for relevance to the research questions. Relevant documents were retained for inclusion and relevant organisations were identified for additional targeted searching. Websites identified by the search engine searches were searched using the websites' own search engines, and available publication lists were screened for relevant documentation. These searches were performed in October 2022 by one author (MD).
- **Database search:** In addition to the grey literature search, a systematic scoping search was performed in bibliographic databases (Ovid MEDLINE, Ovid Embase, and Ovid Social Policy and Practice). The search strategy combined search terms relating to early warning systems for drugs and the individual countries of interest (see **Error! Reference source not found.** for the search strategy for Ovid M EDLINE).

Relevant material was imported into Zotero reference management software, and full texts were obtained for the purpose of data extraction.

After completing a search of both the grey literature and bibliographic databases it was apparent that there was insufficient published literature to adequately answer the questions. The managers of each system were contacted and were requested to provide unpublished documents/protocols on their early warning systems if available. In addition, online interviews were conducted by two authors (DM, BG) via Microsoft Teams with the managers of the Scottish and Dutch systems, while the manager of the Swedish system provided answers via email.

4.2 Data extraction and synthesis

Relevant data were extracted from the sources in narrative form into an extraction sheet in Microsoft Excel. Non-English-language material was translated using Google Translate. We particularly relied on Google Translate for translating a number of key documents relating to Sweden and the Netherlands. Where we were unsure about the accuracy of the translation we corroborated the translated information with the manager of the system in question. Due to the paucity of published information available on each system, most of the information presented in the three case studies was obtained from unpublished documents and from the interviews we undertook. Where information has been obtained from published literature references have been provided, otherwise the information presented in the case studies was obtained through interviews and unpublished documents and protocols.

5 Findings: Case study 1 – Scotland

5.1 Introduction

RADAR (Rapid Action Drug Alerts and Responses) is the Scottish EWS and was established in 2022. The Scottish Drug Deaths Taskforce was established in 2019 as a direct result of an increase in drug-related deaths which led to Scotland reporting its highest ever recorded number of deaths. Optimising public health surveillance is a priority of the Drug Deaths Taskforce and one of the Taskforce's 20 recommendations was the development of an early warning system – RADAR – in order to respond to the current public health emergency [6]. RADAR is a single platform that provides a structured way to collect, assess and communicate information about drugs. It enables individuals to access information on drugs, services, and monitoring that should enable local areas to be held to account. Public Health Scotland was the organisation charged with developing an EWS by the Scottish Government. Under section 2 of National Health Service (Scotland) Act 1978, Public Health Scotland has a duty to improve and protect health and wellbeing and its functions are set out in legislation (Public Health Scotland Order 2019).

5.2 Question 1: Management and administration of Scottish EWS

5.2.1 Objective of Scottish EWS

Public Health Scotland (PHS) coordinates the Scottish EWS (RADAR) and uses a partnership approach to support local services, community members and public health teams to ensure the EWS is relevant and meets the needs of the people and places it serves. The objectives of RADAR are to:

i. Identify trends, risks and clusters of overdose and intoxication
ii. Respond to new and emerging substances, changing harms and other relevant scenarios
iii. Advise on and implement immediate harm prevention and control measures
iv. Provide high-quality current public health information
v. Inform decision-making about resource allocation, prevention and service design and delivery [7]

5.2.2 Co-ordination of EWS

The PHS has overall responsibility for the co-ordination of RADAR and the structure of RADAR Is set out in Figure 1. In total, six groups operate – two PHS groups and four multi-agency groups. The PHS groups are the Programme Team and the Advisory Group.

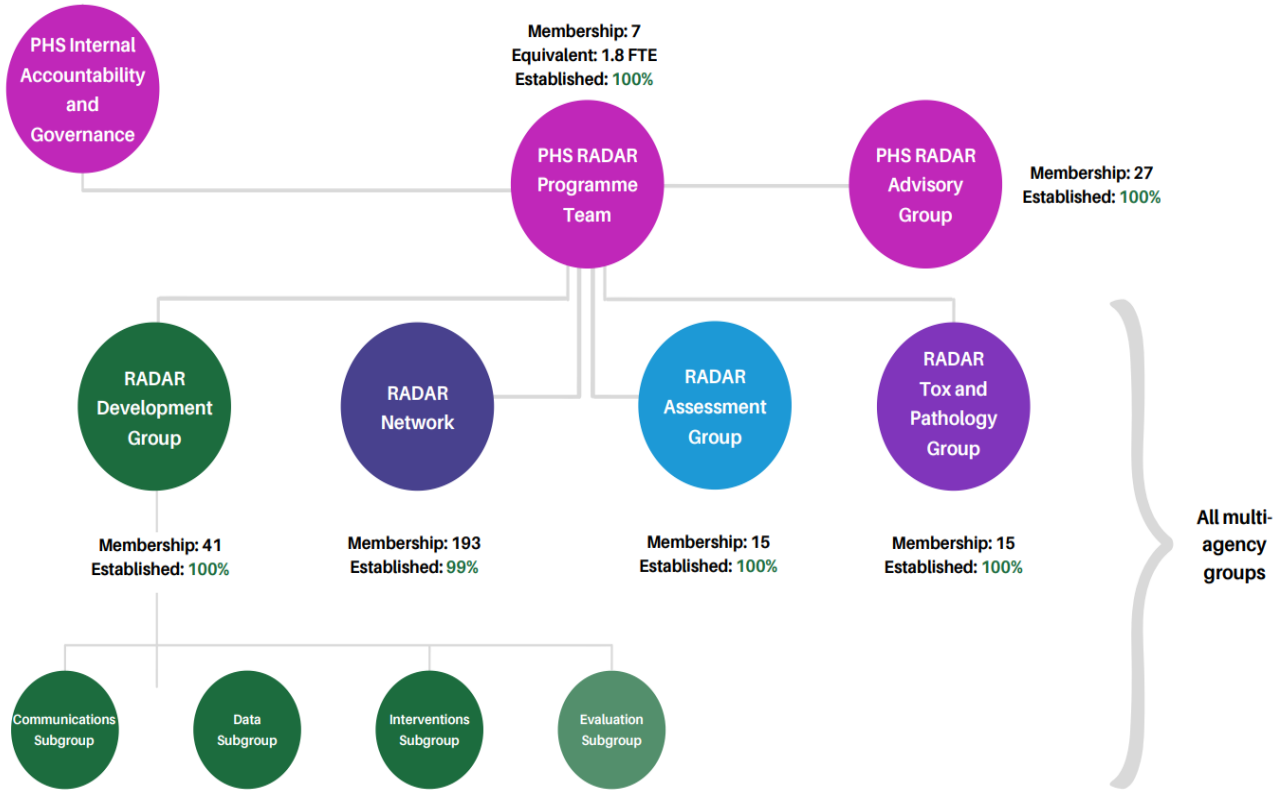

Figure 1 Overall structure of the Scottish EWS

The RADAR **PHS Programme Team** provides internal project management. Its key roles are to: manage progress of the programme; be accountable for actions; keep key partners updated; manage partnerships; and data collation and validation. The team meets for one hour every two weeks at minimum. Its membership is made up of PHS Drugs Team members who work on surveillance and includes: a consultant in public health medicine, organisational lead, programme portfolio manager, public health intelligence adviser, health improvement manager, senior health improvement officer, and a data analyst. The group's priorities are data validation and assessment of protocols, and providing a quarterly update.

The RADAR **PHS Advisory Group** provides internal project advisory and development. Its key roles are to: analyse presenting data; ensure that interventions reflect a public health approach to drugs; advise on how RADAR intersects with wider determinants of health; comment on guidance before it goes to the Development Group; advise on how RADAR communicates with relevant networks; and ensures information is accessible. The group meets for one hour every two months. Smaller subgroups may meet ad-hoc as necessary. Membership includes the RADAR Programme Team plus representation from the following areas: alcohol surveillance, communications, data management, data protection, data visualisation, epidemiology, housing/homelessness, justice, medication assisted treatment, prevention, and suicide. Members of the PHS RADAR Advisory Group may join the Development Group to inform specific work, and the Development Group subgroups can call on the advisory group to provide expert advice if needed. The PHS Advisory Group's priorities are to undertake simulation exercises to ensure preparedness and to create internal protocols to process inputs and outputs.

There are 4 multi-agency groups:

- The **Development Group** is formed of communication, data and intervention subgroups that support system design and development, including the creation of a communication and response toolkit.
- The **Network** is a wide and inclusive group that collects and shares drug trends and data, helps to validate information and processes outputs and communications.
- The **Assessment Group** is a specialist technical team that studies data, assesses potential threats and decides on action to reduce harm.
- The **Toxicology and Pathology Group** is a specialist technical group.

The Development Group

The Development Group is multi-agency group of 41 members who advise on how to progress RADAR and develop the system. It continues the work of the Surveillance Operations Group that operated from May 2021 to January 2022 which led to the creation of RADAR. The Development Group is comprised of three subgroups that will change and develop over time to reflect progress and the needs of the programme. The work of the group is primarily done in the subgroups with the wider Development Group meeting on occasion. The Development Group's roles are to: coordinate and advise on the work of subgroups; provide feedback on key aspects of the system such as look, functionality and accessibility; test the operability of RADAR components in real-world situations; and sign-off on publications. This group meets for 2 hours every 6 months while the subgroups meet for 2 hours every 2 months. The PHS Admin Team provide support for all meetings for the main group and subgroups.

The Development Group has 3 subgroups - communications, data, and interventions. A fourth (evaluation) subgroup will be established in 2023 to conduct an evaluation for the first year of the programme and will feed back recommendations for improvement to the RADAR Programme Team. It will also advise on how the system should be audited and evaluated in the future and identify key metrics/data and information of interest.

1. The communications subgroup develops and implements the communications and marketing element of the RADAR programme, such as creating messaging and protocols to report information to stakeholders, the media, and the public, with a focus on engagement and messaging.
2. The data subgroup is responsible for planning effective and robust data collection methods. It regularly reviews the data for quality and completeness, to ensure its long-term sustainability while RADAR develops. Its responsibilities include: advising on data management and storage, including the use of data warehouses; developing and refining data collection methods and datasets to ensure they are suitable and sustainable; identifying gaps in data and areas for development; development and sign-off of reporting form templates; and inputting into quarterly report.
3. The interventions subgroup advises on what actions to take, and the interventions needed to respond to a situation and to reduce drug-related harm. Its responsibilities are to: review the evidence and make recommendations on appropriate responses and interventions for current or anticipated reports/incidents. Its outputs include an interventions toolkit for use by the Assessment Group and local areas). The toolkit contains local guidance processes, recommended interventions and responses, and a list of resources to signpost information, advice, and support (using guidance developed by Communications Group).

The Network

The Network is a large multi-agency national group currently comprising of 193 members and it supports the operation of the system. Its key roles are to: monitor markets, collect information, and detect trends; collect and share drugs information, using email, forms, and surveys; strengthen local information sharing and communication networks; help to validate information and reports; and communicate outputs from the Assessment Group [8]. At the time of writing (December 2022), the network did not have a chair or co-chair but PHS are keen that external appointees undertake these roles.

Frequent communication is encouraged in the Network. Members are regularly sent emails to disseminate information such as surveys and alerts. Network meetings are held virtually each quarter for a few hours and PHS Admin Team provides support for all meetings. At these meetings updates are provided on RADAR, information is collected on areas of interest, information is shared on key findings such as drug trends and harms, and learning sessions are hosted. Due to the size of the network, it is not possible for all members to give an update during the meeting; information is collected before and after the meetings using forms, reports, and surveys. Members are also invited to contribute on topics of interest or emerging themes ahead of time. Events, such as launch sessions and end of year reviews, may be held in person.

Membership of the Network was scoped by the PHS Surveillance Operations Group who encourage contributions from a range of areas and aim to have representation from sectors including but not limited to [8]:

- Alcohol and Drug Partnerships
- The Ambulance Service
- Blood borne virus leads and networks
- Community members
- Drug services – NHS, voluntary sector
- Drug-related deaths – local and national leads
- Education – universities, colleges and schools
- Families
- Forums and networks
- Hospice and home care
- Hospitals – emergency departments, drug workers
- Hospitality – nightlife, restaurants, festivals, pubs, clubs
- Housing and homelessness – Housing First teams, hostels, services
- Lived and living experience
- Local government – safer communities and community planning teams
- Mental health – services, inpatient and community
- Police Scotland – custody link workers, STOP, harm prevention
- Primary care – GPs, dentists, pharmacies
- Prison – service, inspectorate, union
- Public health – local and national
- Recovery – communities, organisations, fellowship groups
- Secondary care – hospital and community
- Sexual health – NHS, voluntary sector
- Social work – children and families, justice and adults
- Toxicology – drug checking, post-mortem, prison and police testing
- Veteran groups

- Voluntary services
- Young people – youth work

The roles of the network will be described in further detail in Questions 2 and 3.

The Assessment Group

The Assessment Group is a specialist multi-agency technical team with defined roles and responsibilities. that enables RADAR to take rapid action to reduce drug-related harm. The aim of the group is to regularly assess validated information on drug trends and incidents of drug harm, consider the level of risk and decide on the threat level and action needed. When RADAR receives notification of a new drug or an adverse drug-related event, the PHS Programme Team synthesise and validate the available data; the validated data are then presented to the Assessment Group for assessment. Its key roles include reviewing evidence and making assessments while considering situational context and co-founders such as substance risk, underlying comorbidity, and drug interactions; establishing threat level and determining output; creating alerts and responses, including information on context, importance, and action; and communicating to the Network and the National Drug Death Incident Management Team as necessary. The Assessment Group is still under development and further details on structure, process, roles, and responsibilities are yet to be determined.

Meetings on general programme updates and learning are held every six months to keep members up to date. Meetings can be convened at short notice if reports coming into RADAR reach a threshold of potential harm or risk in order to rapidly respond, but this threshold has yet to be determined. Members must be prepared to provide advice and input into the group at short notice and occasionally outside of normal office hours. It is expected that the time commitment will average about 3-4 hours per month, though this will vary by situation. The PHS Admin Team provides support for all Assessment Group meetings. Membership of the Assessment Group was scoped by the PHS Surveillance Operations Group and the following groups were invited to join:

- Alcohol and Drug Partnerships
- Communications
- Drug service
- Emergency department
- Local public health,
- Other toxicology,
- Pharmacy
- Police Scotland
- Post-mortem toxicology
- Public Health Scotland (including representatives from the PHS Programme Team, Advisory Group and National Drug Death Management Team)
- Scottish Drugs Forum.

Depending on the situation, PHS may call on a wider team of topic experts and experts with a broader view. For example, if there was an incident in a school in a city, appropriate RADAR Network from education and youth work would also be invited, as well as colleagues from the local Alcohol and Drug Partnership and the local health board.

The roles of the assessment group will be described in further detail in Questions 2 and 3.

Toxicology and Pathology Investigation Network

The Toxicology and Pathology Investigation Network (TAP IN) provides a forum for discussing matters related to the scientific and forensic investigation of drug-related harms. It aims to promote a better understanding of the investigative processes associated with illicit drug use and to reduce drug harms via effective information sharing. Membership comprises representatives from the following organisations:

- Public Health Scotland
- Scottish Government
- University of Dundee
- University of Edinburgh
- University of Glasgow
- University of Aberdeen
- NHS Grampian
- NHS Greater Glasgow & Clyde
- NHS Lothian
- Scottish Police Authority
- WEDINOS
- Police Scotland
- Drug Research Network Scotland
- Crown Office and Procurator Fiscal Service
- National Records of Scotland

Meetings are held quarterly, and the objective of these meetings is to:

- Discuss matters relating to the identification via toxicological analysis of drugs likely to be used for their psychoactive effect, including re-purposed and newly synthesised compounds.
- Discuss and promote shared understanding of the physical and psychological effects of specific substances, taking account of dosage, interactions with other drugs or prescribed medications, and co-morbidities.
- Support the detection of, and response to emerging threats by providing toxicology and drug analysis results to the RADAR Assessment Group.
- Discuss the challenges (technical, resource, procedural) associated with the effective scientific and forensic investigation of drug-related harms and to agree solutions for these challenges.

If there are issues which TAP IN cannot resolve they are referred to the RADAR Programme Team for resolution and then, by exception, reported to the National Mission Governance Oversight Group for discussion and resolution.

5.2.3 Staffing and costs

The day to day management and running of the EWS is undertaken by PHS staff. An equivalent of 1.8 FTE (full-time equivalent) staff are employed to achieve this.

5.2.4 Data protection and IT platform used

Due to the type of data being collected in the EWS, it was a legal requirement for PHS to undertake a Data Protection Impact Assessment (DPIA); this is an assessment tool which is used to identify, assess and mitigate any actual or potential risks to privacy created by a proposed or existing process or project that involves the use of personal data. The PHS collects information on incidents and events related to drug use to identify any potential trends or threats in the reports. They also collect email addresses, if provided, to follow up on reports. The PHS have put safeguards in place to protect the privacy of individuals and confidentiality of data. Identifiers are normally held separately and access to the RADAR data requires authorisation on a strict role-based basis which requires renewal every 6 months. RADAR program files that contain personal data are stored on PHS secure servers. Data are only accessed by staff with role-based access in the PHS Admin or Drugs Team, using a PHS laptop PC encrypted to AES 256 standard. Data is encrypted during transit and within the servers. All data entered by participants is collected and held on LimeSurvey. Raw data are only observable to the PHS staff responsible for analysing and handling the data (members of the PHS Drugs Team). Raw data are not disseminated to any other party and data dissemination provides aggregate non-identifiable data.

The information collected by the EWS is stored in LimeSurvey and can be extracted using different formats [9]. The data is transferred from LimeSurvey as an Excel file into a protected space, with controlled access for analysis and processing. The use of LimeSurvey, for which PHS has a corporate licence, was recommended by the data protection team. Network members are regularly sent emails to disseminate information such as surveys and alerts. This is initially being done using MS Outlook, but due to the large number of network members, investigations are ongoing to identify software to effectively manage a group of this size and encourage collaboration.

5.3 Question 2: Data collection, validation, and management of Scottish EWS

5.3.1 Sources of data and data collection

Services and local communities are actively encouraged to share information such as drug-related adverse health effects or changes to the drug markets by using RADAR reporting forms, regular monitoring surveys, and the RADAR mailbox [8]. The reporting form (Appendix 2) can be accessed directly on the RADAR website (https://surveys.publichealthscotland.scot/212315) or via a link which is shared by the RADAR Network. The majority of questions are closed multiple-choice questions. While most reports are submitted digitally, for people without access to technology (people in prison, remote areas, those with no computer) a paper form is available to print. PHS also prints and posts paper forms to identified services, such as prisons, and alcohol and drug partnerships who are responsible for sharing forms to suitable services in their local authority area. Where possible, the forms are returned by being scanned and emailed to the RADAR mailbox. Guidelines are being developed for this and PHS are liaising with the Scottish Prison Service to determine the most appropriate methods for use in controlled environments. The use of pre-paid envelopes or submission boxes is also being investigated.

RADAR has a dedicated mailbox (phs.drugsradar@phs.scot) to manage the EWS. People may email the mailbox to ask questions or share information. This mailbox also receives an alert when a Reporting Form is submitted. This mailbox is monitored by a small team of PHS admin and management staff.

RADAR also combines data from PHS systems with information from healthcare providers, prisons, police, and toxicology services These data sets complement and link to similar records currently collected and

processed by the PHS Drugs Team, such as data on suspected drug-related deaths, drug-related hospital admission and post-mortem toxicology. Where possible, statistical indicators are added to datasets to signal significant changes and quickly highlight threats. There are plans to expand data collection to include regular and targeted data collection, for example, quarterly drug trend monitoring forms to collect data and detect changes to drug harms, or enhanced surveillance forms to investigate a particular area of interest. RADAR has identified the following priority project/services to collect data from:

- Police testing as part of a criminal investigation – drug seizures and biological samples involved in cases such as possession and supply.
- Police testing not part of a criminal investigation – samples of drugs not involved in a case such as those found, or handed in.
- Prison project – non-judicial drug checking project.
- Hospital project: A Surveillance Study in Illicit Substance Toxicity (ASSIST) – blood samples from patients attending emergency department related to 'illicit' drugs at the Queen Elizabeth University Hospital.
- Hospital project to identify NPS – blood samples from patients attending emergency department related to drugs at the Royal Infirmary of Edinburgh and Aberdeen Royal Infirmary (and various sites across the rest of the UK).

5.3.2 Data access, monitoring and validation

The PHS Programme Team controls who has access to the data. Sharing of data is done only when appropriate, under secure conditions and the details that could identify a person are removed as far as possible. Data is extracted from LimeSurvey or from Network meetings and stored in a protected space with controlled access in SharePoint for analysis and processing.The data is added to the main database, analysed for trends or changes and the results summarised. To understand the accuracy and importance of the information received, PHS checks the context, source, other reports (including from the Network). If this information warrants a rapid or specific response then the validated information is sent from the PHS Programme Team to the Assessment Grop using a validation and assessment form. If information cannot be validated, PHS will continue to monitor and may investigate further through targeted requests or enhanced surveys.

The procedure around data collection and validation is also described in Figure 2.

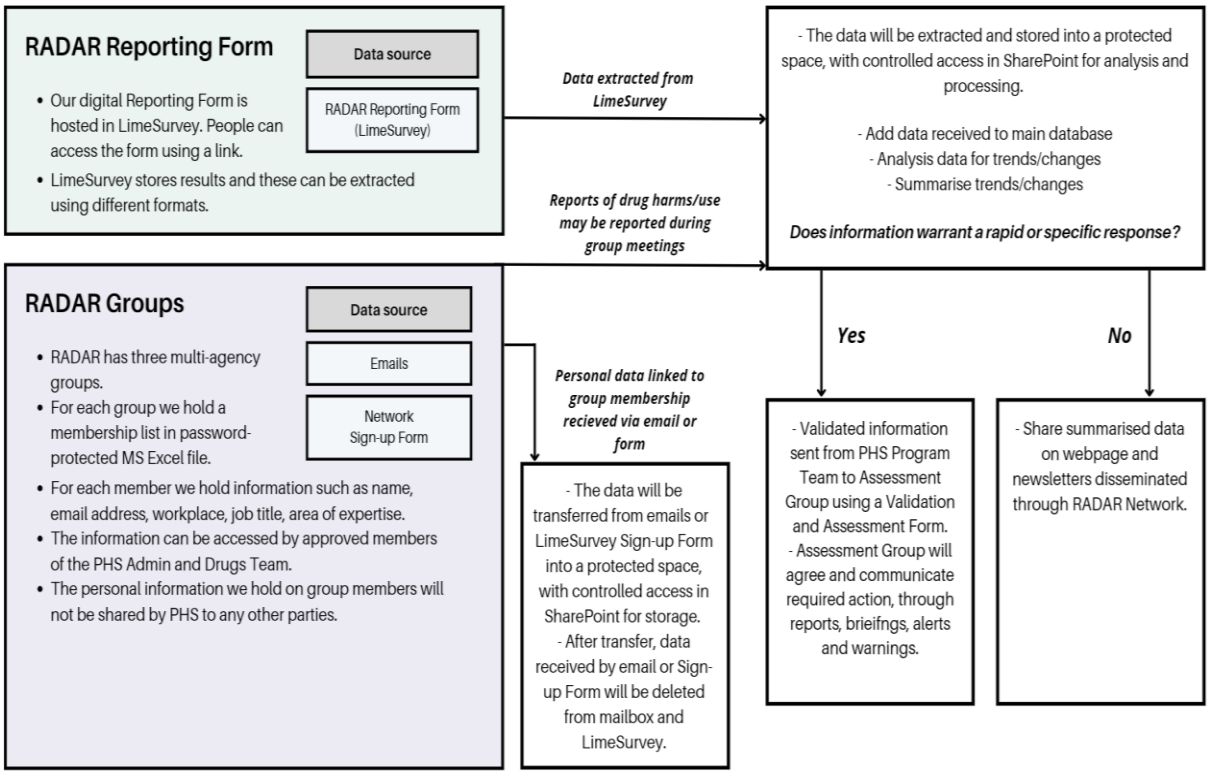

Figure 2 RADAR's data collection and validation procedure

5.4 Question 3: Communication with stakeholders and information dissemination

5.4.1 Assessment of signals and decision making around risk communications

The Assessment Group considers the validated information and agrees on the level of potential risk and the threat level, action needed, and type of response. A validation and assessment form is being developed for the Assessment Group to use when determining the level of risk and the most appropriate response. The action and response agreed by the Assessment Group is shared widely, including to the Network. As the Network is a community that links RADAR with the people most at risk of drug harm, its members can share information quickly to those that need it [7].

5.4.2 Information exchange with stakeholders

Communications may take the form of warnings or alerts, information summaries, risk assessments, educational resources, or reports. It is envisaged that the impact of these communications will be regularly evaluated for effectiveness. If the information does not warrant a rapid or specific response the summarised data is shared on the RADAR webpage and newsletters disseminated through the RADAR network. To date, RADAR has issued one alert about nitazene-type drugs, which was published in January 2023 [10].

5.4.3 Dissemination of outputs

Eighteen reports were validated by RADAR between September 2022 and January 2023 [10]. The Drugs Team at PHS compiles a quarterly report of drug-related indicators which includes data from the RADAR system; the first quarterly report was published in October 2022.

6 Case study 2 – Sweden

6.1 Introduction

In 2017 the Public Health Agency (PHA) of Sweden in collaboration with the National Board of Health and Welfare were commissioned to develop an action plan to respond to high drug mortality. One of the proposals in this plan was the development of an alert system for increased and improved information exchange between authorities, and health and social services through an early warning system. The expansion of naloxone programs and syringe exchange activities were also proposed. Between March 2019 and February 2021, the PHA undertook a pilot project whereby a network with 81 representatives from nine national authorities, five regions and seven municipalities was established and a web portal was developed and tested – Warning System Drugs (VSN). Following the pilot, the PHA of Sweden concluded that the alert system (VSN) could provide a platform and a structure for the rapid sharing of information and knowledge exchange with relevant bodies. In addition, the PHA also determined that it could be used to exchange information that is not urgent and could act as a support for general health promotion work to prevent drug-related deaths and injuries.

6.2 Question 1: Management and administration of Swedish EWS

6.2.1 Objective of Swedish EWS

The main objective of VSN is to detect at an early stage, new and dangerous substances or changing patterns of use that increase the risk of drug-related health harms or deaths. It is envisaged that the increased exchange of information within VSN will:

- Increase vigilance in specific geographical areas and among vulnerable groups.
- Enable those who work and/or are in contact with people who use drugs can pass on information about risks.
- Detect risks at an early stage that may otherwise lead to an increase in drug-related injuries and deaths.
- Provide a better basis for drug prevention work, addiction treatment, and for local drug crime prevention work.

The information that is reported and shared between everyone connected in VSN contributes to many people receiving the same information at the same time. This increases the likelihood of detecting risks at an early stage thereby reducing drug-related harm.

6.2.2 Co-ordination of EWS

PHA Sweden have been given a mandate by the Swedish government to implement and co-ordinate the national VSN. In February 2022, the web portal in VSN transitioned from being a pilot test to a system that is part of the PHA's system management. In connection with this, it was planned that a management organisation together with the management plan for VSN be drawn up.

The VSN network has more than 500 members who are professionals within authorities, regions and municipalities and either work directly with people who use drugs or have a strategic or analytical or investigative role in the drugs field. Following conversations and dialogue with existing VSN users and networks within the Swedish Association of Local Authorities and Regions, the following activities were identified as particularly relevant for participation in VSN: addiction and psychiatry clinics, needle exchange services, clinics that provide medication-assisted treatment for opioid dependence, emergency

and intensive care clinics, ambulance service, individual and family care, and children and adults social services that provide interventions in addiction and addiction care. Professionals in these activities have specialist expertise in various areas and in different ways meet people who use drugs. There may be other professionals from other sectors that are relevant for participation in VSN. If organisations are not already members but wish to connect to VSN, they can complete an expression of interest, which is available on the PHA's website. There is no cap on how many members can be part of the VSN network. Members don't have to share information; some will rarely or perhaps never share their own information but may benefit from getting access to information shared by others in VSN that is important.

6.2.3 Staffing and costs

The cost for the Public Health Agency of Sweden to continue operating VSN was estimated at SEK 2,500,000 (€229,000) annually. In 2021, the Swedish government provided PHA Sweden with one-off funding of SEK 1,500,000 (137,000 Euro) for the implementation of VSN. One staff member is employed to administer the system, including reviewing new events, responding to questions from members, and maintaining contact with IT support who is continuing to develop the system. Another staff member works in the area of NPS and is involved with VSN by sharing information about the work ongoing on classifying NPS.

6.2.4 Data protection and IT platform used

The PHA developed a bespoke platform for the VSN for use in Sharepoint. To access VSN, login information is required, which is provided by the PHA. VSN is not public and the information in the portal is not aimed directly at the general public, but primarily at the network of users. During the pilot project, an assessment was undertaken on the legal issues associated with establishing VSN, including the handling of personal data, confidential information, and public documents in accordance with data protection regulations. The information in VSN is collected in a database and server at the PHA. All submitted events to VSN are considered public documents of the PHA. Information that makes it possible to identify individuals or that breaches confidentiality should not be reported in VSN. It is up to users to ensure that the information they report into VSN does not violate the privacy laws that apply to their organisation and the web portal contains information texts that remind users of this. A moderator at the PHA checks all incoming information to VSN and no information is disseminated to other users before it has been reviewed. Personal data stored and processed in VSN is registered users' first and last name and e-mail address. This data is visible to other users in VSN so that it is easy for users to contact each other and for the PHA to contact users.

6.3 Question 2: Data collection, validation, and management of Swedish EWS

6.3.1 Sources of data and data collection

The exchange of information in the portal starts when a member reports an incident. The form that is completed when members are reporting an incident is described in further detail in Figure 3. All members of the VSN network then receive an e-mail notification that a new event has been reported in the system. In order to view the full text of the event, it is necessary to log in to the portal. In the portal members can also comment on events, read other people's events and search for past events. Professionals who have access to information that may be relevant, but who are not active within a municipality, region or authority, can still report information to VSN by emailing the dedicated VSN email address. All

information uploaded into the system comes from the members or from the Swedish Public Health Agency. There are no routine monitoring systems.

Several of the representatives from the national authorities in the VSN are also members of NADIS (Network for the Current Drug Situation in Sweden), which serves as a reference group for the work of the PHA and the Medical Products Agency in proposing regulation of NPS. The PHA coordinates NADIS and is also Sweden's focal point for the EMCDDA's EWS. Through the establishment of a broader network such as VSN, information from NADIS and/or the EMCDDA can also be shared in VSN if it is of relevance to the network. The information then reaches a wider circle because VSN also has representation from health care and social services. Information from VSN may also be of interest to NADIS and the EMCDDA.

Heading *

Geographical level *

Subject categories *

- ☐ Epidemiology and statistics
- ☐ Seizure
- ☐ Death
- ☐ Observations and trends (national)
- ☐ Pharmacology and toxicology
- ☐ Care and treatment
- ☐ Health risks, side effects, side effects and harms
- ☐ Web, social and traditional media
- ☐ Contamination/impurities/additives and substance abnormalities
- ☐ Contagion and infections
- ☐ External events (international)
- ☐ Ask a question

Alert level

- ☐ Red
- ☐ Yellow
- ☐ Green

Event description * A. Remember not to enter information that is protected by the confidentiality of your authority or business. You may also have a duty of confidentiality in addition to these rules. Therefore, enter only data that does not make it possible to identify individuals.

Reflection Event B. Remember not to enter information that is protected by the confidentiality of your authority or business. You may also have a duty of confidentiality in addition to these rules. Therefore, enter only data that does not make it possible to identify individuals.

Send for immediate approval ☐

Figure 3 Form completed by members reporting an incident to the Swedish VSN

6.3.2 Data access, monitoring and validation

Any information submitted by a member of VSN is reviewed by the PHA before the new information is published. The review primarily involves ensuring that no confidential information or information that makes it possible to identify individuals is present.

The VSN network and web portal is a locked forum where only invited and connected network members have access. However, the members have a responsibility to pass on relevant information from VSN to target groups who may benefit from receiving the information. This applies particularly to urgent (marked in red) information.

Every VSN member can post information and warnings in the portal, concerning, for example, observations of new harmful substances, contaminated substances, or new (local or national) drug use trends. When reporting an observation, the information is tagged as green, yellow or red, depending on the level of urgency of the information. Examples of 'red' information may be observations of very potent, or contaminated, substances that may increase the risk of drug-related deaths. Examples of 'green' information may be new research results or epidemiological data. It is also possible to ask questions, and for other members to comment on the reported information. The information does not need to be verified at the point of reporting. However, the posts are approved manually by a moderator that provides for some degree of quality check. As soon as a post has been published in the portal, it can be read by all other VSN members, who can also decide to further share relevant parts of the information with organisations and people outside of VSN (e.g. drug user unions and individual drug users).

The PHA has identified a need to clarify the audit function in VSN. Currently, it is the responsibility of users to ensure that the information reported is relevant and appropriate based on the purpose of VSN and the PHA's review primarily involves ensuring that no personal data or information that can be traced to individuals is reported. An increase in the number of users and reported events places higher demands on the auditing function in the portal. It will therefore be important to review the resource needs around the audit function to ensure an effective and efficient review going forward.

6.3.3 Evaluation of the early warning system

As the VSN was only established in 2022, no evaluation has been undertaken, however, at the end of the pilot project, a small evaluation was carried out among VSN members. A total 81 representatives from nine national authorities, five regions and seven municipalities participated as test users of the web portal; 53 incidents were reported in VSN and five were marked as red, which means that they were considered urgent in nature. The responses showed that there was some uncertainty in what should be reported into the VSN. Several users hadn't had anything to share that specifically related to acute harm or deaths that warranted a warning. However, they felt that they had benefited in their work with the information that others shared in VSN. Several VSN members had shared information with people who use drugs.

The PHA's conclusions were that VSN can serve as a tool for quickly detecting, assessing and managing critical or emergency situations. In addition, the system can also be used to exchange experiences and information that is not urgent but can be seen as support and knowledge in a general health promotion work to prevent drug-related deaths and injuries. Based on this, the assessment was that VSN could be expanded into a national information sharing system. Expansion at national level would require continued information and communication efforts to invite new users.

The PHA have identified the following tasks to be undertaken going forward in order to assess various aspects of the VSN:

- Follow-up of the number of connected users and how they are distributed across different sectors.
- Surveys or interviews with users about how they use VSN, what information they primarily access, how they use the information in their work, how they pass on information, and obstacles and success factors in the work.
- Analysis of reported information (the number of reported events, based on alert level, category and activity).
- Follow-up of various user functions – e.g. how many people log in and read events.

6.4 Question 3: Communication with stakeholders and information dissemination

6.4.1 Assessment of signals and decision making around risk communications

The information in the VSN can be either quality reviewed (verified) or unverified. Verifying information can take time so being able to share even unverified information can increase the ability to quickly disseminate information that may be of importance for the network to act on. For example, it can indicate trends and thus prepare others for a possible scenario. The urgency of the information in VSN is marked by the person reporting an event who grades the information as red, yellow, or green:

- **Red (information that should be shared quickly)**
  Events to be shared promptly to prevent deaths and raise our readiness. Examples include the discovery of contaminated substances, when an increased number of deaths (one outbreak) is linked to drugs or when a new pattern of administration has been noted, such as nasal sprays with opioids.
- **Yellow (important information but not urgent)**
  Events that are important to share to prevent death or injury that may result in death, but the information is not assessed urgently. Examples include new classifications of narcotics or health-threatening goods, cause of death statistics or major seizures by customs and police.
- **Green (interesting information for information)**
  Events that are for information. Examples are new findings related to drug-related deaths or prevention methods, external events and any questions members may have for others in VSN.

6.4.2 Information exchange with stakeholders

An important task for the VSN members is to spread information further in their own networks – both within their own organisation, and to other target groups who need the information. It is up to the VSN users to assess the content of the information shared in the portal to determine if – from their perspective – there are risks that should be paid attention to, or if further verification of the event is needed, or if warnings need to be issued and/or information passed on. Any further transmission of information requires some target group adaptation. It is particularly important to spread urgent information (e.g. about new or contaminated substances) to people who use drugs. Other important target groups for the dissemination may be non-profit organisations that meet drug users. Each region should also ensure that urgent information is disseminated to any private healthcare providers working with people with drug problems (e.g. private clinics providing medication-assisted treatment of opioid dependence), as these bodies cannot themselves participate in the VSN network. Not all information in VSN is relevant to share outside the network. Currently, only only public organisations have access to the VSN. There is a proposal that the Swedish Public Health Agency should develop a way to disseminate

alerts to user-organisations and non-public organisations so that relevant information reaches those who have no contact with the public health system. Since the VSN was established, 116 events have been uploaded into the system, of which 52 have been commented on, with a total of 147 comments. Sixteen events have been assessed as red (the most serious warning level).

6.4.3 Dissemination of outputs

There does not appear to be any dissemination regarding the system's outputs to date. However, the results of the pilot project have been published.

7 Case study 2 – Netherlands

7.1 Introduction

There is no official early warning system in the Netherlands, however, many of the activities that would normally be associated with such a system are undertaken by the Trimbos Institute, which is an institute for mental health and addiction research and is funded by the Ministry of Health, Welfare and Sport. It coordinates the Drugs Information and Monitoring System (DIMS) which was established in 1992 to coordinate existing drug checking initiatives and to monitor the nationwide presence of illicit drugs [11]. In the 1990s, drug policy in the Netherlands was characterised by great uncertainty about the substances being used, the user groups, and the associated risks. The use of new synthetic drugs such as ecstasy involved risks that were different from those associated with traditional substances of abuse. New user groups emerged who were young and consumed substances on a recreational basis and who had lifestyles that did not revolve around drug use. In order to facilitate harm reduction and prevention activities it was considered necessary to monitor changes in the ever-evolving recreational drug market [12]. Drug checking services were set up whereby users could have the composition and dosage of their drugs tested and also receive information about drugs and safer ways of using them [13]. Through the testing of drugs, employees of the participating services are in close contact with the people who use these drugs, offering an opportunity to give people a test result of their sample; it also gives DIMS insight into people's motivations and risk assessment, and provide personalized harm-reduction advice.

7.2 Question 1: Management and administration of Dutch EWS

7.2.1 Objective of Dutch EWS

The objectives of DIMS are to:

- Monitor what recreational drugs are currently being used and what changes in drug use, including new drugs, are seen over time.
- Identify possible health risks and initiate and implement warning campaigns at an early stage.
- Provide harm reduction among user groups not generally seen at addiction services.

DIMS co-ordinate and manage the drug checking service, the Monitor Drug-related Incidents (MDI), and the Reporting Desk for New Drugs [14]:

- ***DIMS' drug checking service*** is a large network (32 organisations that provide drug addiction and/or prevention services) of testing facilities throughout The Netherlands. The participating organisations provide a simple drug testing service to people who wish to gather information about the content of their drugs. Drug consumers hand in their drugs and receive the laboratory

results approximately one week later, if not sooner. This is done according to an agreement that the DIMS participants sign with the Trimbos Institute [15].

- The ***MDI*** is a drug monitoring system that was established in 2009. It collects data on drug-related adverse health incidents from emergency departments, forensic doctors, first aid services, and ambulance services. A health incident is defined as an acute episode for which medical attention is sought and where the user is under the influence of drugs. This includes both physical and psychological effects as well as bodily injuries sustained while under the influence of drugs [16].
- The ***Reporting Desk for New Drugs*** assembles, analyses, and reports on data collected by a variety of organisations about the production, trade, and consumption of NPS. The Customs Laboratory of the Netherlands and the Netherlands Forensic Institute provide data about seized NPS that have been sent to their laboratories for analysis. DIMS drug checking service provides data about NPS that have been detected in consumer samples submitted for laboratory analysis at a drug checking service. The MDI and the Dutch Poisons Information Centre share data about adverse health-related events related to the use of NPS. Additional information about NPS being used in the Netherlands is also collected from pre-selected online discussion boards about drugs [17].

If there is a situation whereby it may be appropriate to issue a warning due to increased health risks with a substance, the Coordination point Assessment and Monitoring (CAM) may be requested by the Ministry of Health, Welfare and Sport to undertake a risk assessment [18]. CAM's main objectives are to carry out risk assessments in an independent, decisive and multidisciplinary manner; exchange information as widely as possible on trends in drugs and drug use; evaluate the implementation of risk assessments; and review the risk assessment criteria and procedure. Based on the outcome of this risk assessment, the CAM advises the Minister of Health, Welfare and Sport on applicable measures.

7.2.2 Co-ordination of EWS

The Ministry of Health, Welfare and Sport commissioned the Trimbos Institute to monitor drug use in the Netherlands via DIMS and they also fund its operation. The DIMS-bureau reports to the Ministry of Health via the Supervisory Committee (Figure 4). The members of the DIMS Supervisory Committee are appointed by the Ministry of Health. They are tasked with assessing the quality and the organisation of the activities within the framework of DIMS. The committee also needs to approve of any data gathered by the DIMS-bureau prior to release, e.g. for academic publication, policy reports, or to share with collaborating institutions, such as the EMCDDA.

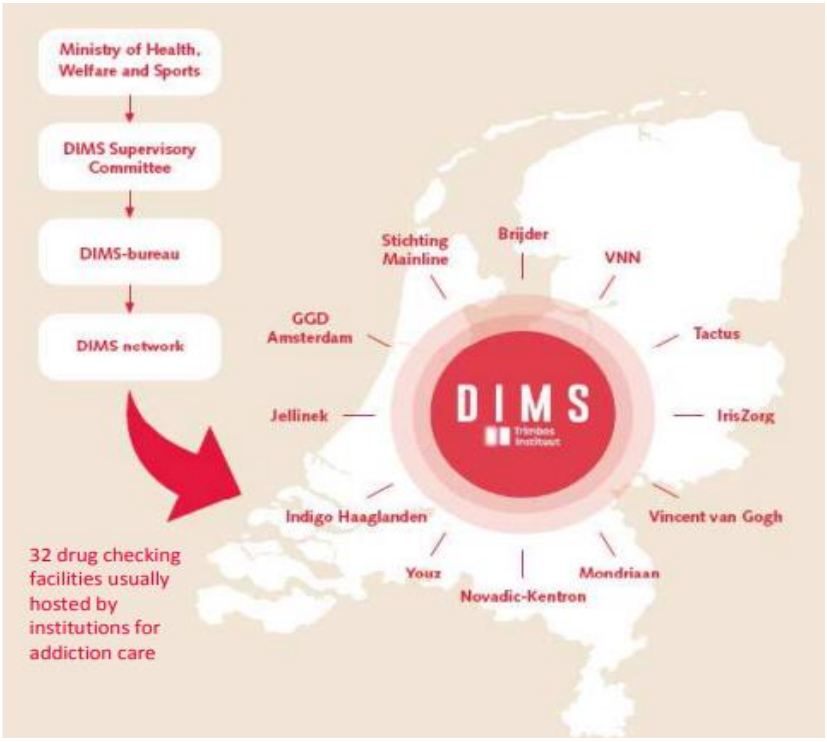

Figure 4 Organisational chart of DIMS

While the Trimbos Institute, through the DIMS system, is responsible for most of the early warning activities undertaken in the Netherlands, CAM is responsible for risk assessment regarding drugs. CAM became operational in 1999 and was formally established by a ministerial regulation in 2000. It has been housed at National Institute for Public Health and the Environment (RIVM) since 2006; prior to this, it was part of the Health Care Inspectorate. The RVIM is a Dutch research institute that is an independent agency of the Ministry of Health, Welfare and Sport. The Department of Nutrition, Health Protection and Prevention of the Ministry of Health, Welfare and Sport is the policy department with responsibility for CAM.

CAM is multidisciplinary and consists of representatives from organisations that are experts in the field of drugs, drug use and drug addiction and representatives of the Ministry of Health, Wellbeing and Sport and the Ministry of Justice and Security. CAM is headed by an independent Chairperson (Head of DIMS). The coordinator of CAM has knowledge and experience in the field of drugs and drug use and skills in the field of organisation and coordination of activities, and also undertakes the role of secretary. The Chairperson, members and their alternates are appointed and dismissed by the Minister. Experts from the following organisations are currently part of the committee:

- Health and Youth Care Inspectorate
- Netherlands Food and Consumer Product Safety Authority
- National unit of the National Police
- Amsterdam Medical and Health Service
- Tactus Addiction Care
- Bonger Institute for Criminology of the University of Amsterdam
- Trimbos Institute
- National Public Prosecutor's Office of the Ministry of Justice and Security
- Drug Information and Monitoring System (DIMS) of the Trimbos Institute
- Netherlands Forensic Institute

- National Poison Information Centre
- Medicines Evaluation Board
- University of Amsterdam, Urban Management
- Novadic Kentron (Addiction Treatment Centre)
- Ministry of Health, Wellbeing and Sport
- Ministry of Justice and Security

The risk assessment committee meets at least three times a year. This with a view to a constant exchange of information about new trends. In addition, the committee also meets when there are serious signals about new drugs or when the Ministry of Health, Welfare and Sport requests a risk assessment.

7.2.3 Staffing and costs

There are seven full time staff in DIMS who undertake the activities associated with the drug checking programme, the MDI, and the Reporting Desk for New Drugs. There are no full-time staff assigned to the CAM and members undertake this work as part of their job roles.

7.2.4 Data protection and IT platform used

There is no single IT platform used. The drug checking programme, the MDI, and the Reporting Desk for New Drugs have separate IT platforms, all of which are managed by the DIMS bureau [14].

7.3 Question 2: Data collection, validation, and management of Dutch EWS

7.3.1 Sources of data and data collection

Drug checking

A nationwide network of drug checking test facilities at drug treatment and prevention institutions across the Netherlands takes part in DIMS. Specific agreements exist that enable drug users to hand in drugs for analysis anonymously, discretely, without the risk of being arrested or prosecuted. This service is usually provided free of charge. Specifically, users are allowed to bring 3 tablets, capsules or blotters, 1g of powder or 10ml of liquid for testing purposes; however, the budget allows for only one sample per person to be sent to an external laboratory for a full analysis. Drug checking in the Netherlands is available for users of both traditional recreational drugs, as well as emerging NPS. Prescription drugs, even when they are bought illegally, are not analysed. Only drugs bought in the Netherlands are analysed apart from samples bought on the internet. Only certified testers who are educated by the DIMS bureau and are under supervision of the project coordinator from one of the participating network members, are allowed to handle drug samples.

DIMS runs two types of drug checking facilities. The vast majority of services are drug checking facilities where at least two testing staff are available for a few hours on a weekly basis. They may directly be able to identify some of the submitted tablets. This is referred to as ‘office testing’. At some facilities, no checking takes place on site; instead, clients hand in samples that are then sent by envelope, and accompanying letter to the DIMS bureau. Information on each sample is collected via an online database that is accessible to all drug checking facilities including:

- Date of purchase
- What substance the sample has been ‘sold as’
- Where it was bought from (geographic area or where on the internet)
- Price

- Intended setting in which the sample will be used
- Whether the substance has already been used, and if so, what the effects were, and if they were as expected

To identify tablets, the external characteristics are first measured and registered. This includes the diameter, thickness, weight, colour, presence of a groove, whether single or double, light or dark speckling (if present), and any logo visible and its profile. After this, a Marquis reagent test is performed to indicate the presence of any of the common recreational drugs such as MDMA, amphetamines or 2C-B. This information is then combined to check an online database that is updated weekly by the DIMS-bureau. The database matches information of the tablet with similar tablets that have been recently analysed in the laboratory. When testing staff can identify a sample, information about its composition and dose is passed on directly to the individual that submitted the tablet, and the tablet will be returned to that individual. The Opium Act waiver allows drug checking staff to handle the samples.

Most of the 200–250 samples handed in every week to the drug checking services in the country cannot be determined on-the-spot, at the point of submission. These are forwarded to the DIMS-bureau for further analysis. In these cases, the individual receives a card consisting of a unique sample number, a phone number to be called to obtain the test results one week later, and general information about the risks of the substance handed in. Also, this card contains a disclaimer, reiterating that drug use is never safe, even if one is 'satisfied' with the results of the analysis. The DIMS-bureau or drug checking services cannot be held liable for any health issues arising from substance use.

At the DIMS-bureau, all samples received are registered, and in case of tablets, also photographed. All samples are carefully re-examined; by doing this, a further 10-20% of the tablets can additionally be identified, by using a larger database of tablets received in the preceding 20 years, which is not available to the drug checking facilities. This database currently contains over 150,000 unique tablets, along with their main characteristics. All other samples that cannot be identified are then coded, packaged and transported to a specialised laboratory for full chemical analysis. On average, a total of 130 samples per week are analysed by this laboratory. Here, samples undergo both qualitative and quantitative analysis within 24 hours, using gas chromatography mass spectrometry (GC-MS) and liquid chromatography diode array detection (LC-DAD). Drug checking locations in the country are required to prioritise samples that in their opinion should be fully analysed in the laboratory. This is done when, for example, people report adverse health events after having consumed the sample, the colour of the Marquis test is suspicious, or if young persons are involved who are going to use drugs for the first time [15].

Reporting desk on new drugs

The Reporting Desk for New Drugs is a large-scale national surveillance study in the Netherlands, which is coordinated by the Trimbos Institute. It assembles, analyses, and reports on data collected by a variety of organizations in the Netherlands about the production, trade, and consumption of NPS. It reports on which NPS have been identified in the Netherlands, and in which quantities they have been detected on the illicit drug market during the last year. Data triangulation is used to monitor NPS market dynamics. The Customs Laboratory of the Netherlands and the Netherlands Forensic Institute provide data about seized NPS that have been sent to their laboratories for analysis. DIMS provides data about NPS that have been detected in consumer samples submitted for laboratory analysis at drug checking services. The MDI and the Dutch Poisons Information Centre share data about adverse health-related events related to the use of new psychoactive substances. Additional information about NPS is also collected from pre-selected online discussion boards about drugs to gauge the interest in and reported consumption of specific new psychoactive substances in the Netherlands [19]. The Reporting Desk for New Drugs publishes an annual

report that is used by the Ministry of Health, Welfare and Sports and CAM to assess the distribution and possible risks associated with the sale, transport, and use of NPS in the Netherlands [17].

The Monitor Drug-related Incidents (MDI)

The Monitor Drug-related Incidents (MDI) is a Dutch monitoring system initiated in 2009, which collects data on drug users who present to medical services with acute toxic effects related to recreational drug use. As part of the MDI, data are collected from the Injury Information System (LIS) of eight emergency departments in the Netherlands. Data are also collected on adverse drug-related health events from first aid services and ambulance services, and from the National Poison Information Center (NVIC), which provides physicians and other emergency responders with information on the possible health effects and treatment of acute poisonings [16].

7.3.2 Data access, monitoring and validation

All test results are centrally collected and stored in databases controlled by DIMS.

7.4 Question 3: Communication with stakeholders and information dissemination

7.4.1 Assessment of signals and decision making around risk communications

If CAM received reports of a new drug of concern or a new trend, then CAM, in consultation with the Ministry of Health, Welfare and Sport, can decide to actively collect information by means of a quick scan. The aim of a quick scan is to compile the available information about a new drug or a new trend in a short period of time. A quick scan is often performed when the information is still too fragmentary to make a proper assessment of whether policy measures are necessary. Based on the information obtained from the quick scan, the Ministry of Health, Welfare and Sport may decide that the CAM must carry out a risk assessment procedure. A quick scan can be limited to collecting the available information, but can also contain recommendations for policy measures, supported by the Risk Assessment Committee or an ad hoc expert committee. In recent years, quick scan reports have been published on 3-MMC (2021), Phenibut (2019), and Fentanyl and Fentanyl analogues (2018).

Risk Assessment Procedure

If there are strong signals about the use of new drugs or new trends in the use of existing drugs, the Ministry of Health, Welfare and Sport may request the CAM to start a risk assessment procedure (Figure 5). The CAM coordinator is responsible for collecting, recording and disseminating the necessary information. Information is collected by CAM in a number of ways. The Risk Assessment Committee may be asked to provide information about the new drug and also collects information through its network and in the scientific literature. Where the risk assessment is complex in nature, the CAM may decide to organise a meeting of the Risk Assessment Committee prior to the risk assessment in the form of a hearing in which external experts are heard. The information is compiled in a report that is circulated to all CAM members.

The risk assessment utilises the Delphi method. It is not anonymous, but it does have the iterative and expertise character of Delphi. In order to obtain a valid outcome, the quorum of members participating in the risk assessment has been set at 10. Before the start of the risk assessment, the committee members first undertake an individual risk assessment on the basis of the information report prepared by the CAM.

The risk assessment consists of arguing (qualitatively) and numerically scoring (quantitatively) a number of criteria, according to a fixed format. There are 16 risk assessment criteria covering four areas: individual health, public health, public order and crime.

Risk to individual's health

1. Magnitude of risk of physical dependence (addiction, tolerance, habituation).
2. Magnitude of risk of mental dependence (see 1).
3. Size of the risk of acute toxicity, apart from the intended effect to the user (frequency and severity of complaints, interactions with other substances, dosages and variations, usual way of ingestion, frequency of use).
4. Magnitude of the risk of chronic toxicity.

Public health

5. Extent of risk with regard to the extent and frequency of use, increase in use internationally.
6. Degree of vulnerability of user (age, experience, knowledge, circumstances).
7. Magnitude of the risk related to the availability or absence of adequate user information (presence and quality leaflet, misleading information, product appearance).
8. Magnitude of the risk regarding the availability of the product.
9. Magnitude of the risk regarding product quality (production method, purity, toxicity by-products, place production).
10. Extent of the risk regarding the reliability of the distribution method, points of sale, traders.
11. Nature and extent of incident reports (hospitals, first aid, National Poisons Information Centre).

Public order

12. Magnitude of the risk regarding nuisance to citizens around use and sale (frequency, severity).
13. Magnitude of the risk regarding lowering the threshold of violence in the user.
14. The extent of the risk of influencing the user's responsiveness (ability to drive, operating equipment, duration of operation).

Criminal involvement

15. Magnitude of the risk related to involvement of (organised) crime in the production and trade of the final product (number of incidents, seizures, acts of violence, degree of organisation, international dimension).
16. Magnitude of the risk related to the involvement of (organised) crime in the production and trade of the raw material (see 15).

The criteria are scored using a scale of 0 to 4 points, where 0=no risk, 1=low risk, 2=moderate risk, 3=high risk and 4=very high risk. If members have insufficient knowledge or experience to assess a certain criterion, they are requested not to score it.

The committee members then meet and the compiled numerical scores and arguments per criterion are presented by the CAM coordinator. If there are striking divergences in scores between different members, the reasons for the different scores are discussed. In a second round members can adjust their score. The coordinator of the CAM compiles the scores and gives the final result. The numerical score is a

tool with the arguments providing the most weight. The policy officials do not provide scores in order to separate the technical risk assessment from the possible policy follow-up. After identifying the risks, the various possible policy measures and their consequences are discussed. However, there is no need to reach a consensus on this. The outcome of the risk assessment and the impact of the discussion is recorded in the risk assessment report, which is adopted by the chair of the Risk Assessment Committee with the agreement of the members. The report is submitted to the State Secretary for Health, Welfare and Sport. On the basis of the interdepartmental consultation, a policy recommendation is submitted to the Minister of Health, Welfare and Sport who is responsible for the final decision on whether to take measures. The Risk Assessment Committee may evaluate the procedure but this is optional. Possible follow-up steps include, but are not limited to:

- Monitoring or investigation must take place
- An information or warning campaign should be held
- Measures must be taken that hinder production and trade: the legislator ensures an adequate legal regulation to import, export and/or prohibit trade (Opium Act, Commodities Act or other legislation).
- A total ban be imposed: the legislator ensures adequate regulations (Opium Act, Commodities Act or other legislation).
- A report must be made to the EMCDDA or Europol through the National Focal Point and the Europol National Unit.

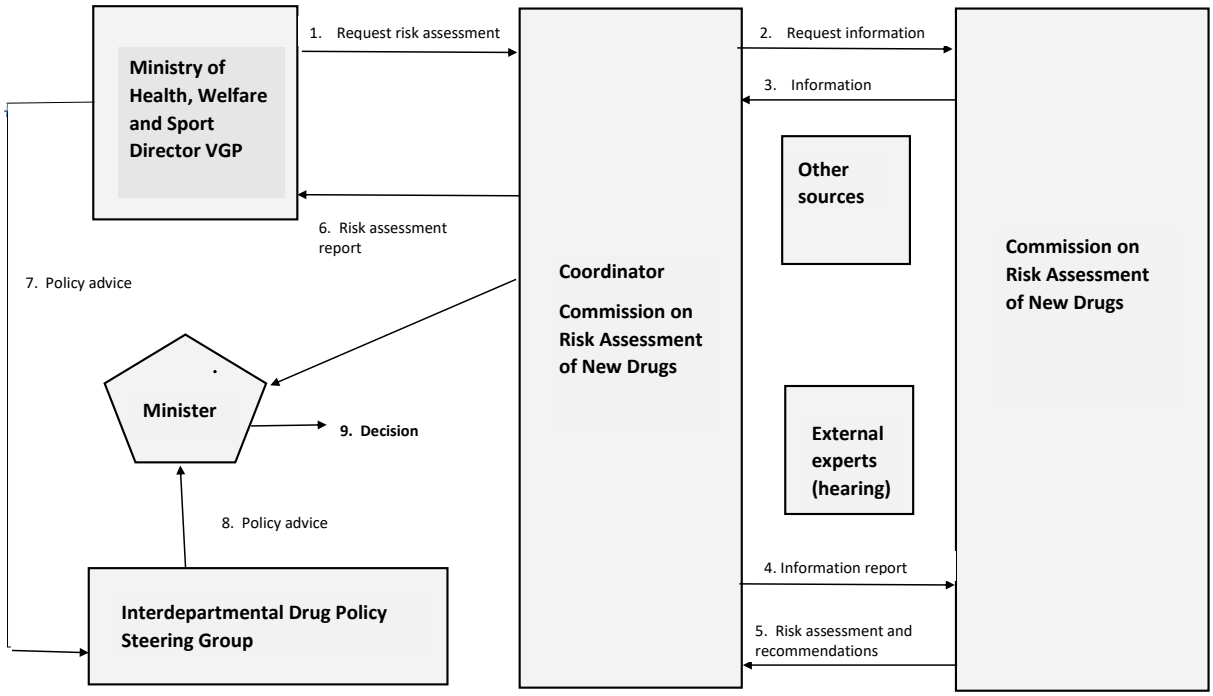

Figure 5 Netherlands' risk assessment procedure

7.4.2 Information exchange with stakeholders

After the risk assessment process, the Minister may decide that the most appropriate action is to issue a warning. There is a 'Red Alert' protocol in place for these situations whereby public health is threatened by the appearance of a worrying substance on the drug market. Red Alert is a Dutch m-

health app developed by the Trimbos Institute in 2016 [20]. Such warnings are typically aimed at people who use drugs and the relevant health authorities. There are three warning levels. Red alerts are only issued for targeted or national warnings. Depending on the course and severity, it may be possible to switch to a different level.

- Internal signaling – this may be chosen if a disturbing substance has been detected or situation reported, which requires alertness and more investigation. Such signals are not publicly issued but DIMS participants may be informed. This is not yet a Red Alert but may be scaled up to one at a later stage.
- Targeted warning – may be issued if there is a worrying substance or situation within a specific target group or region. As part of a targeted warning DIMS informs its participants, the relevant health authorities via its MDI network, relevant teams in the Trimbos institute (communication, drug information line and drug prevention), and other relevant stakeholders (Netherlands Forensic Institute, National Poisons Information Centre). Trimbos also creates a media post and generates a push message for the Red Alert app. If the warning relates to a specific region, then social media in that region is targeted and DIMS participants in that region disseminate the warning. If the warning relates to a specific group there is targeted warning by DIMS participants (via drug checking services, institutions providing drug treatment or prevention services, internet platforms and social media, posters at parties or other locations where the target group is, and via intermediaries who are in direct contact with the target group).
- National warning – may be issued if there is a worrying substance or situation at national level. The same stakeholders are informed by DIMS as occurs for a targeted warning. In addition, there is broad warning at national level via the media.

For the duration of a red alert, the situation is monitored by DIMS. The chairperson of CAM (the head of DIMS) provides an update by e-mail to the other CAM members at least once weekly. The decision to terminate a red alert is taken by the Ministry of Health, Welfare and Sport on the basis of advice from CAM. Since 1999, a red alert has generally been issued every two years while approximately one targeted alert is issued each year. The first national warning targeted the risks of using ecstasy pills contaminated with PMMA (Para-Methoxymethamphetamine).

7.4.3 Dissemination of outputs

Both the Trimbos Institute and the National Institute for Public Health and the Environment (RIVM) disseminate outputs resulting from the early warning activities undertaken in the Netherlands. Each year, DIMS publishes an annual report on their drug checking service [14], the MDI [16], and the Reporting Desk for New Drugs [17].

The RIVM publish quick scans and risk assessments. A quick scan is often performed by CAM when the information is still too fragmentary to make a proper assessment of whether policy measures are necessary. A quick scan may also be necessary to substantiate a decision for a risk assessment. To date, quick scans have been performed on the following substances and published on the RIVM website (https://www.rivm.nl/drugs/quick-scans): 3-MMC, Phenibut, Fentanyl and Fentanyl analogues, levamisole, 4-fluoramphetamine, Gamma Butyrolactone, and 4-methylamphetamine.

A risk assessment of a new drug is an evaluation of known or potential adverse consequences arising from or from the production, trade and use of the new drug and concerns both the quantitative and the qualitative consequences for public health, public order and for society. RIVM also publishes the final risk

assessment report and these are generally more comprehensive than quick scans. The following risk assessments have bee performed and have been published in the RIVM website (https://www.rivm.nl/drugs/risicobeoordelingen).

- 3-MMC (2021)
- laughing gas (2019)
- 4-FA (2016)
- gamma-hydroxybutyric acid (GHB) (2011)
- cannabis (2008)
- khat (2007)
- magic mushrooms: additional information about magic mushroom incidents in Amsterdam (2007)
- magic mushrooms: risk assessment of psilocin and psilocybin containing mushrooms (2007)
- paramethoxymethamphetamine (PMMA) (2003)
- ketamine (2001)
- magic mushrooms: psilocin and psilocybin containing mushrooms (2000)
- 4-Methylthioamphetamine (4-MTA) (1999)
- gamma-hydroxybutyric acid (GHB) (1999)

Finally, members of the public can directly receive information on drug use, including any concerning substances via the Red Alert app. The primary aim of Red Alert is to warn substance users about extremely high-dose or contaminated ecstasy tablets that may be circulating in their area. Upon starting the app, users receive warnings about contaminated substances that may be circulating, and they can quickly access up-to-date general information on these and other substances. The app also provides information on drug-testing facilities. Red Alerts on extremely dangerous drugs circulating in the Netherlands can quickly be conveyed through push notifications: everyone who has the app installed on their smartphone or tablet will receive this notification [20].

7.4.4 Communication with international stakeholders

In addition to stakeholders within the Netherlands, the CAM has contacts with other experts in the field of drugs and drug addiction. At European level, there are contacts within the REITOX (Réseau Européen d'Information sur les Drogues et les Toxicomanies) network, which includes the EMCDDA National Focal Points and the European Medicines Agency (EMA). The Trimbos institute is the Dutch focal point and are responsible for ensuring all required actions at European level are undertaken.

8 Discussion

Drug markets continue to evolve worldwide with new substances continually emerging and changes being observed in the potency and quality of established drugs. It is increasingly being acknowledged that it is important from a public health perspective to develop systems to identify and respond to these threats in a timely fashion to minimise drug-related health harms. This is reflected in the policy goals of agencies such as the EMCDDA and UNODC who have both highlighted the need for early warning to ensure preparedness when dealing with drug issues. In the last decade we have also seen the development of early warning systems in the US, Australia, Scotland, New Zealand and Sweden, reflecting the importance of such systems. The three early warning systems described in this evidence brief have some differences, however, they all have the following attributes – multiple indicators that measure use, harms, and market

characteristics; regular data collection that is accessible and available in a timely manner; triangulation and cross-verification of data to increase certainty in emerging trends; and communication of trends to policy makers, healthcare workers and people who use drugs.

When considering the establishment of a national early warning system it is essential to consider the context of the country in question. Drug checking is a key feature of the Netherlands' early warning system. This provides real-time insight into market trends and new substances that may be circulating as may also identify contaminated supplies. This was particularly evident in 2016 when DIMS reported that each of a batch of pink pills bearing a Superman logo contained a potentially lethal amount (170 mg of PMMA. This led to a red alert being issued. No incidents of illness or death were reported in the Netherlands, which is attributed to the fast response enabled by their drug checking program, however, in the UK, where no testing was available, several people died after taking these tablets[21]. In Ireland, there is no comprehensive drug checking program similar to that in the Netherlands. The Emerging Drug Trends and Drug Checking Working Group published their report in 2021 where they recommended piloting a back of house[1] drug checking system in a festival setting in Ireland and if the pilot evaluation proved positive, a comprehensive front of house[2] approach should be considered [22]. The pilot was undertaken by the HSE at the Electric Picnic music festival in September 2022 whereby people could anonymously dispose of drugs for testing in 'surrender' bins located in medical tents. Three of the substances (3-CMC, 5-MAPB, 4-HO-MiPT) analysed were novel and had not yet been detected in Ireland. A dangerously high level (235mg) of MDMA was found in a 'Mybrand' pill which led to the HSE issuing a risk communication on the first day of the festival [23]. While encouraging progress has been made in relation to drug checking in Ireland, it would require expansion in order to play a central role in an Irish early warning system.

The case studies presented here highlight the importance of systematic and timely triangulation of existing data in rapidly assessing and identifying emerging drug trends. The MDI in the Netherlands provides data on adverse events from a range of sources while in Scotland, a number of projects have been commenced on order to fill important data gaps in relation to emergency departments, prisons, and police testing. An Irish early warning system would likely require improvements to existing data sources, in particular, our emergency department data as there is currently no national data system to record drug-related presentations. The EMCDDA has also highlighted the importance of new indicators in complementing existing data sources to provide insight on emerging trends; these new indicators include web surveys, hospital emergencies, wastewater analysis, syringe analysis, and drug checking services [24].

A central component of any early warning system is communication regarding threats. While the Dutch experience has shown that national red alerts or targeted alerts are thankfully rare occurrences, they can reduce harm and save lives. The Dutch system for assessing the level of risk and deciding on the most appropriate response is long established and appears to be effective with clear roles and responsibilities defined. The available evidence indicates that in order to maximise reach, engagement, and information-sharing, alerts should be clear and simple, evidence-based, action-oriented, and tailored specifically for the required audience [25] [26] [27]. Information or advice that is perceived to be dated, inaccurate, unrelatable, irrelevant, or impractical can undermine trust and engagement with alert systems[28] [29].

[1] Back of House' drug checking is where analysis is undertaken on samples that are obtained through a number of different mechanisms, but does not include accessing substances directly from people who use drugs.

[2] Front of house or 'on-site' testing is delivered by temporary laboratories located at events such as festivals; drug checking results are provided directly to people at events with a quick turnaround of results.

Appendix A Search Strategy

Database(s): **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions 1946 to October 25, 2022**

Platform: OVID

Date of search: 08 November 2022

#	Searches	Results
1	("Illicit Drugs" or "Designer Drugs" or "Psychotropic Drugs" or "Psychotropic Substance" or "New Psychoactive Drug" or "Novel Psychoactive Drug" or "New Psychoactive Substance" or "Novel Psychoactive Substance").mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word]	43426
2	("Early warning system" or "Monitoring system").mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word]	15143
3	1 and 2	102
4	("Data Collection / methods" or "Information Dissemination" or "Risk Assessment / methods" or "Substance-Related Disorders / epidemiology" or "Data Collection / methods" or "Drug Information Services / standards" or "Substance Abuse Detection / methods" or "Substance-Related Disorders / epidemiology").mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word]	23061
5	2 or 4	38180
6	**1 and 4**	**141**
7	(Scotland or Finland or Sweden or Netherlands or Amsterdam) .ab,bt,hw,kf,ot,sy,ti,fx,nm,ox,px,rx,ui.	279448
8	6 and 7	12

Database(s): **Embase**

Date of search: 10 November 2022

#	Searches	Results
1	((('illicit drug'/exp OR 'illicit drug' OR 'designer drug'/exp OR 'designer drug' OR 'psychotropic agent'/exp OR 'psychotropic agent' OR new) AND psychoactive AND ('drug'/exp OR drug) OR novel) AND psychoactive AND ('drug'/exp OR drug) OR new) AND psychoactive AND substance	3940
2	'early warning system' OR 'drug surveillance program'	29630
3	**1 and 2**	**109**

Database(s): **APA PsycInfo** 1806 to December Week 1 2022

Platform Ovid
Date of search: 08 November 2022

#	Searches	Results
1	(Psychoactive Drugs or Illicit Drugs).mp	5857
2	Monitoring Systems.mp.	554
3	1 and 2	8
4	Risk Assessment.mp. or Data Sharing/ or Data Collection/ or "dissemination of AOD information".mp. or Information Dissemination/ or substance abuse epidemiology.mp. or Epidemiology/	97291
5	2 or 4	97809
6	1 and 5	457
7	("dissemination of AOD information" or substance abuse epidemiology).mp.	12
8	2 and 7	**0**

Database resources searched (November 2022)	Results
Ovid MEDLINE	141
Embase	109
APA PsycInfo	0
Total	250
Total minus duplicates	157

Google search strategy

Date limit: 01/01/2010 – 10/20/2022		
1	"early warning system" drugs	About 574,000 results
2	"early warning system" drugs Sweden	107 results
3	"early warning system" drugs The Netherlands	143 results
4	"early warning system" drugs Scotland	124 results

Targeted website searches

October 2022			
Website	**Web address**	**Search terms**	**Results**
HRB National Drugs Library	https://www.drugsandalcohol.ie/	“Early warning” "risk assessment"	44 344

Trimbos institute	https://www.trimbos.nl/	“Early warning”	4
Public Health Scotland	https://publichealthscotland.scot/	“Early warning”	8
EMCDDA	https://www.emcdda.europa.eu/emcdda-home-page_en	“Early warning system”	About 53
Public Health Agency (PHA) of Sweden	https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/	“Early warning”	2
National Drug & Alcohol Research Centre	https://ndarc.med.unsw.edu.au/	“Early warning system”	71
United Nations Office on Drugs and Crime	https://www.unodc.org/	“Early warning system”	About 480

Appendix B Form for collecting RADAR data in Scotland

No.	Question *Notes*	Data set	Reason for collection	Example
Group 1: What would you like to report? (10 questions)				
1	**Reason for report**	Multiple choice with comments (small open text boxes) Adverse effects (on mental or physical health) Concern (e.g. drug litter, anti-social behaviour) Death New drug New trend Overdose Other (specify)	Summary/filter detail of submission.	
2	**Source of report**	***Multiple choice*** First-hand report Witness/bystander Service/professional/worker Other	To support validation process.	
2a	**Which of these best describes your place of work** (if Q2 is 'service/professional/worker')	***Multiple choice*** Ambulance Drug service Education Hospital Hospitality/nightlife Housing/homelessness Mental health Pharmacy Police Public health Prison Social work Toxicology Youth work Other (small open text box)	To filter responses by area of work. To highlight key areas that may be underrepresented in the data. To monitor any patterns in submissions (reach). To monitor any patterns in emerging harms. To inform targeting harm reduction techniques or training.	
2b	**Name of workplace** (if Q2 is 'service/professional/worker' then)	50-character text box	To monitor any patterns in submissions (reach). To monitor any patterns in emerging harms. To inform targeting harm reduction techniques or training.	
3	**Date of incident**	Pop up calendar dd/mm/yyyy	To know when the incident happened. Informs decision on how to respond. If delay between incident and report is substantial it would not result in any immediate action. Helps to determine scale and speed of response. Using the date we can correlate across range of incidents, circumstances, interventions, or activities. Date of report is not sufficient as people may report issues months after they have happened. Month of incident is not sufficient; a key aspect of effectiveness and credibility of response is timeliness.	*If we see a sharp rise in a short period of time this is an indication that the situation is one, we need to respond to quickly and may well be more widespread than we thought.*

4	**Area of incident/event**	***Multiple choice*** Scotland wide 32 local authorities England Northern Ireland Wales Other (small open text box)	To link into services and local health and government. To filter responses by local authority. To support validation and assessment of harms/clusters. To form epidemiological response.	*NHS Health Board requests data for their area*
5	**Setting of incident**	***Multiple choice*** Accommodation (hotel, hostel, care home) Educational setting (school, college, university) Event (festival, concert) Prison Private residence Pub/club Public place (street, park) Workplace Unknown N/A Other (small open text box)	Helps to identify the type of incident. Informs us of the skills we need to assess report and respond. Identifies any related patterns of incidents.	*Evidence of increasing drug use in a school can be better assessed by inviting colleague from educational settings to join us on the Assessment Group to share expertise.*
6	**Postcode sector/name of town** *If postcode is unknown please enter name of nearest town*	20-character text box	Helps to coordinate and focus local resources. Identifies related geographical clusters of incidents/events. Postcode allows us to have an accurate incident area, without identifying particular properties.	*Several reports of overdose in one postcode area highlights potential cluster.*
7	**Suspected/ confirmed deaths linked to incident/ event?**	***Multiple choice*** Yes - suspected Yes - confirmed No N/A Other (small open text box)	National priority. Informs potential severity of known harm. Assists in filtering responses by risk to life.	
7a	**How many people were affected?** (if No.7 is 'Yes-suspected' or 'Yes-confirmed' then)	Multiple choice with numerical options. Each answer must be at least 0. Suspected drug-related death Confirmed drug-related death Overdose Other	Informs severity of potential harm. Supports identification of required action/resources.	
Group 2: What drugs(s) were involved? (17 questions)				
8	**Adverse effects**	***Multiple choice*** Aggression/violence Amnesia (memory loss) Anxiety/panic Chest pain Confusion Death Decreased energy Depression/low mood Difficulty breathing Hallucinations Hyperthermia Hypothermia Increased energy Injury Loss of consciousness Nausea/vomiting Seizures Suicidal thoughts/ideation Other (small open text box)	Data on drug harm is a national priority. Highlights if a particular substance is producing unwanted and/or unexpected adverse effects.	*An increase in people reporting hyperthermia may indicate changing drug patterns that needs investigating.*

9	**Drugs involved**	***Multiple choice*** Alcohol Amphetamine Anabolic steroids Benzodiazepines (diazepam/Valium) Benzodiazepines (etizolam) Benzodiazepines (alprazolam/Xanax) Benzodiazepines (other) Buprenorphine (Subutex) Buprenorphine (Buvidal) Cannabis Cocaine (crack) Cocaine (powder) Gabapentin Heroin Ketamine LSD (acid) MDMA (ecstasy pills) MDMA (powder) Methadone Methamphetamine (crystal meth) Nicotine (cigarettes, tobacco) Nicotine (vapes) Nitrous oxide (laughing gas) Pregabalin Solvents (aerosols, butane) Syn *(fake drug)* Synthetic cannabinoids (spice) Other (small open text box)	Data on drug combinations (polydrug use) informs potential risks and harms. Fake drug added to non-credible submissions.	*Our comms and response would differ depending on if someone reportedly overdosed on 1 pill, or 1 pill mixed with several other drugs.*
10	**Primary drug involved**	Single choice list drop-down Options same as list above in Q9	Highlights if a particular substance is causing concern.	
11	**Drug names (is the drug known by another name?)**	50-character text box	Drugs are called different names that often vary between different groups, areas and communities. This data supports the accuracy of the response/ validation. It is not always obvious what drug slang or colloquial names refer to – this will help us to understand it to keep current and relevant. It will aid communication and alerts if we know how to refer to the drug. Including a range of names in communications helps people to recognise a particular substance. Use a range of names supports credibility/familiarity/community members identifying with PH messaging. Other reports may have been received but for the same substance under another name. Information on 'other names' will allow us to cross reference reports.	*If we put an alert out related to etizolam, people who are taking drugs they call "blues", or "vallies", may not recognise the alert applies to them.*
12	**Amount and pattern of consumption**	50-character text box	Information on consumption patterns allows us to tailor harm reduction advice. Knowing how much someone taken to experience harm will inform the level of potential threat posed.	*Our comms and response would differ depending on if someone reportedly overdosed on 1 pill, as opposed to 20.*

13	**Route of administration**	***Multiple choice*** Injected - intramuscular (into a muscle) Injected - intravenous (into a vein) Injected - subcutaneous (under the skin) Smoked - in a glass pipe Smoked - in a homemade pipe Smoked - in a joint/cigarette Snorted Swallowed Vaped - using electronic device Vaped - from foil or glass device N/A Other (small open text box)	Harm reduction Need to know if people are injecting or smoking or taking pills to be sure harm reduction approach is appropriate, credible, etc.	*Our response to reports of people injecting cocaine could include injecting guidance and information on less harmful routes of administration.*
14	**Drug appearance**	***Multiple choice*** Crystal Edible (food or drink) Herbal (plant matter) Liquid Paper Pills (in blister packets or medicine-type packaging) Pills (sold loose or in bags) Powder Other (small open text box)	Helps us to describe drug in communications. Informs harm reduction and route of administration guidance.	
15	**Colour**	***Multiple choice*** Blue Black Brown Green Grey Orange Pink Red Purple White/off-white Yellow Colourless Other (small open text box)	Helps us to describe drug in communications. Informs harm reduction and route of administration guidance.	
16	**Identifiable or unusual features?**	100-character text box	Helps us to describe drug in communications.	*In addition to form and colour people may report pill is crumbly, well-pressed, has 2 break lines.*
17	**Would you like to share a photo of the drug?**	Yes/No (mandatory) Yes – moves to next question. No – moves to Q17a		
17a	(if Q17 is 'Yes' then)	Upload	These photos can be included in alerts or reports to aid understanding of the drug and allow for easier identification.	*Distinctive green ecstasy pill wthl pink flecks is linked to suspected DRD at event. Image can be shared in alerts.*
18	**Testing data**	Yes/No (mandatory) Yes – moves to next question. No – moves to Q18a	Important to know who has performed testing so we can follow up on the result. Adds credibility and reliability to our communications. Helps us to validate and assess reports. Helps us target harm reduction responses.	*We receive a report about street benzos causing overdoses. Testing informs us the substance is a street benzo, in which case we will give specific benzo harm reduction information.*

			Can highlight harmful ingredients/adulterants. Builds evidence on drug market/ changing trends that can inform PH strategic response. An absence of testing data demonstrates a gap in knowledge, and this can inform service provision.	*Testing informs us that it is a benzo cut with a synthetic opioid; in this case we will give specific polydrug use/opioid/benzo harm reduction information and implement suitable interventions.*
18a	**What were the results of the drug testing?** (if Q18 is 'Yes' then)	***Multiple choice with comments*** (small open text boxes) Healthcare testing Hospital testing Police testing Post-mortem toxicology Prison testing Reagent test kits Test strips WEDINOS Other		
19	**Drug source**	***Multiple choice*** Family member Friend Home-grown Online (dark web) Online (open web) Prescribed Social media Street dealer Other (small open text box)	Changes to drug source can be monitored overtime, informing service provision. The source will inform our interventions and communication methods. Source can inform potential threat level and spread of use.	*If problem drugs are being sold on social media, our communication should also use social media to share information.*
20	**Drug cost**	50-character text box	Costs influences use and consumption patterns. Drugs are impacted by inflation and monitoring cost will help us to understanding impact on the market.	*If heroin prices suddenly triple, this would indicate shortages in supply, and we could predict other opioid drugs may emerge.*
21	**Would you like to add information about another drug?**	Yes/No (mandatory) Yes - loops survey back to group 2. No – next question	Polydrug use is a risk factor for drug related harm. Often people will report taking more than one substance.	
22	**Would you like to share an email address?**	50-character text box	Contact after if more information or follow up is necessary.	