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JATC2 Task 7.4 / Information sheet 5:

The need for a harmonized collection of novel nicotine and tobacco products associated with adverse health incidence across the EU

Why do we need to report adverse health incidence?

The use of novel tobacco products (NTP) and e-cigarettes can lead to serious health effects and potentially increase the risk of smoking-related diseases, but the prevalence and severity of these effects are unclear. The lack of centralized data collection in the EU and the insufficient physician awareness, contributes to missing information on adverse health consequences, hindering effective regulation and public health protection.

The use of novel tobacco products (NTP) and e-cigarettes can lead to serious health effects, potentially increasing the risk of smoking-related diseases and leading to premature death. The extent to which these health effects are prevalent and the severity of them, remains unclear. Currently, physicians may overlook the link between physical symptoms and the use of tobacco and related products. This can be due to the rarity of the symptom or a lack of knowledge or awareness about the consequences of tobacco use. This results in missing information about possible adverse health consequences of tobacco products, potentially causing preventable risks to the public. Moreover, the European Union lacks a centralized system for recording health incidents related to the use of NTP or e-cigarettes and the level of data collection varies between countries. As a consequence, this information does not reach national regulators in all countries. A more comprehensive data collection of health incidents across the EU would facilitate the identification of patterns and the detection of products with elevated health risks or instances of health-harming product misuse.

As part of Joint Action on Tobacco Control 2 (JATC-2, 2021 – 2024, D7.6) task 7.3 aimed to map the characteristics of reporting of adverse health incidents by national agencies and provide recommendations for a harmonized data collection approach across the EU. A comprehensive description of the activities, outcomes and recommendations can be found in deliverable D7.6 Report on harmonized data collection approach, on the JATC2 website.

The current data collected on adverse health incidence

Data collection practices, including the type of information gathered and the methods of storage and analysis, vary significantly across countries, complicating data comparison and analysis. Additionally, there is often a lack of knowledge about different tobacco products, leading to misclassification, and inconsistent reporting to authorities.

A survey conducted among 15 EU Member States (MS) revealed that ten MS collect national-level data on adverse health incidents, with some also having regional centers for data collection and evaluation. Various authorities, primarily Poison Control Centers (PCCs) and hospitals, gather this data, which includes personal patient information, incident causes, symptoms, and other relevant details. However, differences in data collection, storage, and analysis methods across countries complicate data comparison, and a lack of knowledge about tobacco products often leads to misclassification. Additionally, some countries lack the infrastructure for analyzing and reporting data to authorities, while others only report when serious health problems are identified.

From the reported data it is difficult to differentiate between cases related to accidental and intentional

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product use. However, most countries reported that children from the age of 0 to 4 are frequently involved in intoxications. The number of reported cases differed widely between MS. For example, Italy, Sweden, and Germany reported more than 100 adverse events after e-cigarette use, while Italy and Germany reported more than 100 adverse events after heated tobacco product (HTP) use. Sweden reported over 2400 adverse event incidents after the use of (white) snus.

What can we learn from existing reporting systems

Norway and the UK have developed robust systems for reporting adverse events related to e-cigarettes, which allow for detailed reporting by both healthcare professionals and users. These systems highlight the need for a harmonized severity scale and a centralized, open-access system within the EU to comprehensively track health incidents related to all tobacco and nicotine products.

Outside the EU, Norway and the UK have developed robust systems for reporting adverse events related to e-cigarettes. Norway's E-cigarettes Adverse Events Reporting System (HELSe norgE) includes platforms for both healthcare professionals and users, and facilitates detailed and user-friendly reporting without fixed categories. The UK's Yellow Card System, managed by the MHRA, allows consumers and healthcare professionals to report adverse events related to e-cigarettes and e-liquids through various channels. The MHRA reviews and acts on these reports. Both systems face challenges such as encouraging user participation and ensuring data privacy. They also do not currently include other tobacco and nicotine products like cigarettes and snus. Another critical issue is the lack of a harmonized severity scale for health incidents related to tobacco or nicotine products within the EU, which is prerequisite for comparing data across Member States.

These examples show that encouraging both users and healthcare professionals to use a reporting system is essential to improve the understanding of the health effects of novel tobacco and nicotine products. Moreover, clear and specific descriptions of the health incident and product in question are crucial, and data for both mild and severe cases, as well as information about comorbidities and co-exposure is needed. Ideally, a centralized system with open access would integrate such data, gathering a comprehensive and up to date dataset on health incidents associated with tobacco and nicotine products.

Regulatory recommendations

Documenting adverse effects of novel tobacco and nicotine products is essential for clinical progress, product safety, and understanding chemical threats. A harmonized EU system with standardized reporting, user-friendly submission processes, comprehensive data collection, and regular education for healthcare professionals would enhance data accuracy and support public health strategies. A centralized, accessible database would improve transparency and inform regulatory decisions.

The documentation of adverse effects related to novel tobacco and nicotine products is crucial for clinical and medical progress, product safety monitoring, and the clarification of chemical threat situations. A harmonized EU system would enable the collection of data from a variety of perspectives and enhance our understanding of the health effects of novel tobacco and nicotine products. The following recommendations support the development and enhancement of national systems while also preparing for the establishment of a harmonized EU-wide system:

- Implementation of a standardized reporting format, that at least includes:
  - o Patient/user's personal data
  - o Detailed description of the health incident (start, cause, symptoms, product, co-exposures, comorbidities, treatment, seriousness, outcome)
  - o Detailed information on the product (brand name, manufacture, nicotine concentration, place of sale)

    The proposed template by JATC-1 (JATC-1 - WP7 - D7.4 Report on a proposed system for the reporting of adverse effects, 2019)4 presents a template for the reporting of adverse effects by economic

operators and competent authorities, which can be directly adopted by all MS to guarantee uniform wording and format.

- Development of a reporting system that allows both users and healthcare professionals to submit information
  - o Use a detailed form for healthcare professionals and a simplified reporting form for users
  - o Enable users to have easy access to a reporting form on a website, for example via a QR code on the packaging of the product

- Collect data for both mild and severe cases, while taking into account any comorbidities or co-exposures that may be involved
- Educate health care professionals such as general physicians, pediatricians and pulmonologists about novel tobacco and nicotine products on a regular basis to keep their knowledge up to date.
- Inform health care professionals about the need to report incidents and provide them with the tools for reporting, such as a reporting format and database system.
- Create the infrastructure to collect and integrate reported data, preferaby in a centralized and openly accesible system.
- Facilitate distribution of analysed data and reports to regulators, providing them with the necessary information to make informed decisions that support public health strategies.
- Make selected analysed data freely available to all interested parties to improve transparency and enable informed decision-making, thereby supporting research.
- Maintain and update the database, as new products enter the market.
- Ensure and promote awareness of the system among its potential users, to maintain its relevance and accuracy.