MEDICAL DEVICES

CD-P-PH/CMED

SURVEY RESULTS

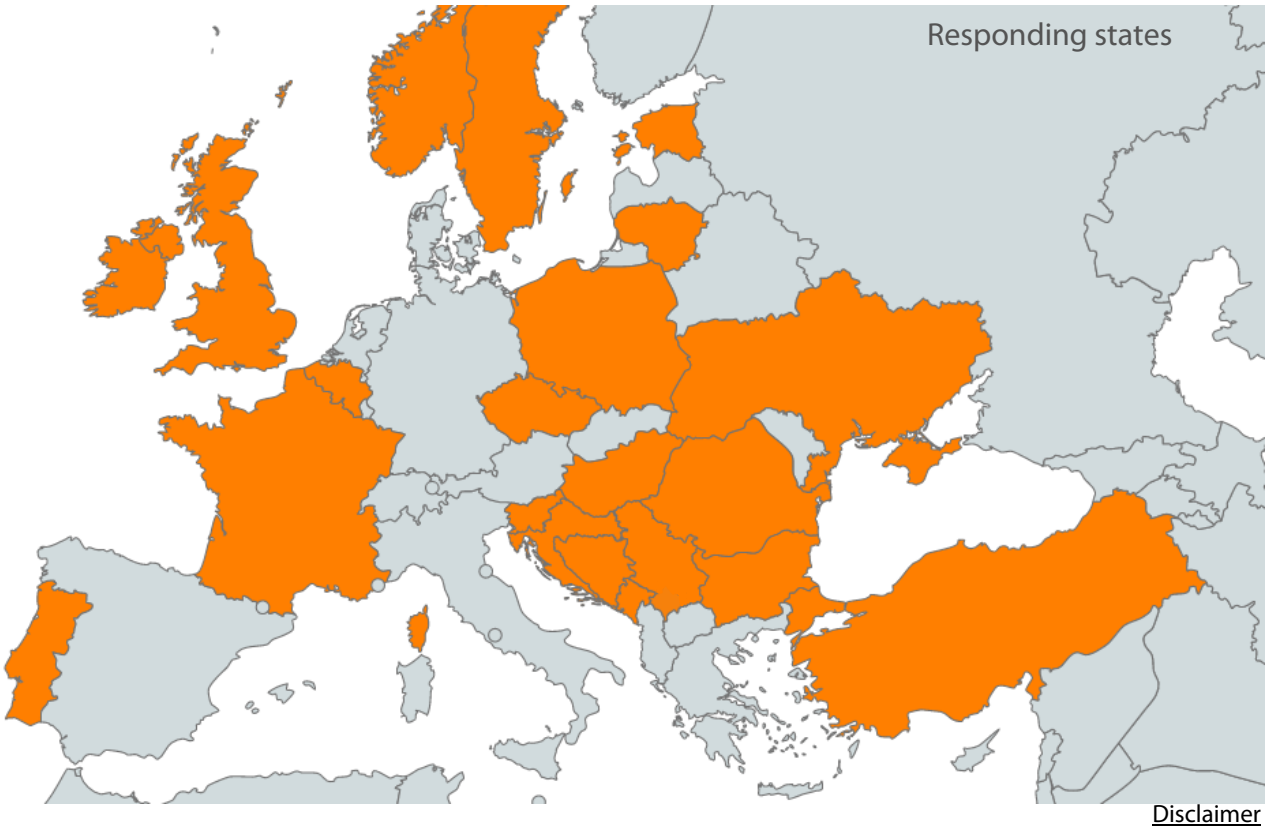
edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Introduction

Medical devices comprise a wide variety of products (>500 000), and the field is currently seeing major developments in terms of new technologies and new types of products. Due to the complexity of the area, work to establish effective legal frameworks and monitoring systems is still ongoing. Within the EU, new legislation – Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro medical devices (IVDR) – have recently entered into force. Compared to the regulation of medicines, the regulation of medical devices is relatively new and this is reflected in the systems and processes in place to handle irregularities and the resources available to deal with them.

A survey was carried out within the framework of the work programme of the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED). The aim was to get an overview of the current state of affairs in Council of Europe member states regarding how authorities perceive and address the issue of falsification of medical devices. This visual report provides a selection of the questions/answers and comments with the key findings. The wider context of the field of medical devices, as described above, must be taken into account when looking at the results.



Disclaimer

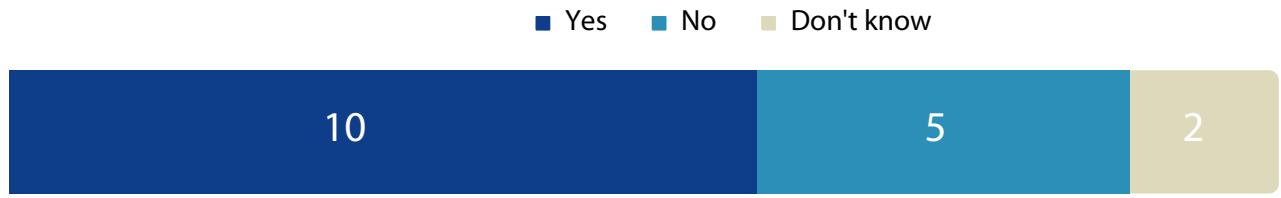
Source data

Regulatory framework

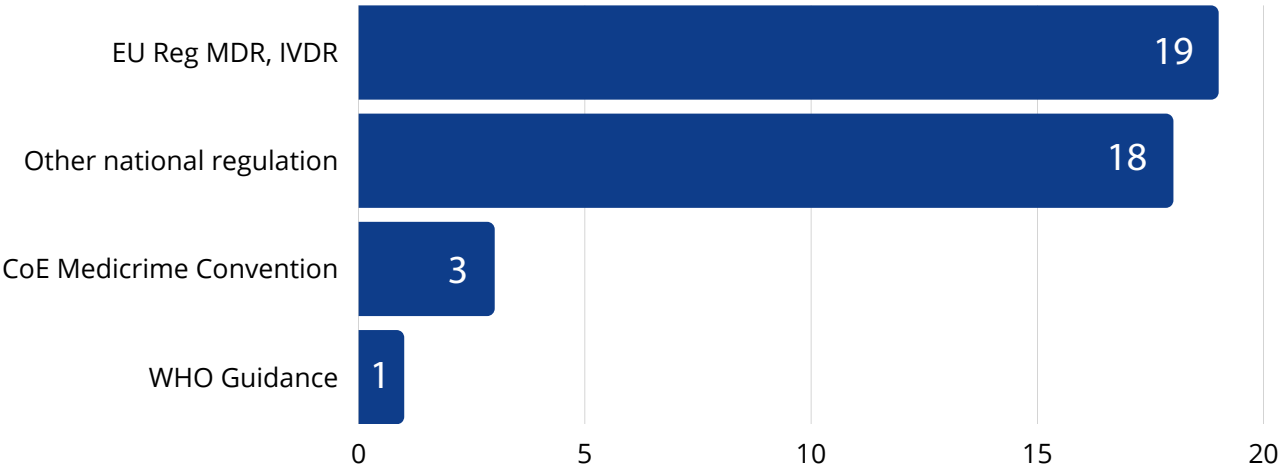
The responses received show that regulations are mostly in place, but the ways in which they are used differ.

Regulation 2017/745 applies in all EU countries and is used in several other countries. Most countries also have additional national regulations; no countries had no regulations. As Regulation 2017/745 is relatively new, several countries replied that it was too early to assess whether it was sufficient to address the problem of falsification. Several countries also replied that the regulations were in place, but not used to their full potential.

In your opinion, is the regulation in place sufficient to address problems originating from falsifications or other fraudulent handling of medical devices?



What regulations are in place in your country or are used to support the regulation of medical devices:



Note: Nine of the responding countries have ratified the MEDICRIME Convention, which is different from the feedback shown in the graph above. This means that awareness of the convention in the medical device sector can be improved.

Source data

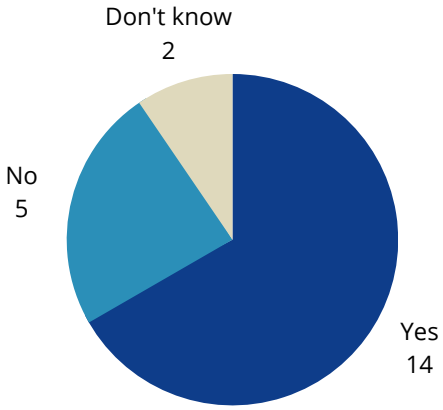
Investigation of falsified medical devices

Most countries have experience of investigating cases of falsified medical devices, but few cases result in prosecutions.

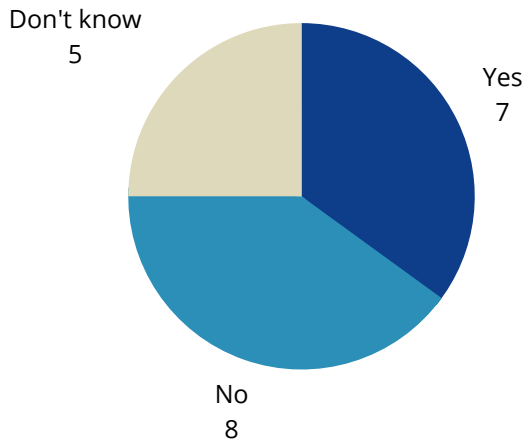
Only seven countries reported having knowledge of criminal investigations on cases of falsified medical devices and only five, knowledge of prosecutions. Countries could select more than one answer when asked about follow-up of investigations, and the results had to be evaluated per country.

When asked about the main obstacles to investigations, the responses were very varied; inexperience with these cases by several actors involved in an investigation or the supply chain was cited as a factor.

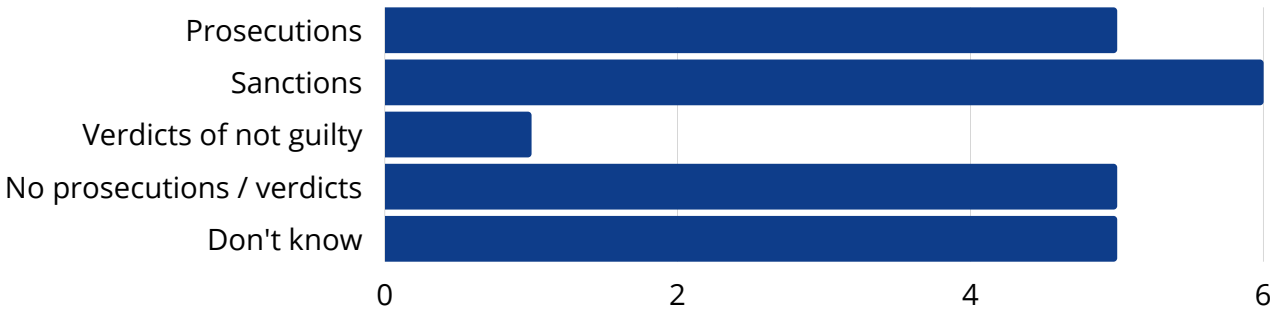
To the best of your knowledge, has your authority investigated any cases of falsified medical devices in the last three years?



To the best of your knowledge, has there been any criminal investigation into a case of falsified medical devices in your country in the last five years?



These investigations have resulted in:



Note: Countries could select more than one answer.

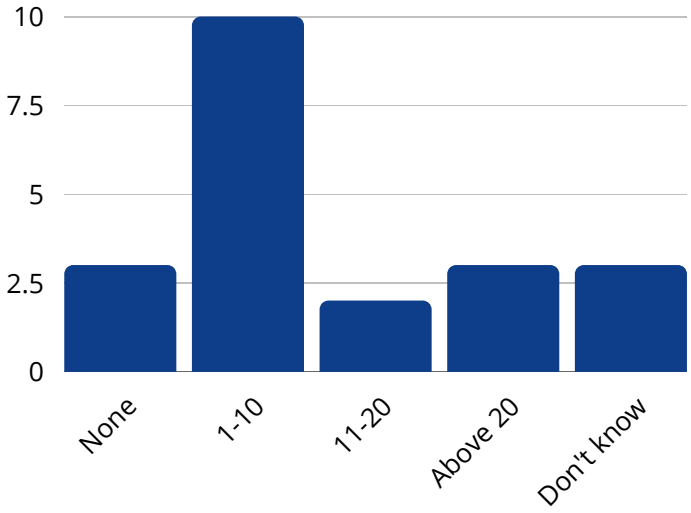
Source data

Detection of falsified medical devices

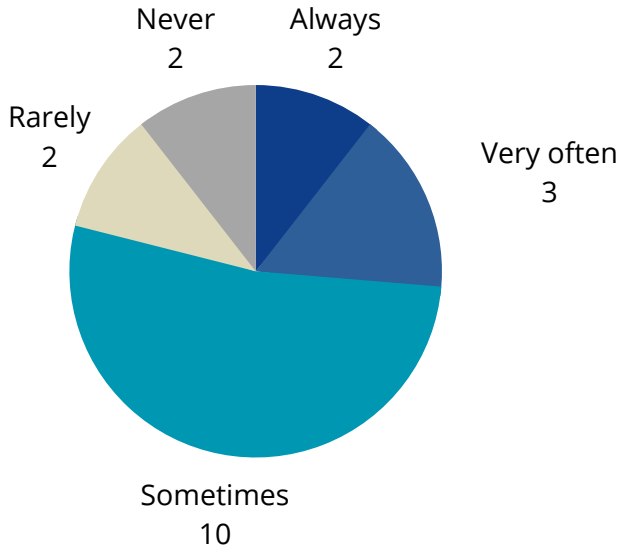
Most countries have observed cases of falsified medical devices.

For observations, the authorities need to both identify the product as a medical device and to detect it as a falsification. Many countries reported difficulties with both of these evaluations steps.

Approximate numbers of suspected falsified medical devices observed by your authority in the last two years (2020/2021)?



Do you experience difficulties in identifying whether a medical device is a suspected falsification?

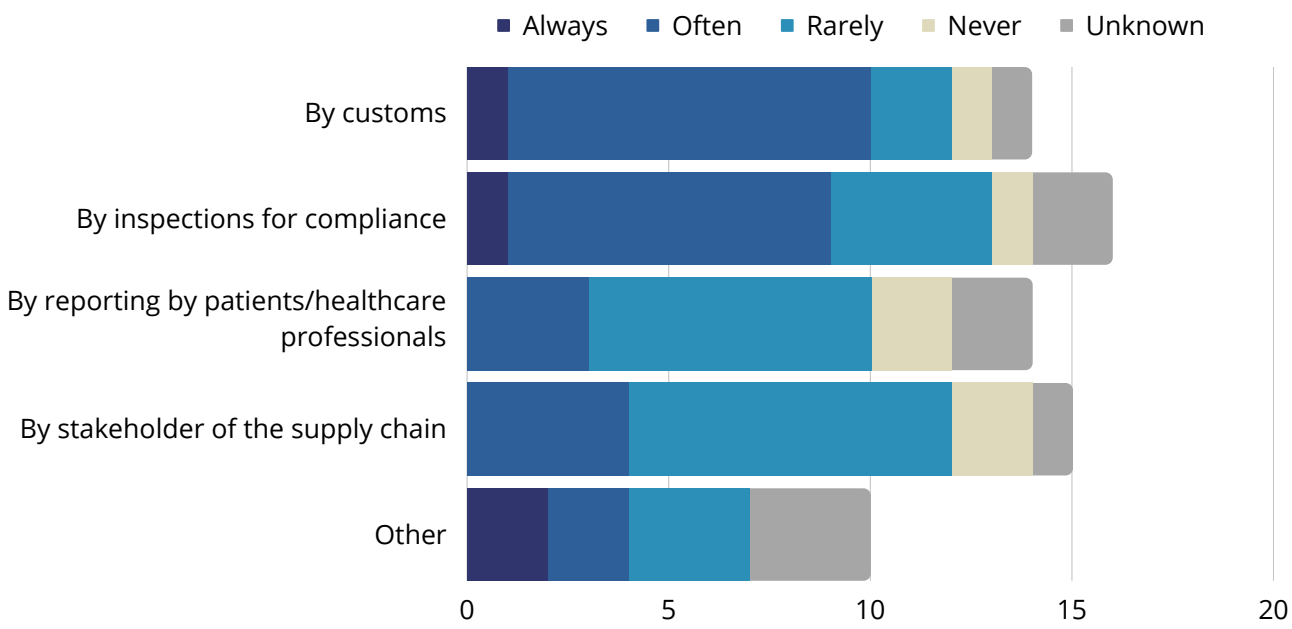


Various actors are involved in the detection of suspected falsifications.

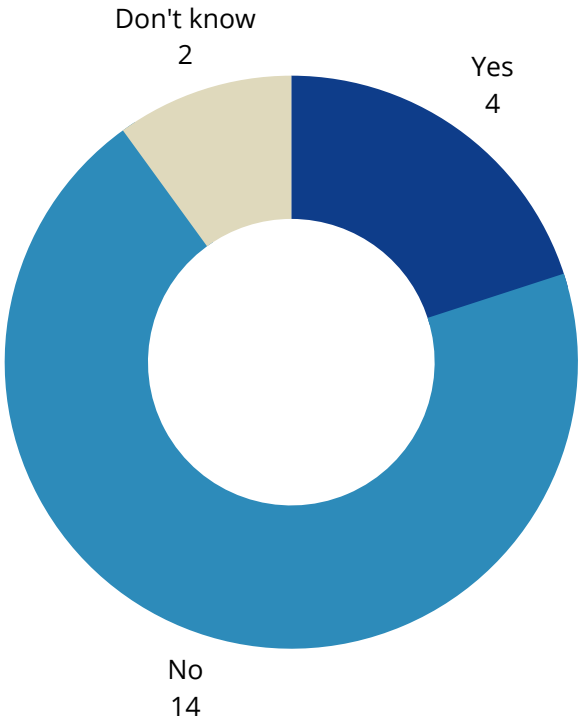
Cases of suspected falsification are detected at various stages in the supply chain, from the manufacturer to healthcare providers and patients. Many countries responded that they would benefit from tools for detection, but only three countries reported having checklists and then only for a specific authority. Another need highlighted by several countries was the collection and sharing of data on cases of suspected falsification, which would be beneficial.

Source data

How were the cases detected?



Do you have any tools for customs, inspectors, patients or stakeholders to help them detect a suspected falsified medical device?



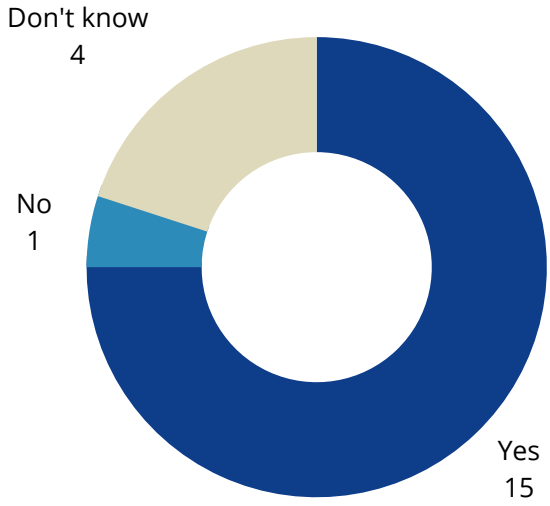
Source data

Reporting

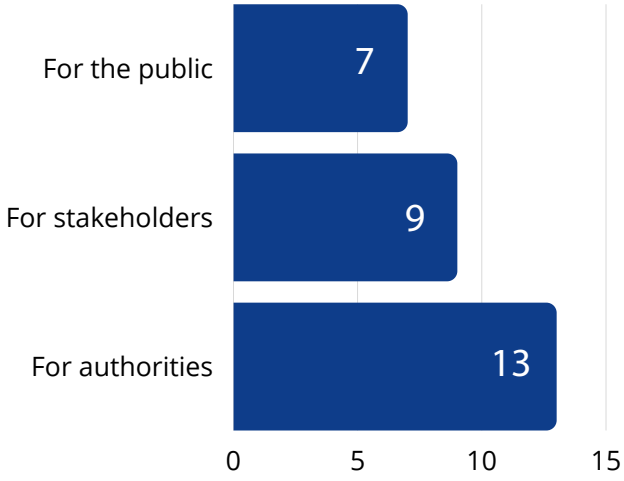
Reporting of suspected cases appears to be mandatory in most countries for stakeholders in the supply chain, but systems for reporting are lacking in many countries.

Countries were also asked who they reported suspected cases to. Most answered that they always or often reported to the relevant health regulatory authorities in other countries, but only a minority reported to the police, customs or stakeholders.
Only one country said that they use the EDQM Know-X database to report suspect cases and eleven countries were unaware of it, highlighting the lack of knowledge about this tool.

Are stakeholders in the medical device supply chain obliged to report suspicious/falsified medical devices in your country?



Is there an easy-to-access system for reporting suspected falsified medical devices in your country?



Do you use the EDQM KnowX database (knowx.edqm.eu) to share information on falsified medical devices?

Only one out of 19 respondents uses the database. Eleven respondents said they were not aware of the database, but expressed interest in learning more about it

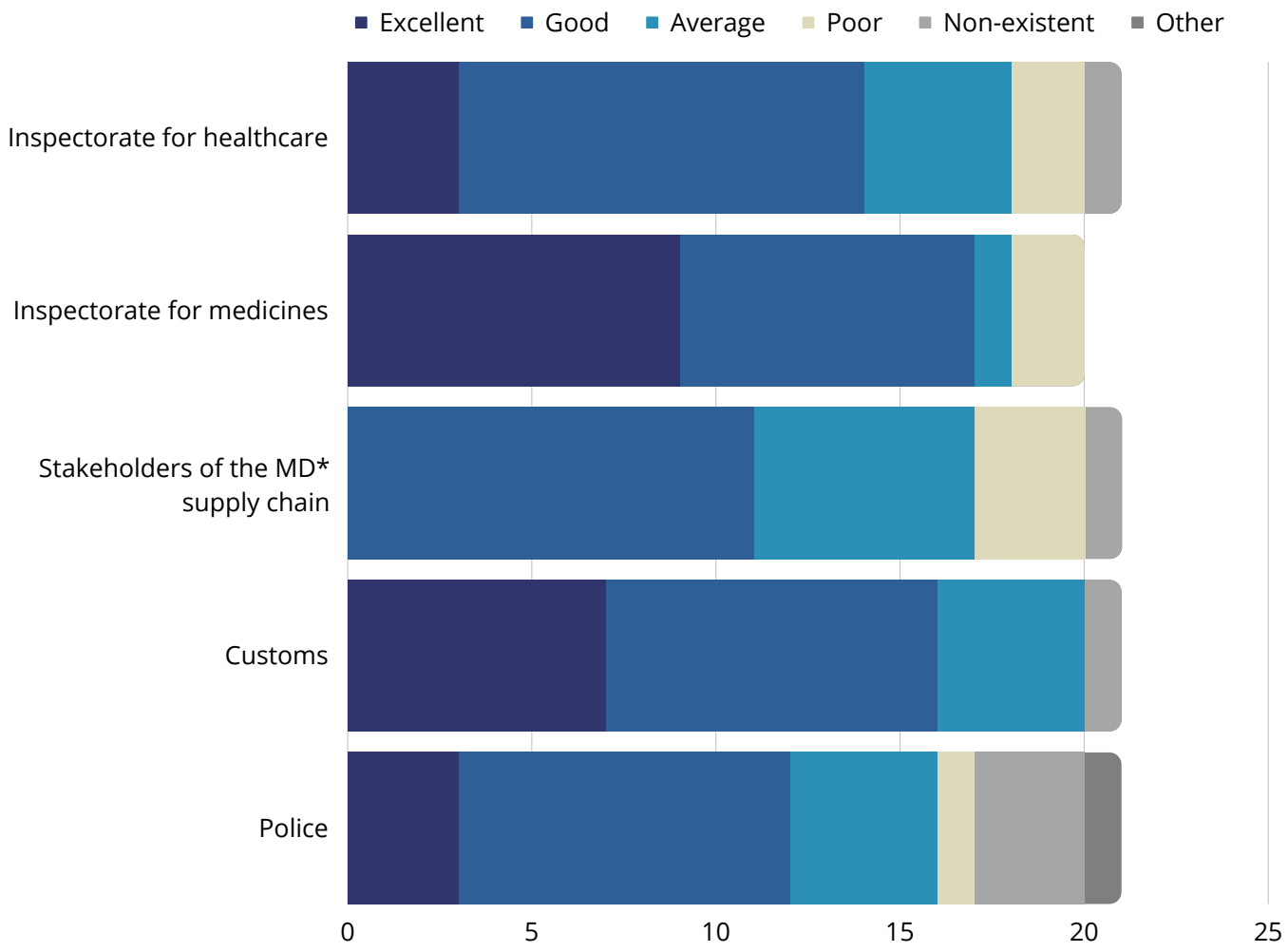
Source data

Co-operation

National co-operation is generally considered to be good, but varies and in some instances needs improvement.

Co-operation between stakeholders and actors involved in the detection and investigation is vital in cases of falsification. Several countries pointed out that a lack of experience with these cases impacted co-operation, as did a lack of resources and the low priority of medical device cases in law enforcement authorities.

Regarding enforcement of suspected falsified medical devices, how would you rate the quality of co-operation of your authority with the following?



*MD: medical device

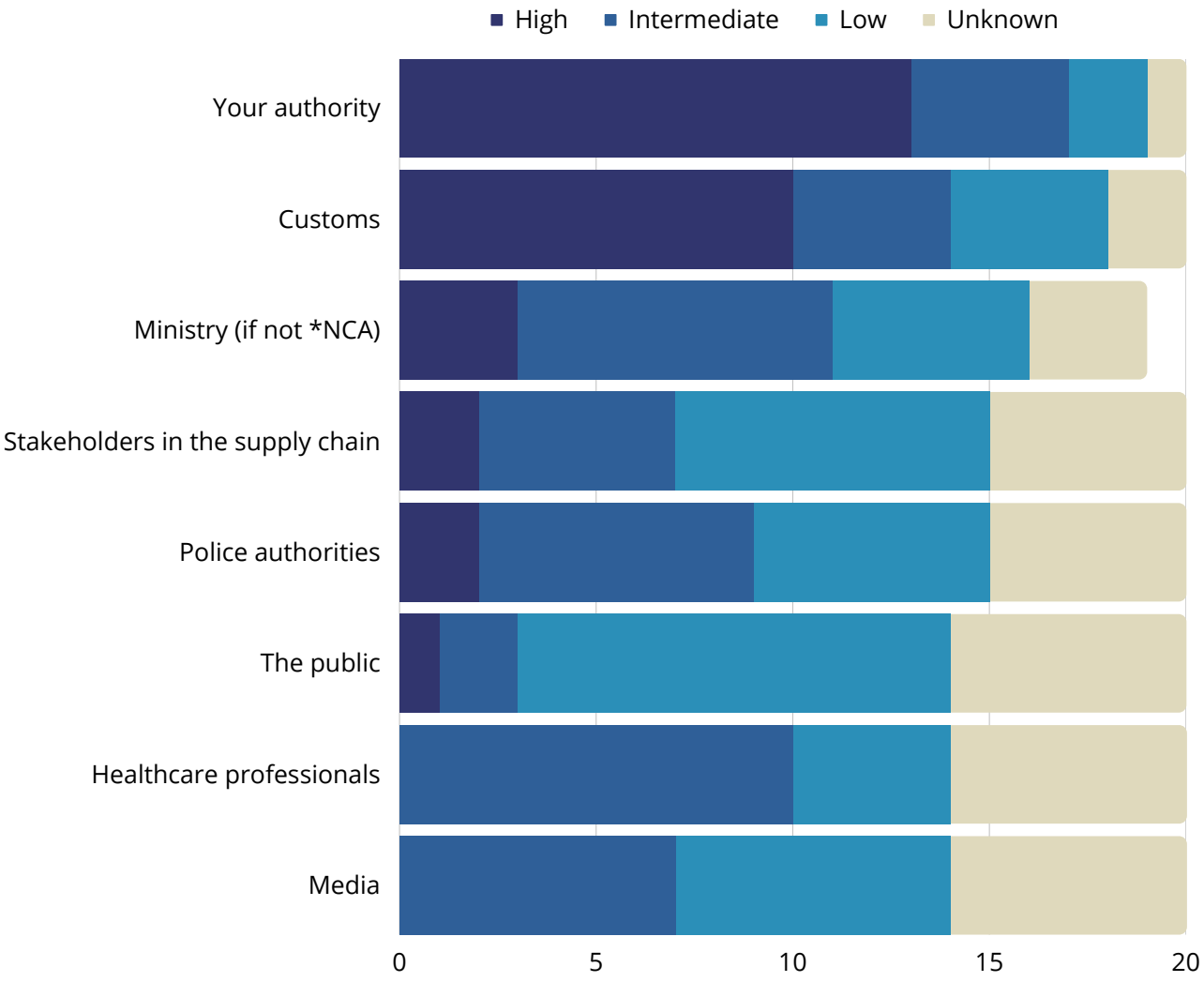
Source data

Awareness

Awareness of the falsification of medical devices is considered to be high in some authorities, but rather low among other groups.

Most countries occasionally issue communications on falsified medical devices, usually in connection with criminal cases or market surveillance, but also to raise awareness. Published articles in national media are limited to a few occasions a year, and in several countries there is no media coverage at all.

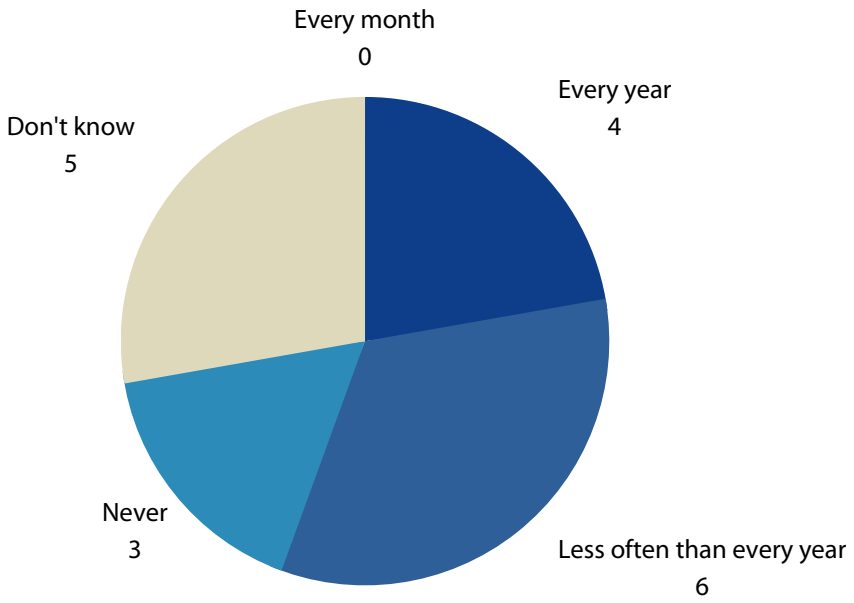
How would you rate the awareness of the existence of falsified medical devices by the following?



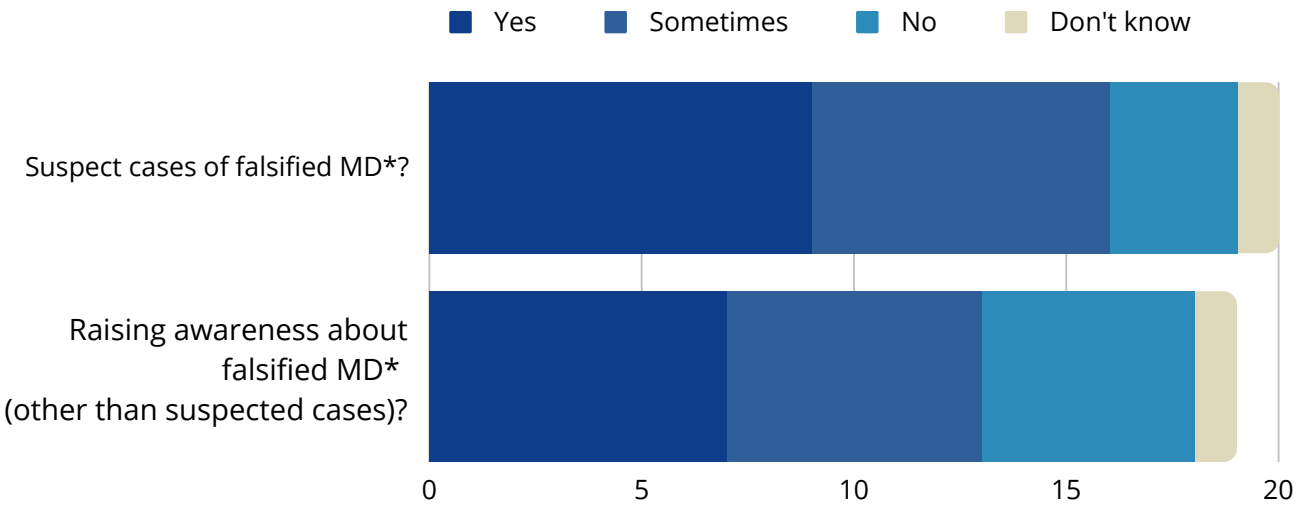
*NCA: National Competent Authorities

Source data

Are there reports in your national media on cases of falsified medical devices?



Does your authority communicate about:



*MD: medical device

Source data

Summary conclusion

The survey responses showed that there are cases of falsified medical devices which confirms that the issue exists; however:

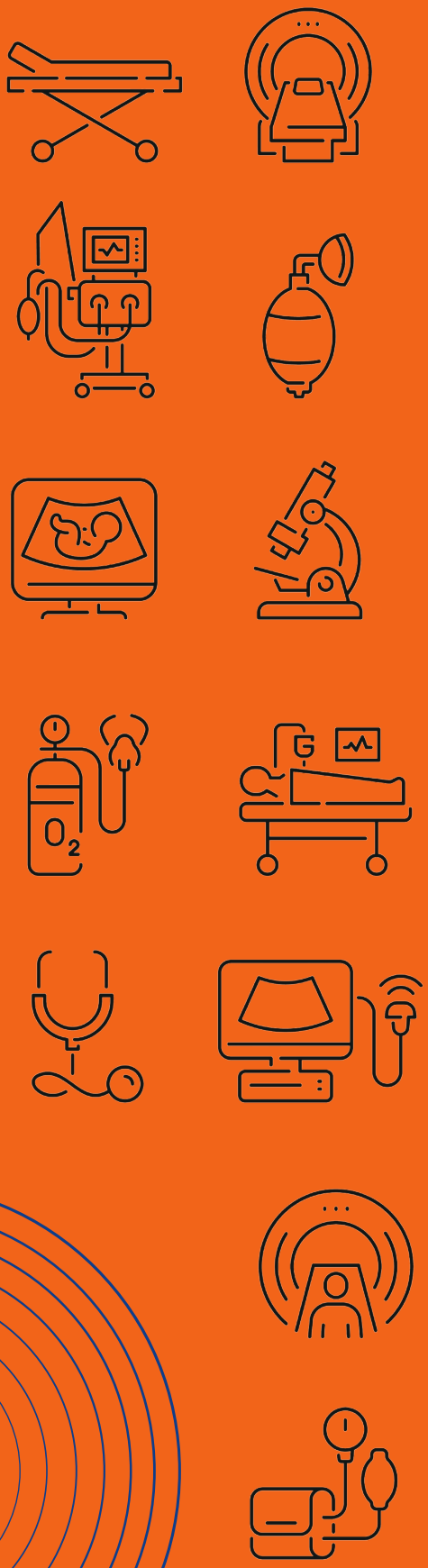
There are few investigations (at criminal level, in particular), and even fewer prosecutions.

There is practically no data (collection) and, to date, little exchange of information.

The implementation of the EU regulations is in its early stages and thus little information exists on their impact in addressing the falsification of medical devices.

A general problem seems to be a lack of understanding of the nature of medical devices, and consequently a lack of awareness of the problem of falsification at most levels. Better application of existing legislation and better enforcement could also have a positive impact on other aspects, such as information exchange, informing of authorities/stakeholders, awareness of the issue and more.

Source data



The steering body, the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), oversees the work programme carried out by the Committee of Experts on minimising the public health risks posed by falsified medical products and similar crimes (CD-P-PH/CMED).

The committee's members work in an enforcement environment mainly in health, but also in police or customs authorities. It serves as a platform for the exchange of information, support, co-operation and initiation of projects in order to make progress in the fight against falsified medical products.

Layout and graphic design: EDQM

Contact

EDQM - Council of Europe
7 allée Kastner, CS 30026
F-67081 Strasbourg
FRANCE

www.edqm.eu
cdpph@edqm.eu
edqm
@edqm_news

MEDICAL DEVICES
SURVEY RESULTS