



THEFTS, LOSSES & DIVERSIONS OF MEDICINES

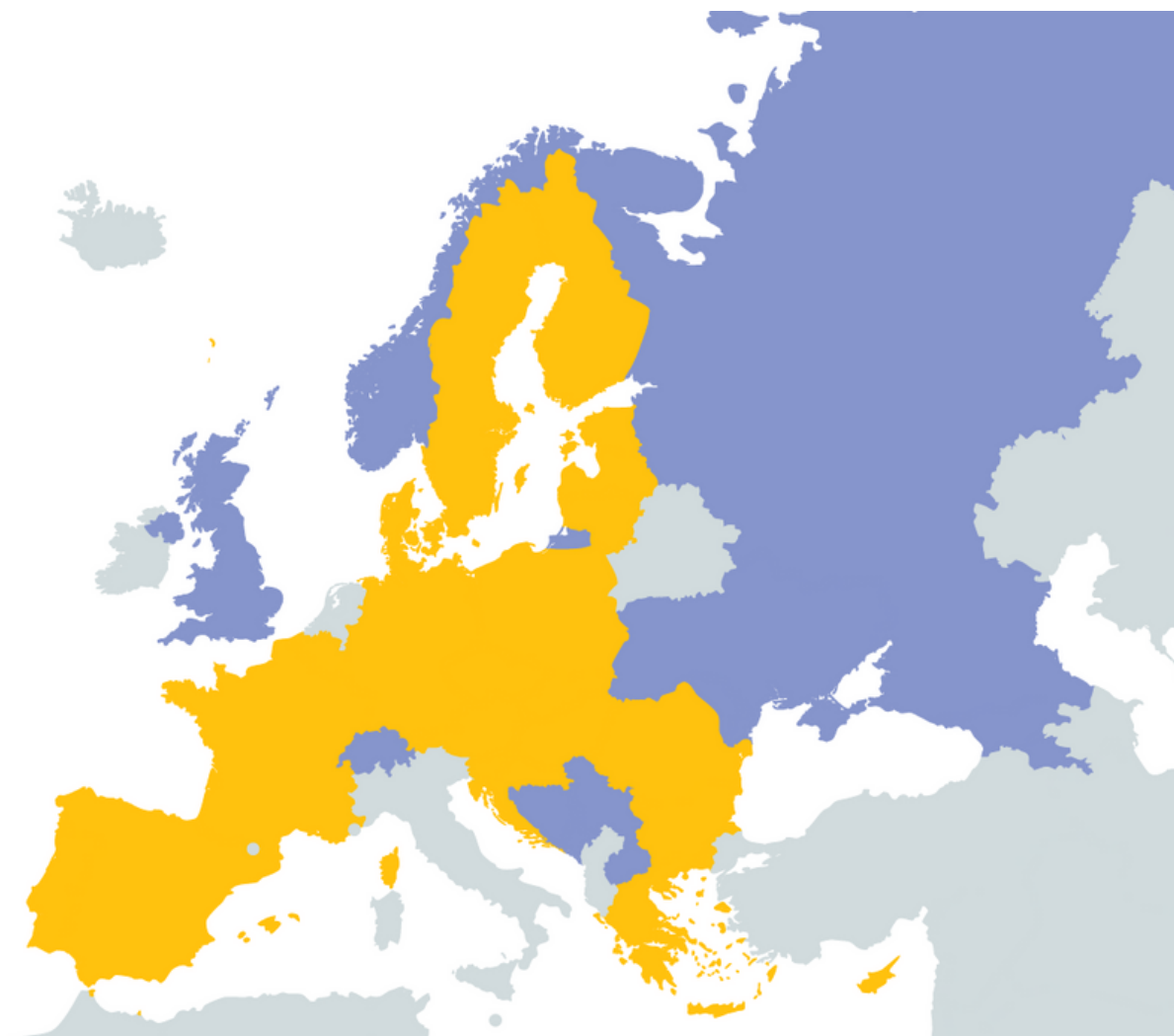
Respondent information

The Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED) has prepared a Council of Europe (CoE) Recommendation on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain. To better formulate this recommendation a CoE-wide survey was carried out in 2021 targeting health regulatory authorities to get their views on the situation.

Recommendation on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain. To better formulate this recommendation a CoE-wide survey was carried out in 2021 targeting health regulatory authorities to get their views on the situation.

Answers were received from:

-  **24 out of 27 EU countries**
-  **13 out of 20 non-EU countries**



Survey addressed to national health authorities in all CoE member states

 Raw data, April 2021



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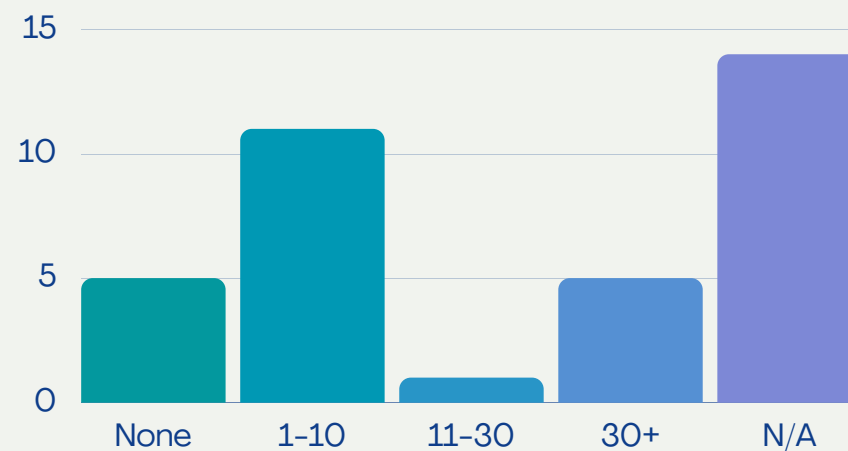
THEFT OF MEDICINES



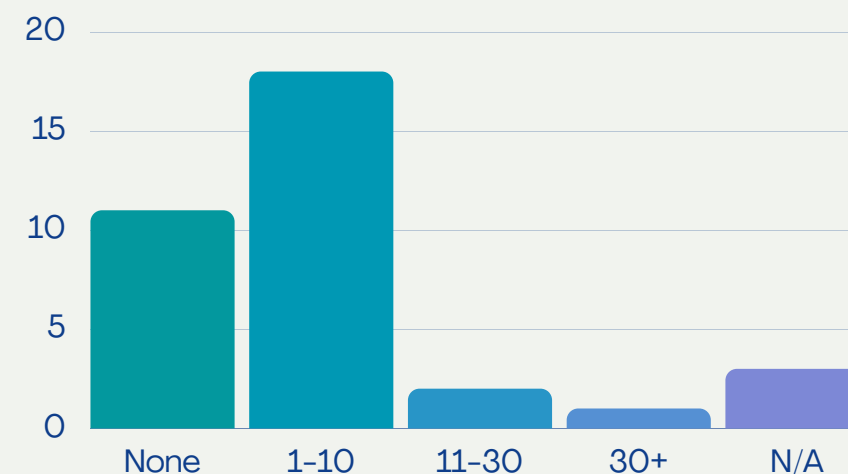
While theft is defined in the national criminal codes, for the sake of clarity in answering this survey, the working group used the following understanding: "Theft of a medicine is the taking away of a medicine that does not belong to the person(s) who are taking away the medicine in a deceptive/deceitful way and that is principally motivated by financial gain".

Answers on theft highlight the lack of reporting to health regulatory authorities

What is the number of pharmaceutical thefts in your country per year?



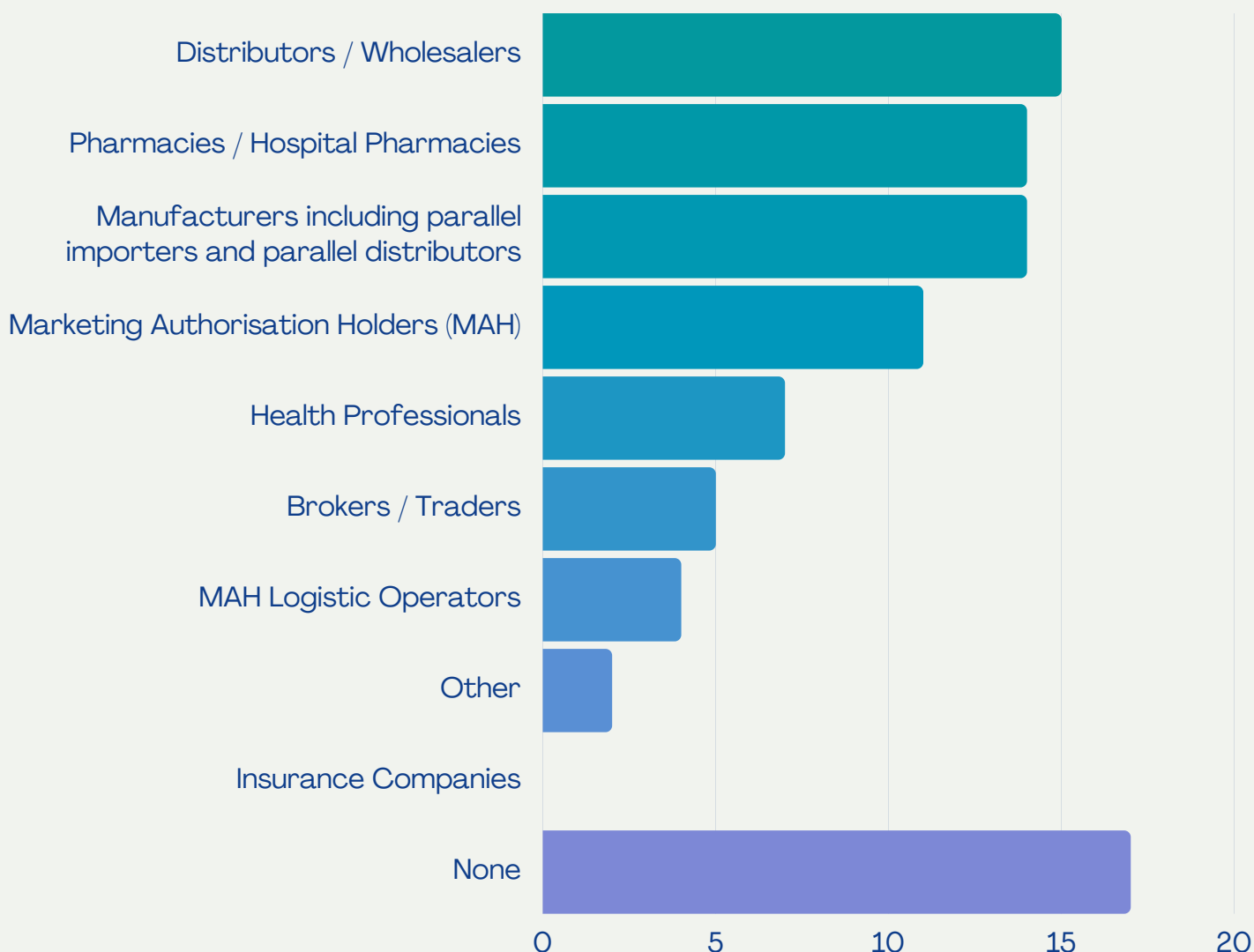
What is the number of pharmaceutical thefts reported to your authority per year?



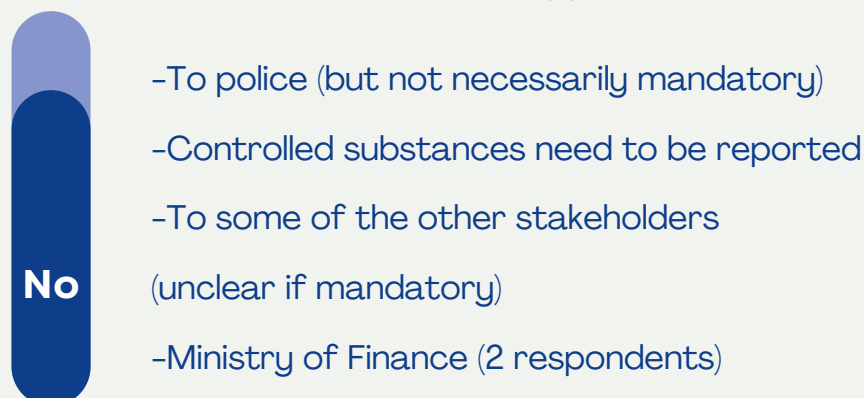


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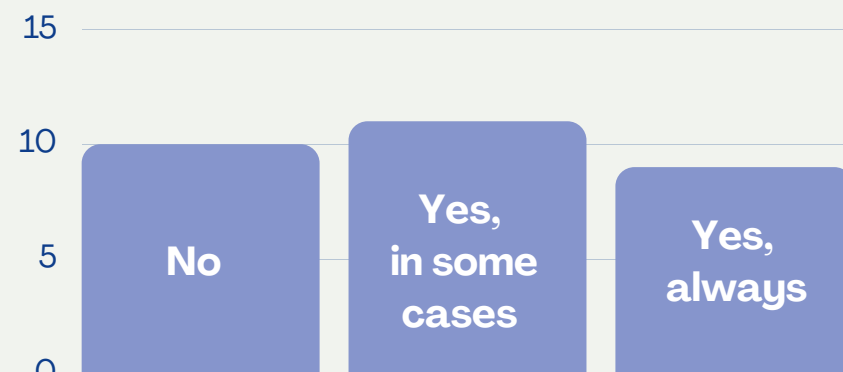
Is it mandatory for any of the stakeholders listed below to report pharmaceutical thefts to your authority?



Are any of the stakeholders listed obliged to report theft to another authority?
If so, which one(s)?



Do parallel distributors established in your country report to you about possible offers of suspicious medicines they receive?





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DIVERSION & LOSS OF MEDICINES

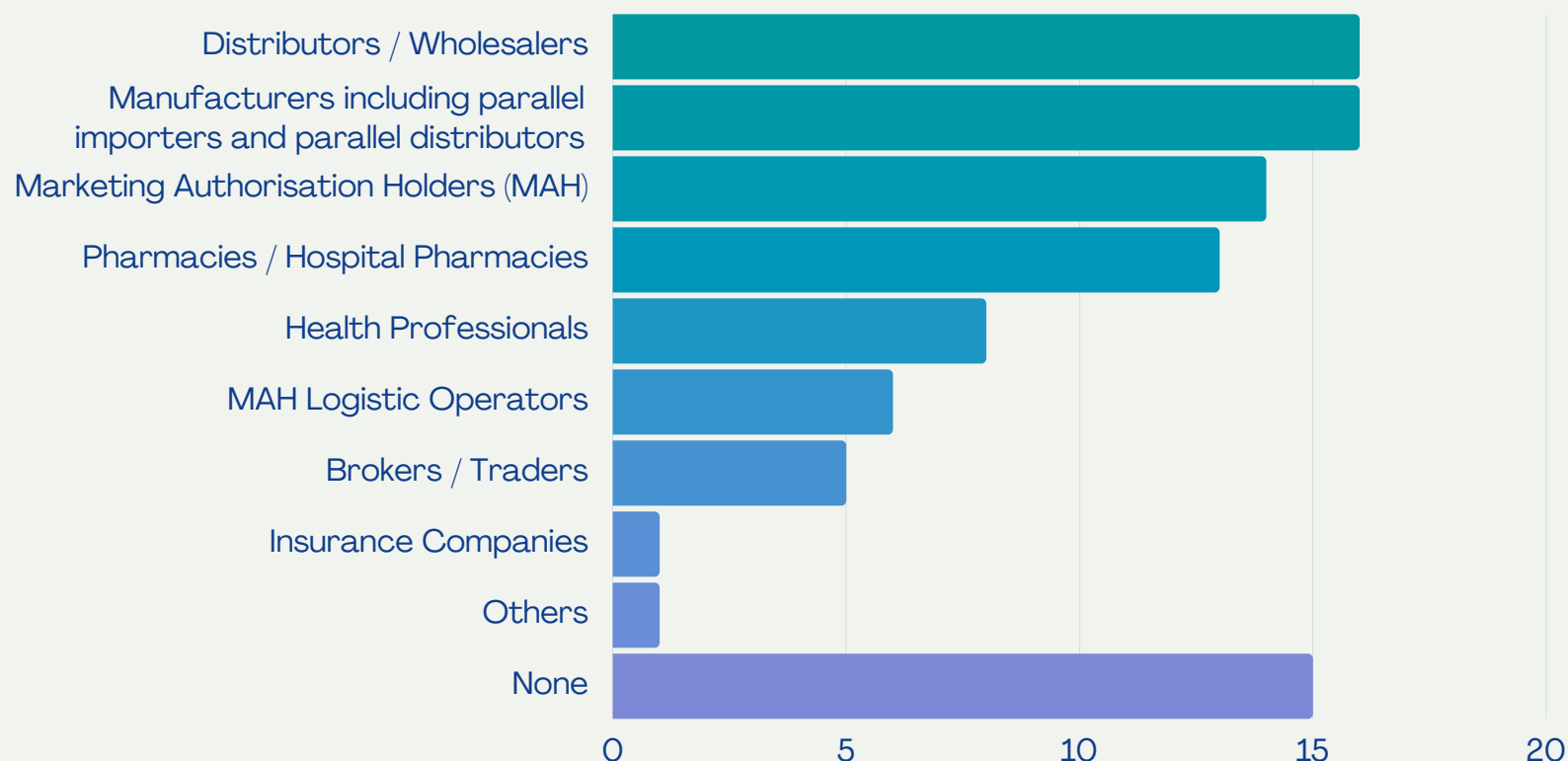


Diversion of a medicine: products that are rerouted out of their intended legal supply chain into another supply chain by unauthorised actions; whether the second supply chain is legal or not is not of relevance.

Loss of a medicine: the accidental misplacing or disappearance of a medicine with the result that the whereabouts of the medicine is unknown at a specific moment under the condition there is no intent involved in the displacing or disappearance.

Diverted and lost medicinal products are often overlooked and not reported to the health regulatory authority. They are often undiscovered thefts and thus equally endanger public health

Is it mandatory for any of the stakeholders listed below to report losses of medicines?



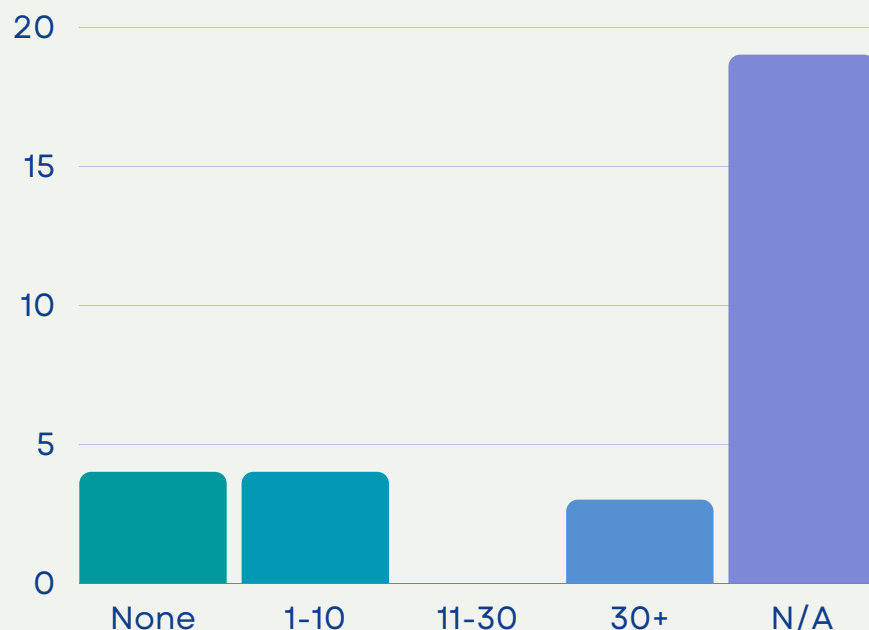


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Can you give an estimate of the number of reported losses per year?

No

Can you give an estimate of the number of losses per year?

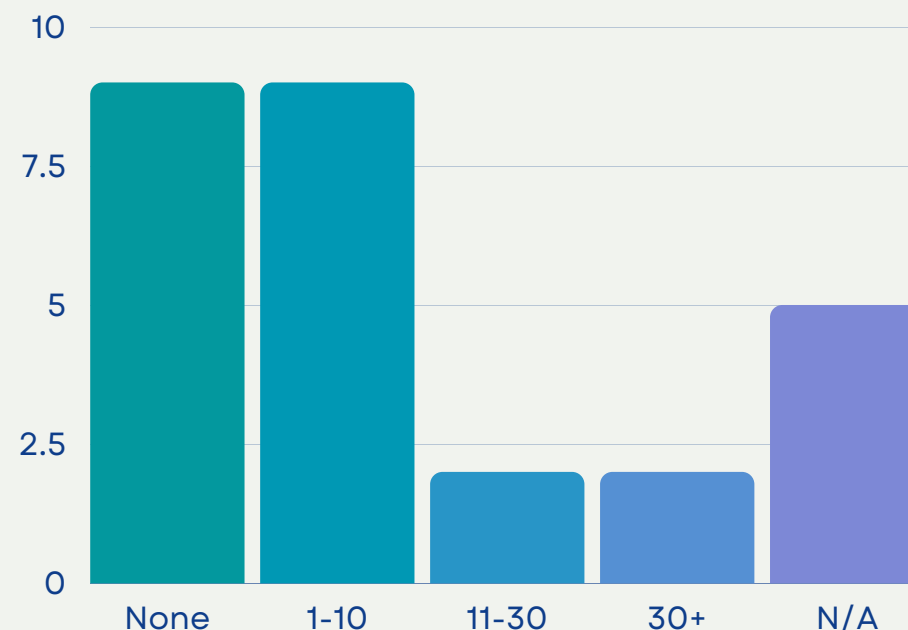


What is your estimate based on?



On the reports from the distribution chain

Has your authority dealt with cases of diversion of medicines? If so, how many?





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REPORTING

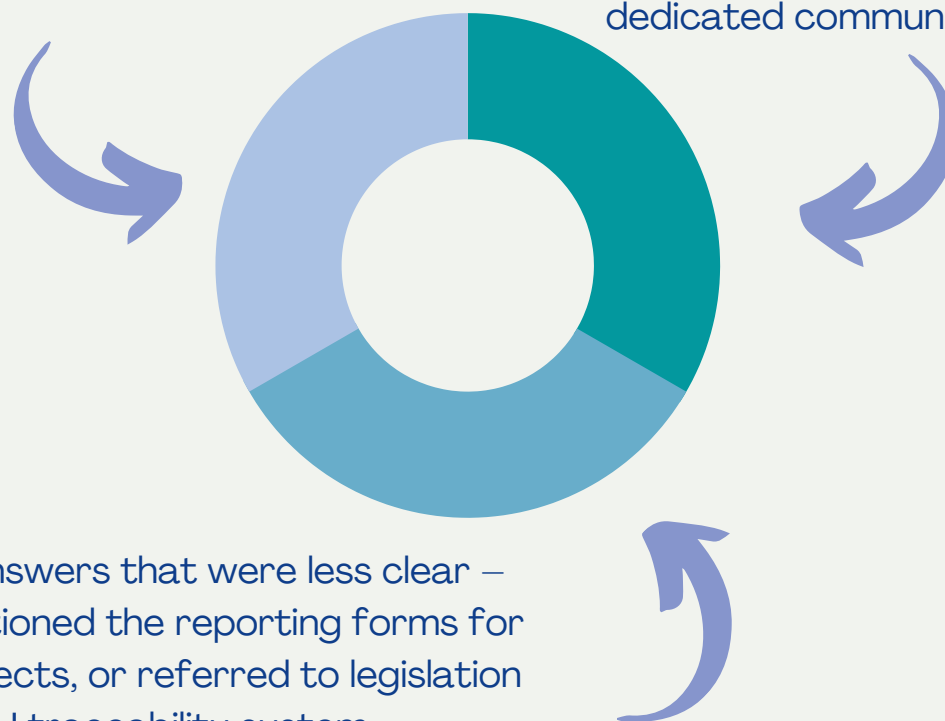


Reporting: the act of notifying authorities about unaccounted disappearances of medicinal products, through a system of user-friendly reporting channels, data management and information sharing.

While data sharing and co-operation with other authorities has proven helpful, many competent authorities are still not prioritising this aspect

1/3 clearly stated they do not have a system in place, or not specifically for these types of incidents.

1/3 seem to have a system in place, e.g. with dedicated forms on the authorities' websites or other dedicated communication channels.



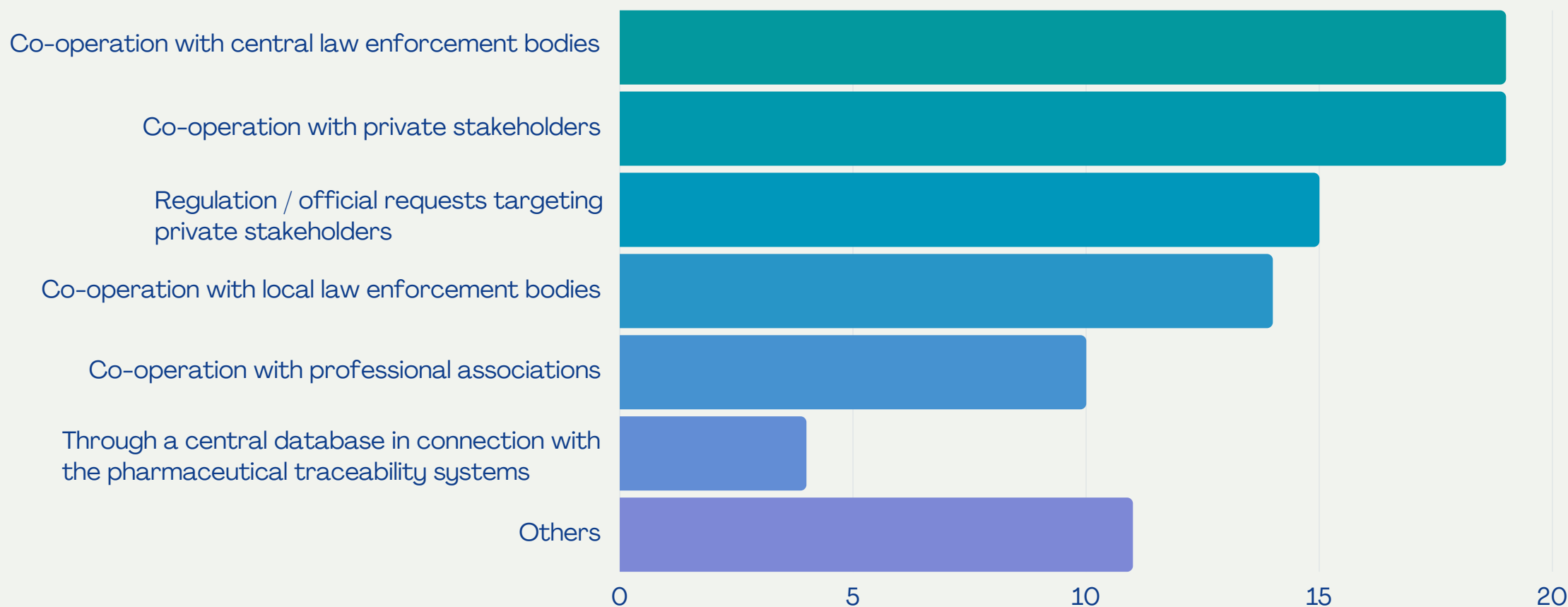
1/3 gave answers that were less clear – many mentioned the reporting forms for quality defects, or referred to legislation or to the EU traceability system.



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Informing stakeholders

What is the mechanism for informing stakeholders about medicinal product thefts and the available reporting channels?



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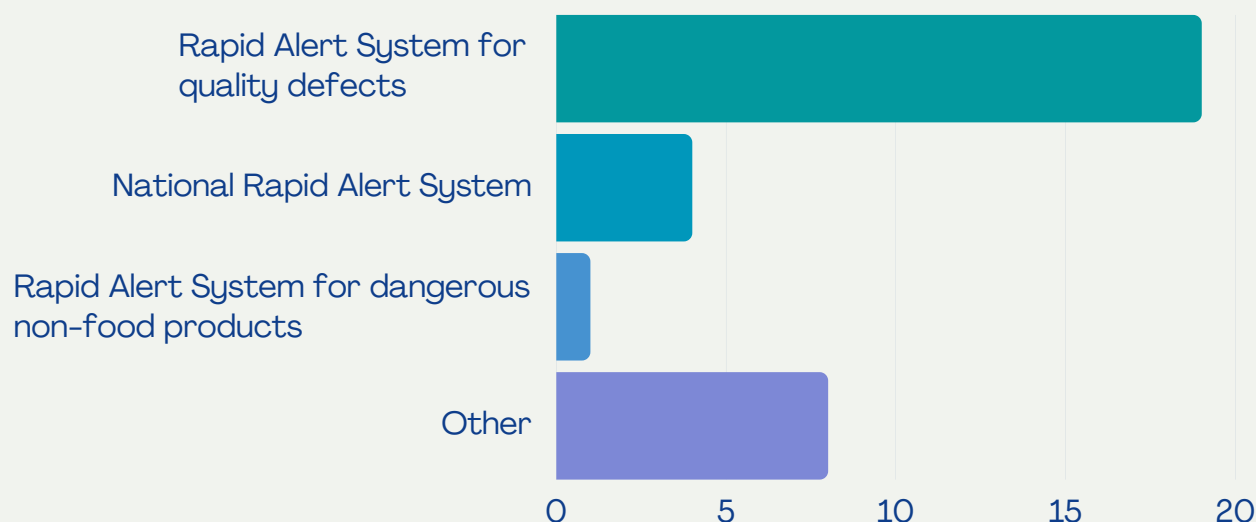


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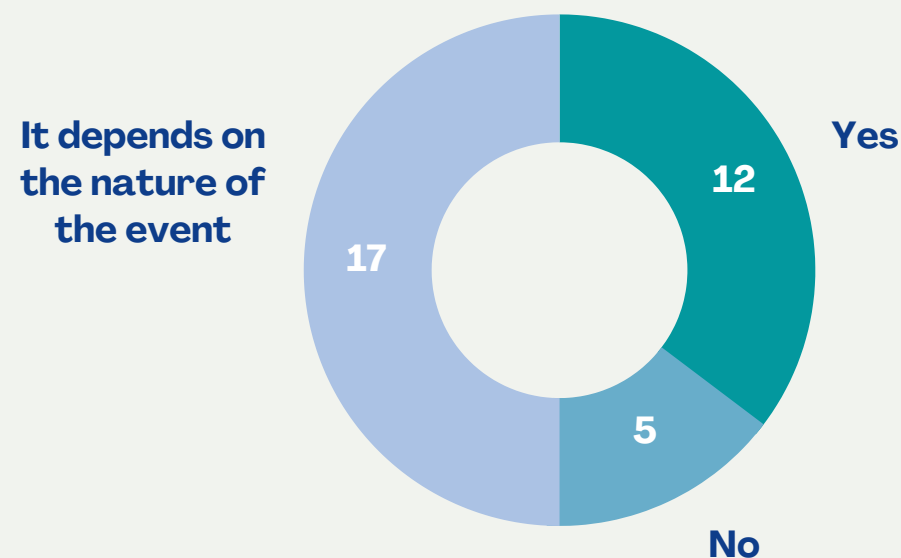
Systems for reporting pharmaceutical thefts

While this feedback seems to indicate that notifications on theft take place, this is not supported by available data on thefts. Currently, reporting of theft is not mandatory in most countries, so even if reporting channels exist, they may not always be used

How are member states' competent authorities notified?



Does your authority receive detailed information about the stolen/lost products?

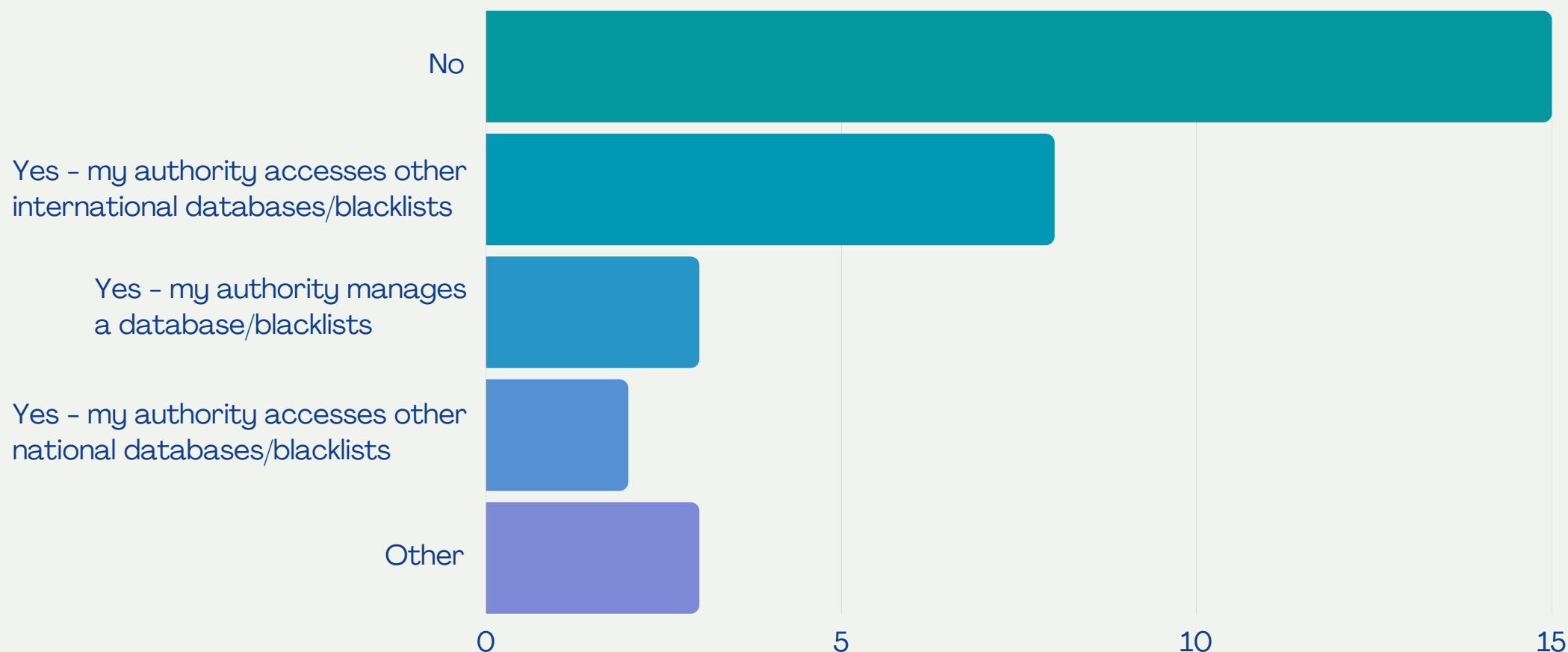




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Access to databases / blacklists

Does your authority have access to any databases / blacklists of medicines that have been stolen in your country or abroad?





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SUMMARY



The CD-P-PH/CMED is a committee of experts in the field of combating falsified medical products, whose 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.

The survey results highlight that in the majority of countries, not much is known about unaccounted disappearances of medicines. This lack of data on the problem across CoE member states represents a real threat to public health.

Medicines that have “disappeared” are no longer protected by the regulatory supply chain – they may be modified or poorly stored, and ultimately they may be redirected into the legal supply chain without any warranty that they are what they claim to be. A regulatory authority that knows when products have disappeared can prevent this.

