

# Summary page:
# TEHDAS2 public consultation on Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – "Citizen Information Point"

This consultation has 6 pages and 30 questions. The first and the second pages are common to all TEHDAS2 public consultations and cover demography of the responder and overall quality of the document. Pages 3, 4, 5 and 6 consist of questions specific to this document.

Demography

## 1. Country *

Belgium

## 2. Type of responder *

Other
Professional representative organisation

## 3. Are you responding behalf of several organisations? *

If yes: On behalf of how many organisations?

No

## 4. Sector *

Other
Medical doctors

## 5. Organisation size *

Micro (1–9 employees)

6. Professional role / function

Secretary General

Quality

7. Is the document easy to understand? *

3

8. How well does the document address the key issues related to its subject matter? *

3

9. How feasible do you find the guidelines or technical specifications to implement, as outlined in the document? *

3

## 10. Generic feedback

Do you have any suggestions for improving the document? Are there any additional topics or areas that should be covered? Max. 5000 characters.

Healthcare professionals cannot be held accountable for the legal application of the opt-out and other legal requirements to inform patients about the EHDS. Any information conveyed to patients needs to be based on information provided by the HDAB.
The guideline also suggests that healthcare professionals may act as intermediaries in communicating of clinically relevant significant findings. From an ethical point of view, the exercise of the patient's right to be informed and not to be informed needs to be clarified further at national level.

The guideline should make clear that the right to opt out under the EHDS must be implemented in accordance with the wording of the Regulation, article 71. Specifically, that the opt-out right of natural persons applies only to that the processing of personal electronic health data relating to them for secondary use under this Regulation.

It should not be understood as requiring, encouraging or implying a broader national right to opt-out from secondary uses of health data that are already governed by separate national legal bases, including existing frameworks for health research, statistics, quality development and health system planning.

In addition, in order to meet citizens' expectations — largely oriented towards receiving individualised information on the use of their own data (p 16) — the guideline opens the possibility, without making it mandatory, of developing tools enabling access to personalised information. Such developments, however, raise important questions, particularly with regard to data security and protection, as individualised access may increase risks related to re-identification, user authentication or access management. A data protection impact assessment should be carried out prior any initiative.

**The following questions are specific for TEHDAS2 Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – "Citizen Information Point"**
**Generic questions**

## 11. Are you currently part of a Health Data Access Body (HDAB) and/or do you expect to have a role in fulfilling HDAB responsibilities under the EHDS Regulation in the future? Multiple choices are possible. *

No, I do not expect to be involved in HDAB responsibilities

12. How familiar are you with national requirement of health information portals? *

Some knowledge

13. Will this guideline impact your organisation or activities? *

No – please explain
However it will influence CPME members, and CPME Members' members.

**Guideline structure and readability**

14. Is the scope and aim of the guideline clearly described? *

Yes

15. What are your thoughts on the terminology used in the document? Is it clear and appropriate for the context? Please explain your answer. *

Max. 5000 characters.

Mostly clear and appropriate.

16. Is the overall structure of the guideline (e.g. division into mandatory and optional information) helpful for HDABs setting up a citizen information point? *

No – please explain
N/A

17. Are the responsibilities of HDABs well distinguished from optional features, good practices and other non-mandatory considerations? If not, please explain your answer. *

No – please explain
N/A

18. Do you see any challenges in setting up the citizen information point when following the guideline? *

No – please explain
National application.

**Guideline content, implementation feasibility**

19. To what extent does the guideline provide a helpful and feasible interpretation of Article 58 of the EHDS Regulation? *

3

20. Do the implementation considerations in the document reflect the purpose of CIPs to provide easily accessible information about secondary use of health data to citizens? *

No

What changes or additions would help? Max. 5000 characters.

Exercise of the right to not be informed about significant findings.

21. Does the guideline sufficiently account for accessibility for a diverse audience? *

No

What changes or additions would help? Max. 5000 characters.

It is more for an expert audience. Suggestion to include practical examples.

22. Are there any legal issues that remain unclear or unresolved in the current version of the guideline? *

Yes – Please explain
The guideline does not make it sufficiently clear that the right to opt out under the EHDS should be understood precisely in accordance with the wording of the Regulation, article 71. Specifically, that the opt-out right of natural persons applies only to the processing of personal electronic health data relating to them for secondary use under this Regulation. It should not be understood as requiring, encouraging or implying a broader national right to opt-out from secondary uses of health data that are already governed by separate national legal bases, including existing frameworks for health research, statistics, quality development and health system planning.

23. Are there any ethical issues that remain unclear or unresolved in the current version of the guideline? *

Yes – Please explain
Exercise of the right not to be informed about significant findings.

24. Are there any procedural issues that remain unclear or unresolved in the current version of the guideline? *

No

25. What kind of support would be most helpful for an HDAB to set up a citizen information point according to this guideline? *

Please select all that apply.

More examples in the guideline

Training or workshops

**What is an information point**

26. How well does the guideline support your understanding of citizen information points? *

Please rate on a scale of 1 to 4, where 1 means “not at all” and 4 means “to a large extent”.

| | 1 | 2 | 3 | 4 | not applicable |
|---|---|---|---|---|---|
| Clarity of definition | ○ | ○ | ○ | ○ | ◉ |
| Relevance of examples | ○ | ○ | ○ | ○ | ◉ |
| Usefulness of implementation guidance | ○ | ○ | ○ | ○ | ◉ |

Optional comment or examples:
Max. 5000 characters.

No answers

**What information should be provided?**

27. How well does the guideline support your understanding of what information should be provided? *

Please rate on a scale of 1 to 4, where 1 means “not at all” and 4 means “to a large extent”.

| | 1 | 2 | 3 | 4 | not applicable |
|---|---|---|---|---|---|
| Clarity of definition | ○ | ○ | ○ | ○ | ◉ |
| Relevance of examples | ○ | ○ | ○ | ○ | ◉ |
| Usefulness of implementation guidance | ○ | ◉ | ○ | ○ | ○ |

Optional comment or examples:
Max. 5000 characters.

The draft guidelines while correctly supporting the userfriendliness of materials, did not provide sufficient examples about how information will reach citizens.
On the right to receive information about significant findings (page 12), the draft guidelines should correct the hierarchy to whom to communicate an incidental finding. According to Article 58(3) of the EHDS Regulation, the health data user should inform first the health data access body, who then should inform the health data holder, and following national legislation, it can either be the health professional or the natural person.

**How should the information be provided?**

28. How well does the guideline support your understanding of how information should be provided? *

Please rate on a scale of 1 to 4, where 1 means “not at all” and 4 means “to a large extent”.

| | 1 | 2 | 3 | 4 | not applicable |
|---|---|---|---|---|---|
| Clarity of section | ○ | ○ | ○ | ○ | ◉ |
| Relevance of examples | ○ | ○ | ○ | ○ | ◉ |
| Usefulness of implementation guidance | ○ | ○ | ○ | ○ | ◉ |

Optional comment or examples:
Max. 5000 characters.

No answers

**When should the information be provided?**

29. How well does the guideline support your understanding of when information should be provided? *

Please rate on a scale of 1 to 4, where 1 means “not at all” and 4 means “to a large extent”.

| | 1 | 2 | 3 | 4 | not applicable |
|---|---|---|---|---|---|
| Clarity of timeline | ○ | ○ | ○ | ○ | ◉ |
| Relevance of examples | ○ | ○ | ○ | ○ | ◉ |
| Usefulness of implementation guidance | ○ | ○ | ○ | ○ | ◉ |

Optional comment or examples:
Max. 5000 characters.

No answers