Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data

This consultation has 10 pages and 73 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, 6, 7, 8, 9 and 10 consist of questions specific to this document.

Demography

1. Country *

Belgium

2. Type of responder *

Other
European Doctors

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

If yes: On behalf of how many organisations?

No

4. Sector *

Health care provider

5. Organisation size *

Not applicable / Individual citizen

6. Professional role / function

Senior Policy Advisor

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.

The guidelines should explain:

- how to involve citizens in the definition of 'public interest';
- how to deal with conflicts of interest/competing duties within same the HDAB and between public entities (e.g. when there is an hierarchy relationship), to ensure HDAB independence against undue pressure, political or commercial influence.

These questions are specific for TEHDAS2 draft guidelines for HDABs on minimum categories and limitations on the reuse of health data

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? *

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

12. To what extent does the guideline provide helpful and feasible interpretation of Article 53 of the EHDS Regulation? *

3

13. To what extent does the guideline provide helpful and feasible interpretation of Article 54 of the EHDS Regulation? *

3

14. Is the overall structure of the guideline (e.g., sections on assessment, definitions, implementation, recommendations) helpful for HDABs' daily work? *

If no: Please explain what structural elements hinder your daily work

Somewhat

15. Are the implementation considerations throughout the document feasible for your national or institutional context? *

If no: What changes or additions would help?

Yes

Any legal, ethical or procedural issues regarding the draft guideline

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

If yes: Please explain

Yes
More clarity on how to deal with possible conflicts of interest/competing duties within the HDAB and between public entities (e.g. when there is an hierarchy relationship, for example, a Minister/Ministry orders access to datasets for purposes where fundamental rights can be at risk). In order to ensure independence for the HDAB against undue pressure, as well as political or commercial influence, external scrutiny is needed on the HDAB activities. This should be further addressed and clearly voiced in section 6.3.3 – Recommendations for implementation, page 21. Section 6.1, page 13 – include a reference to the EDPB Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak guidelines on research. The guidelines discuss the processing for the for the purpose of scientific research. It also reverts to Article 29 Data Protection Working Party, Guidelines on consent under Regulation 2016/679, 17/EN, WP 259 rev.01, 28 November 2017, as revised on 10 April 2018. Editorial issues: - Section 6.3.2 General reflection, page 18 – confirm if it is preferable to refer to 'data minimisation and purpose limitation' instead of 'data-protection obligations' in the sentence "The necessity test, together with proportionality checks in Articles 68(1)(b), 69(2)(b) and 70, ensures that public interest is weighed against data-protection obligations rather than asserted abstractly." Are there other obligations? Should it then be considered to assert against fundamental rights too? - Page 60, definition of "Areas of occupational health" – the GDPR uses the term "occupational medicine" in Article 9(2)(h). Also the definition proposal is not correct, it is identical to "Areas of public health". Kindly revise the definition. - Page 61, definition of "Authorised user" – kindly confirm if the intention is only to allow a natural person, or if should also include a legal person considering the definition of Article 2(2)(u) of the EHDS Regulation. It should take into account criminal and civil liability in case the authorised user causes material and non-material damage to any natural or legal person.

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

If yes: Please explain

Yes
There should be an overall macro analysis on how research is being positively or negatively impacted by the ethical decisions made. Dashboards in HDAB websites should be promoted for transparency towards citizens.

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

If yes: Please explain

Yes
We agree with the consideration that "(…) the definition of ' public interest' could or even should be informed by the public themselves, including citizens and patients, as their values should guide what constitutes public good." – Section 6.3.2 General reflections, page 19. This section should explain how to involve citizens in the definition of 'public interest'.

19. Do you have any remarks on the section with “Open questions – Matters still to be refined" in the guideline? *

Max. 5000 characters.

a) Section 9.3 Interpretation of Article 54(d) in relation to medical research involved controlled substances, page 47 - “the careful balance required between public health protection and enabling innovation” needs to be further developed in relation to criteria to be used by HDAB. There should be an indication on how the decision-making was made to allow the use of narcotics, with transparent reference to the values and principles that led to a decision in favour of another. CPME agrees that the EHDS must not be used to promote or normalise the use of narcotics, among other harmful and unhealthy products or services (e.g. gambling and gaming, addictive algorithms, digital addictions). See also CPME Policy on Adverse Health Effects of Cannabis, November 2023, https://www.cpme.eu/api/documents/adopted/2023/11/cpme_ad_11112023_069.final. CPME Policy on Commercial Determinants of Health, November 2024, https://www.cpme.eu/api/documents/adopted/2024/11/cpme_ad_09112024_071.final. CPME Policy on Novel Tobacco and Nicotine Products, November 2019, https://www.cpme.eu/api/documents/adopted/2019/CPME_AD_Board_16112019_074_ This should not impede studies that allow understanding addictive practices as a goal to eliminate them.
b) Section 9.5 Arrangement of ethical and legal support in the HDAB assessment process, page 48 – CPME agrees with the suggestion of mapping national ethical requirements and make them publicly accessible via the EHDS Board or HealthData@EU. We would also agree with a solution that ensures exchange and discussion at EU level on the application of national ethical requirements to avoid forum-shopping. This discussion should not impede the possibility of certain countries being more specialised on analysing access to data from clinical trials, and other on providing access to genetics data.
c) Section 9.7 building a monitoring system for identifying possible misuse, page 49 – this is one of the most important points to ensure the credibility of the system and trustworthiness of the HDAB. All efforts should be made to implement rigorous monitoring. The suggestion of assigning “voluntary qualitative risk rating” defeats the purpose of having a real examination and scrutiny. A risk-based analysis still seems to be a theoretical approach to the concrete case.

20. Do you have any recommendations for topics to be covered in future updates of the guideline or complementary documents? *

Max. 5000 characters.

The guidelines should explain:

- how to involve citizens in the definition of 'public interest';
- how to deal with conflicts of interest/competing duties within same the HDAB and between public entities (e.g. when there is an hierarchy relationship), to ensure HDAB independence against undue pressure, political or commercial influence.

21. What kind of support would be most helpful for your HDAB to implement this guideline effectively? *

Legal guidance on borderline cases (e.g. between innovation and marketing)
A helpdesk or advisory mechanism (national or EU level)
Training or workshops

Article 53(1)(a) – Use in the public interest

22. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "use in the public interest"?

3

23. Clarity of definition

3

24. Relevance of examples

3

25. Usefulness of implementation guidance

3

26. Optional comment or examples

Max. 5000 characters.

No answers

Article 53(1)(b) – Policy making and regulatory activities

27. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "policy making and regulatory activities"?

3

28. Clarity of definition

3

29. Relevance of examples

3

30. Usefulness of implementation guidance

3

31. Optional comment or examples

Max. 5000 characters.

Section 6.4.2 recommendations for implementation, page 23 - The first recommendation - “HDABs should develop mechanisms to enable the prioritisation of tasks, if there is sufficient justification for doing so.” - is not understood in this section. The idea of the provision, unless interpreted differently, would be to see if the applicant has a mandate or not under national legislation to carry out a task that allows requesting to the HDAB electronic health data for policymaking or regulatory activities purposes. Either the applicant falls in the category of having a mandate, or it does not. The prioritisation of tasks does not seem to fit in this analysis.

Article 53(1)(c) – Statistics

32. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Statistics"?

3

33. Clarity of definition

3

34. Relevance of examples

3

35. Usefulness of implementation guidance

3

36. Optional comment or examples

Max. 5000 characters.

Section 6.5.1 – General reflections, page 24 – revise punctuation of last paragraph of section.

In relation to education (missing section in the online form), please note: Section 6.6.2 recommendations for implementation, page 26 – suggestion to change in final bullet the wording to ‘significant’ or ‘non-negligible’, instead of ‘non-insignificant’.

Article 53(1)(e) – Scientific research

37. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Scientific research"?

3

38. Clarity of definition

3

39. Relevance of examples

3

40. Usefulness of implementation guidance

3

41. Optional comment or examples

Max. 5000 characters.

Section 6.7.3 general reflections, page 30 - It is welcomed the idea of HDAB using independent highly-qualified external scientific advisory Board to facilitate assessment of ‘scientific research’, since it can guarantee the independence of HDABs and allow expert knowledge in complex scientific research protocols.

Article 53(1)(f) – Improvement of health care

42. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Improvement of health care"?

3

43. Clarity of definition

3

44. Relevance of examples

3

45. Usefulness of implementation guidance

3

46. Optional comment or examples

Max. 5000 characters.

No answers

Article 54

47. Which concrete indicators or red flags should prompt HDABs to suspect a prohibited secondary use (e.g. vague objectives, sensitive populations, commercial ties)?

Max. 5000 characters.

Agree with proposed examples of vague objectives proposed by the applicant; requesting access to data of vulnerable populations, in particular when proceedings have been triggered by the European Commission to Member States based on Article 7(1) of the TEU which include violation of the rule of law, democracy, human rights; in case the applicant has commercial ties, as well as cases of sharing data with countries without an adequacy decision under the General Data Protection Regulation (e.g. multinational companies).

48. Do you already have a system in place to monitor that data is not used in a way it should not be?

If yes, please describe the system and give examples, if possible.
Max. 5000 characters.

No answers

Article 54(a)–(b) – Decisions detrimental to individuals or groups and disadvantaging or discriminating decisions

49. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "decisions detrimental to individuals or groups and disadvantaging or discriminating decisions"?

No answers

50. Clarity of definition

No answers

51. Relevance of examples

3

52. Usefulness of implementation guidance

3

53. Optional comment or examples

Please provide structured examples of discriminatory uses that have been identified or anticipated, with references. Max. 5000 characters.

Section 7.1, page 33 – the last paragraph of this section referring to recital 62 of the EHDS, only applies to applications under a permit process, or should this reasoning be applied to practices ongoing where entities are using data brokers?

Article 54(c) – Marketing activities

54. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "marketing activities"?

3

55. Clarity of definition

3

56. Relevance of examples

3

57. Usefulness of implementation guidance

3

58. Optional comment

Please provide structured examples of (prohibited) marketing uses that have been identified or anticipated, with references. Max. 5000 characters.

Section 7.2.2 on recommendations should clearly indicate that any kind of patient profiling for marketing purposes should be prohibited.

Article 54(d) – Developing harmful product or service

59. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "developing harmful product or service"?

3

60. Clarity of definition

3

61. Relevance of examples

3

62. Usefulness of implementation guidance

3

63. Optional comment or examples

Max. 5000 characters.

Figure 1, Pag 10 – add in the table under “purposes prohibited Art 54” development of harmful products the wording “and services”

Section 7.3.1 General reflections:
- Page 38, CPME welcomes that HDABs apply the precautionary principle approach when residual uncertainty persists.
- page 39, another example to consider is the impact of the legalisation of cannabis in certain countries, which should not allow the use of the EHDS to conduct covert study markets to extend cannabis consumption to other countries – please see CPME Policy on Adverse Health Effects of Cannabis, November 2023. https://www.cpme.eu/api/documents/adopted/2023/11/cpme_ad_11112023_069.final.
- Pag 39 – CPME welcomes good practices for post-permit transparency.

Article 54(e) – Ethical provisions under national law

64. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "ethical provisions under national law"?

3

65. Clarity of definition

3

66. Relevance of examples

3

67. Usefulness of implementation guidance

No answers

68. Optional comment or examples

Do you find it necessary to implement a “single application” format also for the ethical assessment? Currently the ethical assessment would need to be done/applied for in each member state where the national law requires it. Thus, the “single application” principle does not materialise with the ethical assessment. Max. 5000 characters.

Any alignment of application formats should not circumvent national ethics committees requirements.

Article 52
Article 52(3) – Intellectual property rights (IPR) and trade secrets

69. How well does the document support your understanding of the importance to always consider (i) if the requested data is limited by IPR and trade secrets, and (ii) the necessity to take measures to protect such IPR and trade secrets?

3

70. Clarity of definition

3

71. Relevance of examples

3

72. Usefulness of implementation guidance

3

73. Optional comment

Please provide concrete examples (dataset type + legal/organisational/technical safeguards) used to protect IPR or trade secrets. Max. 5000 characters.

Section 8.1.2 on recommendations should include an indication of what happens when a trade secret is violated by the HDAB.