Summary page: TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on fees related to EHDS regulation

This consultation has 5 pages and 26 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 and 5 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 business model regulators are proposing for secondary use and the impact of non-eligible costs when preparing datasets descriptions for health data access bodies needs to be clearly described. The additional tasks to health data holder seem to amount working for free for the HDAB.
The scope of Article 62(2) should be interpreted to include the time spent with dataset descriptions and updates under Article 60(3) of the EHDS.
Member States should be encouraged to make full use of the flexibility provided by Article 62 (1) subparagraph 3 to reduce fees for non-commercial applicants like public entities and universities, taking account of the fact that the data was already collected by the healthcare system using public funds and health insurance contributions from citizens.
Member States should consider if any imbalance may arise if the system allows enrichment from private companies or corporations (as data users) accessing data in the EHDS, and if there is no adequate return to the patient and the healthcare system.
The costs and fees favour big institutions or corporations, as you will require solid funding to be able to carry out research. There needs to be assurances that the fees do not distort study opportunities of individual healthcare providers, small centres, and professional associations.

The following questions are specific for TEHDAS2 draft guideline for Health Data Access Bodies on fees related to the EHDS regulation

What fees are to be paid

11. In what role/perspective are you replying to this questionnaire according to the definition of the EHDS? *

as a Health Data Holder (DH)

12. As a Health Data Holder, have you already shared data with data users?

No

13. As a possible future Health Data Access Body or a Health Data Holder, are the eligible costs identified representative of the tasks required to respond to a data user's request? What is well captured? What is missing? What should be excluded?

Max. 5000 characters.

Tasks that should still be considered as eligible relate to all actions/tasks from health data holders that take time and are costly, for example a feasibility analysis, verification, data preparation. The scope of Article 62(2) should be interpreted to include the time spent with dataset descriptions and updates under Article 60(3) of the EHDS.
An economic study would be helpful to compare the cost for the healthcare system to do these tasks by regular health data holders (with medium to low data maturity) vs high data maturity, and this at the expense of clinical work which would not be carried out.
CPME recommends that secondary use obligations related to data management should not be carried out by small clinical practices, with medium or low data maturity. These activities should in general be made by trusted health data holders and by health data holders with high data maturity.

14. Have you developed, or do you plan to develop a data warehouse or equivalent infrastructure to support the secondary use of the health data you hold?

No

15. As a Data User, have you already previously submitted requests for secondary use of health data from data holders?

No answers

16. What type of data access projects have you pursued or are planning to pursue?

No answers

17. As a Data User, do you consider current or proposed fee structures predictable enough to support budgeting in grant applications?

Max. 5000 characters.

No answers

18. Are you planning to compare fees between Heath Data Access Bodies from different Member states to inform your future application strategy?

No answers

19. In your opinion, what level of detail should be displayed in the invoice provided to data users? *

Max. 5000 characters.

N/A

20. In your opinion, are the proposed fees related to the eligible costs fair? *

3

If you selected 1, 2 or 3 above, please explain why it is not fair. *
Max. 5000 characters.

The scope of Article 62(2) should be interpreted to include the time spent with dataset descriptions and updates under Article 60(3) of the EHDS.

21. Do you consider that, in some cases, specific project-related data discovery efforts should be recoverable through fees, even though general discovery costs are not covered by the EHDS Regulation? Please provide examples if applicable. *

Max. 5000 characters.

The scope of Article 62(2) should be interpreted to include the time spent with dataset descriptions and updates under Article 60(3) of the EHDS. The guidelines recognise that the level of effort required for this task may vary depending on the volume and complexity of data. The creation, updating and maintaining datasets descriptions should be an eligible cost for compensation for health data holders. Health data holders need to be compensated for incurred costs irrespective of whether datasets descriptions are used or not. It is also important to have clarity on whether “data consolidation” costs are eligible costs (term mentioned in Deliverable M6.1, Section 4.1.4 data subset creation, page 35) as well as good practice tasks (e.g. additional validation steps, identified in Deliverable M6.1 Section 4.2 Data preparation - data validation before delivery, page 46).

To whom the fees are paid

22. In your opinion, is the recommended scenario clear enough? *

3

If you selected 1, 2 or 3 above, please explain which part(s) are unclear and what aspect should be clarified?
Max. 5000 characters.

Would the adoption of a centralised model increase the fees due to the invoicing tasks?

23. What challenge do you foresee in applying the recommended model in your national or organisational context (e.g. legal, financial, operational)? *

Max. 5000 characters.

Explain the advantages for a DU of using the HDAB if a parallel system at national level can be faster and cheaper, or by engaging directly with a trusted health data holder.

When the fees are paid

24. In your opinion, is the recommended scenario clear enough? *

3

If you selected 1, 2 or 3 above, please explain which part(s) are unclear and what aspect should be clarified?
Max. 5000 characters.

N/A

25. What challenges do you foresee in applying the recommended model in your national or organisational context (e.g. legal, financial, operational)? *

Max. 5000 characters.

No being reimbursed in a timely manner, not being reimbursed for tasks carried out but counted as illegible, working as a HDH at the expense of clinical work.

Areas for further exploration

26. In your opinion, are there aspects that have not been addressed in the document and should be added to the pending questions section?

Max. 5000 characters.

Member States should be encouraged to make full use of the flexibility provided by Article 62 (1) subparagraph 3 to reduce fees for non-commercial applicants like public entities and universities, taking account of the fact that the data was already collected by the healthcare system using public funds and health insurance contributions from citizens. Member States should consider if any imbalance may arise, if the system allows enrichment from private companies or corporations (as data users) accessing data in the EHDS, and if there is no adequate return to the patient and the healthcare system.