Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on penalties for non-compliance related to the EHDS regulation

This consultation has 4 pages and 20 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 and 4 consist of questions specific to this document.
Demography

1. Country *

Netherlands

2. Type of responder *

Other
non-profit foundation

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

If yes: On behalf of how many organisations?

No

4. Sector *

Other
Health data research infrastructure

5. Organisation size *

Small to medium enterprise (10–249 employees)

6. Professional role / function

No answers

Quality

7. Is the document easy to understand? *

3

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

2

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.

Generic feedback over all the guidelines:
- The implementability of the guidelines constitutes a significant concern. It is essential that, at the outset, the workflow of the “data journey” can at least be executed end-to-end in a minimal form. This should then gradually evolve from a basic process into an increasingly comprehensive one. Accordingly, it is not advisable to attempt to regulate and operationalise all details from the very beginning through implementing acts. Instead, a learning-by-doing approach should be adopted. At the same time, a critical challenge lies in preventing the creation of excessive discretionary space for Member States to establish divergent national legislative arrangements (as illustrated by the shortcomings experienced under the GDPR). Therefore, particularly in the initial phase, a learning and growth perspective should be applied, combined with clearly defined, directly implementable requirements per phase regarding the HOW, which do not allow for differing interpretations or implementations across Member States.

- Each guideline should be designed to incorporate an iterative learning and development trajectory. In this context, implementation should commence with a limited scope, including a reduced set of mandatory fields and/or requirements, while, at the same time, establishing predefined timelines at which additional obligations will be introduced, without predetermining in advance the specific nature of those future obligations. Each implementation phase should serve as a basis for evaluation, on the grounds of which decisions shall be taken as to the introduction of further mandatory elements in subsequent phases.

- The guidelines set out in Chapter 4 are largely drafted from a cohort- and research-oriented perspective. Since the data in question predominantly originate from the healthcare sector, the guidelines should also be formulated from a clinical care perspective. Accordingly, in addition to research expertise, the appropriate (clinical) expertise should be duly involved in the development of the substantive guidelines, including expertise relating to Chapters 2 and 3 of the EHDS.

- Each guideline should include cross-references to other relevant guidelines and should also contain explicit references to Chapters 2 and 3 of the EHDS. At present, the overall coherence between the guidelines is insufficiently ensured, and the timelines and processes for input and consultation meetings are, in some cases, (too) short. Moreover, there are significant differences in the level of detail, with some guidelines being highly high-level, while others are detailed and technical. In certain instances, the substantive content is also not fully aligned across the documents. The inclusion of an overall reader’s guide for the full set of documents would improve accessibility and usability; in addition, attention should be given to ensuring consistent terminology and a uniform roles and responsibilities model.

- In the development of the TEHDAS2 documentation, which describes the full process

of data application, data discovery and related procedures, it has been observed that the documentation is largely drafted from the perspective of a centralised analysis environment. Insufficient clarity is provided regarding the concept of federated analytics, its implications (for example, the requirement that permits must also be capable of being 'controlled' by data stations), as well as the respective advantages and disadvantages of centralised versus federated approaches.

Generic feedback on this particular guideline:
- Section 5.3 covers the maximum height of penalty. What is the background of these figures, and with what other regulations or penalty framework do they align? This is helpful in understanding the origin of the maximum penalty height

These questions are specific for TEHDAS2 draft guideline for Health Data Access Bodies on penalties for non-compliance related to the EHDS regulation

Part 1: Clarity and Implementation of Enforcement Scenarios

11. To what extent do you find the guideline practically useful for understanding and applying enforcement measures as an HDAB or stakeholder?

No answers

Please explain your rating.
Max. 5000 characters.

No rating, no comment

12. In your opinion, is the recommended approach to enforcement measures and fines (e.g. revocation, exclusion, periodic penalties) as outlined in the guideline clear enough? *

1

If not clear enough, what aspect(s) would need further clarification (e.g. calculation method, triggers, interaction with national laws)?
Max. 5000 characters.

no rating, no comment

13. What challenges do you foresee in implementing or complying with penalty-related provisions across borders (e.g. consistency, notification, coordination)?

Max. 5000 characters.

no comment

14. Does the guideline provide sufficient examples or practical elements to help understand how to apply penalties or enforcement measures?

2

15. Which types of examples would be helpful to include?

Max. 5000 characters.

The guideline gives clear details on the process of penalties and how to implement these in an HDAB setting. However, it lacks a framework of what penalty in which situation is appropriate. This needs to be addressed, also this can be addressed within a growthmodel also taking into account undesirable differences between member states.

Part 2: Timing, Transparency, and Procedural Safeguards

16. Is the timing of penalty imposition and related communication processes (e.g. 4-week response period, deadlines for compliance) realistic and feasible in your operational context? *

2

17. Do you consider the procedural safeguards (right to be heard, legal remedies) described in the guideline sufficient to ensure fairness and due process?

If partially: Please explain

Yes

18. What are your views on the proposed transparency obligations (e.g. publication of sanctions, use of the HealthData@EU IT tool)? Are there any concerns regarding reputational risk or legal conflicts?

Max. 5000 characters.

The principle of this guideline is based on stimulating secondary use, however creating ‘blacklists’ might not be the most desirable effect.

19. In your view, does the guideline sufficiently address the challenges of ensuring consistency and mutual recognition of enforcement decisions across Member States?

2

Please explain your rating
Max. 5000 characters.

It is left to the member states to decide the actual penalty, this has a high potential to create differences in penalties between member states under similar circumstances. Hence, the need for a framework and a growthmodel accounting for these possible unwanted situations

20. Do you consider that additional guidance, tools, or capacity-building measures (e.g. training, penalty matrices, model templates) would be necessary to support effective implementation by HDABs?

If partially: Please explain

Yes