HEALTH DATA TALK SERIES:

Happy first birthday to the European Health Data Space (EHDS)! What does it mean for Belgium?

Interview with Inge Franki, EU Unit Manager at the Belgian Health Data Agency (HDA) and on the front row of shaping the EHDS for secondary use of health data in Belgium

Q1: The EHDS (European Health Data Space) regulation was approved 1 year ago (March 26, 2025) in European parliament. How far are we with the legislation?

Since March 2025, the EHDS is in implementation phase. Although the Regulation is in force, its obligations apply gradually. This phased approach is explicitly designed to give Member States, healthcare providers, data holders, data users and vendors the necessary time to adapt. In 2029, most of the articles regarding secondary use will enter into application. By 2031, the EHDS regulation will be fully applicable with third-country access.

How are we ready at European level?

The Regulation sets the legal framework, but many technical and operational details are still being defined in implementing acts. Implementing acts are specific guidance documents with specifications, technical details and requirements, that help to ensure that an adopted European law is applied consistently across all European countries. Implementing acts are complementary, as they do not change the regulation as such. Regarding the EHDS for secondary use, the implementing acts are being prepared in the Second Joint Action Towards the European Health Data Space (Tehdas2[1]), carried out by 29 European countries, preparing recommendations and specifications for different topics such as fees and penalties, the minimum categories, the procedures for data access, technical specifications for the Data Access Application Management System (DAAMS), guidelines for minimisation & pseudonymisation & anonymisation & synthetic data, technical specifications for both the common IT infrastructure and the secure processing environment, as well as guidelines for the implementation of the opt-out mechanism. During the past year, there have already been two waves of public consultations, and a third wave is scheduled for May-June this year (2026), representing a total number of 21 recommendation documents. These public

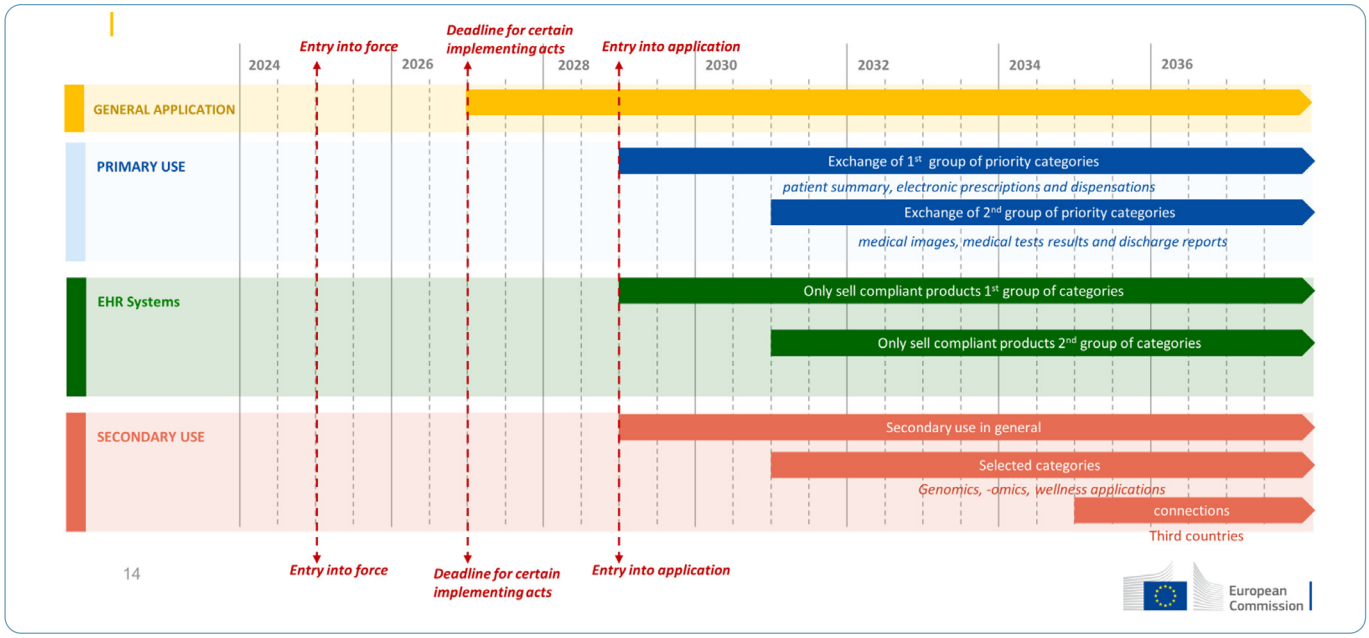


Figure 1: Timeline for implementation

1 For more information about the implementing acts, visit the TEHDAS 2 website: https://tehdas.eu/public-consultations/

consultations collect, process, and include relevant feedback from different stakeholder groups about the feasibility and challenges of the recommendations outlined. Once these documents are finalized, the Tehdas2 team hands them over to the European Commission, that will convert these guidelines into actual implementing acts, based on different discussions with the member states at political level. This is called a comitology process. A majority in the representation of member states need to approve the implementing acts in a voting procedure. Today, the first implementing act describing the functions of the EHDS board has been voted positively. In the coming year, the remaining 11 implementing acts will be voted.

How are we doing at a national level?

The HDA (Health Data Agency) has been closely involved with the initiatives at European level, and is thereby trying to contribute as much as possible to these guidelines. With this, we are also trying to be at the front row to follow the developments, to anticipate and to communicate with our stakeholders.

In the last year, the HDA has focused intensively on preparing the ground for a national implementation plan. Thereby, setting the governance structure and assigning clear roles and responsibilities have been a priority. The success of the implementation of the EHDS for secondary use will not only depend on the functioning of the health data access body (HDAB), but merely on how the HDAB will be imbedded in a national, collaborative structure. Thereby, the nomination of the HDA as a coordinating HDAB and as a national contact point, functioning as an interfederal institution, now urgently needs to be politically approved at inter-ministrial level. In addition, the collaboration with the information security committee (ISC) as a permitting entity, the designation of trusted data holders and the development of hospital data networks as health data intermediation entities are under preparation, but will need to be formalized further.

In the coming year, the focus will shift more on the legal preparations and how the necessary translation to national legislation can be done. But before being able to initiate and finalize the legislative part, the governance structure needs to be clarified.

Q2: In your role as EU Unit Manager at the HDA, what are the biggest lessons learned in preparing Belgium for the EHDS implementation regarding secondary use so far? (lessons, challenges, hurdles, focus on regional challenges)

The EHDS is a major game-changer, that will directly affect stakeholders at different levels, ranging from public and private institutions, hospitals to general practitioners, patients and citizens. Thereby, bridging between European politics, national politics and all these stakeholders is a major challenge. With this, we learned that ensuring a two-way communication, including both clear top-down communication as bottom-up active participation during the implementation phase is crucial to successfully implement the EHDS. Moreover, the HDA has the important task to communicate at different levels, but also to increase knowledge about the EHDS at these different levels. The HDA has already done an incredible job in launching the HDAcademy, but will need to continue focusing on stakeholder mapping and creating awareness, as well in enabling and supporting stakeholders to prepare and increase EHDS readiness.

At political level, active involvement of the regions is fundamental. The political decision to move towards an interfederal agency has been a major step forward, that now urgently needs to be further discussed and brought into practice.

Another major upcoming challenge will be the HDA preparedness for the volume and complexity of data requests and access applications that will be coming to us. An initial analysis of current practices for data access applications and requests at large public institutions showed a high variety in handling and processing these requests, with usually a very decentralized way of working. This highlights the need for a transitioning period in which the involvement of the HDA will be gradually increased. A realistic estimation of the required capacity and the preparation for a smooth collaboration with the future (trusted) data holders will be a major objective to achieve during this transition period.

Our technical team is working very hard, making us a frontrunner in Europe in the development and deployment of a national metadata catalogue and a data access application management system (DAAMS). However, we learned that the definition of the requirements and specifications seem to be very complex discussions to reach agreement upon at European level. Although the HDA is ahead with the development of its digital business capabilities, we are still waiting for final specifications at European level,

mainly regarding the Secure Processing Environment (SPE) and the metadata standards. A final definition of EHDS requirements will only be available after the final definition of the implementing acts in 2027, which we need to anticipate upon and make sure we are able to switch gears quickly. This is also the reason why we are now working hard in preparing the SPE development, but are also waiting for the final guidelines.

As a last point, EHDS primary and secondary use seem to be organized as two separate tracks within the EHDS regulation and this seems to be reflected in the governance structures, both at European and national level. Although many efforts have already been made to bring them closer together, this will need continuous work. A lot of work needs to be done on semantic interoperability, facilitating the only-once principle and data quality. These are topics that can only be tackled by joint efforts.

Q3: What does it mean, 1 year EHDS, for secondary use of data in Belgium? What are Belgium's largest achievements in the field? Impact in real life already today? what can we learn from other countries?

With the legal foundation of the HDA, Belgium is ahead of many Member States in having already established a (future) HDAB (Health Data Access Body) for secondary use. The HDA will thereby also function as the national contact point with the central services for secondary use of health data.

The HDA has established two core operational EHDS building blocks for secondary use, namely our metadata catalogue to support data discovery and a data access application management system (DAAMS), supporting a structured system to request (access to) data. With over 480 datasets, we are mapping already a vast amount of available health data in our country. The HDA now opens the possibility to request data that is published in the catalogue, but also accepts open data requests of data not publicly available in the catalogue yet. Thereby, the HDA has moved forward as a facilitator for secondary use of health data.

Aside from that, Belgium (and the HDA) can also already rely on the experience of the Information Security Committee (ISC) and with that, the road is clear for objective access application evaluation and permit delivery.

And of course, our HDAcademy has become a well-known structure for disseminating EHDS knowledge and provides high-quality learnings at different levels.

Although we are well on our way, we can learn a lot from other Member States. The Nordic countries like Norway, Denmark and Finland for example are already well advanced in secondary use of data. Belgium can learn from the Nordic efficiency, specifically in their organizational infrastructure of health data and patient registries, which they can now optimally position in the secondary use of data. Findata in Finland is almost fully operational and demonstrates the benefit of a centralized health data access body. Nevertheless, the early-stage implementation at Finnish Social and Health Data Permit Authority (Findata) also highlighted the difficulty of capacity and risk of bottlenecks. This was a valuable lesson for Belgium in identifying the need to establish trusted data holders that can reduce the workload on the HDAB (Health Data Access Body), optimize efficiency and enforce the optimal use of established and experienced institutions.

Also, closer to home, there is a lot of experience. The Netherlands have a strong user orientation and have invested heavily in communication campaigns and materials. Ireland has extremely good practices in actively working with their patient involvement panels. France is progressing using a similar approach as Belgium, but is very advanced in their development of a combined strategy of health data management and AI.

Q4: How does Belgium position itself within the HealthData@EU cross-border infrastructure? Is Belgium ready to connect in the first wave of countries? (readiness)

The HDA will be the national contact point for secondary use of health data. This means that the HDA will need to connect to the Central Services of the European Commission. This connection, the so-called cross border gateway, with the central services will actually consist of two different levels:

1/ It will enable the HDA to exchange applications forms for data requests and data access applications with the central services, for instance when a multi-country request or application ….

2/ It will also allow the HDA to send metadata from their national health data catalogue to the central metadata catalogue operated by the European Commission, which collects metadata from national contact points in Europe. With this connection, our metadata will be automatically pushed into the European central catalogue.

Several member states have already established a (test) connection with the Central Services and have thereby encountered several technical difficulties (e.g. Health DCAT[2] incompatibility), that are currently being resolved.

The final connection with the Central Services will not be activated before March 2029, as the EHDS will not be into application before that time and legal restrictions apply. Therefore, the HDA is following closely the developments with the cross border gateway, but has not established nor tested the connection itself yet. At the moment, we focus on our national data access management system (DAAMS) and on populating our metadata catalogue. Nevertheless, we are following very closely by attending the connectathon sessions. Moreover, within the framework of the direct grant project HeDERA (Health Data Enabled for Re-use Across Belgium), a platform and integration engineer will be hired in 2026 and will be actively involved in testing the connection.

In summary, while some implementation steps remain, such as operationalisation and scaling, the current progress indicates a high level of readiness to connect to HealthData@EU within the envisaged timelines.

Q5: If you could prioritise one action for Belgium to accelerate EHDS readiness (regarding secondary use), what would it be?

Without any doubt, a first priority at the moment is to formalize the political decision on the governance structure. Once this decision is officially agreed upon at inter-ministrial level, the HDA will be able to accelerate with the related legislative requirements at national level and can proceed with the procedural and technical connections.

Q6: How do you evaluate the readiness by stakeholders? Challenges, hurdles?

Larger federal and regional Institutions like Sciensano, INAMI/RIZIV (National Institute for Sickness and Invalidity Insurance), FAGG (Federal Agency for Medicines and Health Products), Department of Health, AVIQ (Walloon Agency), IMA (Mutual Insurance Agency), and others, seem to be quite familiar with the EHDS (European Health Data Space) Regulation. Moreover, they already have strong public health expertise in data collection and in its re-use. We also notice a very high participation rate in our working groups, which ensures a close collaboration and communication. Besides the direct work on infrastructural readiness, the HDA also attempts to provide tools to increase their internal data maturity, which is also essential when thinking of secondary use of data.

Regarding hospitals, we notice a huge difference in EHDS readiness. Larger hospitals seem to be relatively more experienced with secondary use of health data and data extraction. Still, the risk of administrative overhead, the lack of resources to prepare datasets, metadata, and quality labels required under the EHDS Regulation are hurdles to take. Moreover, there is still data fragmentation: data is spread across multiple systems, often poorly interoperable. Therefore, a lot of discussions are ongoing with hospital data networks and the possibility to function as Health Data Intermediation Entities. By centralizing the work, we will try to optimize efficiency, harmonize and standardize the work. Practical working sessions are organized in the course of 2026 to come to practical workflows in performing their tasks in name of the hospitals as data holders.

The HDA still needs to take large steps in approaching independent health care providers and smaller organisations and at the moment, we still urgently need to open up this discussion. However, we hope that the work in collaboration with hospital networks as intermediation entities may provide us with some lessons learned that we can transfer to this stakeholder group.

The private sector and industry seem to be relatively advanced in their EHDS awareness and clearly see the EHDS as a breakthrough for access to population-level data. Many larger companies seem to have a very mature level of internal data management structure. Nevertheless, we are aware that they still have many questions and concerns on IP (Intellectual Properties Rights) and trade secrets as well as the impact of opt-out, which are highly on our radar.

Citizen awareness remains low. For citizens, trust-building is key. We should avoid the risk of misunderstanding secondary use as "commercialisation of health data". Industry access to health data remains a sensitive topic in Belgium, both politically and socially. We should emphasise data use as serving public interest.

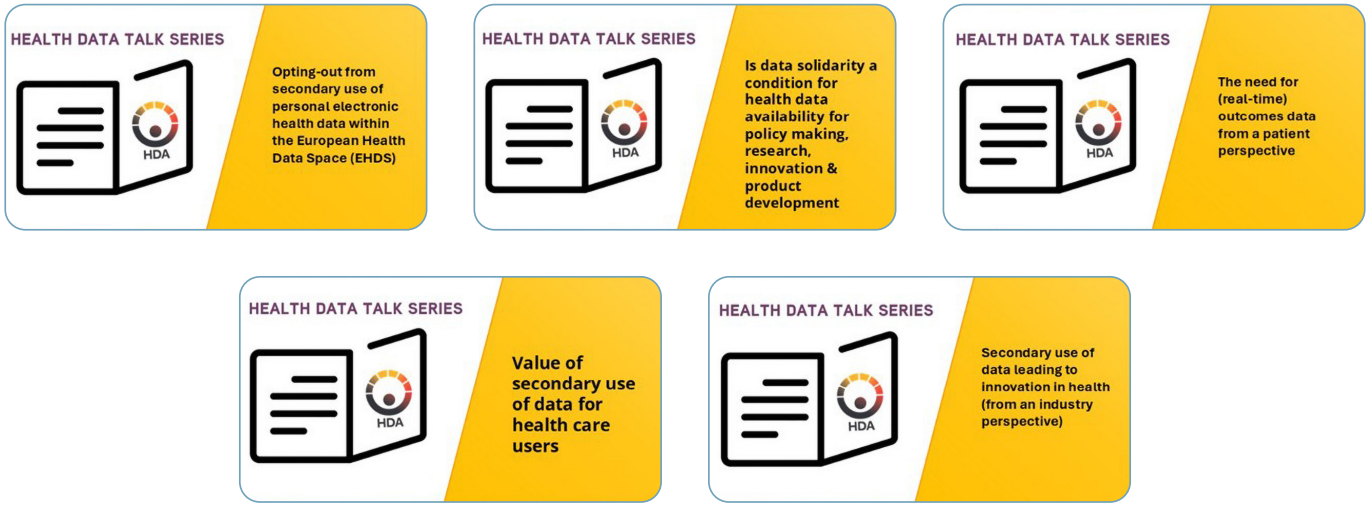
Communication[3] and the HDAcademy[4] play a critical role in addressing stakeholder readiness challenges for the EHDS secondary use in Belgium. By offering targeted communication messages, training, practical guidance and a shared learning space, the HDAcademy helps bridging key gaps in knowledge,

2 https://academy.hda.belgium.be/course/view.php?id=29
3 Follow the Belgian Health Data Agency on LinkedIn to stay informed about the latest news and updates on the HDA and the EHDS Regulation: https://www.linkedin.com/company/belgianhealthdataagency/posts/?feedView=all
4 Find out more about the HDA's learnings through the HDAcademy: https://academy.hda.belgium.be/?lang=en

skills, and mindset. It supports stakeholders in moving from legal uncertainty to operational confidence by clarifying the EHDS framework, data governance responsibilities, technical requirements, and security and privacy mechanisms in place. In a first phase, we will concentrate on initiatives increasing EHDS awareness. These materials will be used to strengthen understanding and knowledge of the EHDS regulation concerning the secondary use of health data. Videoclips and micro-learnings provide an initial introduction to various aspects of the regulation.

In a second phase, we will provide in-depth modules that contain both theoretical insights and practical examples, exercises and case studies. These will provide answers to specific questions and challenges. In a third phase, the various in-depth modules will be combined into individual learning paths so that stakeholders have their own personalised learning journey. The learning pathway includes all the necessary modules to apply the acquired knowledge and skills in the execution of the daily tasks.

Discover all Health Data Talk articles on the HDA Academy



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