National Health Care Institute

International agenda 2024/2025

National Health Care Institute

March 2024

| Taking care of good healthcare |

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1. Introduction

The Dutch healthcare system is based on the principles of a high level of access to care, and affordable, high-quality healthcare services. Everyone is obliged to take out medical health insurance and health insurers are obliged to accept every citizen for the standard health insurance package. The National Health Care Institute (in Dutch: Zorginstituut Nederland) carries out tasks relating to two Dutch statutory health insurance schemes: the Health Insurance Act (Zorgverzekeringswet) and the Long-Term Care Act (Wet langdurige Zorg, Wlz). Our role in maintaining the quality, accessibility and affordability of healthcare in the Netherlands involves various tasks given by the Ministry of Health, Welfare and Sport. For more information about our tasks and activities, please refer to the website.[1]

Our work is becoming increasingly international. One significant project that exemplifies this is EUnetHTA, a project aimed at advancing cooperation on health technology assessment (HTA), to which the National Health Care Institute dedicated substantial efforts. The success of this project has now transformed into a European regulation (2021/2282). Looking ahead, we are now preparing for a new phase where European collaboration will be even more crucial, provided all goes as planned with the implementation of the regulation. We expect it to become of significant value for our national work from 2025 onwards.

Furthermore, the EU pharmaceutical package that is currently under negotiation serves as a reminder of how pharmaceutical products are intricately entwined in European healthcare systems. This package raises important discussions about for example evergreening, the strengthening of evidentiary requirements and the promotion of an environmentally sustainable eco-friendly pharmaceutical ecosystem. It is both fascinating and insightful to witness how these and other developments emphasise the interconnectedness of our work at a European level. As a member of MEDEV we have written a joint ESIP-MEDEV Position Paper on this revision.[2]

As the National Health Care Institute we believe care and information are entwined. Therefore, the European Health Data Space (EHDS) has our attention. The EHDS is a health specific system comprised of rules, common standards and practices, infrastructures and a governance framework. This will impact the Dutch healthcare system given, for example, the EU requirement to exchange the European patient summary cross border and the width of the defined secondary use.

Finally, the global ecological crisis represents an enormous challenge for our societies, for population health and for our healthcare systems. Authoritative reports (IPCC[3], 2023) show that the effects of climate change, loss of biodiversity and pollution on public health are more serious and more acute than ever thought before. Mitigation and adaptation measures are being taken across all societal domains, including the healthcare industry which is a substantial contributor worldwide. The National Health Care Institute loyally supports these developments when it comes to its legal and statutory tasks in healthcare coverage and healthcare quality. If relevant, international and European consequences of transitional sustainability policies are being integrated into our work (e.g., CSRD[4]). With international professional and scientific organisations we cooperate to develop and accelerate the transition to a healthcare system that is sustainable in both economic and ecological terms.

1.1 Goals of this International Agenda 2024/2025

When performing its tasks, the National Health Care Institute participates together with various other countries in an increasing number of international activities. This International Agenda succeeds the agenda of 2023/2024 and has been formulated to describe the relevant topics concerning our international activities for 2024 and 2025. In this document we also describe our position on relevant topics. As such, the International Agenda serves various goals, namely to:

- Provide an overview of our international activities in 2024 and 2025.
- Determine which international activities (e.g., international networks, projects and conferences) are relevant to our tasks and activities.

1 english.zorginstituutnederland.nl/about-us
2 ESIP-MEDEV_position_on_the_revision_of_the_EU_pharmaceutical_legislation.pdf
3 https://www.ipcc.ch/report/sixth-assessment-report-cycle/
4 *Corporate Sustainability Reporting Directive, cf.* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L2464

– Create awareness of our international corporate positions for both colleagues as well as external stakeholders.

The National Health Care Institute cooperates with other Dutch national bodies that focus on healthcare and that also participate in international activities[5].

1.2 Focus

The activities described in this document focus on 2024 and 2025, but sometimes a longer horizon is described. Both national and international developments can have an impact on these international activities. The COVID-19 pandemic has shown that reality can change overnight. The consequences of unforeseen developments will be taken into account when needed. Where necessary, activities will be altered, added or stopped. When a topic calls for research specifically, it is described as such in the National Health Care Institute's long-term research agenda. Our geographical focus is on Europe, although countries outside Europe are not necessarily excluded.

This document focuses on international activities that fall within our formal tasks, as assigned by the Ministry of Health, Welfare and Sport. This means that other healthcare related topics, however relevant they might be, may not be mentioned in this International Agenda, because they are not part our tasks.

1.3 Appropriate care: a concept that is represented in all our tasks

Appropriate care is the approach to care delivery in the Netherlands for keeping care good, accessible and affordable for all. Everyone in the healthcare sector is working on this: healthcare professionals, patients' organisations, health insurers and the government. The concept is represented in all our tasks. Appropriate care should make sure that everyone can continue to get the care they need.

In order to guarantee the quality, accessibility and affordability of the Dutch healthcare system the National Health Care Institute has, together with the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*), formulated 4 principles that should lead to the best appropriate care. These 4 principles for appropriate care are:

1. Value-driven: care should be delivered efficiently and effectively, with the aim of making gains that are relevant to the patient in terms of health and functioning, at a fair price.
2. Created together with and jointly around the patient: the ability of the patient is central to shared decision-making, with multidisciplinary expertise and viewed in the social context of the patient.
3. Is the right care in the right place: (more expensive) care is prevented, care is moved and organizes around people, and regular care is replaced with smart care and eHealth.
4. About health rather than disease: all government policy focuses on health promotion and reduction of health inequalities (health in all policies), and on one's own perceived health and functioning (positive health), and disease and more demanding care should be prevented (prevention).

Because appropriate care also focuses on health and disease prevention, it goes beyond the actual provision of care. It is also, for instance, about providing assistance for persons in their own neighbourhood or environment. In appropriate care, healthcare professionals collaborate with social care providers as necessary, for instance from municipalities or volunteer organisations.

Important steps were taken in 2022 towards that goal:

1. In June 2022, the National Health Care Institute published the '*Kader Passende zorg*' (Appropriate Care Framework). This expresses the four tenets of appropriate care in 12 concrete guiding principles. They state what the stakeholders (such as GPs, the patients themselves, hospitals, health insurers and the governmental authorities) should do to achieve appropriate care.
2. The Appropriate Care Framework is the foundation underpinning the Integrated Care Agreement (IZA). The IZA contains all the agreements for organising and funding appropriate care in primary healthcare, home care services and district nursing, hospital care and mental healthcare. The IZA has been signed not only by all the healthcare stakeholders but also by the Association of Dutch Municipalities. The IZA contains agreements for making the – usually separate – worlds of care and welfare work together more,

5 *For example the Ministry of Health, Welfare and Sport, (Ministerie van Volksgezondheid, Welzijn en Sport, VWS), Dutch Healthcare Authority (Nederlandse Zorgauthoriteit, NZa), Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd, IGJ), National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM), Zorgverzekeraars Nederland (ZN), Centraal Administratie Kantoor (CAK), Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen, CBG-MEB) and the Netherlands Organisation for Health Research and Development (ZonMw).*

aiming to provide the right care for people in the right place. That is because medical treatment is by no means always the correct care. For example, it is better to help people in debt get their lives back on track rather than just treating the symptoms caused by the stress of being in debt.

Thanks to the IZA (plus the other healthcare agreements WOZO and GALA), appropriate care entered its next phase in 2022, progressing from thinking to doing. All the stakeholders are working together to provide appropriate care. The National Health Care Institute is working on or involved in the implementation of a large number of IZA agreements. Our main task is to make sure that the insured package is managed appropriately. Appropriate package management means that we no longer only ask whether care works and for whom but also impose conditions on how care may be provided and by whom.

Another result of the Integrated Care Agreement (IZA) is the action plan to follow target groups. This is based on the agreement of the different parties to monitor the results of the agreement. The aim is to monitor the effects of all efforts on people's health and on the financial and personnel sustainability of the healthcare system over the next 5 to 10 years. The five target groups are:

- People with limited health literacy
- People with mental health problems
- People with cardiovascular disease or at risk of it
- People with or at risk of cancer
- Elderly people with fragile health

Since appropriate care equals sustainable care more attention is also given to reducing the cost of climate and environmental impact in healthcare. Value-based healthcare includes these impacts, as well as social and economic costs in the equation, known as 'triple bottom line (Mortimer, 2018).

1.4 Reader's guide

The International Agenda 2024/2025 contains 8 chapters. Chapter 1 provides background information to this document. Chapter 2 presents our international strategic collaborations and our reasons for collaborating internationally. In the following chapters we will refer to these reasons and connect them to the organisations we collaborate with. Chapter 3 generally describes our international activities, clustered by topics that focus on health package management. Chapter 4 describes our activities in the field of quality of care. Chapter 5 describes our activities in the field of the digital transformation in healthcare. Chapters 3-5 also include our positions and actions to clarify the direction the National Health Care Institute will choose in 2024/2035. Chapter 6 provides an overview of networks and projects relevant to us. Chapter 7 contains a list of international publications from 2022 and 2023 to which National Health Care Institute colleagues have contributed. Chapter 8 is for the acknowledgments.

During 2024 and 2025 the objectives for each topic will be evaluated, including the corresponding international networks. This evaluation will act as input for the next International Agenda and international activities will be adjusted, where necessary.

2. International strategic collaborations

This chapter describes our main international activities and how international collaboration benefits our activities.

2.1 Package management and HTA

Many of our international activities focus on our tasks related to healthcare package management, including prices of medicines and Health Technology Assessments (HTA). Taking into account the fact that most pharmaceutical companies operate internationally, collaboration with other countries is crucial. The market authorisation for new medicines is assessed by the European Medicines Agency (EMA), making this a European matter rather than a national one. This is amplified by the EU HTA Regulation.

Pharmaceutical spending per capita in the Netherlands (and other countries) is rising due to many new drugs coming to the market and the high prices often associated with them threatening the affordability of healthcare[6]. Preserving an affordable healthcare system through for example risk adjustment focused on our package management tasks, therefore remains one of our international priorities in forthcoming years.

The National Health Care Institute is committed to national and European legislation[7] to reduce the climatic and environmental impact of medicine use, to reduce spillage, to inform patients and eliminate inappropriate care such as overtreatment or prolonged chronic use.

The next sections describe our most prominent international activities related to package management and HTA, including the relationship between data and package management.

2.1.1 The Regulation (EU) 2021/2282 on health technology assessment (EU HTAR)

We are currently in the implementation phase of the EU HTAR. The Coordination Group has been formed along with the subgroups. The Coordination Group oversees the work that is done in the subgroups in the area of Joint Scientific Consultations (JSC), Joint Clinical Assessments (JCA), Identification of Emerging Health Technologies (EHT) and the Development of Methodological and Procedural Guidelines. The National Health Care Institute is an active participant in all the subgroups and the Coordination Group during this preparatory phase and intends to continue from January 2025, as the Regulation applies from 12 January 2025 for oncology medicines and ATMPs. We actively engage in discussions at the EU level during this preparatory phase. We deliver the co-chair for the JCA-subgroup. We value that the Regulation starts with oncology medicines as people with cancer is one of the groups that we monitor as a result of the Integrated Care Agreement (IZA), see also paragraph 1.3.

Additionally, we are taking preparatory measures within our organisation. For instance, we have formulated our ambition regarding the Joint Clinical Assessment (JCA) subgroup. By 2025, we aim to take on the role of (co)-assessor three times in the field of ATMPs. Furthermore, we are consulting with stakeholders to explore how we can make the most efficient use of the JCA reports and the impact on the HTA process in the Netherlands. Stakeholders involved include patients, medical organisations, health insurers and health technology developers. We are preparing our employees through internal workshops and external courses. We are also in discussions within the Beneluxa- initiative on how to utilise the JCA reports in this context.

It is clear that the EU HTAR is an opportunity for collaboration in the area of medical products and medical devices. But we also acknowledge that there is still a lot to be done in European cooperation to ensure the success of the EU HTAR. We will be part of and witness to these developments in the coming years.

2.1.2 Heads of HTA Agencies Group (HAG)

The Heads of HTA Agencies is an independent group of 32 European healthcare agencies working together to advance strategic collaboration in HTA. The HAG derives from HOFA (EUnetHTA Heads of HTA Agencies) and was established under EUnetHTA JA3 and aims, among other things, to support the development of the basis for joint work on all HTA within the EU HTAR. With the ending of the EUnetHTA Consortium, the

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6 OECD: 'Health at a Glance: 2021' (2021)

7 Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy and The Urban Waste Water Treatment Directive (UWWTD) (Council Directive 91/271/EEC)

National Health Care Institute also ceased its function as HAG secretariat. Agencies from Portugal (INFARMED), France (HAS) and Sweden (TLV) took over this task. The HAG will exist at least until the application of the EU HTAR Regulation in 2025, and possibly longer if it is decided to maintain the group alongside the Coordination Group.

2.1.3 The Beneluxa Initiative

For many years we have been an active member of the Beneluxa Initiative. This is a partnership between Belgium, the Netherlands, Luxembourg, Austria and Ireland. The aim of the Beneluxa Initiative is sustainable access and appropriate use of high quality and affordable medicines in the participating countries. The Beneluxa Initiative members work together on all aspects relevant to decision-making for pharmaceuticals, including horizon scanning, HTAs, information sharing and policy exchange, and pricing and reimbursement agreements. International collaboration on HTA is (with the EU HTAR) becoming more important in Europe. Regional collaborations with a select group of countries with a broader scope such as Beneluxa Initiative can strengthen the position of participating countries. Therefore, this initiative will be important for the National Health Care Institute in the coming years.

2.1.4 International Horizon Scanning Initiative (IHSI)

The National Health Care Institute is a full member at IHSI and is chair of the Executive Committee (EXCO) and Board of Directors of the international horizon scanning initiative. This initiative was set up by the Dutch Ministry of Health, Welfare and Sport. To ensure the quality of the database we participate in the Quality Management Committee (QMC) of IHSI and give ECRI feedback on which items to improve. ECRI is an independent, nonprofit health services organisation and was chosen by IHSI to develop the IHSI database. This database creates awareness of which new drugs will come to market within the next two to five years. This enables decision-makers and HTA organizations to better understand forthcoming innovations and their influence on currently available products, but also to use the data to lower prices.

2.1.5 International GRADE working group

The National Health Care institute has been active for many years in the GRADE working group, a global working group with participation by countries and institutes that (like the Netherlands) apply GRADE as their assessment method. The main office of the GRADE working group resides at the McMaster University in Canada, and prominent institutes like the WHO partake in this working group. The working group collaborates to continuously improve the GRADE method and produces international guidance to apply this method. Products like the WHO's Essential Medicines list and international strategies for evidence ecosystems are also created with input from this working group. Evidence Ecosystems are the blueprint for our cyclic health package management. Participation in this working group therefore serves different purposes. It is important for the improvement of our assessment method, for the incorporation of the needs of our organization, and also for global consensus on important strategic topics.

2.2 How international collaboration benefits our activities

In a globalised world, international cooperation in the field of health is crucial, just like it is for many other subjects. Improved collaboration allows countries to share for example knowledge, resources and expertise, thus tackling challenges collectively. When collaborating with others, the National Health Care Institute believes it is important to have an impact that leads to valuable outcomes. When formulating our activities in the following chapters, we have tried as much as possible to focus on activities that lead to outcomes influenced by our activities and making those activities as effective as possible.

For us, working with other countries can have various benefits, depending on aspects such as the context and topic. We have defined five reasons for international collaboration. For each topic in Chapters 3, 4 and 5 we selected the most important two related to that topic.

Being stronger together

Collaboration makes the participating countries stronger than when they operate alone. This can for example be helpful in negotiations with large international pharmaceutical companies about prices and conditions of medicines.

Dividing the workload

Another reason is that working together with other countries allows the workload to be divided between those countries. One example is EU HTA Regulation, which has ensuring the efficient use of resources within the EU as one of its most important goals.

Influencing policy

By participating in international activities, the National Health Care Institute tries to influence European policy, leading to new policy that best serves the Dutch public. This is done by co-authoring or providing feedback on policy papers and positioning papers and by contributing to European and other agendas.

Obtaining knowledge

International collaboration can lead to new ideas and inspiration and it can help us keep up to date with the latest developments, even on our front runner activities. It is also useful to have a picture of reimbursement differences between countries and the reasons behind those differences. Reimbursement decisions are often discussed in the Dutch media and knowing the reimbursement schemes in other countries can create support for our own decisions and can help in explaining those decisions to the general public.

Sharing knowledge

Not only do we learn from other countries, but many countries look at the Netherlands when it comes to the organisation of health care. We regularly physically or digitally welcome international delegations that want to learn from the Dutch healthcare system, our role in that system and our ideas for improvement. These exchanges of information provide valuable lessons, both for the delegation and for us. In order to ensure that we are able to accept such requests in the future from organizations that can benefit most from our knowledge and experience, we have formulated guidelines for assessing such requests.

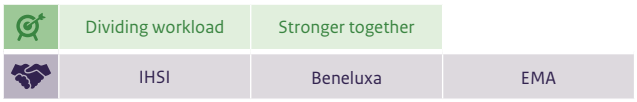
Another way of sharing our knowledge with other countries is by participating in international projects. Decisions as to whether we participate in new projects in the future, will be based on criteria that include whether the goal of the project is in line with our primary tasks and activities.

3. Healthcare package management

The National Health Care Institute performs health technology assessments and advises the Minister of Health, Welfare and Sport on whether to include or exclude medicines, interventions and medical devices in the basic package. We clarify the contents, boundaries and limitations of the healthcare package and advise on the healthcare system as a whole. This helps the Minister of Health to pursue government policy by implementing and amending legislation on the basic package. When in dispute about basic health package coverage, we make binding decisions on disagreements between health insurers and patients.

In order to fulfil these tasks related to healthcare package management, the National Health Care Institute works internationally on different topics as mentioned in the following paragraphs. As discussed in chapter 1, when performing our tasks related to healthcare package management, we use the appropriate care framework which describes what appropriate care is, how it should be delivered and who should be involved.

3.1 Horizon scanning



To ensure that patients have timely access to medical interventions, an expedient start of the HTA process with several necessary steps is crucial. Horizon scanning is an essential tool in this process. The Netherlands is actively scanning the horizon to anticipate the impact of emerging new medicinal products in a timely manner. To improve the efficiency and quality of this activity, for instance by sharing workload and obtaining more relevant information, the National Health Care Institute leads the international horizon scanning initiative (IHSI)[8], set up by the Dutch Ministry of Health, Welfare and Sport.

Initially, IHSI focuses on pharmaceuticals. However, the possibility of horizon scanning for medical devices[9] is being explored and options for international horizon scanning of (high risk) medical devices will be on the IHSI-agenda in the coming years. This is a priority for the National Health Care Institute.

The international collaboration between Austria, Belgium, Ireland, Luxembourg and the Netherlands in the Beneluxa Initiative[10], also uses horizon scanning to identify in good time forthcoming products to work on together (e.g. assessments and joint procurements).

International collaboration on horizon scanning is also ensured by the EU HTAR through the Emerging Health Technologies working group (EHT).

Positions and actions

- International horizon scanning for pharmaceutical products will contribute to the efficiency and quality of national Dutch horizon scanning.
- The National Health Care Institute actively encourages the foundation of fully transparent and publicly accessible international horizon scanning for pharmaceutical products and is for that reason actively involved in setting up IHSI.
- The National Health Care Institute encourages the use of IHSI within the EHT subgroup under the EU HTAR coordination group.
- In order to increase the available information on horizon scanning, early non-confidential information about new products from manufacturers should be made available. Collaboration with EMA to explore their role is recommended. HTA bodies can help EMA to determine what information is most relevant.
- The National Health Care Institute believes that horizon scanning of medical devices will become more important in the coming years and therefore will support further international horizon scanning of high-risk and expensive medical devices preferably through IHSI.

8 www.ihsi-health.org

9 *For this document we use a definition of 'medical device' that is in line with article 2 of the European Medical Device Regulation. Medical device category encompasses a wide range of products. In short, it encompasses all medical equipment, implants, assistive devices (medical aids), software, AI algorithms, and digital solutions which are used for specific healthcare or medical purposes and are subject to European Medical Regulation for market entry. Medicines and consumer products such as wellness apps are not part of our definition.*

10 www.beneluxa.org

3.2 Alignment and synergy with regulators (EMA)

	Influencing policy	Obtaining information			
	EMA	MEDEV	HTAi	ISPOR	EU HTAR

Market authorisation takes place prior to health technology assessments and reimbursement decisions. EMA has contact with pharmaceutical companies at an early stage and has detailed information about pharmaceutical products. This is relevant for the reimbursement process as well.

The National Health Care Institute, would like, in collaboration with other European national competent authorities on pricing and reimbursement, to increase collaboration with EMA. When the contact with companies and EMA in an early stage is strengthened, this stimulates information that is relevant for HTA organisations and payers being taken into account in trials. We often see products enter the market with limited added value compared to the current standard of care, leading to negative reimbursement decisions. Complementing post-launch evidence generation (PLEG) might be helpful in this. Together we would like to build on registries as a basis for follow-up and source of additional studies. The needs of HTA agencies in PLEG can be taken into account before market authorization. Therefore, as the National Health Care Institute, we were also actively involved in the DARWIN initiative from EMA in which we represented the payer community in the EU Darwin Advisory Board. This involvement was discontinued at the end of 2023.

In addition, we would like to exchange knowledge on methodology like the use of real-world data and on products. The National Health Care Institute is contributing to the discussion with EMA on what information is needed by HTA organisations and payers, about patient populations and comparators for example. This collaboration can be continued through other initiatives with which EMA also collaborates such as the EU HTAR, in particular on joint scientific consultations, and GetReal Institute on RWD/RWE in which individual regulators participate.

Positions and actions

- Governance structures and terms for data accessibility set by EMA should enable access to data for all stakeholders, with the aim of ensuring equal opportunities to use registry data for multiple purposes.
- As previously mentioned, we often see products enter the market with limited added value compared to the current standard of care, leading to negative reimbursement decisions. Increasing the bar for market entry might be useful for some products.

3.3 HTA methodology

	Obtaining knowledge	Sharing knowledge	Dividing workload		
	ISPOR	HTAi	H2020-HTx	SUSTAIN-HTA	EU HTAR
	GRADE Working Group				

The important basis of the HTA work we do at the National Health Care Insitute is our methods. These methods rely on international methods in epidemiology and health economics and will develop and change over the years. In order to keep our methods up-to-date and relevant we need to be involved in the continuous process of development of HTA methods. We are involved in European methodological projects, such as HTx, as part of the IMI and Horizon-2020 projects, but also participate in methodological activities as part of the EU HTAR or as part of international societies, such as HTAi and ISPOR. The National Health Care Institute hosted the HTAi Annual Meeting in Utrecht in 2022. In addition, we are involved in several more informal networks of HTA organisations that work together on specific topics or keep each other informed about their ongoing projects.

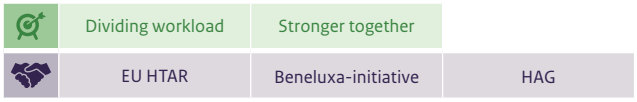
Specific attention should be given to several methodological topics such as the methods for using real-world data (RWD) (section 3.5), using patient registries for obtaining RWD (section 3.6), indication-wide assessments (section 3.7), determining how to assess personalised medicine (section 3.8) and developing price and reimbursement methods (section 3.9). Increasingly the inclusion of 'environmental aspects' in the assessment is taken into consideration. We will be involved in a new project that is funded by the European Union,

through the Horizon Europe Programme which is SUSTAIN-HTA (2024-2027). This project will focus heavily on the implementation of new, innovative, HTA methods in HTA practice and the National Health Care Institute will play an important role in this as a work package leader for implementation.

Positions and actions

- Reliable future-proof methods are essential for HTA. We therefore invest in sustaining existing methods and developing improved methods for new situations. Methods are in essence international and for that reason the National Health Care Institute needs to be involved in the most important organisations and projects that sustain and develop HTA methods.
- There are a number of areas needing specific methodological attention and in which the National Health Care Institute will invest such as RWD, patient registries, personalized medicine, developing price and reimbursement methods and a cyclic or iterative approach to HTA.

3.4 European HTA



In regard to our international activities, European HTA is the most important priority of the National Health Care Institute, and is therefore also described in strategic Chapter 2. In order to increase the efficiency of HTA in Europe, European collaboration is necessary. The National Health Care Institute has been actively involved in EUnetHTA[11], a collaboration between the 27 member states of the European Union, since its start in 2006. We were the coordinator of EUnetHTA Joint Action 3 (2016-2021), which came to an end in May 2021. In its two-year successor, EUnetHTA21, we also fulfilled an active role by leading this consortium and we were part of various working groups. This project aimed to facilitate the implementation of the EU HTAR that will be applicable in 2025 in which pharmaceutical products and medical devices will be jointly assessed. EUnetHTA21 functioned as a bridge between EUnetHTA JA3 and this regulation. We are currently preparing our processes in order to be ready for 2025, using our experiences with the templates and formats developed under EUnetHTA21. We also involve stakeholders, as we believe that it is important to work and learn together.

In the interim period and as of 2025, the National Health Care Institute is an active participant in all the subgroups, co-chairs the Joint Clinical Assessment Subgroup and actively participates in the Coordination Group. We have formulated our ambition regarding the Joint Clinical Assessment (JCA) subgroup and by 2025, we aim to take on the role of (co)-assessor three times in the field of ATMPs.

The Netherlands is also a member of the Beneluxa[12] Initiative. This is a collaboration between Belgium, the Netherlands, Luxembourg, Austria and Ireland on horizon scanning, HTA and price negotiations. The National Health Care Institute has prioritised the Beneluxa collaboration and contributes to the development of Beneluxa HTA. The collaboration on HTA concerns assessments, both pharmacotherapeutic and pharmaco-economic, and appraisal.

In September 2021 a new HTA-focused collaborative network for high-level strategic exchange and discussion was inaugurated, the Heads of Agencies Group (HAG). HAG is a strategic discussion and guidance body regarding EU HTA collaboration and supports the preparation of national systems and capacities for the adoption of the HTA Regulation. HAG derives from the Heads of Agencies (HOFA) established under EUnetHTA JA3. The entry into force of the regulation allowed the Commission to undertake the formal establishment of the Coordination Group, prior to the implementation of the EU HTA system, for the purpose of preparing all necessary elements for the functioning of a permanent EU HTA system. The legislation places a significant amount of decision-making power with the Coordination Group. The HAG is seen by its members as the predecessor of the future Coordination Group.

Positions and actions

- The National Health Care Institute will prepare its processes for the entry into force of the EU HTA regulation in 2025, together with stakeholders.

11 www.eunethta.eu
12 www.beneluxa.org

- We are an active participant in all the subgroups and the Coordination Group during the current preparatory phase and intend to continue this from January 2025, as the Regulation applies from 12 January 2025.
- Beneluxa HTA is prioritized for the forthcoming years. The National Health Care Institute will proactively further develop the Beneluxa collaboration.

3.5 Real-world data and evidence (RWD/RWE)

	Obtaining knowledge	Sharing knowledge			
	ISPOR	GetReal Institute	H2020-HTx	SUSTAIN-HTA	H2O

For many health technologies, only limited evidence on the effectiveness and cost-effectiveness is available at the time when a reimbursement decision needs to be taken. The reasons for this limited availability are many, but are for instance related to their applicability to small patient groups or the complexity of the health technologies involved. And even for health technologies for which sufficient evidence from clinical trials is available, uncertainties regarding effectiveness may remain. For those reasons, the use of data (routinely) registered in clinical practice, known as real-world data (RWD), may provide relevant information for evaluating or re-evaluating the value. However, there are still a lot of questions on the methodology for assessing RWD, its limited validity in substantiating effectiveness, and the usability (and quality) of the real-world data (RWD) which is the starting point for generating evidence (RWE). Therefore, it is necessary to optimize current methodologies and develop other new methodologies and to evaluate in which situations RWD are useful. In conclusion, further exploration of the possibilities and limitations of using RWD and RWE is a focal point in 2024 and 2025. This will be done through involvement in international projects and activities such as the GetReal Institute, the ISPOR RWE working group, H2020-HTx and the new Horizon Europe SUSTAIN-HTA project. Given that RCT results can differ from use in practice, the use of RWD / RWE to monitor and evaluate use after a positive reimbursement decision is especially significant when the reimbursement is given based on certain conditions (i.e. cyclic package management).

Positions and actions

- Evidence from clinical trials should remain the gold standard. However, for some products the (additional) use of real-world data (RWD) for HTA may be beneficial. Further development of the methodology and the applicability of RWD needs more attention and will require collaboration with international HTA partners and other international stakeholders.
- The impact of the use of RWE on national decision-making should be shared between countries so that we can learn what the possibilities and limitations are for using RWE in making decisions on pricing and reimbursement of health technologies.

3.6 Registries

	Influencing policy	Stronger together		
	EMA	GetReal Institute	ISPOR	ERN

In order to obtain RWD, patient registries will become increasingly important as a starting point for products (pharmaceuticals and medical devices) for which the clinical information is limited when market entrance occurs. Especially in the case of orphan diseases, international cooperation on data collection is essential to obtain enough data to learn from this. Often it is important to know which national and international registries exist, and how national registries might be combined at a European level in order to deal with, for example, the problem of small patient groups at the national level.
Registries which can be used to evaluate drugs, should preferably be owned by physicians or patients. If however an international registry is owned by a pharmaceutical company, the data should be available publicly without unreasonable delay. It is also important that the registries are disease-based (not drug-based). The quality of the data and collection process should be of a high standard. When pharmaceutical companies are asked for additional information by EMA and need RWD, they should be able to use data from the registry. In this way, pharmaceutical companies are not forced to start their own data collection. The qualification process of a registry by the EMA is important to ensure the quality of the registry data.

The National Health Care Institute supports the current process of qualification of registries by EMA. Examples are the European Cystic Fibrosis Registry and the European Bone Marrow Transplantation Registry. In addition, when EMA asks for registries to be set up in order to assess the safety of pharmaceuticals they should support governance structures and terms for data accessibility enabling access to data for all stakeholders, with the aim of ensuring equal opportunities for the use of registry data for multiple purposes.

The European Reference Networks (ERN), which are networks for rare diseases, are setting up European registries. In 2024 and 2025, the National Health Care Institute seeks to explore how the ERNs and our need for registries can reinforce each other. Through the continued work on the Metachromatic Leukodystrophia International (MLDi) registry and other rare neurological disease registries we will actively contribute to the governance and funding of high-quality international registries for rare diseases.

Methodological criteria for patient registries can be used to support national programmes such as the management of disease-specific patient registries for monitoring expensive medicines. An example is the REQueST tool[13], developed under EUnetHTA JA3.

Positions and actions

- Registries should be set up more at a European level, should be disease-based (not drug-based), and should be available for use by different stakeholders. This is especially relevant for (ultra-)rare diseases.
- Also for international registries, healthcare providers or patients should be the owners of the registries, not pharmaceutical companies or manufacturers of medical devices. The work that has been done on MLDi can be used a starting point.
- The National Health Care Institute supports EMA's qualification of registries run by physicians, so that pharmaceutical companies can obtain the requested data without starting a new registry.
- Data collected in international registries should be presented according to FAIR (findable, accessible, interoperable, reusable) principles (see also section 5.2).
- Registries' data should focus on relative effectiveness, so that HTA bodies can use the data for reimbursement decisions.
- We support the qualification process of a register by the EMA to ensure the quality of the registry data.
- Tools and criteria that are already developed by other organisations should be used as much as possible, such as the REQueST tool that was developed under EUnetHTA.

3.7 Indication-wide assessments including a cyclic and iterative approach to HTA

	Obtaining knowledge	Sharing knowledge			
	H2020-HTx	GINAHTA	HTAi	ISPOR	SUSTAIN-HTA

A new approach to (pharmaceutical) assessment is indication-wide assessment, in which the assessment focuses on a certain illness or indication (disease models), including all (pharmaceutical) products for treating that illness or indication. This more holistic approach has the advantage that the assessment compares multiple and different (pharmaceutical) products designed for that indication, making the assessment broader and therefore more effective. Furthermore, assessing multiple products related to a certain illness or indication creates a more cyclic evaluation of the health insurance package, thus contributing to appropriate care. Some countries, e.g., Sweden, France, the UK, and the Netherlands, are experimenting with a cyclic approach including the use of disease models and it is important to learn how this approach might be used for package management and reimbursement assessments. This model could also be applied to medical devices. It is also important for these approaches to ensure alignment with the clinical guideline community.

Position

- The use of indication-wide assessments could be a more common method of assessment for reimbursement decisions, encouraging a more cyclic health package management approach based on appropriate care methodologies. Methodologies should preferably be developed in international collaborations.
- The National Health Care Institute will actively contribute to a cyclic and iterative approach to HTA as part of the lifecycle working group of HTAi.

13 https://eunethta.eu/request-tool-and-its-vision-paper/

- We will share our experiences with experimenting on a life-cycle approach with other HTA bodies that work on a life-cyclic approach such as NICE, TLV and CADTH. This may lead to further development of common approaches.

3.8 Personalised medicine

	Obtaining knowledge	
	H2020-HTx	SUSTAIN-HTA

Personalised medicine indicates treatments tailored to individual patients. In oncology, for example, increasing knowledge about mutations in genes is leading to an increased number of pan-tumour indications. Development of these medicines is increasing, as is their off-label use. As part of the national programme on Molecular Diagnostics (finished end 2023) the National Health Care Institute has outlined the assessment appraisal and reimbursement schedules for these kinds of products. We interact closely with other HTA bodies in Europe on this matter. In order to fully utilize the advantages of personalised medicine, availability of data is essential. Terms and conditions for use of data should be made on a European (worldwide) level. Also, data infrastructure terms and agreements should be made. The National Health Care Institute contributes to these terms, conditions and agreements on a national level but is convinced that their genericity makes international use possible.

Position

- HTA-methods and reimbursement models should be suitable for personalised (or precision) medicinal interventions and developed in an international context (Horizon 2020 project HTx).
- Further implementation of those models as developed in H2020-HTx and other international projects and initiatives will be discussed and initiated through SUSTAIN-HTA.

3.9 Models and methods for pricing and reimbursement

	Sharing knowledge	Obtaining knowledge			
	ISPOR	HTAi	HTx	Beneluxa-Initiative	PPRI
	EMA				

More and more HTA and payers are confronted with drugs the value of which is difficult to assess as there are considerable uncertainties surrounding their effectiveness, cost-effectiveness and efficacy. Conditional reimbursement and innovative payment models might help to provide access in a justifiable manner. Therefore alternative business and pricing models (e.g., pay for performance and outcome-based payments) are being explored in order to improve the current Dutch dichotomous model of reimbursement. As other countries are also confronted by these uncertainties, we see that several countries are working on managed entry agreements and payment models. International cooperation can support the development of models and schedules, and can also be useful when it concerns specific products. HTA and payers should exchange more information on substantive conditions and data collected post-launch. The National Health Care Institute will need to be actively involved in current and new initiatives that will address pricing and reimbursement models, for instance through the Beneluxa-Initiative and new Horizon Europe projects.

Positions and actions

- Development of new reimbursement and pricing models is useful to facilitate access to expensive health technologies while ensuring sustainability of the healthcare system.
- The development of conditional reimbursement (with e.g. managed entry agreements, personal reimbursement models) could be effected in international collaborations especially for treatments of (very) rare diseases.

3.10 Mechanisms for pricing of pharmaceuticals and medical devices

Stronger together			
Beneluxa-Initiative	MEDEV	PPRI	

Access to affordable medicines and medical devices must remain on the political agenda in order to guarantee the sustainability of European healthcare systems and the cost-effectiveness of these medicines and medical devices. For instance, small companies are often bought up by large firms that then increase prices significantly. Therefore, in order to keep Dutch healthcare affordable, it is important that sustainable and affordable prices are paid for pharmaceuticals and medical devices. European legislation on patents and the protection of intellectual property during a transfer should therefore be reconsidered. At the same time, national pricing and reimbursement mechanisms must be strengthened to ensure the sustainability of healthcare systems and patients' access to care. Payers have a key role to play in maintaining and safeguarding access for all insured persons to affordable and high-quality healthcare, including medicines, medical devices and other healthcare innovations (e.g., ehealth developments).

Furthermore, to reduce prices, joint negotiations with other countries may be necessary (e.g., through the Beneluxa-Initiative[14]).

HTA decisions need to be based upon reliable information. The lack of transparency on the price of comparative treatments will take away the basis of HTA-analyses. Furthermore the confidential price negotiations prevent payers from strengthening their position.

Positions and actions

- Smaller manufacturers of (orphan) drugs should, within legal boundaries, be actively supported in order to prevent large companies from dominating markets and setting (exorbitant) prices.
- Where deemed relevant, the National Health Care Institute supports increased transparency of legal frameworks for intellectual property, reference pricing mechanisms and alternative payment models at both a European and international level.

3.11 Orphan Medicinal Products and Advanced Therapy Medicinal Products

Stronger together	Influencing policy				
MEDEV	HTAi	H2020-HTx	ERN	EU HTAR	

An increasing number of drugs are orphan medical products (OMPs) that target small and very small patient groups. Patient groups with (inheritable) rare diseases are often very heterogeneous. Because of the small patient groups, there might be hurdles to obtaining sufficient data. Furthermore, there is often a lack of relevant or valid outcome measures and long-term effectiveness is unknown. Especially for advanced therapy medicinal products (ATMPs) the uncertainties about long-term effectiveness hamper the assessment of the value of the products. In addition, orphan drugs are often expensive. Current frameworks for assessment or appraisal may need to be studied to see whether adaptations are needed to allow better assessment of orphan drugs.

Furthermore, greater numbers of drugs are being defined as orphan drugs, which gives manufacturers years of exclusivity and opportunities to demand higher prices. In this context, orphan drug regulations are sometimes misused. What frequently happens after negotiations is that the number of indications is increased, leading to a larger group of patients being eligible for reimbursement, but still at the initial high orphan drug price. Collaboration between countries is necessary to stop such mechanisms, e.g., by limiting patent periods when extra indications are added. The orphan drug regulations should therefore be evaluated and amended by, e.g., revising the current prevalence threshold, combining the current criteria for orphan designation (prevalence and expected low return of investment), including a refined definition of 'significant benefit' and by regularly reviewing market exclusivity.

14 www.beneluxa.org

The National Health Care Institute is taking steps at both the national and international level to develop methodologies and approaches to the assessment, appraisal and reimbursement of potentially curative interventions. The development and refinement of such approaches is being done in collaboration with other HTA agencies and payers.

Positions and actions

- Orphan drug regulations should contain mechanisms by which those regulations can no longer be misused. The National Health Care Institute wants to participate in these discussions through its relevant networks.
- Methodological approaches, both in HTA as well as in pricing and reimbursement, should preferably be developed through international collaborations on orphan drugs and in particular on ATMPs.
- The National Health Care Institute wants to have an active role in the assessment of ATMPs within the EU HTAR.

3.12 Medical devices

	Influencing policy	Obtaining knowledge			
	INAHTA	H2020-HTx-project	HTAi	ISPOR	EU HTAR

The pace of development of new medical devices is increasing. Each year, a growing number of devices and technical modifications to existing medical devices enter the market[15] and expectations are that this trend will continue in the next few years. In 2017, the European Union Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) were adopted. Drivers of this legislative paradigm shift were a desired increase in the safety of medical devices, more transparency as well as better long-term monitoring possibilities. This new regulation aims to improve the safety of medical devices and the transparency of the market entry system in Europe, e.g., by getting Member States to implement a harmonised notification process for notified bodies, and by applying the new scrutiny mechanism. Transparency, with a wholly or partly publicly accessible European database for medical devices (EUDAMED), has a key role in ensuring the safety and traceability of health technology.

The MDR became applicable on 26 May 2021, with a transition period for legacy devices lasting until 26 May 2024. However, discussions are ongoing to prolong the transition period. In-vitro diagnostics needed to be compliant by 26 May 2022. Higher risk devices (class D) and certain influenza tests (class C), have a transition period until May 2025 and 2026 respectively, whilst lower risk devices (e.g. class B and A sterile devices), have a transition period until May 2027. One of the biggest hurdles for the MDR and IVDR were the certification and training process of notified bodies, ultimately resulting in delays and lengthy waiting times for manufacturers. Implementation of these new regulations and monitoring its consequences is a focus point of the Dutch Ministry of Health, Welfare and Sport. The National Health Care Institute is monitoring the implementation process, in relation to its tasks in health package management and the quality of care. The new regulation concerns market entry only and does not provide for a centralised authorisation procedure for the reimbursement of medical devices.

Because of the increased pace of the introduction of new medical devices onto the market, the option of European horizon scanning for medical devices needs to be explored. See section 3.1 for more information on horizon scanning. The methods used for pharmaceutical horizon scanning may be partly adopted, the nature of this field is different compared to that of the pharmaceuticals. It is also important to pay attention to post-marketing surveillance after introduction.

Faster availability and patient access to relevant innovative medical devices is important, without losing sight of safety. More and better research when it comes to medical devices needs to be done to narrow the evidence gap for assessing the effectiveness of medical devices (in particular those with a medium or high risk).

15 *For this document we use a definition of 'medical device' that is in line with article 2 of the European Medical Device Regulation. Medical device category encompasses a wide range of products. In short, it encompasses all medical equipment, implants, assistive devices (medical aids), software, AI algorithms, and digital solutions which are used for specific healthcare or medical purposes and are subject to European Medical Regulation for market entry. Medicines and consumer products such as wellness apps are not part of our definition.*

Positions and actions

- Horizon scanning should take place at a European level, not only for pharmaceuticals but also for medical devices and healthcare innovations (e.g., telemedicine, robotics, AI, wearables), to anticipate the introduction of these new devices and provide timely market access.
- A centralised authorisation procedure for the market entry of high-risk medical devices (such as implants) is necessary to anticipate the growing number of new medical devices. At the same time, national pricing and reimbursement mechanisms must be strengthened to ensure the sustainability of healthcare systems and patients' access to care. This centralised authorisation procedure should be obligatory in European procedures, but not in national procedures.
- The creation of a European database for medical devices (EUDAMED) that is fully accessible to patients and healthcare providers is crucial. Since EUDAMED is delayed, we are actively monitoring the developments.
- Although reality is complex, it is desirable that clinical evidence is available for high-risk medical devices (classes IIb and III, IVD: C and D) at the time of market approval (CE marking) if it is needed for reimbursement decisions.
- Patient-relevant data (at least for the treatment approach as such, if not for a specific product) should be available at the time of market access. Data that may be missing should be provided by trials set up by manufacturers. These obligations should be communicated or mandated directly by the responsible notified bodies when setting up the post market clinical follow-up (PMCF), and should be part of any manufacturer consultation.
- Awareness of the importance of medical devices as part of healthcare should be increased at the national and international levels, as soon as their safety, effectiveness and neutral climate and environmental impact are reliably established.
- Horizon scanning of medical devices will also be part of the EU HTAR.

4. Quality of care

From 1 April 2014 onwards, the National Health Care Institute has been tasked with the legal responsibility to improve the quality of Dutch healthcare. We do so by improving transparency of care and guiding patients in their search for high-quality care. Patient-centeredness is key here.

We actively encourage the coherent development and implementation of guidelines and indicators and publish data on the delivered quality of care online[16]. Agreements on what constitutes high-quality, appropriate care as well as how to organise and deliver it are formulated in guidelines. Coherent indicators can then be used to measure the specific quality of the care delivered. In the Netherlands private parties in healthcare (organisations of patients, healthcare providers and insurers) are responsible for the development of guidelines and indicators. The National Health Care Institute has various legal instruments to stimulate the development of guidelines and indicators. If the stakeholders are unable to reach an agreement, irrespective of the reason, we can take the lead in developing a quality standard. Increasingly, ecological metrics are taken into account when revising or developing guidelines.

4.1 Creating insight into the quality of care

	Obtaining knowledge		
	GIN	GINAHTA	GRADE Working Group

One of our legal responsibilities is to provide insight into the quality of care and make information available for patients that supports informed decisions. Currently we administer a database with data that are delivered to us by healthcare providers according to predefined indicators, which are defined by patients, healthcare providers and health insurers. The data in the database should lead to information that can help patients to choose between different healthcare providers or treatments that are available to them. There is room for improvement when it comes to optimal use of data to improve the quality of care. In our analyses on how we, as a governmental agency, should contribute to this impetus we will also look at international examples and best practices. We will use our connections with GIN and GINAHTA, among others, to share and collect international experiences, guidelines and quality indicators.

Improving the impact on climate and environment is to be seen as quality improvement implied by appropriate care. Making healthcare more sustainable is an urgent process that makes use of theories, models, concepts and tools from the quality improvement impetus (cf. ISQua, IHI). The National Health Care Institute facilitates and stimulates their application in greenifying the healthcare routine.

Positions and actions

- The responsibilities and legal instruments of the National Health Care Institute need to be executed in the way that generates most impact on quality of care and offering appropriate care to patients.
- Transparency on outcomes of care is important. This outcome information empowers patients to choose the most appropriate care and healthcare provider.
- Besides patients, information about quality of care also needs to be available for healthcare providers so they can learn from it, for improving the organisation of appropriate care and outcomes, and for health insurers for healthcare procurement.
- For the finetuning of our instruments and legal responsibilities the National Health Care Institute will consult international examples and best practices.

4.2 Collaboration between government and private parties in healthcare

	Obtaining knowledge	Sharing knowledge
	GINAHTA	GRADE WG

16 https://www.zorginzicht.nl/openbare-data

An important topic of our work is the collaboration and division of responsibilities between government parties (ours specifically) and patients, healthcare providers and health insurers. In the collaboration on improving the quality of healthcare between public and private parties they each have a separate role. The private parties describe in guidelines within the legal framework, how appropriate care is given and implement those guidelines. To represent the public interest we need to know what is going on in society. Our vision, actions and instruments need to contribute to what happens for example in a doctor's office. On the other hand, to make sure our work leads to actual improvement in the quality of care, we need to work together with patients, healthcare providers and health insurers to implement improvements in healthcare practice. Therefore, we want to find the right way to collaborate with these stakeholders in healthcare, each with their own responsibility. Mutual clarity on the division of responsibilities is important to get an agreement about the collaboration. Information on how government organizations in other countries collaborate with private parties on the same subject, their learning systems, and the agreements that they have, could help us reinforce this collaboration in the Netherlands. Our participation in the GINAHTA working group has resulted in a Lancet publication (2022) on the collaboration of different stakeholders within the evidence ecosystem to improve cyclic simultaneous updates of HTA recommendations and medical guidelines.

Positions and actions

- The National Health Care Institute represents the public interest by focusing on quality, sustainability, accessibility and affordability of care.
- We are interested in collaborations and learning systems between public and private parties in other countries and will share the lessons obtained.
- In 2024 and 2025 we are exploring which additional international collaborations could benefit our work in the area of quality of care, and how we can contribute to them. Interesting subjects to look at in an international context are, among others, shared decision-making, 'green' healthcare practices and value-based healthcare.

5. Healthcare's digital transformation

Healthcare systems across Europe are facing unprecedented pressure[17]. While the quantity and quality of care have improved, the scale and complexity of healthcare needs have grown, with public expectations of more personalised and convenient services. At the same time, staff and other resources have become increasingly constrained, and the gap between supply and demand has grown. Most countries look to digital transformation to close this gap, but progress has been slow, and the digital maturity of providers, both within and between countries, varies widely.

In most countries, the COVID-19 pandemic has exacerbated these workforce pressures. Hospitals had to reorganise their services in the shortest time frames. Moreover, the absence of suitable treatments and the risks and fear of contracting the virus have increased physical and mental health pressures, impacting the capacity of the workforce still further. Over the past decade, healthcare has been shaped by the emergence of many life-extending and life-enhancing therapies and medical technologies, leading to improved health outcomes and increased costs. The pace and scale of innovation have accelerated with the development of health technologies such as digital medicine, genomics, robotics and artificial intelligence.

Research shows that Dutch hospitals have reached a high level of maturity (based on the Electronic Medical Record Adoption Model (EMRAM) of HIMMS[18]). Hospitals that are more digitally mature perform better in relation to patient safety measures. It shows that they are better positioned to create a learning healthcare system. Based on the work of our project, Governance on registries (RoR), there is still a need for major improvements in user-friendly and process-oriented registration that is standardised and structured. Nowadays doctors need to a lot of copy-paste work for their files, even for order management. As a result data managers are needed to get high quality data for registries. Local examples show that if the registration process is optimised to support the doctors, automated data delivery for registries is possible.

5.1 The European Health Data Space

The European Health Data Space (EHDS) is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at:

- empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support for their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high risk AI systems (primary use of data).
- providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data).

Currently, the level of digitalisation of health data in the EU varies from one member state to another, making it more difficult to share data across member-state borders. The proposed regulation requires all electronic health record (EHR) systems to comply with the specifications of the European electronic health record exchange format, ensuring that they are interoperable at EU level.

As such, the European Health Data Space is a key pillar of the European Health Union and it is the first common EU data space in a specific area to emerge from the European strategy for data. Both will impact the Dutch healthcare system given the demand from the EHDS to exchange the European patient summary cross border and the width of the defined secondary use goals (Chapter IV, section 1, article 33)[19], which includes the mandate for public sector bodies (article 34.1.b). Each country needs to establish a Digital Health Authority for primary use of data and a Health Data Access Body (HDAB) for the secondary use of data. Data holders need to make their data available for both the primary and secondary goals, this requires a step-up for the whole sector to make data interoperably available. If the regulation will be adopted in spring 2024, member states will have 5 years to update their legislation as well as organising the foreseen DHA and HDAB.

The Ministry of Health, Welfare and Sport is the lead for the negotiations for the EHDS. The Netherlands

17 https://www.ilabour.eu/blog/digital-transformation-in-european-healthcare/
18 https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/electronic-medical-record-adoption-model-emram
19 https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022PC0197

played an important role via the RIVM in the Joint Action Towards the European Health Data Space – TEHDAS [20]. TEHDAS2 is expected to start in May '24. The TEHDAS2 main objective of the joint action is to prepare the ground for the harmonised implementation of common measures, enabling the secondary use of health data in the proposed EHDS. The Ministry of Health, Welfare and Sport granted ICTU - an impartial consulting and project organization within the Dutch government. - together with RIVM, Nictiz and CBS the project to develop a proposal for the Dutch HDAP.

Currently, the National Health Care Institute primarily uses declaration data for analysis and has a desire for broader use of data – such as data from registries as well as public health data – given the transition to appropriate care. How to get access to this data in a privacy friendly matter is subject of study. Can we do this analysis federated with privacy enhancing techniques or do we need to request the data including pseudonymisation techniques where we are still able to couple data sources.

The HDAP impacts the Quality Registries as well as for example the KIK-V Programme in the care of the elderly. KIK-V is based on sector wide agreement and on a federative data system where data providers (read: primarily health care organisations) provide their data once in a datastation which can be analysed by all parties with a legitimate information need. The information requestor only get the answer, not the (raw) dataset. At first glance the way KIK-V has set-up its way of working matches the foreseen functions in the HDAP.

Position and actions

- In 2024 we will investigate the impact on our tasks, and how to prepare for the legislation
- We will also explore and discuss with the Ministry of Health, Welfare and Sport how this transition will interact with the implementation of the Wegiz and the information paragraph in quality standards and how we can support this transition

5.2 Data strategy

Our aim is to only allow care products (services, medicinal products, devices, and technology) into our healthcare system that have been proven to have added value to people's health. In order to do so, the National Health Care Institute needs data to evaluate the evidence that the care is provided according to the standard of care and science. The availability of data, data exchange options and new technologies are the basis for this. Together with the Dutch insurers we provide guidelines on how to evaluate these new (hybrid)services.

At the same time there is the rapid and unstoppable digital transformation of healthcare. In our vision the actual care delivery by professionals and healthcare information technology are integrated topics. Appropriate care is equal to appropriate data and appropriate technology. We integrate this digital transformation process into our own activities by, e.g., contributing to national legislation and agreements on information exchange and the architectural framework (reference architecture), - a framework for pharmaceutical registrations and our overall quality standard for digital healthcare solutions. The National Health Care Institute encourages the implementation of digital healthcare solutions because of its effects on increasing the accessibility and affordability of healthcare. Of course a guarantee for the quality of the digital forms of care is required. In addition, we explore the applicability of new technologies and innovations, build knowledge of AI and follow international developments.

In 2023 the National Health Care Institute updated its data strategy plan and vision for a data driven way of working. A growing quantity of data is being collected, both nationally and internationally. There are a lot of developments and opportunities for using data. It is therefore important to have a clear data strategy that will help to strengthen conditions for the proper and responsible use of data in healthcare and to further explore the benefits of data science in healthcare. In 2024 we will explore how these developments can

20 https://tehdas.eu/

benefit our activities in appropriate care projects, health package management (including the use of real-world data) and quality of care (e.g., shared decision-making) both on a national and an international level.

We monitor international trends, developments and projects in digital transformation, medical technology, eHealth, big data, AI, distributed learning, etc. Developments in these areas happen fast and it is important to keep up in order to support individual patients with data-based developments. The DARWIN-EU project to which the National Health Care Institute had been contributing until quite recently is a first stepping stone to a system whereby through federated data networks international data should become available for our purposes.

Position and actions

- The National Health Care Institute tries to exert influence on and contribute to developing European and international legislation, terms and conditions, agreements, frameworks and standards.
- We contribute to and learn from European research projects such as H2020 HTx, H2O, DARWIN-EU and TEHDAS2.
- We respond to European consultations.
- We examine connection points for Dutch legislation for interoperability in an international context.
- We will share, translate and introduce European and international use of the regulatory sandbox method to strengthen the integration of e-health as a regular part of the Dutch healthcare system. The basis for this will be on our collaboration with the UK Care Quality[21] Commission.

5.3 Interoperability

Interoperability is an important topic that is on the EU's agenda and the Dutch agenda. In 2023 the WEGIZ law was adopted – law for electronic information exchange in the medical care. The National Health Care Institute supports parties to develop an information paragraph for the Dutch quality of care standards. Information exchange issues are well-known, as exemplified by the thousands of unnecessary deaths each year due to medication errors. These medication errors are the result of an incomplete or incorrect medication overview. In 2023 medication transmission for the first adopted quality standard with an information paragraph. For the collection and comparison of quality data and other information for the public, it is important that agreements are made about the exchange of information. Other countries are facing similar problems. However, some countries have put together practices, for example Estonia, Sweden, Norway, Finland and Denmark.

To ensure correct interoperability, the EC composed an interoperability framework. The new European Interoperability Framework (EIF) describes 4 layers of interoperability:

- Legal interoperability: The EIF proposes that EU and national legislation and policies must be made clear, coherent in respect of one another and make good use of technology[22].
- Organisational interoperability: The EIF encourages public administrations to simplify their organisations, to streamline their processes and to listen to the needs of the business community and the general public.
- Semantic interoperability: The EIF calls upon public administrations to structure their data in commonly agreed formats.
- Technical interoperability: The EIF promotes the sharing and reuse of common infrastructures, services and IT-systems.

For each layer, we look at front-running countries and explore the best practices in those countries to learn from such and - where applicable – try to implement them in the Netherlands, in the same way as we currently do in the elderly care sector which we are planning to extend more broadly in the long term care (via the programme KIK-V). The National Health Care Institute looks for collaborations with countries to learn from the front-runners and to share our knowledge with countries who want to learn from us (for example our

21 Care Quality Commission (cqc.org.uk)
22 *The EIF structure also describes 12 underlying principles and 47 recommendations for improving interoperability*

sustainable information system, the architectural framework that is used nationally is inspired by EIF). Improvement in interoperability is necessary and can be achieved by focusing on standardisation, models and frameworks and architectural principles (Such as FAIR and registration agreements for multiple use and reuse, see previous paragraph and the model dataset and agreement sets developed for KIK-V).

There are new and innovative ways to improve the exchange of information and data. The National Health Care Institute sees promising developments, from data exchange to data visiting. We want to understand the capabilities of these innovations, the impact they will have and the possible opportunities and threats of these new innovations. The volume and complexity of data are growing at an exponential rate. There is an increasing acknowledgement of the importance of making healthcare data findable, accessible, interoperable and reusable (FAIR) to make data unambiguous and reliable. Following the FAIR principles will help to improve data sharing. The Netherlands is one of the front runners in adopting the FAIR principles. We are interested in international collaborations in this respect and in sharing our knowledge on the FAIR principles.

Position and action
- In international projects, where possible, the FAIR principles should be leading when storing and sharing data. We encourages this within projects in which we are participating.
- We facilitate the rare disease registry MLD to become FAIR and interoperable with 2 other international registries.

5.4 International standards

	Obtaining knowledge	Sharing knowledge			
	HIMSS	IHE	GRADE WG	EHDS	OHDSI-OMOP

Using open and international standards helps to improve interoperability. It is important for us to follow international developments, and simultaneously to encourage international harmonisation endeavours.

Position and action
- Dutch healthcare should, where possible, be aligned with international standards (ontologies and/or classifications like SNOMED or technical standards such as W3C semantic web), instead of creating our own national standards.
- We follow international developments.

5.5 Innovation

	Obtaining knowledge	Influencing policy

The latest technological developments (especially when combined with a clear data strategy and good conditions for interoperability) will speed up the number of innovations in healthcare. This digital transformation will not only bring opportunities for improving healthcare (personalised medicine, AI, medtech, robots, green IT), but also some major challenges (privacy, ethical issues, security, climate impact, lack of scale-ups). In 2023 we published a report on the state of affairs in the Netherlands based on the digital healthcare Sandbox 2020-2022.[23]

To keep up with the latest developments in innovations with the use of technology and data, we also adopted a digital innovation strategy 'Datalogica'. The 'Datalogica' programme will conduct the following three main activities: 1. following national and international trends and developments in technology and data innovation; 2. mapping out international innovative initiatives and looking for good examples from which we can learn, in order to help stakeholders and individual patients. We are prepared to participate in initiatives or connect with other initiatives that are relevant to us and 3. initiating data-driven experiments that contribute to the (digital) transformation of healthcare.

In 2024 the two focus areas will be: Artificial Intelligence and eHealth.

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Positions and actions

- To keep up with the latest innovation developments, we follow international trends and developments in (data) innovation, map out international innovative initiatives and look for good practices from which we can learn.
- To support stakeholder interaction and dialogue on the responsible introduction and upscaling of healthcare innovations from an early stage.

6. Networks and projects

The National Health Care Institute participates in a variety of international networks and projects, each of which is described below. If a certain network or collaboration focuses on a specific topic, that network is listed above the topic described in Chapters 3, 4 and 5.

Beneluxa-initiative (www.beneluxa.org)

Objective: HTA cooperation and information exchange.

Agenda:
- Short statements, collaboration on horizon scanning and early HTA.
- Conducting assessments together, dividing the work load .
- More information-sharing (practically about processes, and strategically).
- More information-sharing about products (between assessors).
- More combined price-negotiating (and joint assessment in order to realise this).
- Horizon scanning at a European level.

Our involvement: Active member. Beneluxa is one of our prioritized collaborations.

The Regulation (EU) 2021/2282 on health technology assessment (EU HTAR)

Objectives:
- Providing a legal framework facilitating the collaboration between Member States in the area of HTA. The governance-structure consists of the Coordination Group and four subgroups, for:
  - Joint Clinical Assessment (JCA).
  - Joint Scientific Consultations (JSC).
  - The development of Methodological and Procedural Guidance.
  - The Identification of Emerging Health Technologies (EHT).

Our involvement: The National Health Care Institute participates actively in all the subgroups, the Coordination Group and the Comitology Committee during this preparatory phase and intends to continue from January 2025, as the Regulation applies from 12 January 2025 onwards. We actively engage in discussions at the EU level during this preparatory phase. The EU HTAR is one of our prioritized collaborations.

EIF (European Interoperability Framework, www.ec.europa.eu/isa2/eif_en)

Objective: To give specific guidance on how to set up interoperable digital public services.

Agenda:
- To offer public administrations 47 concrete recommendations on how to improve governance of their interoperability activities.
- To establish cross-organisational relationships, streamline processes supporting end-to-end digital services.
- To ensure that interoperability efforts are not compromised by either existing or new legislation.

Our involvement: Member.

EMA (European Medicines Agency, www.ema.europa.eu)

Objective: to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union.

Agenda:
- Facilitate development and access to medicines.
- Evaluate applications for marketing authorization.
- Monitor the safety of medicines across their life cycle.
- Provide reliable information on human and veterinary medicines in lay language.

Our involvement: Informal representative of the HTA community and collaborative partner.

European Reference Networks (https://ec.europa.eu/health/ern_nl)

Objective: European Reference Networks are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources.

Our involvement: Advisory Board Member.

G-I-N (Guidelines International Network, www.g-i-n.net)

Objective: to lead, strengthen and support collaboration in guideline development (including technology assessments and appraisal), adaptation and implementation.

Agenda:
- Facilitating networking, the exchange of knowledge and improving methodology.
- Promoting excellence, helping to create high-quality clinical practice guidelines that foster safe and effective patient care.
- Sharing a wide variety of support tools and publications to enhance guideline development and knowledge-transfer.

Our involvement: Member.

GINAHTA (Guidelines International Network Heath Technology Assessment,
www.g-i-n.net/working-groups/ginahta)

Objective: to explore common methods and facilitate collaboration and the sharing of products between the HTA (represented by INAHTA) and guideline communities (represented by G-I-N).

Agenda: The working group acts as a facilitator to unite efforts of the HTA and the guideline community by:
- Identifying common methods (including assessment and appraisal methods).
- Identifying complementary aspects between the products of both communities.
- Detailing a platform for promoting collaboration and sharing products.

Our involvement: Member.

GO FAIR (www.go-fair.org)

Objective: To contribute to and coordinate the coherent development of the Internet of FAIR data & services through community-led initiatives in different activity streams.

Agenda:
- Support for the creation and running of GO FAIR Implementation Networks (IN).
- Ensuring optimal coordination between existing initiatives that target the development and implementation of components of the Internet of FAIR Data & Services.
- Advocating and supporting choices compliant with the FAIR guiding principles.

– Focus on early developments in the European Open Science Cloud (EOSC) with a global perspective.

National Health Care Institute's involvement: Observer.

Heads of Agencies (HAG)

HAG

Objective: HAG is a strategic discussion and guidance body regarding EU HTA collaboration and supports the preparation of national systems and capacities for the adoption of the HTA Regulation.

Agenda:
- Supporting the development of the basis for joint work on all HTA activities at EU level within the model of EU cooperation anticipated by the Regulation on HTA.
- Supporting the preparation of national systems and capacities for the adoption of the HTA Regulation.
- Supporting the joint work performed at the technical and scientific level by HTA bodies across Europe.

- Advising policy makers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA.

Our involvement: Member.

GRADE working group (www.gradeworkinggroup.org)

GRADE

Objective: to improve and extend GRADE methodology (technology assessment and appraisal) and to spread the use of GRADE methodology in health guidelines, HTA and systematic reviews.

Agenda:
- Creating opportunities for support.
- Helping GRADE networks/centres (e.g., Dutch GRADE Network) with training, promotion, dissemination and implementation of GRADE.
- Providing methodological support for national, regional or professional organisations.
- Specific project groups on e.g., Non-Randomized Studies, Economic Evaluations (cost-effectiveness).

Our involvement: Member.

H2O (health-outcomes-observatory.eu)

H2O

Objective: To empower patients with tools to monitor their outcomes independently, to promote the use of their outcomes in decision-making with clinicians, to create transparency of outcomes to facilitate value-based healthcare models and to create an ethical governance model for patient-reported health data in the interest of patients, science and society.

Agenda:
- H2O aims to create a robust data governance model that gives patients control of their data and enables ethical, secure analysis of the data when patients consent to this, in the interests of society, science and patient care. Standardised and structured health data will be available for analysis in order to enhance health research prospects, promote the development of new treatments that reflect outcomes reported by patient and sustain more efficient healthcare systems.

Our involvement: from 2022 – 2024: Observer. From 2024 – 2026: Representative of governmental organizations in the Board.

HIMSS (Healthcare Information and Management System Society, www.himss.org)

HIMSS

Objective: Reform the global health ecosystem through the power of information and technology.

Agenda:
- Providing expertise in health innovation, public policy, workforce development, research and analytics to advise leaders, stakeholders and influencers from across the ecosystem on best practices.
- Delivering key insights, education and engaging events to healthcare providers, payers, governments, start-ups, life sciences and other health services organizations, ensuring they have the right information at the point of decision.

Our involvement: No formal involvement.

Horizon 2020 HTx (Next Generation Health Technology Assessment, www.htx-h2020.eu**)**

Objective: Development of next generation HTA methods.

Agenda:
- To develop HTA methods that would fit to personalised (or precision) medicine.
- To test and implement these methods in the practice of HTA bodies.

Our involvement: Lead of Work Package 4: Implementation into system and processes.

Horizon Europe SUSTAIN-HTA (Support Utilisation of Sustainable and Tailored Innovative methods for HTA)

Objective: to build a supporting infrastructure to ensure ongoing implementation of the latest and fit-for-purpose Health Technology Assessment (HTA) methodologies and tools in HTA practice.

Agenda:
- Creating a sustainable framework to understand the needs of European HTA bodies for new innovative HTA methods and tools
- Aligning the needs with the development of methods and tools by academic groups

Our involvement: Lead of Work Package 2: Implementation

HTAi (Health Technology Assessment international, www.htai.org**)**

Objective: To foster international scientific collaboration on HTA.

Agenda:
- Further development of HTA methods, for example, deliberative processes in HTA.
- Interaction with stakeholders such as patients and technology producers, on HTA methods and implementation (HTAi Policy Forum).
- Sustainable healthcare systems.

Our involvement: Member of the Board, participation in annual conference.

IHE (integrating the healthcare enterprise, www.ihe.net**)**

Objective: Enable seamless and secure access to health information that is usable whenever and wherever needed.

Agenda:
- To improve healthcare by providing specifications, tools and services for interoperability.
- To engage clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions for vital health information needs.

Our involvement: No formal involvement.

IHSI (International Horizon Scanning Initiative, www.ihsi-health.org)

Objective: Horizon scanning aims to highlight important pharmaceutical and medical technology innovations before they reach the market by continuously gathering data and analysing research and literature. This gives a better picture of expected costs and allows timely decision-making and (joint) price negotiations.

Our involvement: Chair of the Executive Committee and Board of Directors and participant in the Quality Management Committee. IHSI is one of our prioritized projects.

ISPOR (The Professional Society for Health Economics and Outcomes Research, www.ispor.org)

Objective: To further develop tools for health economic assessments and outcome research.

Agenda:
- Development of methods of RWE and their implementation in HTA practice.
- Refinement of health economic models and their use in decision-making.
- Increase interaction between method developers, for example, academics and consultancies, and users such as HTA bodies.

Our involvement: Member, representative in the ISPOR HTA Roundtable Europe, participation in annual European Conference.

ISQua (International Society for Quality in Healthcare, https://isqua.org/)

Objective: learn from and share with the international network of professional and scientific healthcare improvement professionals.

Agenda: co-production of a Green Paper on sustainability and healthcare quality improvement.

Our involvement: co-authorship, participation in annual conference, keynote lecture.

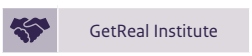
INAHTA (International Network of Agencies of Health Technology Assessment, www.inahta.org)

Objective: To enhance collaboration between international HTA bodies.

Agenda: We are co-producing a White paper on 'green HTA' to be published in 2024. To facilitate the exchange of methods and processes between HTA bodies worldwide.

Our involvement: co-authorship, participation.

GetReal Institute (www.getreal-institute.org)



Objective: The GetReal Institute builds on the success of two IMI projects: GetReal and The GetReal Initiative, and brings together a wide variety of stakeholders to drive the sustainable development and adoption of tools, methods and best practices in the generation and use of RWE for better healthcare decision-making.

Agenda:
- To be a platform to reach common understanding and prioritisation of critical opportunities and challenges in the generation and use of RWE.

- To be an incubator and design lab for strategies and tools to clarify scientific and operational uncertainties in RWE approaches and methods.
- To provide high quality RWE education and training resources.
- Connecting RWE-related initiatives within Europe and beyond.

Our involvement: Member.

MEDEV (Medicine Evaluation Committee, www.medev-com.eu**)**

Objective: Informal information-sharing between the national bodies responsible for the assessment, pricing and reimbursement of medicines to support them in their role at a national level.

Agenda:
- Exchanges on ongoing and planned assessments for reimbursement, methodologies and pharmaceutical policy.
- Review of EU-level activities impacting on national assessment, pricing and reimbursement.
- Timely analyses of drug related trends and innovations, and political and legal initiatives of the European Institutions.

Our involvement: Member.

Pharmaceutical pricing and reimbursement information (PPRI, https://ppri.goeg.at/**)**

Objective: Sharing information on issues of pharmaceutical policies from a public health perspective.

Agenda:
- Generating and sharing evidence-based expertise and experience in policies, in particular related to pricing and reimbursement of medicines and medical devices. This is done through research, policy advice, knowledge-transfer to policy-makers, capacity-building, price data provision, development of glossaries, reporting systems and indicators and enhancing networks of public authorities.

Our involvement: Member.

TEHDAS II

Objective: To prepare the ground for the harmonised implementation of common measures, enabling the secondary use of health data in the proposed EHDS[24].

Agenda:
- The mission to bring together the best current knowledge in order to develop, in active cooperation, guidelines and technical specifications for common use by all members states and the Commission for the implementation of the European health data space (EHDS) on the secondary use of health data.

Our involvement: No formal involvement. Updates are provided via the Community of Secundary Use of the Information Board. We also maintain informal contacts.

24 TEHDAS2 project application submitted - Tehdas

7. List of publications National Health Care Institute colleagues contributed to (2022 and 2023)

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