National Health Care Institute

International strategic agenda 2022/2023

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Inhoudsopgave

1 Introduction

The Dutch health care system is based on the principles of a high level of access to care, and affordable, high-quality health care services. Everyone is obliged to take out medical health insurance and health insurers are obliged to accept every citizen. The National Health Care Institute (Zorginstituut Nederland, or ZIN) 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). ZIN's role in maintaining the quality, accessibility and affordability of health care in the Netherlands involves various tasks given by the Ministry of Health, Welfare and Sport. For more information about the tasks and activities of ZIN, please refer to the website[1].

The COVID-19 pandemic stimulated a discussion about the EU's current limited role in national health care systems, especially during a crisis. The EU is currently only playing a supporting role in health policy, a closely guarded competence of its member countries. The Commission's response to COVID-19 was a European Health Union package, encompassing various measurements: upgrading the European Centre for Disease Prevention and Control (ECDC), extending European Medicines Agency's (EMA) mandate[2], and creating a regulation that would make ad hoc emergency measures permanent. Another measure was the creation of a new agency, the Health Emergency Preparedness and Response Authority (HERA), inspired by its US counterpart Biomedical Advanced Research and Development Authority (BARDA), which can mobilize resources quickly in emergencies. These initiatives not only better prepare Europe for crises, but aim to increase solidarity as well, an important cornerstone for ZIN in health care.

1.1 Goals of this international strategic agenda (ISA) 2022/2023

When performing its tasks, ZIN participates with various other countries in an increasing number of international activities. This international strategic agenda (ISA) 2022/2023 was formulated to maintain focus on these international activities, and to decide which activities are relevant for ZIN and its tasks. The ISA describes relevant topics and international activities for 2022 and 2023 and succeeds ISA 2020. It also describes ZIN's position on relevant topics. As such, the ISA serves various goals:

- To provide an overview of ZIN's international activities in 2022 and 2023;
- To determine which international activities (e.g., international networks, projects and conferences) are relevant for ZIN's tasks and activities;
- To create awareness of the international corporate positions of ZIN for both colleagues as well as external stakeholders. This will increase ZIN's impact in international networks where agendas and joint positions are determined, and during ZIN presentations and workshops at conferences.

ZIN works together with other Dutch national bodies that focus on health care and that also participate in international activities[3].

1.2 Focus

The activities described in this ISA focus on 2022 and 2023, 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.

The geographical focus of ZIN's international activities is Europe, although countries outside Europe are not necessarily excluded.

1 english.zorginstituutnederland.nl/about-us
2 www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-ema-mandate-extension
3 *For example the Ministry of Health, Welfare and Sport, (Ministerie van Volksgezondheid, Welzijn en Sport, VWS), Dutch Healthcare Authority (Nederlandse Zorgautoriteit, 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).*

ZIN has also formulated a long-term research agenda. This ISA describes all relevant topics that ZIN focuses on internationally by, e.g., participating in international networks and projects. When a topic calls for research specifically, it is described as such in ZIN's long-term research agenda.

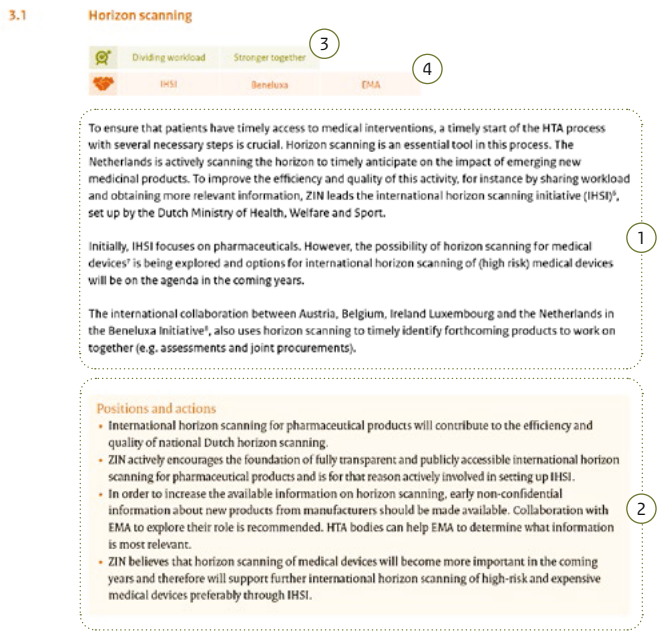
This ISA focuses on international activities that fall within ZIN's formal tasks, as assigned by the Ministry of Health, Welfare and Sport. This means that other healthcare related topics, however relevant they might be, may not be mentioned in this ISA, because they are not part of ZIN's tasks.

1.3 Reader's guide

This document contains 9 chapters. Chapter 1 describes the introduction and background information. Chapter 2 gives ZIN's vision for its international activities. Chapters 3 to 5 describe our international activities clustered by topics that focus on health package management (chapter 3), quality of care (chapter 4) and health care digital transformation (chapter 5).

When describing the topics in Chapters 3, 4 and 5, four different elements are shown (see picture below):

1. A short description of the topic and ZIN's focus in 2022 and 2023.
2. ZIN's positions on that topic (if applicable) and actions that need to be taken in order to steer the topic in the desired direction, i.e. align it with those positions.
3. Participation in international activities can have multiple objectives. However, the most important objectives for 2022 and 2023 for each topic are highlighted. These objectives are explained in the next chapter.
4. A list of international collaborations or projects in which ZIN is participating, which should help achieve the described objective of that specific topic.



A complete list of collaborations and projects in which ZIN participates, including descriptions, can be found in Chapter 6. Chapter 7 describes the sources, Chapter 8 a list of our 2020 and 2021 international publications and Chapter 9 the acknowledgements.

During 2022 and 2023 the objectives for each topic will be evaluated, including the corresponding international networks. This evaluation will act as input for the next ISA and international activities will be adjusted, where necessary.

2 ZIN's international strategy

This chapter describes why we collaborate with other countries and how that helps us achieve our goals. Corresponding topics are described in more detail in Chapters 3, 4 and 5.

Every person in the Netherlands is entitled to health care offered in the basic health insurance package. In order to guarantee the quality, accessibility and affordability of the Dutch health care system ZIN has, together with NZa[4], formulated 4 principles that should lead to the best appropriate care. The principles have been adopted as guidance for Dutch health care design by the Dutch government. These 4 principles are:

1. Appropriate care is value-driven: care should be delivered efficiently and effectively, with the aim of making gains that re relevant to the patient in terms of health and functioning, at a fair price.
2. Appropriate care is created together with and jointly around the patient: the ability of the patient is central to joint decision-making, with multidisciplinary expertise and viewed in the social context of the patient.
3. Appropriate care 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 if possible.
4. Appropriate care is 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).

These 4 principles translate into all our tasks related to package management and HTA (Chapter 3), quality of care (Chapter 4) and healthcare's digital transformation (Chapter 5). Our strategy and main focus regarding those topics and their international context are described in the paragraphs 2.1, 2.2 and 2.3.

2.1 Package management and HTA

Most of our international activities focus on our tasks related to health care package management, including prices of medicines and Health Technology Assessments (HTA). Taking into account the fact that most pharmaceutical companies are international or even global, collaboration with other countries is crucial, as we are stronger if we stand together. Also, the market authorization of new medicines is assessed by the European Medicines Agency, making this a European matter rather than a national one. Lastly, pharmaceutical spending per capita in the Netherlands (and other countries) is rising due to many new drugs coming onto the market and the often high prices often associated with them which threaten the affordability of health care[5]. Preserving an affordable health care system through for example risk adjustment, focused on our package management tasks, therefore remains one of our international priorities in the forthcoming years.

The next sections describe ZIN's most prominent international activities related to package management and HTA. Other activities are described in the next chapters.

2.1.1 *EU Regulation on HTA*

The EU Regulation on HTA entered into force in January 2022, and will apply from January 2025, using a progressive approach. The implementing phase has already started, including the setting up of the necessary governance structure by installing the Coordination Group and preparatory documents to ensure effective application from this date. ZIN is member of the Coordination Group together with our Ministry of Health, Welfare and Sports.

Project EUnetHTA21, which started in September 2021, functions as a bridge between EUnetHTA JA3 and entry into force of the regulation. As in EUnetHTA JA3 ZIN plays an active role in this project. We host the secretariat and are part of various working groups focusing on the scoping process and the assessment

4 *Dutch Healthcare Authority (Nederlandse Zorgauthoriteit, NZa)*
5 *OECD: 'Health at a Glance: 2021' (2021)*

report template. During EUnetHTA21 we will work on adopting formats that have been developed under EUnetHTA and fine-tuned under EUnetHTA21 in our own national processes.

One of the possible approaches in sharing workload in the forthcoming EU HTA collaboration is the formation of centres of excellence. Countries would then specialize in certain aspects or focus areas of HTA, making collaboration more efficient because expertise is brought together. If such an approach is pursued, ZIN will encourage the formation of such centres and is willing to be part of one or more centres of excellence. In 2022 we will discuss which focus suits us best, involving stakeholders where relevant.

Preparing for the application of the EU HTA regulation in 2025 is ZIN's international priority in the forthcoming years. We strongly support a European HTA system because it helps us to work more efficient by dividing workload and it helps us to unite and standing stronger together as European countries.

2.1.2 *Beneluxa*

ZIN has been active for many years in Beneluxa, a partnership between Belgium, the Netherlands, Luxembourg, Austria and Ireland in which, among other things, medicines are jointly assessed. Because EUnetHTA JA3 came to an end in May 2021 (and with it the joint assessments) and under EUnetHTA21 only 1 or 2 joint assessments are planned in the coming years, the joint assessments within Beneluxa will be important for ZIN in the coming years. To further support this, ZIN led a project that aims to compare the processes of the individual countries in order to arrive at a more joint Beneluxa process. In addition, the collaboration goes further than the clinical assessments and scientific consultations that will be done under de EU HTA regulation. Appraisal and negotiations are also taking place jointly under Beneluxa, making Beneluxa complementary to the EU HTA regulation and one of ZIN's international priorities.

2.1.3 *Heads of Agencies Group (HAG)*

ZIN hosts the permanent secretariat for the Heads of Agencies Group (HAG), consisting of representatives of European HTA agencies. This HAG derives from HOFA (EUnetHTA Heads of HTA Agencies established under EUnetHTA JA3) and aims, among other things, to support the development of the basis for joint work on all HTA activities at EU level within the model of EU cooperation anticipated by the forthcoming HTA Regulation. The HAG will exist at least until the entry into force of the regulation for member states in 2025, and possibly longer if it is decided to maintain the group alongside the Coordination Group.

The HAG can help its members to prepare together for the forthcoming EU HTA regulation. Moreover, members of the HAG can cooperate in areas that are not covered by the EU HTA regulation, making this a valuable group for ZIN.

2.1.4 *International Horizon Scanning Initiative*

ZIN is chair of the Executive Committee and Board of Directors of the international horizon scanning initiative (IHSI), set up by the Dutch Ministry of Health, Welfare and Sport. The database developed under IHSI 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.

ZIN started horizon scanning in 2017. We find it of great added value to scan the horizon together with other countries within IHSI, because this brings efficiency. Moreover, it helps the cooperation between countries if those countries have the same information. Because Phase 1 studies will be included in IHSI, the database will be even more comprehensive than our national database. Lastly, IHSI has the potential to scan the horizon for medical devices.

2.2 Quality of care

From 1 April 2014 onwards, ZIN has been tasked with improving quality of care by the Ministry of Health, Welfare and Sport of the Netherlands. We do so by improving transparency of care and guiding patients in their search for high quality care. Patient centeredness is key here.
Consultations involving patients, health care providers and health insurers result in joint descriptions of appropriate health care that are translated into quality standards. If the stakeholders are unable to reach an agreement, irrespective of the reason, ZIN can take the lead in developing a quality standard.

Currently we have few international collaborations that focus specifically on quality of care, and our international network on the subject is relatively small. In 2022 we are exploring if we can join international networks, how they could benefit our work, and how we can contribute to them. At the same time we will be looking at possible international collaborations. Interesting subjects to look at are, among others, shared decision-making and value based health care. This exploration might lead to a stronger international position for ZIN when it comes to quality of care. However, for now we mainly aim to broaden our access to knowledge by learning internationally.

2.3 Healthcare's digital transformation

More recently, from 1 January 2020 onwards, ZIN has become involved in standardizing and optimizing digital information-sharing between stakeholders in Dutch long-term care, youth care and care provided under the Social Support Act (in Dutch: *Wet Maatschappelijke Ondersteuning*). As with our activities focusing on further improving the quality of care, ZIN's international activities that focus on standardizing and optimizing information sharing in particular (e.g. through artificial intelligence, better interoperability of data and innovation) are limited. Our activities focusing on this topic are described in Chapter 5.

In 2022 and 2023 we will investigate what kind of connection might serve us best in these areas. The main goal of joining additional networks would be to obtain knowledge and to see if our activities can benefit from that knowledge. Preparatory to that, a study was conducted at the end of 2019 to get a picture of relevant networks in Brussels that focus on standardizing and optimizing information sharing between stakeholders. The results of this study has been used in 2022 to determine which networks ZIN can benefit from, and to explore whether joining those networks would be useful.

2.4 How international collaboration benefits our activities

The COVID-19 pandemic proves how important international collaboration is. When collaborating with others, ZIN 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 ZIN, 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 European HTA, a European project with the goal of exchanging health technology assessment reports instead of doing the same analyses in each country separately.

Influencing policy

Participating in international activities is one way in which ZIN tries to influence European policy, leading to new policy that serves the Dutch public best. 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. Some countries are ahead of the Netherlands or may have innovative ideas or best practices. ZIN can learn from these countries and where possible apply their solutions in the Netherlands by obtaining knowledge about the other's experience. 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.

In order to stay up to date with European and international trends in health care, ZIN carries out a desk research study annually in that analyses reports from, among others, WHO and OECD on various European health care systems and how they are performing. The goal is to see which international findings and trends in these reports are relevant for our activities.

Sharing knowledge

Not only do we learn from other countries, but many countries look to the Netherlands when it comes to organizing health care. We can help these countries by sharing our experience and knowledge. We regularly (digitally) welcome international delegations that want to learn from the Dutch health care 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. We have seen an increase in recent years in the number of requests from delegations wanting to visit us. In order to ensure that we will be 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 ZIN will participate in new projects will be based on criteria that include whether the goal of the project is in line with our primary tasks and activities.

3 Health care package management

ZIN 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 health care package and advice on the health care 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 health care package management, ZIN works internationally on different topics as mentioned in the following paragraphs. When performing its tasks related to health care package management, ZIN uses its appropriate care framework which describes what appropriate care is, how it should be delivered and who should be involved. Please refer to Chapter 2 for more information on this framework.

3.1 Horizon scanning

	Dividing workload	Stronger together	
	IHSI	Beneluxa	EMA

To ensure that patients have timely access to medical interventions, a timely 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 timely anticipate on the impact of emerging new medicinal products. To improve the efficiency and quality of this activity, for instance by sharing workload and obtaining more relevant information, ZIN leads the international horizon scanning initiative (IHSI)[6], 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[7] is being explored and options for international horizon scanning of (high risk) medical devices will be on the agenda in the coming years.

The international collaboration between Austria, Belgium, Ireland Luxembourg and the Netherlands in the Beneluxa Initiative[8], also uses horizon scanning to timely identify forthcoming products to work on together (e.g. assessments and joint procurements).

Positions and actions

- International horizon scanning for pharmaceutical products will contribute to the efficiency and quality of national Dutch horizon scanning.
- ZIN 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.
- 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.
- ZIN 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.

6 www.ihsi-health.org

7 *For this document we use a definition of 'medical device' that is in line with the article 2 of 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 health care 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.*

8 www.beneluxa.org

3.2 Alignment and synergy with regulators (EMA)

	Influencing policy	Obtaining information				
	EMA	MEDEV	HTAi	ISPOR	EUnetHTA21	EU DARWIN

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

ZIN 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 the taking into account in trials of information that is relevant for HTA organisations and payers. 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 in account before market authorization. Therefore, as ZIN, we are also actively involved in the DARWIN initiative from EMA in which we represent the payer community in the EU Darwin Advisory Board.
In addition, we further would like to exchange knowledge on methodology like the use of real-world data and on products. ZIN is contributing to the discussion with EMA on what information is needed by HTA organisations and payers, about, e.g., patient populations and comparators.

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.
- 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.
- ZIN would like to increase collaboration with EMA in order to include wishes and needs from an HTA perspective in an early stage, and to have access to relevant information.

3.3 HTA methodology

	Obtaining knowledge	Sharing knowledge	Dividing workload		
	EUnetHTA21	ISPOR	HTAi	H2020-HTx	CG

The important basis of the HTA work we do at ZIN are 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 international methodological projects, such as HTx, as part of the IMI and Horizon-2020 projects, but also participate in methodological activities as part of EUnetHTA21 or as part of international societies, such as HTAi and ISPOR. ZIN is hosting the HTAi Annual Meeting in Utrecht in 2022.

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), how to assess personalized medicine (section 3.8) and developing price and reimbursement methods (section 3.9). We may also be involved in new projects that are funded by the European Union, for instance through the Horizon Europe Programme.

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 ZIN needs to be involved in the most important organisations and projects that sustain and develop HTA methods.
- There are a number of areas that needs specific methodological attention and in which ZIN will invest such as RWE, patient registries, personalized medicine, developing price and reimbursement methods and a cyclic or iterative approach to HTA.

3.4 European HTA

	Dividing workload	Stronger together			
	EUnetHTA21	Beneluxa	Malta project	HAG	CG

European HTA is ZIN's most important priority when it comes to our international activities, and is therefore also described in strategic Chapter 2. Because Chapter 3 describes all the relevant topics about our health package management tasks, it is described here as well.

In order to increase the efficiency of HTA in Europe, European collaboration is necessary. ZIN has been actively involved in EUnetHTA[9], a collaboration between the 27 member states of the European Union, since its start in 2006. ZIN was the coordinator of EUnetHTA Joint Action 3 (2016-2021), which came to an end in May 2021. In its two-year successor, EUnetHTA21, ZIN is again playing an active role. We are hosting the secretariat and are part of various working groups. This project is preparing for the EU HTA regulation that will come into force in 2025 in which pharmaceutical products and medical devices will be jointly assessed. EUnetHTA21 functions as a bridge between EUnetHTA JA3 and this regulation and its implications. We will prepare our processes for the entry into force of the regulation in 2025, using our experiences with the templates and formats developed under EUnetHTA21.

The Netherlands is also a member of the Beneluxa[10] Initiative. This is a collaboration between Belgium, the Netherlands, Luxembourg, Austria and Ireland on horizon scanning, HTA and price negotiations. ZIN has prioritized the Beneluxa collaboration and contributes to the development of Beneluxa HTA. The collaboration on HTA concerns assessments, both pharmacotherapeutic and pharmaco-economic, and appraisal. The relative effectiveness analyses format (REA) that was developed under EUnetHTA JA3 and will be fine-tuned during EUnetHTA21 can be used as a starting point. Furthermore, common statements are made. In 2021 ZIN performed a study of the different HTA pathways, timelines and reimbursement decisions in all collaboration countries, providing input for a more aligned Beneluxa process.

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 allows 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. ZIN hosts the secretariat of HAG.

9 www.eunethta.eu
10 www.beneluxa.org

ZIN, as one of the strongest and most experienced European HTA organizations, has a role in helping other less-developed and less resourced national HTA organisations in the development of their HTA methods and processes. In 2022 ZIN is continuing to support Malta in building an HTA system for pharmaceuticals, as part of the project 'Investing in human capital to create more opportunities and promote the well-being of society'.

Positions and actions

- We will prepare our processes for the entry into force of the EU HTA regulation in 2025.
- Beneluxa HTA is prioritized for the forthcoming years. ZIN will proactively further develop the Beneluxa collaboration. This is done alongside the EUnetHTA21 project.
- ZIN is continuing to support Malta in building an HTA system for pharmaceuticals in 2022.

3.5 Real-world data (RWD)

	Obtaining knowledge	Sharing knowledge				
	EUnetHTA21	ISPOR	GetReal Institute	H2020-HTx	EU DARWIN	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 to (re-)evaluate 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 focus point in 2022 and 2023.

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				
	EUnetHTA21	EMA	GetReal Institute	ISPOR	ERN	EU DARWIN

In order to obtain RWD, patient registries will become increasingly important as a starting point for products (pharmaceutical and medical devices) for which the clinical information is limited at market entrance. 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 the 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 register by the EMA is important to ensure the quality of the registry data.

ZIN 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, networks for rare diseases, are setting up European registries. In 2022 and 2023 ZIN seeks to explore how the ERN's and ZIN's need for registries can reinforce each other.

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[11], 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.
- Also for international registries, healthcare providers or patients should be the owners of the registries, not pharmaceutical companies or manufacturers of medical devices.
- ZIN 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.
- ZIN supports the qualification process of a register by the EMA to ensure the quality of the registry data.
- ZIN actively participates in EU DARWIN through its EU Advisory Board, representing the payer community
- We should use tools and criteria that are already developed by other organisations such as EUnetHTA, for example the REQueST tool as much as possible.

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

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

Obtaining knowledge	Sharing knowledge	
H2020-HTx	GINAHTA	HTAi	ISPOR

A new model for (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 this approach and it is important to learn how disease models 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.
- ZIN will actively discuss a cyclic and iterative approach to HTA in the Annual Meeting of HTAi which will be organised in Utrecht in June 2022.

3.8 Personalised medicine

Obtaining knowledge
H2020-HTx

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. It is important to develop methodologies further for the assessment appraisal and reimbursement schedules for these kinds of products. ZIN interacts 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 European (worldwide) level. Also, data infrastructure terms and agreements should be made. ZIN 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).

3.9 Models and methods for pricing and reimbursement

	Sharing knowledge	Obtaining knowledge				
	ISPOR	HTAi H2020	HTx	Beneluxa	PPRI	EMA

More and more HTA and payers are confronted with drugs of which the value 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 have to cope with these uncertainties as well, more 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. ZIN will need to be actively involved in current and new initiatives that will address pricing and reimbursement models, for instance through the Beneluxa 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) should preferably be done in international collaborations.

3.10 Mechanisms for pricing of pharmaceuticals and medical devices

	Stronger together		
	Beneluxa	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 health care 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 health care innovations (e.g., ehealth developments).

Furthermore, to reduce prices, joint negotiations with other countries may be necessary (e.g., through Beneluxa[12]).
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, ZIN supports increased transparency of legal frameworks for intellectual property, reference pricing mechanisms and alternative payment models at both a European and international level.

12 www.beneluxa.org

3.11 Orphan Medicinal Products and Advanced Therapy Medicinal Products

	Stronger together	Influencing policy			
	ESIP	MEDEV	HTAi -H2020	H2020	HTx

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 (ATMP's) the uncertainties about long-term effectiveness hamper the assessment of the value of the products. Also, orphan drugs are often expensive. Current frameworks for assessment or appraisal may need to be studied to see whether adaptations may be 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.

ZIN 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 payer.

Positions and actions

- Orphan drug regulations should be evaluated and amended to stop mechanisms by which those regulations can be misused. ZIN 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.

3.12 Medical devices

	Influencing policy	Obtaining knowledge				
	INAHTA	H2020-HTx	ESIP	EUnetHTA21	HTAi	ISPOR

The pace of development of new medical devices is increasing. Every year, a growing number of companies are introducing devices and technical modifications to existing medical devices[13] onto the market and expectations are that this trend will continue in the next few years. Furthermore, up until now the notification process was neither transparent nor particularly solid. For this reason a new regulation on medical devices and in-vitro diagnostics came into force on 26 May 2017, adopting new requirements for medical devices and in-vitro diagnostics (MDR). Medical devices need to comply with the new rules by no later than 26 May 2021 and 26 May (2022 for in-vitro diagnostics. 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.

13 *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.*

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.

Implementation of this new regulation and monitoring its consequences is a focus point of the Dutch Ministry of Health, Welfare and Sport. ZIN is following 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.

ZIN is developing an overall quality standard for the use of digital healthcare solutions (including eHealth, medical devices and technology) to encourage the use of these digital solutions. ZIN considers it important to investigate what the application possibilities are at European level. In line with this development ZIN is exploring the introduction of a monitor that offers an overview for useful (to health care professionals and patients) and reliable eHealth applications, medical devices and medical technology. To be complete this should be a cross-border monitor.

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 wholly or partly adopted. 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 and a high risk).

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, it should become clear what the (temporary) alternative is.
- 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 PMCF, and should be part of any manufacturer consultation, regardless of whether this consultation is done by EUnetHTA21 or another body.
- Awareness of the importance of medical devices as part of healthcare should be increased at a national and an international level.
- Consequences of the new regulation about in-vitro diagnostics, the IVDR, need to be investigated.

4 Quality of care

ZIN has legal responsibilities to stimulate improvement in the quality of Dutch healthcare. In order to improve the quality of Dutch health care, ZIN actively encourages the coherent development and implementation of guidelines and indicators and publishes data on the delivered quality of care online[14]. 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. ZIN has various legal instruments to stimulate the development of guidelines and indicators.

When performing its tasks related to quality of care, ZIN uses its appropriate care framework which describes what appropriate care is, how it should be delivered and who should be involved. Please refer to Chapter 2 for more information on this framework.

4.1 International learning during the revision of our responsibilities and instruments


Obtaining knowledge


GIN - GINAHTA

Our responsibilities in stimulating improvement in the quality of care was one of the main subjects during the quinquennial evaluation of ZIN in 2019/2020. ZIN and the Ministry of Health, Welfare and Sport agreed that this was the right moment to revise our responsibilities and instruments and to explore how, and to what extent, we can learn from international practice while formalizing our own instruments and activities.

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 is 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. During the revision of our responsibilities and instruments in 2022, our responsibility for the use of data on quality of care will also be revised. 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 movement 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.

To learn more about our activities regarding the more technical aspects of healthcare data, see Chapter 5.

Positions and actions

- The responsibilities and legal instruments of ZIN 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 health care provider.
- Besides patients, information about quality of care also needs to be available for health care providers so they can learn from it, and for improving the organisation of care and outcomes, and for health insurers for healthcare procurement.
- During the revision of our instruments and legal responsibilities ZIN will consult international examples and best practices.

14 www.zorginzicht.nl

4.2 Collaboration between government and private parties in healthcare


Obtaining knowledge sharing knowledge

An important topic in the revision of our responsibilities and instruments for quality of healthcare (and our work in general) is the collaboration and division of responsibilities between government parties (ZIN specifically) and patients, healthcare providers and health insurers (private parties). In the collaboration on improving the quality of health care between public and private parties they both have their own role. The public parties make legal frameworks and policy. The private parties describe in guidelines, within the legal framework and policies, 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 and 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 division of responsibilities is important to get an agreement about the collaboration. Insight 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.

Positions and actions

- ZIN represents the public interest by focusing on quality, accessibility and affordability of care.
- ZIN is interested in collaborations and learning systems between public and private parties in other countries and will share lessons obtained.

5 Healthcare's digital transformation

Healthcare data has specifically caught Europe's attention, as described in the Mission Letter from Ursula von der Leyen (President of the European Commission) to Stella Kyriakides, Commissioner-Designate for Health[15], in the propositions for the EU health agenda 2020-2025 made by the Dutch government[16] and in the European Health Data Space plans [17]. Healthcare no longer works without agreements on access to, availability of and exchange of data and terms and conditions on the use of both existing and new technology. On the one hand data can be very concrete when it comes to facts and figures. On the other hand data can be very abstract bearing in mind the increasingly complexity of processes, ethics, starting points for architectural agreements, legislation for the use of technology and the privacy policies needed to make data accessible, so that everyone concerned can work and learn from the data available.

On a national level, ZIN has a growing role in health care's digital transformation and is picking it up in various ways. Keeping in mind that nowadays national boundaries are more or less virtual and cross-border healthcare is a given fact that is served by international legislation, terms, conditions and agreements. From that perspective, ZIN continuously seeks international collaboration.

When performing its tasks related to healthcare's digital transformation, ZIN uses its appropriate care framework which describes what appropriate care is, how it should be delivered and who should be involved. Please refer to Chapter 2 for more information on this framework.

5.1 Data strategy

	Obtaining knowledge			
	GetReal Institute	eHealth stakeholder group	GO FAIR	EU DARWIN

ZIN's aim is to only allow care products (services, medicinal products, devices, and technology) into our healthcare system that have proven to have added value to people's health. In order to do so ZIN needs data. The availability of data, data exchange options and new technologies are the basis for this. 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 in 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. ZIN encourages the implementation of digital healthcare solutions because of its effects on increasing the accessibility and affordability of health care. Of course a guarantee for the quality of the digital forms of care is required. In addition ZIN explores the applicability of new technologies and innovations, builds knowledge of AI and follows international developments.

In 2020 ZIN developed a data strategy plan. 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 health care.

Giving meaning to data can lead to useful information. Correctly operationalising data, allows it to be used for important tasks of ZIN. There are already international initiatives focusing on the use of big data. ZIN is exploring international initiatives and learns from the good practices of other countries. This benefits 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).

15 https://ec.europa.eu/commission/commissioners/sites/default/files/commissioner_mission_letters/mission-letter-stella-kyriakides_en.pdf
16 'The Netherlands' propositions for the EU health agenda 2020-2025', https://www.permanentrepresentations.nl/documents/
17 https://ec.europa.eu/health/ehealth/dataspace_en

ZIN follows 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.

Position and actions

- ZIN 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 GO-FAIR, Personal Health Train, H2O and IHI.
- We respond to European consultations.
- We examine connection points for Dutch legislation for interoperability in an international context.
- ZIN 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. ZIN is currently collaborating with CQC UK based on their experience with sandboxing in healthcare, also focusing on the safe and effective implementation of e-health innovations.

5.2 Unambiguous and reliable information-sharing

	Obtaining knowledge	Sharing knowledge	
	ESIP	EUnetHTA21	GO FAIR

Sharing unambiguous and reliable information is a continuous topic and it will be even bigger in consequence of the assessment of the response to the Covid-19 outbreak. Improving the sharing of information about healthcare is on the agenda of many European countries and has a high priority in the Netherlands too. Improving the sharing of information will result in better quality care at lower costs. Collaboration between the different stakeholders in different countries is necessary to realise the ambitious goal of improving information sharing in healthcare.

There are new and innovative ways to improve the exchange of information and data. ZIN 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 is 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. ZIN seeks international collaboration and shares knowledge on the FAIR principles.

Reuse and multiple use of data is one of the main topics of the Information Council because of the current registration burden on Dutch healthcare. Responsible management and use of data increases the reliability of information. Technology permits the combination of a growing number of data sources, even if the data is unstructured. ZIN has already done a number of pilots with innovations that can facilitate multiple use and reuse of data, such as FAIR data, the Personal Health Train or the block chain. Such innovations and shared architectural principles (following the FAIR principles) are also being developed by other countries. ZIN wants to explore the initiatives taken by front-running countries to see what technical solutions other countries are investigating or implementing, and to collaborate with those countries to share knowledge on this subject and help one another with this important architectural principle. ZIN uses the lessons learnt to determine future positions on this subject.

Position and action

- In international projects, where possible, the FAIR principles should be leading when storing and sharing data. ZIN encourages this in projects in which it is participating.
- In international projects focusing on the use of data, ZIN is a key link between stakeholders when sharing minimum conditions for the one-time registration, multiple use principle.

5.3 Interoperability

	Obtaining knowledge	Sharing knowledge
	HIMSS	IHE

Interoperability is an important topic that is on the EU's agenda and is part of the objectives of the Information Council (Informatieberaad). 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. 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.
- 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, ZIN looks to front-running countries and explores the best practices in those countries to learn from those practices and - where applicable – try to implement them in the Netherlands. ZIN looks for collaboration with countries to learn from the front-runners and to share our knowledge with countries who want to learn from us (for example our 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 standardization, models and frameworks and architectural principles (Such as FAIR and registration agreements for multiple use and reuse, see previous paragraph).

5.4 International standards

	Obtaining knowledge	Sharing knowledge
	HIMSS	IHE

Using open and international standards helps to improve interoperability. It is important for ZIN 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. ZIN follows international developments.

5.5 Innovation


Obtaining knowledge | Influencing policy


ESIP

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 many great opportunities for improving healthcare (personalised medicine, AI, medtech, robots), but also some major challenges (privacy, ethical issues, security).

The Dutch healthcare package system allows an 'open' entitlement to the reimbursement of many innovative forms of care. After market entry, the lion's share of new therapeutic devices, interventions and digital technologies flows into the statutory insured package without prior assessment. This is causing an increase in reimbursed interventions that have not undergone prior assessment, leading to potential unwanted consequences such as adverse effects and inefficient use. In 2022 ZIN is investigating options for proactively promoting the appropriate introduction and upscaling of new healthcare technology as well as options for better discriminating between innovations that actually improve care at the patient level and those that lead to inappropriate care and unnecessary costs.

To keep up with the latest developments in innovations, ZIN adopted its innovation strategy 'Datalogica 2020-2022' with the main focus on three key activities. These activities, with both a national and international scope, are as follows: 1. following international trends and developments in data innovation; 2. mapping out international innovative initiatives and looking for good practices from which ZIN can learn, in order to help stakeholders and individual patients. ZIN is prepared to participate in initiatives or connect with other initiatives that are relevant for ZIN and 3. initiating data-driven experiments that contribute to the (digital) transformation of healthcare.

Positions and actions

- To keep up with the latest innovation developments, ZIN follows international trends and developments in (data) innovation, maps out international innovative initiatives and looks for good practices from which ZIN can learn.
- To support stakeholder interaction and dialogue on the responsible introduction and upscaling of healthcare innovations from an early stage, namely prior to and soon after market authorisation.

6 Networks and projects

ZIN 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 Chapter 3, 4 and 5.

Beneluxa (www.beneluxa.org) *strategic priority*

Beneluxa

Objective: HTA cooperation and information exchange.

Agenda:
- Short statements, collaboration on horizon scanning and early HTA.
- Doing assessments together, dividing the work load although assessment by EUnetHTA is preferred.
- 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.

ZIN's involvement: Active member. Beneluxa is one of ZIN's prioritized collaborations.

Coordination group *strategic priority*

CG

Objectives:
- Joint clinical assessments.
- Joint scientific consultations.
- Identifying emerging health technologies (horizon scanning).
- Supporting voluntary cooperation between Member States.
- Developing and adopting the methodological guidance, procedural steps, and timeframes on the basis of which the joint assessments and consultations are performed.

eHealth Stakeholder group (by the European Commission's Directorate-General for Communication Networks, Content and Technology, DG CNECT)

eHealth group

Objectives: To provide advice and expertise, contributing to policy development and the implementation of the Communication on enabling the digital transformation of health and care in the Digital Single Market, in particular in relation to the following areas:
- Health Data, including the development of a European electronic health record exchange format.
- Digital health services.
- Health data protection and privacy issues.
- Cybersecurity for health and care data.
- Digital tools for citizen empowerment and person-centred care.
- Artificial intelligence and health.
- Other cross-cutting aspects linked to the digital transformation of health and care, such as governance, financing and investment proposals and enabling technologies.

ZIN's involvement: Member.

DARWIN EU (Data Analysis and Real World Interrogation Network, www.ema.europa.eu)


DARWIN

Objective: To provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real-world healthcare databases across the European Union (EU).

Agenda:
- Establishing and expanding a catalogue of observational data sources for use in medicines regulation;
- Providing a source of high-quality, validated real-world data on the uses, safety and efficacy of medicines;
- Addressing specific questions by carrying out high-quality, non-interventional studies, including developing scientific protocols, interrogating relevant data sources and interpreting and reporting study results.

ZIN's involvement: Representative of the payer community in DARWIN's Advisory Board.

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


EIF

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.

ZIN's involvement: Member.

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


EMA

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.

ZIN's involvement: Informal representative of the payer community and collaborative partner.

EUnetHTA21 (eunethta.eu) *strategic priority*

EUnetHTA21

Objective: A two-year project that succeeds EUnetHTA JA3.

Agenda:
- Advancing the development of HTA methodology further, aiming at addressing key methodological issues, with a specific focus on areas where divergent opinions still persist;
- Providing input to a potential new legal framework on HTA;
- Ensuring that methodological and other developments are applicable and usable not only on a European but also on national and regional levels;
- Production of 6-8 Joint Scientific Consultations;
- Production of 1-2 Joint Clinical Assessments.

ZIN's involvement: We host the secretariat and are member of the hands-on group for various deliverables. EUnetHTA21 is one if ZIN's prioritized international projects.

European Implementation Network (www.einnetwork.org)

EIN

Objective: Working on implementation at European level.

Agenda:
- Further development and international orientation to enhance further development of effective theory and insights for implementation (especially those for daily work in practice) and to encourage implementation in complex adaptive systems. Learning and development is an important theme to work on.

ZIN's involvement: Member.

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

ERN

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.

ZIN's involvement: No formal involvement.

ESIP (European Social Insurance Platform, www.esip.eu)


ESIP

Objective:
To preserve high-profile social security for Europe and to reinforce solidarity-based social insurance systems, and to maintain the quality of European social protection.

Agenda:
- Encouraging transnational dialogue and the exchange of best practices between national social security institutions in Europe.
- Providing a strategic network for developing common positions to influence the European decision-making process.
- Providing a consultation forum for the European institutions and other multinational bodies active in the field of social security.

ZIN's involvement: Member (until 1 January 2023).

GetReal Institute (www.getreal-institute.org)


GetReal Institute

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.

ZIN's involvement: Member.

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


G-I-N

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.

ZIN's involvement: Member.

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


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 join 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.

ZIN's involvement: Member.

GO FAIR (www.go-fair.org)


GO-FAIR

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.

ZIN's involvement: Observer.

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 supporting and collaboration opportunities.
- 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).

ZIN's 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.

ZIN's involvement: From 2022 – 2024: Observer. From 2024 – 2026: Representative of governmental organizations in the Board.

Heads of Agencies (HAG, htahag.eu) *strategic priority*

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.

ZIN's involvement: Host of the Secretariat.

Heads of Medicines Agencies (HMA, www.hma.eu)

HMA

Objective: The HMA is a network of the heads of the National Competent Authorities (NCA) whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area. The HMA co-operates with the EMA) and the European Commission in the operation of the European medicines regulatory network.

Agenda:
- Addressing key strategic issues for the network, such as the exchange of information, IT developments and sharing of best practices.
- Focusing on the development, co-ordination and consistency of the European medicines regulatory system.
- Ensuring the most effective and efficient use of resources across the network, including developing and overseeing arrangements for work-sharing.
- Co-ordinating the mutual recognition (MRP) and decentralised procedures (DCP).

ZIN's involvement: No formal involvement.

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.

ZIN's involvement: No formal involvement.

Horizon 2020 HTx (Health Technology Exchange, www.htx-h2020.eu)


H2020 - HTx

Objective: Development of next generation HTA models.

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.

ZIN's involvement: Lead of Work Package 4: Implementation into system and processes.

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


HTAi

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.

ZIN's involvement: Member of the Board. Local Host of the HTAi 2022 Conference.

IHE (integrating the health care enterprise, www.ihe.net)


IHE

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.

ZIN's involvement: No formal involvement.

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

IHSI

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.

ZIN's involvement: Chair of the Executive Committee and Board of Directors. IHSI is one of ZIN's prioritized projects.

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

INAHTA

Objective: To enhance collaboration between international HTA bodies.

Agenda:To facilitate the exchange of methods and processes between HTA bodies worldwide.

ZIN's involvement: Member.

Investing in human capital to create more opportunities and promote the well-being of society (EU funds for Malta)

Malta

Objective:
- To help Malta organise processes for healthcare quality and the reimbursement of medicines. To support processes for healthcare quality in Maltese hospitals.
- To facilitate a new system for the assessment and appraisal of medicines in Malta.

ZIN's involvement: Partner.

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

ISPOR

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.

ZIN's involvement: Member.

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


MEDEV

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:
- Rapid assessments of (new) medicinal products of common interest.
- 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.

ZIN's involvement: Member and co-chair.

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


PPRI

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.

ZIN's involvement: Member.

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