

Nordic Medtech Growth 2

Innovation & Health Economics



Health Technology Assessment (HTA) in the Nordic countries

Introduction to and Status of HTA's Role in
the Value Chain of Medical Technology

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A report developed by the Nordic medical device industry associations within the project “Nordic Medtech Growth 2” funded by the Nordic Minister Council via Nordic Innovation.

1 Introduction Nordic Medtech Growth 2

Medical and health-care technologies change quickly. Variation in or absence of routines for health-technology assessment within the specialist health service is a great challenge for the industry.

That there are differences in decision-making processes related to new health technologies within the health-care system is one of the concerns for all suppliers in the industry for medical devices and in-vitro diagnostics.

This is the background for the project Medtech Growth 2, which has been organized by national associations for medical suppliers in the Nordic region.

The project has produced two reports. This report, Health-Technology Assessment (HTA) in the Nordic Countries, gives an introduction to HTA processes in the Nordic countries. Both reports are meant to be tools for all engaged in the value chain of health technology.

The other report, Value-Based Procurement (VBP), gives an introduction to value-based health care and value-based procurement in the Nordic countries and in Europe.

Without important contribution from governments, national agencies, academic institutions, and employees within the national associations, it would have been impossible to reach the goals of the project.

Trond Dahl Hansen

Project owner, NMG2, and CEO of Medtek Norway

1.1 Goal and Purpose

The goal and purpose of this report is to help companies and other stakeholders understand how the Nordic countries are working with health-technology assessment.

Another purpose has been to network and find new arenas for collaboration within the area of HTA, i.e., with relevant governmental agencies as well as regional and local health providers.

1.2 Implementation

To reach the goal of helping stakeholders understand how the Nordic countries are working with health technology assessment, the project group has attempted to describe what and how different public stakeholders work with HTA as a tool to implement new products and procedures within the health-care sector. In order to achieve that, a common Nordic arena with the different associations for medical technology in the Nordic countries and reference groups was established to improve dialogue and exchange competencies. The knowledge and experiences from this work are found in this report, so it can work as practical guide about HTA processes in each country.

1.3 Project Organization

ORGANIZATION:

Partners: Finnish Health Technology Association,
FiHTA (now Healthtech Finland)
Medicoindustrien, Denmark
Medtek Norway
Sailab, Finland
Swedish Medtech

PROJECT ORGANIZATION:

Project owner:

Trond Dahl Hansen
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Nordic project manager:

Martin Bergius
Boston Scientific AB and Medtek Norge

Steering group:

Trond Dahl Hansen, CEO of Medtek Norge
Anna Lefevre Skiöldebrand, CEO of Swedish Medtech
Peter Huntley, CEO of Medicoindustrien Denmark
Tom Stålberg, advisor at FIHTA, Finland
Laura Simik, CEO of Sailab, Finland

Project resources:

Hartvig Munthe-Kaas, Medtek Norge (until May 1, 2017)
Henriette Ellefsen Jovik, Medtek Norge
Petrus Laestadius, Swedish Medtech
Sofia Medin, Swedish Medtech
Jan Heidebrandt, Swedish Medtech
Louise Reuterhage, Swedish Medtech
Malin Hollmark, Swedish Medtech
Anne Englev, Medicoindustrien Denmark
Antti Vatanen, Sailab Finland

National reference groups:

Each country has had a widely composed national reference group. The groups have consisted of representatives from the government side, purchase groups, professionals like doctors, and academia.

2 HTA definitions

WHO and EUnetHTA Definitions

Health-technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic, and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value (EUnetHTA).

Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

Nordic definition of HTA used in the NMG2 project:

Health-technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic, and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value (EUnetHTA).

3 HTA Process by country

3.1 Denmark

Background and Status

The Danish Health Authorities stopped making HTA for medical devices in Denmark in 2012. Medical devices are evaluated in the procurement process instead. In some procurements, the evaluation is 60% quality and 40% price, and in other procurements, it is 100% price and no quality.

The procurement or tender can for example look at

- improvement of patient safety,
- introduction of new, innovative products, and
- facilitation of rational use of resources within specialist health care.

Key Process Elements

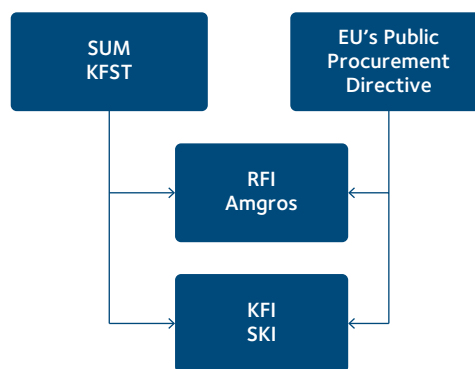
HTA is used for pharmaceuticals in Denmark but not for medical devices. HTA on pharma is made by Medicinrådet and by Amgros.

Medicinrådet and Amgros are planning to use HTA for medical devices as well. Medicoindustrien has made written a paper to Medicinrådet. The paper describes some of the big differences between the way pharmaceutical products and medical devices are approved and why a HTA approach/ methodology for pharma cannot be used for medical devices.

Medicinrådet is an independent council that evaluates the efficacy of pharmaceutical products in comparison with costs. The plan is that in the future, the council will evaluate medical devices as well.

Key Stakeholders

HTA on Medical Devices



Definitions:

SUM: Sundhedsministeriet (Ministry of Health)

KFST: Konkurrence- og Forbrugerstyrelsen (Danish Competition and Consumer Authority)

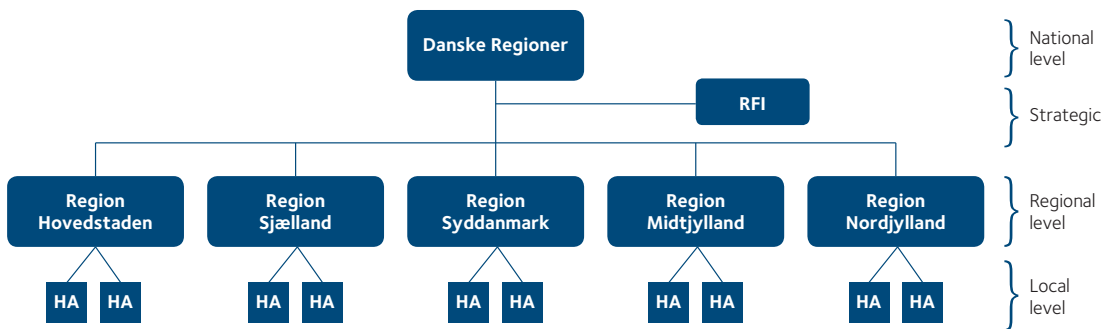
RFI: Regionale Fællesindkøb ([the Danish Regions' Common Procurement for the five regions in Denmark](#))

KFI: Kommunernes Fællesindkøb (Municipality Common Procurement).

SKI: Statens og Kommunernes Indkøbsservice (the State's and the Municipalities' Procurement Service)

Please note that there is no formal interaction between the medical industry and the research centers.

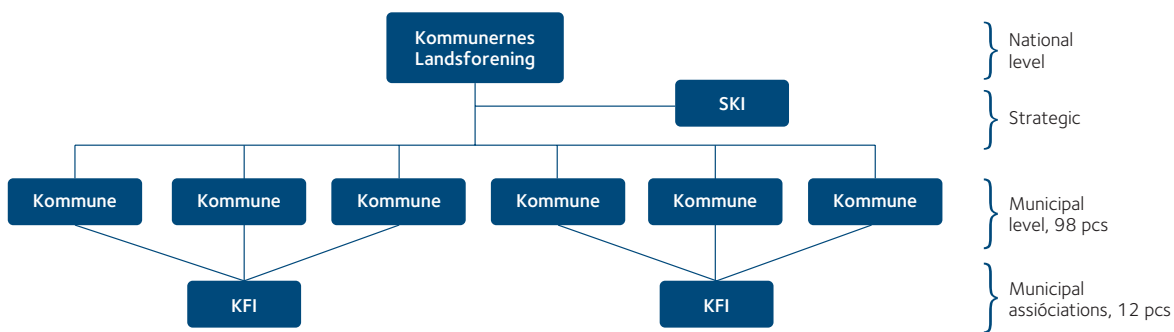
The Danish Tender Structures



Definitions:

HA: Hospitals

Region Hovedstaden, Region Sjælland, Region Syddanmark, Region Midtjylland, and Region Nordjylland are Regional Health Authorities



KFI: Kommunale Fællesindkøb (Municipal Joint Procurement)

Further Description of Elements in Process

The regions and the municipalities don't use HTA in their tenders on medical devices, neither by themselves nor through KFI or SKI. They don't have the resources to do that.

As mentioned above, Medicinrådet and Amgros are planning to use HTA on medical devices in the future. When exactly is not known. Therefore, Medicoindustrien has written a paper describing the differences between the way pharmaceutical products and medical devices are approved and why an HTA approach for pharmaceutical products cannot be used for medical devices. The paper is in Danish and is attached to this paper.

Links and Contact List

<http://www.sum.dk/> (the Ministry of Health)

<http://www.kfst.dk/> (the Danish Competition and Consumer Authority)

<http://www.regioner.dk/> (Danish Regions is the special interest organization for the five regions in Denmark)

<http://www.regioner.dk/rfi> (Danish Regions' Common Procurement for the five regions in Denmark)

<http://www.kl.dk/> (a special interest organization for the ninety-eight Danish municipalities, Kommunernes Landsforening (KL))

<https://www.ski.dk/Sider/Forside.aspx> Staten og Kommunernes Indkøbsservice (SKI) makes some of the procurement for the regions and the municipalities in Denmark. SKI is owned by the Danish state (55 percent of the shares) and KL (45 percent of the shares).

<http://www.amgros.dk/da/> Amgros is a public-sector organization owned by the five regional authorities in Denmark. It is the pharmaceutical procurement service of the regions. Amgros also makes procurement within medical devices on a small scale.

<http://www.ika.dk/medlem/kommunale-indkoebsfaellesskaber/> IKA is a community of public purchasers and has existed for 30 years.
<https://www.regionh.dk/> (the Capital Region of Denmark)
<http://www.regionsjaelland.dk/Sider/default.aspx> (The Region of Zealand)
<https://www.regionsyddanmark.dk/wm157175> (The Region of Southern Denmark)
<http://www.rm.dk/> (The Region of Central Denmark)
<http://www.rn.dk/> (The Region of Northern Denmark)

Private HTA Consultants in Denmark:

Incentive A/S, Holte stasjonsvei 14, DK 2840 Holte
<http://www.incentive.dk/>
KORA, Det Nationale Institut for Kommuner og Regioners Analyse og Forskning, Købmagergade 22, DK-1150 København C <http://www.kora.dk/>
CFK, Center for Folkesundhed og Kvalitetsudvikling, Olof Palmes allé 15, DK-8200 Aarhus N



3.2 Finland

Background and status

A Significant Social-Welfare and Health-Care Reform is Ongoing in Finland

A major change in welfare and health care is under way in Finland, with the main legislation to be decided upon by the Parliament in autumn 2017 / spring 2018. The political process has been very complex, and the proposed legislation has changed fundamentally several times with the consequence that the time frame has changed multiple times as well.

The responsibility for providing social-welfare and health-care services will be transferred from hundreds of municipalities to less than twenty larger autonomous administrative entities. This major change has directly affected the outcome of the Nordic Medtech Growth 2 project. For example, public procurement will no longer be handled on a local level but by the new larger entities that will be established. In practice, this means for example that about half or more of the municipal budgets will be reallocated to these few regional entities. Also, the health-technology-assessment procedures are undergoing great change during this major reform. As main decisions regarding the reform are still pending, the status of HTA is open and will be restructured during the months to come.

Health Technology Assessment (HTA) is Under Reorganization in Finland

The Finnish Office for Health Technology Assessment (FinOHTA) was established in 1995. It was situated in the National Institute for Health and Welfare (THL) and financed by the Ministry of Social Affairs and Health. FinOHTA was very active at a European level and was a key participant in the development of EUnetHTA, especially the core model for screening. However, FinOHTA was terminated at the end of 2016.

In 2014, a Council for Choices in Health Care (COHERE Finland) was nominated and given the task to issue recommendations on including or excluding health technologies in the range of public health services in Finland. According to its statement, the Council will consider research findings and other evidence from various sectors as well as ethical matters related to health care and matters related to the organization of health care. That is, the responsibility is closely linked to HTA. The Council is a permanent body working under the umbrella of the Ministry of Social Affairs and Health and is appointed for periods of three years. After the termination of FinOHTA, it is the only remaining body related to HTA, and therefore, it now has a key role in defining the coming governmental mechanisms on how to balance costs and cost-effectiveness when defining health-care-service choices. Consequently, the Council has published several reports in the autumn of 2017 to describe the background and present status but also in order to give recommendations for future changes in legislation and policies as well as creating a new organizational framework for HTA. These reports are briefly covered below and listed among the links to national web pages.

Key Process Elements

HTA in General

HTA in Finland has closely been following the EUnetHTA approaches, and FinOHTA was actually very active in the process of creating a common understanding of how to conduct HTA within EU. For example, FinOHTA was the secretariat for the HTA document regarding screening. A new guidance book on Finnish HTA was published in September 2017 (HTA-opas. Versio 1.1. Helsinki: Suomalainen Lääkäriseura Duodecim; 2017, available only in Finnish: <http://www.kaypahoito.fi/web/kh/hta-opas>).

It is worthwhile to note that there are also Current Care Guidelines (Käypä Hoito) published by the Finnish Medical Society Duodecim. The society published a new guidance book on how to create such guidelines (Hoitosuositusryhmien käsikirja: <http://www.terveysportti.fi/dtk/khk/koti>) in December 2016. These national, evidence-based clinical-practice guidelines support

health-care decision making and are published in two versions, one for the professionals and one for the patients concerned.

International Influence on the Coming Finnish HTA System

In order to create a new HTA system in Finland, the Ministry of Health and Social Welfare has analyzed HTA from an international perspective and published a report on this in October 2017 (Katsaus terveydenhuollon priorisointiin eri maissa, Marjukka Mäkelä, Maija Saijonkari and Neill Booth). A link to the report is listed below. The report concentrates on Sweden, Norway, and the UK but is in a table format also covering the Netherlands, Austria, Canada, Germany, Denmark, the state Oregon in the USA, New Zealand, and Estonia. The report provides benchmarking for the coming Finnish model and contains an extensive literature review. It seems obvious that the HTA methods as such will be fully aligned with the EUnetHTA and other international best practices.

The Finnish HTA Process

No decisions on the coming Finnish model are yet available. COHERE Finland has a key role between the terminated FinOHTA and the possible next organizational body. COHERE Finland has described and evaluated various alternative models in a report published in October 2017 (Näytön arviointi ja käyttö uusissa SOTE-rakenteissa—Vaihtoehtoja terveydenhuollon menetelmien arvioinnin järjestämisestä Suomessa, Kristian Lampe ja Ulla Saalasti-Koskinen). A link to the report is listed below. The report concludes that a strong independent agency needs to be established on a national level but points out that regional aspects need to be allowed. The focus areas for this agency are envisioned to be

- the need for HTA data at national and regional levels,
- international HTA collaboration,
- description of HTA data production in key reference countries,
- alternatives to organizing HTA data production, and
- preliminary discussion on assessing technology and practices in social services.

Another important report was also published in October 2017 (Kustannusvaikuttavuuden käyttämisestä yhtenä terveydenhuollon palveluvalikoiman määrittelykriteerinä, Neill Booth, Pasi Aronen and Marjukka Mäkelä). The report emphasizes that there are three main principles that the government defining the service choices of Finnish health care:

First, the significance of a health issue is assessed using both medical data and societal values. Second, the justifiability of medical services and methods is assessed by examining their relative effect and safety to the

severity of the health issue. Third, the ethical aspects and, when the method has only a minor impact, the costs will also be taken into account.

That is, the report emphasizes all the general aspects of HTA, including aspects related to the organization, financial carrying capacities of the society and legislation. The report clearly points out that there are no clear legislative nor current policies on how costs and cost effectiveness need to be taken into account. A link to the report is listed below.

The central sections of the report are the following:

- Definitions of cost-effectiveness and other central concepts
- Presenting the strengths and weaknesses of financial assessment
- Threshold values and their use
- The suitability of financial assessment for prioritization, NICE used as example
- The availability of cost-effectiveness data in Finnish health care
- How COHERE could include the assessment of cost-effectiveness in their work

Key Stakeholders

The Council for Choices in Health Care (COHERE Finland), working in conjunction with the Ministry of Social Affairs and Health, has the key role in preparing for the changes needed in order to re-establish a profound HTA procedure after the termination of FinOHTA. The Council has a permanent secretariat and a network of experts covering medicine, odontology, nursing care, science of law, and health economics but also has representatives from the relevant governmental bodies: the Ministry of Social Affairs and Health, the National Institute for Health and Welfare, the National Supervisory Authority for Welfare and Health, the Social Insurance Institution, and the Association of Finnish Local and Regional Authorities. It thus has the necessary coverage and expertise in order to build up a relevant proposal of the way forward.

In order to ensure that the coming HTA model will be valid for all stakeholders, it is strongly recommended that the ministry, the Finnish Medical Society Duodecim, and the health-technology trade organizations work together with COHERE Finland in order to find a common understanding of all mechanisms needed for the benefit of the patients.

Further Description of Elements in Process

The recently published reports mentioned above describe and assess the opportunities for using cost-effectiveness as one of the criteria for defining health-care service choices. As this is critical for making the major social and health-

care reform successful, it is obvious that the creation of an organization to take care of HTA is managed by the Ministry of Health and Social Welfare. This is also welcomed by the industry. It is nevertheless critical that the mechanisms between introducing new health-care technology, health-technology assessment, and possible best medical practices guidance (Käypä hoito) are made efficient and transparent and that they are based on EUnetHTA and other internationally acceptable HTA principles.

Links to National Web Pages and Contact List

Swedish link in brackets, if available

Finnish Office for Health Technology Assessment (FinOHTA):

<http://www.inahta.org/members/finohta/>

Council for Choices in Health Care (COHERE Finland):

<http://palveluvalikoima.fi/en/frontpage>

(<http://palveluvalikoima.fi/sv/framsida>)

The Finnish Medical Society Duodecim, Current Care Guidelines:

<http://www.kaypahoito.fi/web/english/home>

(<http://www.kaypahoito.fi/web/svenska/hem>)

The Finnish Medical Society Duodecim:

<https://www.duodecim.fi/english/>

(<https://www.duodecim.fi/svenska/>)

Guidance book on Finnish HTA (HTA-opas. Versio 1.1. Helsinki: Suomalainen Lääkäriseura Duodecim; 2017), available only in Finnish:

<http://www.kaypahoito.fi/web/kh/hta-opas>

Guidance on how to create current care guidelines (Hoitosuositustyöryhmien käsikirja, 2016), available only in Finnish: <http://www.terveysportti.fi/dtk/khk/koti>

Review report on health-care prioritization in various countries (Katsaus terveydenhuollon priorisointiin eri maissa, Marjukka Mäkelä, Maija Saijonkari and Neill Booth, 2017), available only in Finnish: [Katsaus terveydenhuollon priorisointiin eri maissa \(STM: n raportteja ja muistioita 2017:18\)](#)

Report on assessment and use of evidence in the new health and social services structure—alternatives to organizing health-technology assessment in Finland (Näytön arviointi ja käyttö uusissa SOTE-rakenteissa – Vaihtoehtoja terveydenhuollon menetelmien arvioinnin järjestämisestä Suomessa, Kristian Lampe ja Ulla Saalasti-Koskinen,

2017), available only in Finnish, abstract in English: [Näytön arviointi ja käyttö uusissa SOTE-rakenteissa – Vaihtoehtoja terveydenhuollon menetelmien arvioinnin järjestämisestä Suomessa \(STM: n raportteja ja muistioita 2017:12\)](#)

Report on using cost-effectiveness as one defining criterion for health-care service choices (Kustannusvaikuttavuuden käyttämisestä yhtenä terveydenhuollon palveluvalikoiman määrittelykriteerinä, Neill Booth, Pasi Aronen and Marjukka Mäkelä, 2017), available only in Finnish, abstract in English: [Selvitys kustannusvaikuttavuuden käyttämisestä yhtenä terveydenhuollon palveluvalikoiman määrittelykriteerinä \(STM: n raportteja ja muistioita 2017:30\)](#)

3.3 Norway

Background and status

Health-technology assessment (HTA) is a knowledge summary based on a systematic summary of research concerning effect and safety (a systematic overview) and an assessment of the consequences, usually in terms of health economics (nyemetoder.no).

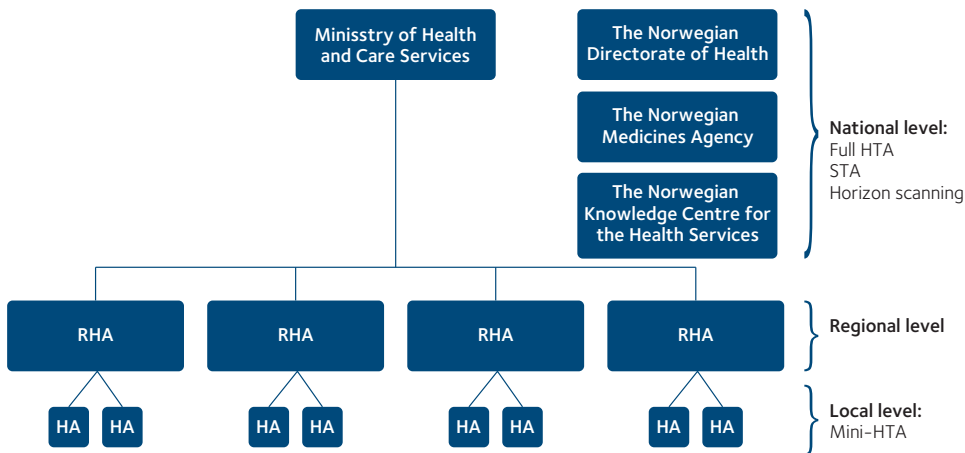
Purpose of the Norwegian HTA System

- to improve patient safety connected to the introduction of new health technologies,
- to ensure that patients as quickly as possible gain equal access to new health technologies that have been documented as being effective and fulfil requirements concerning safety and are cost-effective,
- to ensure that new health technologies that are ineffective and/or harmful for patients are not introduced and that old health technologies are disinvested,
- to provide an appropriate decision-making platform for priority setting within the specialist health service based on HTA,
- to ensure rational use of resources within specialist health care, and
- to implement a predictable and systematic process for introducing new health technologies.

Key Elements in the Norwegian HTA System

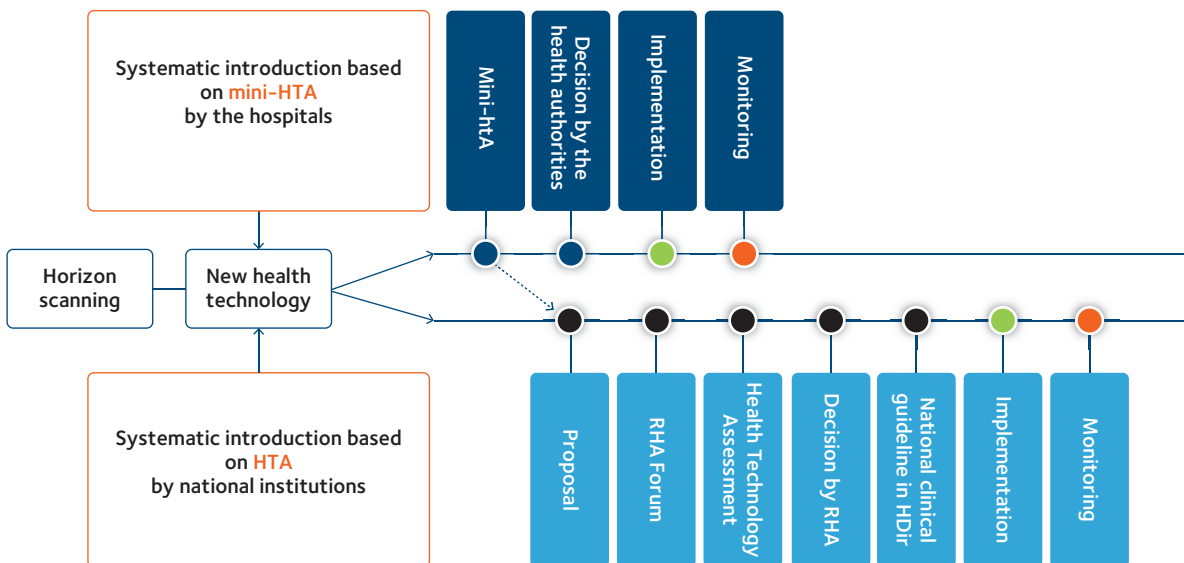


Key stakeholders



STA = Single Technology Assessment
 RHA = Regional Health Authorities, HA = Hospitals

Key process



Broad Cooperation

The Ministry of Health and Care Services (HOD) is the owner of the system, and it is based on a broad cooperation between the four regional health authorities (the South-Eastern Norway Regional Health Authority, the Western Norway Regional Health Authority, the Northern Norway Regional Health Authority, and the Central Norway Regional Health Authority) including all the hospitals, the Procurement Services for Health Enterprises Ltd, the Norwegian Institute of Public Health, the Norwegian

Medicines Agency, the Norwegian Directorate of Health, and the Norwegian Radiation Protection Authority. In addition, a broad stakeholder group is established consisting of representatives from patient organizations, industry, professional associations, and universities to contribute to the development of the system. The continuous dialogue with the industry associations within the pharmaceutical, medical-devices, and laboratory fields is important.

Further description of elements in process

Product	Description	Duration	Knowledge base	Proposals	Executive responsibility	Decision-making responsibility
<i>Horizon scanning</i>	Early detection of new methods		Information from manufacturer, the specialist health service, systematic literature searches, international networks for horizon scanning	Not based on proposal, but identification via a set of different channels	(in the process of clarification)	Not decision-making level
<i>Mini-HTA</i>	Tool in connection with the introduction of new health technologies in HAs (effect, safety, costs, ethics, organisation)	5-7 days	Published systematic overviews and studies identified through systematic literature searches*	HA clinic/department/division	HA clinic/department/division	HA
<i>STA for other health technologies</i>	Systematic overview of effect, safety and health economics, other consequences	Up to 6 mths.	Clinical studies and health-economic models submitted by manufacturer, and systematic literature searches	RHA Forum	The Norwegian Knowledge Centre for Health Services	RHA ¹
<i>Full HTA</i>	Systematic overview of effect and safety, health economics, ethics, legal and organisational consequences	8-12 mths.	Clinical studies identified through systematic literature searches ² Health economics analysis prepared by the Norwegian Knowledge Centre for Health Services	RHA Forum	The Norwegian Knowledge Centre for Health Services	RHA Norwegian Directorate of Health
<i>National clinical guidelines</i>	Systematically developed, knowledge-based advice and recommendations	18-36 mths. ⁴	Knowledge-based practice assessed in the context of values, resource use, prioritisation criteria, laws and regulations. Use of GRADE methodology ³	Norwegian Directorate of Health	Norwegian Directorate of Health	Norwegian Directorate of Health

Mini-Health-Technology Assessment (Mini-HTA)

Mini-health-technology assessment (mini-HTA) is a simplified HTA, generally based on systematically summarized research and used locally by the health authorities to support decisions concerning the introduction of a new health technology. A mini-HTA consists of a three-part form as well as guidance. The questions in the form consider circumstances linked to effect, safety, costs, organizational consequences, and ethical aspects linked to the introduction of the new health technology.

[https://nyemetoder.no/Documents/Administrativt%20\(brukes%20kun%20av%20sekretariatet!\)/System%20Description%20\(23012014\).pdf](https://nyemetoder.no/Documents/Administrativt%20(brukes%20kun%20av%20sekretariatet!)/System%20Description%20(23012014).pdf)

Processes for Mini-HTA / Local HTA

1. Systematic introduction based on mini-HTAs by the hospitals (health authorities)	
Horizon scanning	Identification and notification of new health technologies.
Mini-HTA	Initiated by the professional community and/or management and conducted by the individual hospital (without an order/application process). Generates a basis for a decision.
Decision by health authority	A decision concerning introduction is taken or the issue is elevated to national level.
Implementation	Introduction of health technology within the health authority after the decision has been taken.
Monitoring	Follow-up and monitoring of new health technology.

Processes for National HTAs (STA and Full HTA)

Horizon scanning	Identification and notification of new health technologies.
Proposal	Proposal for HTA is submitted through completion of a proposal form, which is then sent to the Norwegian Directorate of Health secretariat by the specialist health service, the Norwegian Directorate of Health, producers, patient organisations, etc.
Norwegian Directorate of Health secretariat	Receives and reviews proposals for HTAs. Forwards to the Norwegian Knowledge Centre for Health Services and the Norwegian Medicines Agency for assessment of relevance. The coordinators in the Regional Health Authorities are notified.
Coordination Committee RHA	Prepares a draft for the prioritisation of orders/applications for the RHA Forum.
RHA Forum	Prioritises and delegates tasks concerning single technology assessments or full HTAs.
HTA	Performing HTAs at national level through: <ol style="list-style-type: none"> 1. <u>Single technology assessment (STA)</u>, an appraisal of a single health technology in relation to a particular area of use/indication, at an early stage. <ol style="list-style-type: none"> a. Medicines. Conducted by the Norwegian Medicines Agency. b. Other health technologies. Conducted by the Norwegian Knowledge Centre for Health Services. 2. <u>Full health technology assessment</u> (comprehensive assessment of, for example, a set of health technologies within an area of therapy). Conducted by the Norwegian Knowledge Centre for Health Services.
Decision by Regional Health Authorities	Decision concerning the possible introduction of a new health technology is taken within existing decision-making structures in the Regional Health Authorities, based on a completed HTA within the financial framework of the RHAs.
Guidelines	Decision concerning the possible introduction of a method is coordinated with

	national clinical guidelines under the auspices of the Norwegian Directorate of Health, possibly involving the formulation of new guidelines.
Implementation	Decisions are implemented through existing guidelines and authority structures in accordance with national clinical guidelines.
Monitoring	Follow-up and monitoring of new health technology.

Single Technology Assessment (STA)

Single (Rapid) Technology Assessment (STA) involves an assessment of effect, safety, and cost-effectiveness. In the case of medical devices and procedures, it may also be relevant to evaluate other consequences or preconditions for effective use. The documentation may be submitted by a manufacturer.

[https://nyemetoder.no/Documents/Administrativt%20\(brukes%20kun%20av%20sekretariatet!\)/System%20Description%20\(23012014\).pdf](https://nyemetoder.no/Documents/Administrativt%20(brukes%20kun%20av%20sekretariatet!)/System%20Description%20(23012014).pdf)

Full HTA

Full Health-Technology Assessment (full HTA) is a more comprehensive systematic assessment of new or established health technologies that evaluates effect, safety, and cost-effectiveness. An HTA often also covers issues related to ethical, legal, organizational, and social consequences.

[https://nyemetoder.no/Documents/Administrativt%20\(brukes%20kun%20av%20sekretariatet!\)/System%20Description%20\(23012014\).pdf](https://nyemetoder.no/Documents/Administrativt%20(brukes%20kun%20av%20sekretariatet!)/System%20Description%20(23012014).pdf)

Horizon Scanning (identification and notification of new health technologies)

Horizon scanning, also known as alerts or early awareness in an international context, encompasses the identification and, where appropriate, assessment of new health technologies at an early developmental stage.

Horizon scanning is one of the principal components of the HTA system, and it identifies and provides information on new health technologies at an early stage with the aim of enabling health authorities and health services to make the necessary preparations for the introduction of new health technologies within the specialist health service in due time.

[https://nyemetoder.no/Documents/Administrativt%20\(brukes%20kun%20av%20sekretariatet!\)/System%20Description%20\(23012014\).pdf](https://nyemetoder.no/Documents/Administrativt%20(brukes%20kun%20av%20sekretariatet!)/System%20Description%20(23012014).pdf)

Scope, Content and Use of the Various HTAs in the System

	Mini-HTA	STA	Full HTA
Effect	X	X	X
Safety	X	X	X
Costs	X	X	X
Cost-effectiveness		X	X
Budget consequences		X	X
Ethics	X		X
Organisation	X	(X)	X
Law			X
Medicines		X	X
Medical devices	X	X	X
Procedures	X	X	X
Organisational initiatives			X
Screening			X
Highly specialised services			X
Single health technology	X	X	X
Several health technologies			X

3.4 Sweden

Background and status

In Sweden, health-care staff is obliged to carry out their duties in line with science and proven experience according to Swedish law. At the same time, the ever-increasing number of published research articles makes it impossible for the individual health-care provider to assimilate flow of new knowledge. The research results may need to be sorted, reviewed, and compiled to be comprehensible. HTA is here an important tool for introducing new medical methods, but also for monitoring and as a basis for revision of the existing medical technology, for example, when deciding on a possible phaseout.

There are today few examples how procurement authorities utilize HTA and there is no concrete proposals and conclusions for how to link the HTA and procurement processes. At the same time, many initiatives are today focusing on the entire purchasing process, where procurement is only a minor part. It is likely that there will be better opportunities to include HTA if it is introduced early in the purchasing process, when there is still time to develop the documentation necessary in a future procurement.

Key Stakeholders

Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU; Statens beredning för medicinsk och social utvärdering)

SBU is a national agency, tasked by the government with assessing health-care and social-service interventions in a broad perspective, covering medical, economic, ethical, and social aspects. The SBU process can also be performed by other relevant stakeholders, like regional HTA organizations and universities.

SBU assessments are based on systematic literature reviews of published research. Based on current research, SBU can find out which medical effect methods have, whether there are risks associated with them, and whether the methods are of any value. Suggestions for topics for assessment by SBU may come from various sources, such as individuals, organizations, government authorities, and decision-makers in the health-care sector. The topics selected are very important to our health and quality of life. For example, some projects evaluate medical conditions for which there are regional variations in treatment methods and outcomes. High priority may also be given to topics that are ethically controversial or cases where the implementation of an intervention would cause considerable disruption to the existing organization of health-care delivery.

SBU also chairs a national HTA network. The network includes representatives from regional HTA organizations, The National Board of Health and Welfare, and TLV. It cooperates to avoid duplication of work and to both further develop the HTA methodology and find a common approach.

The Dental and Pharmaceutical Benefits Agency (TLV; Tandvårds- och läkemedelsförmånsverket)

The Dental and Pharmaceutical Benefits Agency (TLV) is a government agency whose remit is to determine whether a pharmaceutical product, medical device, or dental-care procedure will be subsidized by the state. TLV also performs health-technology assessments of medical devices and regulates the pricing and reimbursement of medical-device consumables.

The agency's aim for the health-technology assessments is to achieve

- greater transparency of direct costs and other costs associated with the introduction and use of medical devices,
- an increased understanding of cost effectiveness,
- better use of existing resources for knowledge-based assessments that are applicable and available for the whole of Sweden,
- a more knowledge-based and equitable use of medical devices throughout Sweden, and
- promotion of a managed introduction of medical devices in Sweden.

The target audience for TLV's medical-device health-technology assessments are primarily decision-makers at regional and county-council level but also includes government agencies, patient associations, researchers and health-care providers, as well as medical-device producers and distributors. However, the results of each evaluation do not mean that the county council directly purchases the product. The evaluations are designed to support decision-making.

TLV carries out evaluations of products or methods that involve a large group of patients and that are based on criteria that county councils and municipalities have requested. It evaluates whether the product or the method can make the patient more able to manage herself and whether the product or the method allows cost savings for public health services.

Once an evaluation is complete, the report is sent to all county councils / regions and the company concerned. The report is also published on the TLV's website.

The criteria TLV consider important when choosing which new methods or products to evaluate are

- financial impact,
- disease severity,
- epidemiology of the disease,
- insufficiently met clinical needs,
- high / low clinical efficacy, and
- unequal today's solution

The National Board of Health and Welfare (Socialstyrelsen)

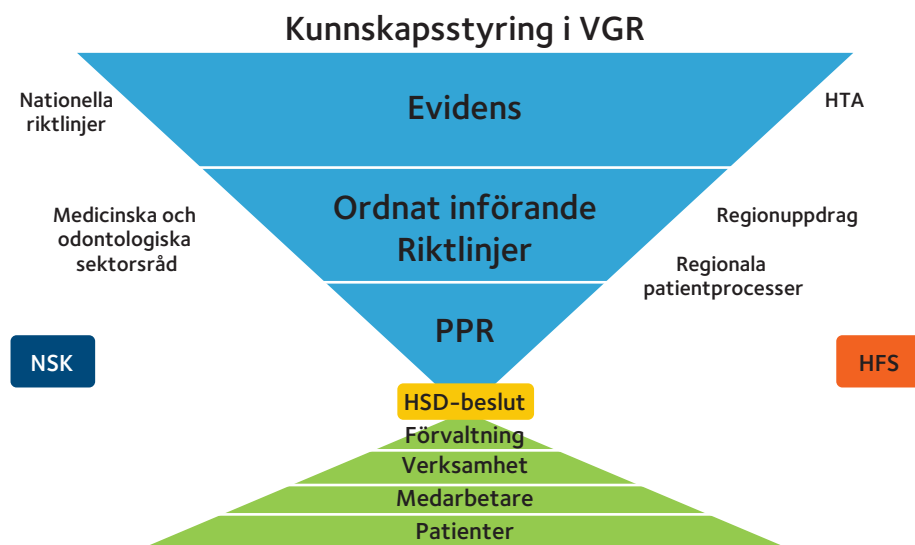
The National Board of Health and Welfare is a government agency with a very wide range of activities and many different duties within the fields of social services, health and medical services, patient safety and epidemiology.

The agency

- collects, compiles, analyzes, and passes on information,
- develops standards based on legislation and the information collected, and
- undertakes other official duties such as maintaining health-data registers and official statistics.

Regional HTA-Organizations

HTA reports are also to some extent produced by local HTA organizations in Sweden's county councils. To facilitate the medical and administrative decision, a mini HTA can be used when introducing new methods. The various county councils determine how they want to organize their work with HTA and introducing new medical devices and methods. In the picture below, you can see how the region of Västragötaland presents how it works.



Abbreviations:

- NSK: Nationell samverkan för kunskapsstyrning
HFS: Nätverket hälsofrämjande hälso- och sjukvård / Swedish Health-Promoting Hospitals and Health Services Network
HSD: hälso- och sjukvårdsdirektör / health-care director

National Work for the Introduction of Medical Devices and Methods

In 2016, the Swedish government and the Swedish Association of Local Authorities and Regions made an agreement to carry out a preliminary study on how to improve the process of introducing new medical devices.

The preliminary study aimed to find ways for county councils to collaborate with one another and coordinate a more orderly and systematic introduction of medical devices and methods. In addition, the preliminary study was to map the county council's needs for health-economic knowledge bases and the way in which the county council would use these in the process of implementing medical devices.

The preliminary study was presented in March 2017.

The main conclusion of the preliminary study was that the goal of the collaboration to introduce new medical devices should be that patients across the country have equal access to cost-effective solutions. The study also stated that the complexity of the medical-devices area meant that there will never be one solution to the problem of introducing new medical devices and methods.

Close collaboration between county councils and government is thus a prerequisite for a coordinated introduction of medical devices and methods. Generating evidence for the use of new methods is central; as are views on what is sufficient evidence for a decision to be taken.

Initially, it is likely that only a few products or methods per year will be relevant to such a process.

The preliminary study pointed out some areas for further investigation and work:

- Implement a national project where county councils, authorities, and companies in collaboration develop a horizon-scanning process for medical devices.
- Establish a process for collaboration between county councils and governmental agencies for the selection of medical devices and methods that should be subject to nationally organized implementation.
- Designate contacts in all county councils who act as links between the national and the regional levels.
- Improve the follow-up of the introduction of new medical devices and methods.

Key process

Full HTA

A *full HTA* (health-technology assessment) is a comprehensive systematic literature review for assessment of new or established health technologies that evaluates cost / financial impact, effectiveness, safety, and cost-effectiveness. It includes a critical appraisal of the evidence and describes the characteristics and current use of the technology. A full HTA often also covers issues related to ethical, legal, organizational, and social consequences.

Typically produced by:

- SBU
- TLV

Mini-HTA, Including Rapid Review

A *mini-HTA* is a comprehensive systematic literature review for assessment of new or established health technologies that evaluates cost / financial impact, effectiveness, and safety. It includes a critical appraisal of the evidence and describes the characteristics and current use of the technology. A mini-HTA often also covers organizational issues. In Sweden, it is often produced by the local health authorities to support decisions in connection with the introduction of a new health technology.

Typically produced by:

SBU
TLV
Socialstyrelsen
HTA-centrum, VGR
HTA-O, Skåne
CAMTÖ, Örebro
Regionala metodrådet/ CMT, Östergötland
HTA-metodrådet, Stockholm

Rapid Review

A *rapid review* is a quicker type of mini-HTA. It does not include a comprehensive systematic literature review but reviews the highest level of evidence or recent evidence and may restrict the literature to one or two databases. It evaluates effectiveness and safety and describes the characteristics and current use of the technology. It may include cost / financial impact and a critical appraisal of the evidence.

A Summary of the Parts Included in Each Form of Assessment

HTA elements	Full	Mini	Rapid
Comprehensive systematic literature review, or a systematic review of high level evidence	always	always	never
Review of high-level or recent evidence	never	never	often
Description of the characteristics and current use of the technology	always	always	always
Critical appraisal of the quality of the evidence base	always	always	optional
Evaluation of safety and effectiveness	always	always	always
Determination of the cost effectiveness	always	never	never
Evaluation of costs/financial impact	always	always	optional
Evaluation of organizational consequences	always	optional	optional
Evaluation of ethical, social and legal consequences	optional	optional	optional

Horizon Scanning

Horizon scanning is the systematic identification of health technologies that are new, emerging, or becoming obsolete with the aim of enabling health authorities and health services to make the necessary preparations for the introduction of new health technologies in due time.



4 HTA Template—case Norway

This HTA template is developed by the Norwegian Governmental Agency Nyemetoder.no. There are numerous different templates that can be used in the Nordic countries. The intended use of this HTA template is to serve as a guide and example of an HTA framework as well as a checklist when understanding, preparing and submitting an HTA.

1 Introduction

The national system for the introduction of new health technologies within the specialist health service will involve the rapid assessment of health technologies in relation to the introduction of medical devices, diagnostic methods, procedures and pharmaceuticals.

Two templates for Single Technology Assessment (STA) have been prepared:

1. Template on submission of documentation for the STA of medical devices, diagnostic methods and procedures
2. Template on submission of documentation for the STA of pharmaceuticals

****The System Description is the main document. We refer to it for information about the national system, and description of various types of Health Technology Assessments (HTAs) Nettside- [klikk her](#)**

****This template will be for submission of documentation to the Norwegian Knowledge Centre for the Health Services for Single Technology Assessment (STA).**

The actual template should only be used by the manufacturers that are asked to send in documentation. The template is to be used after RHA Forum (Regional Health Authorities Forum for the commissioning of HTAs) requests (through the use of a proposal order) the Norwegian Knowledge Centre for the Health Services to carry out a STA. The Norwegian Knowledge Centre for the Health Services will then ask for documentation by the actual manufacturer in accordance with the guidance in this template.

Questions concerning the template or any requests for assistance, meetings, etc. in regard to submission of documentation should be sent to: Metodevurdering@kunnskapsenteret.no

The economic analyses in the health technology assessments that are to be conducted are based on the recommendations in the Norwegian Directorate of Health's guideline for health economic analyses, which in turn follow the recommendations in the Ministry of Finance's guideline to socio-economic analyses and the Ministry of Government Administration, Reform and Church Affairs' Instructions for Official Studies and Reports. The template on submission of documentation for STA also contains a number of specific requirements as regards content and requirements concerning reporting. These are in part based on the requirements in the guideline for health technology assessments for the National Institute for Health and Clinical Excellence (NICE). It will also be necessary to seek assistance concerning the health technology description in the Norwegian Knowledge Centre for Health Services manual "Slik oppsummerer vi forskning" (in Norwegian) or the Cochrane Handbook.

The Norwegian Knowledge Centre for Health Services asks manufacturers to ensure that the documentation is presented systematically as proposed in this template. Deviations from the template and elements that are considered by the manufacturer not to be relevant must be justified. Documentation may be submitted in either English or a Scandinavian language. The documentation should be submitted electronically in Word format. **If a health economic model has been used to calculate cost-effectiveness, it is assumed that this will also be submitted and that it has been created using a program that is familiar to the Norwegian Knowledge Centre for Health Services (Excel, TreeAge).**

If the documentation contains confidential information (commercial secrets or data awaiting publication), which cannot be published by the Norwegian Knowledge Centre for Health Services, this must be agreed in advance. The Norwegian Knowledge Centre for Health Services will publish completed reports on its website.

The template has been prepared by the Norwegian Knowledge Centre for the Health Services in collaboration with the national working group for the introduction of New Health Technologies in the Specialist Health Service.

2 Technology to be appraised

Briefly describe what task the submission of STA documentation is to respond to.

3 Information about the manufacturer's / manufacturer's representative

Applicants contact information.

4 Background

4.1 Description of the health technology

- 4.1.1 *What type of health technology is involved*
Medical devices? (If yes, outline category)
Diagnostic methods?
Procedures?
Other methods? Please specify
- 4.1.2 *How does the health technology work? State the principle.*
- 4.1.3 *Is the health technology new or a further development of an existing health technology?*
- 4.1.4 *Is the health technology or procedure already in use for other patient groups or for other indications?*
- 4.1.5 *What is the status of the health technology concerning any certification, CE-marking, use or approval in a) Norway and b) other countries (internationally)?*
- 4.1.6 *Describe briefly the development process for the health technology or procedure*
- 4.1.6 *List ongoing studies or other documentation which may become available for assessment during the next twelve months and subsequent years*

4.2 Description of the context for use

- 4.2.1 *What patient groups/conditions are to be helped using the health technology or procedure?*
 - Describe the most relevant patient group(s), including current and anticipated developments in prevalence/incidence.
 - Describe the disease(s) for which the health technology is indicated, including consequences of the disease in the short and long term, as well as severity of the disease

- 4.2.2 *What advantages is the health technology intended to give compared with the current health technology?*
- 4.2.3 *Which treatment(s), including other health technologies will be displaced – either partly or entirely- by the new technology?*
 - What place is the health technology thought to have in the everyday clinical set-up/health service?
- 4.2.4 *How many patients will be affected?*
- 4.2.5 *Describe any Norwegian national clinical guidelines for the condition which could be affected by the health technology*
- 4.2.6 *Will the health technology or procedure result in changes in the course of diagnostics or treatment?*
- 4.2.7 *Will the introduction of the new technology result in changes of the infrastructure (organization of the health service, spatial requirements, training, monitoring, follow-up, administration or costs)?*
- 4.2.8 *What are the key groups for comparison? Justify the choice on the basis of Norwegian clinical practice.*
- 4.2.9 *Could introducing the new technology have negative consequences for vulnerable patient groups?*
- 4.2.10 *Describe the current Norwegian treatment tradition / practice*

5 Clinical effect

What clinical documentation is available to demonstrate that the health technology is effective and safe?

In cases where the actual health technology has been through clinical studies, a certification and/or an approval process in Norway or abroad, the information should be included.

Additionally, systematic searches for studies involving the new technology and comparison alternatives must be performed in relevant databases detailing relevant outcome objectives. For information about systematic searches see the Norwegian Knowledge Centre for Health Services health technology manual «slik oppsummerer vi forskning» (In Norwegian). <http://www.kunnskapssenteret.no/verkt%C3%B8y/slik-oppsummerer-vi-forskning>

5.1 Description of the study identification

5.1.1 Inclusion and exclusion criteria

- Describe what has been done to identify relevant clinical data, both published and unpublished.
- In connection with searches for published studies, describe the selection of electronic databases, which databases were searched, state the date and time of the search and enclose complete search strategies with the number of hits (may be in enclosures). The search will be checked by an employee of the National Knowledge Centre for the Health Services.
- Describe the inclusion and exclusion criteria in the studies:

Inclusion criteria	Population/patient group/indication Intervention Comparison Endpoint Study design Linguistic limitations Study quality
Exclusion criteria	Specify whether there were any special exclusion criteria

5.1.2 Selection of studies

- Describe the process for the selection of studies and create a flow chart for the process.
- If possible, state the number of studies of each type/design that were available during each stage in the process. If appropriate, adapt the flow chart developed by PRISMA (<http://www.prisma-statement.org/statement.htm>)
- Specify whether data from a single study has been published in several publications.

5.1.3 Relevant studies

- Prepare a complete list of relevant studies.

Study (acronym, ID no.)	Reference	Population	Intervention	Comparison
Type of design				
Study 1				
Study 2				
Etc.				

- If any of the identified studies will not be used further as part of the documentation basis, this must be stated and justified.

5.2 Description of studies included

5.2.1 Studies included

- Give a brief summary in text and describe details from each study in table form. Specify any important differences between the studies.

Study (acronym, ID no.)	Study 1	Study 2	Etc.
Location/place conducted/country			
Design/study type			
Duration of the study			
Randomisation method			
Blinding method (investigator, patient, outcomes assessor)			
Intervention (n=)			
Comparison/control (n=)			
Primary outcome (including measurement tools and measurement times)			
Primary outcome (including measurement tools and measurement times)			
Follow-up time			

5.2.2 The patients/participants in the studies

- Describe the patients/participants in each study
- Give a brief summary in text and describe details from each study in table form. Specify any important differences between the studies.

Study (acronym, ID no.)	Inclusion criteria	Exclusion criteria
Study 1	Important inclusion criteria such as age, gender, diagnosis, severity, etc.	
Study 2		
Etc.		

- Present an overview table of important baseline characteristics of the patients in the studies included.

Study (acronym, ID no.)	Intervention	Comparison
Study 1 (n=)	(n=)	(n=)
Age		
Gender		
etc.		
Study 2 (n=)	(n=)	(n=)

5.2.3 Endpoints

- Describe the endpoints in each study
- The choice of endpoints should be in line with the guidelines by EUnetHTA. Describe the selections for this research issue. When appropriate, state whether the tools used have been validated and are valid in Norway.

Study (acronym, ID no.)	Primary outcome	Validity in current practice	Secondary outcome, including side effects	Validity in current practice
Study 1				
Study 2				
etc.				

5.2.4 Statistical analyses and definition of study groups

- Describe the research hypothesis that was investigated and the statistical analyses that were used.
- Specify the strength calculation and sample size calculation, including the assumptions that have been made.
- State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.

Study (acronym, ID no.)	Hypothesis	Statistical analysis	Sample size, strength calculation	Handling of data (withdrawals, missing measurements, etc.)
Study 1				
Study 2				
etc.				

5.2.5 Flow chart

- Present a flow chart of the patient's progress through the study (randomised patients, withdrawal from the groups, replacement of groups, etc.). See for example Consort's chart.

5.3 Detailed description of included studies

5.3.1 Give a detailed description of all included studies included.

- See the Norwegian Knowledge Centre for Health Service's health technology manual "Slik oppsummerer vi forskning" (in Norwegian).
- A complete quality evaluation of all studies must be enclosed.
- The evaluation will be checked by an employee of the National Knowledge Centre for the Health Services.

5.4 Presentation of results

5.4.1 Present results for all relevant endpoints.

- Where possible, data must be presented as "intention-to-treat" analyses (analyses where all the patients are analyzed in the group in which they started). Depending on the study design and type of endpoint, other types of analysis may also be relevant (e.g. "on-treatment" and "safety-on-treatment").

- Always define which patients are included in the analysis and, where applicable, the reasons why any patients were not included in the analyses.
- State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.
- Data should be presented in the form of text, table and graphics where possible.

5.4.2 Meta-analyses

- If there is more than one study, consideration must be given to performing meta-analyses. Clearly present the assessment behind the decision regarding whether or not meta-analyses are suitable.
- In cases where meta-analyses are included, provide at least the following: selection method (random or fixed effects model, choice of effect parameter, sensitivity analyses) and test for heterogeneity.

5.4.3 Indirect comparisons

- If there are no directly comparable studies (head-to-head studies), consideration must be given to the execution of indirect comparisons. See the EUnetHTA's guidelines for indirect comparisons.
- Present clearly the assessment behind choices made, how the studies for indirect comparison were identified, how the data was extracted and the method adopted for analysis.

5.5 Summary of the key findings

- Briefly summarize key findings of presently available clinical documentation, with a focus on effects and side effects of the new health technology (the device or procedure).
- Give a brief summary of the strengths and weaknesses inherent in the documentation available for the new health technology (the device or the procedure).

5.6 Relevance to Norwegian conditions

- Briefly discuss how and to what extent the provided documentation is relevant for the application.
- Identify factors which could be of significance for the external validity of the study results when applied in normal clinical practice.

6 Cost-effectiveness

6.1 Previously published cost-effectiveness analyses

6.1.1 Identification of other relevant published analyses

- If published health economic analyses that are relevant to the case exist, the Norwegian Knowledge Centre for Health Services wishes that such analyses are enclosed.
- Fill in the following table summarizing identified studies.

Study	Year	Country in which the study was conducted	What type of model analysis?	Patient population (age, gender, state of health, etc.)	Incremental QALY* benefit	Incremental costs	ICER**	Comparison
Study 1								
Study 2								
Etc.								

* QALY: Quality-Adjusted Life Years ** ICER: Incremental Cost-Effectiveness Ratio

6.1.2 Previously published mini-HTA?

- Enclose the search results from the relevant mini-HTA (can be found in the MedNytt database).

6.2 In-house cost-effectiveness analysis

- The recommendations in the table below specify a standard analysis for evaluations of the cost-effectiveness of different measures. 'Standard analysis' means health technologies, assumptions and unit values that are preferably to be common. The column on the right specifies the section in the Norwegian Directorate of Health's guideline in which each of the elements in the analysis is discussed.

Element in the analysis	Standard analysis	Section in the Norwegian Directorate of Health's guideline
Comparison alternative	The measure or measures which the new measure will essentially replace.	2.4
Analysis perspective	The health service's perspective for both health benefits and costs If applicable, the social perspective too	2.5
Time horizon	Sufficiently long to ensure that all important future differences in costs and consequences between the alternatives are identified	2.6
Analysis method	CUA*	2.8
Objectives for health and indicators for health benefits	QALY and life years	2.7
Method for measurement and personal valuation of health benefits	Generic MAU** instruments	2.7
Inclusion of production effects	May be included if relevant. Method selection must be justified. The results should be shown with and without production effects.	2.9
Discounting	4% per year for both costs and health effects.	2.10
Method for handling uncertainty	PSA***, one-way sensitivity analyses (shown in tornado diagram) and scenario analyses	2.12

* CUA: Cost-Utility Analysis

** MAU: Multi-Attribute Utility

*** PSA: Probabilistic Sensitivity Analysis

- 6.2.1 *The patient group in the analysis*
- Describe the patient group at which the analysis is aimed. Does it differ from the target group as defined in 4.2.1, and if so, how?
- 6.2.2 *The structure of the analyses*
- Describe and explain the structure of the analyses.
 - Is the analysis based on modelling or based directly on costs and health effects collated as part of a comparative efficacy study (piggyback analysis)? Or a combination of these?
 - If modelling is used, state how the course of the disease with the current treatment is modelled and the new treatment. State the reasons for the choices made during construction of the model.
 - If the analysis is based directly on a comparative efficacy study, please describe the collation of costs and health effects in detail, such as choice of target group, determination of how the data (costs, quality of life data) is to be acquired and analysed, and choice of time interval/time frame for data acquisition.
- 6.2.3 *Concerning the methods: the intervention(s) and comparator(s)*
- In connection with the selection of comparison alternative, follow the recommendations in the Norwegian Directorate of Health's guideline (section 2.4) and in the EUnetHTA's guidelines on how to carry out a health technology assessment.
 - Is use of the method in the analysis in accordance with the use investigated in the clinical studies? If not, explain why.
- 6.2.4 *The perspective and time horizon of the analyses*
- In STAs for health technologies, the analysis must be carried out using both the societal perspective and the health care perspective.
 - The Norwegian Knowledge Centre for the Health Services refers applicants to the Directorate of Health's guidelines and its recommendation 5, in addition to section 2.5 about perspective:
 - Societal perspective: The analyses should at the first hand be carried out using the societal perspective, and should give an overview of the consequences for all involved actors. It is recommended that the analyses should be carried out using the societal perspective where all significant costs and consequences are included, regardless who it involves, e.g. the public health service, municipality, companies, patients, relatives.

- Health care perspective: In analyses on new efforts in the health service, the most important costs will most often be from the health and care services, and the most important health effects will be related directly to the patients. We recommend to rely on a broad perspective related to consequences.
- The time horizon of the analysis should be sufficiently long to ensure that all important differences in costs and health effects between the comparison alternatives are identified. This will often result in a need for a life-cycle perspective.

6.2.5 *Use of efficacy data in the model*

- It is recommended that clinical efficacy data from the included studies, should be included in the model in the form of hazard ratios (or alternatively relative risks or odds ratios) for an event or condition applied to a background risk taken from Norwegian epidemiological data (see the section below).
- Describe all the stages in the calculation of probability for different events in the model.
- Clinical, hard endpoints (e.g. number of cases of relapse, infarction, death, etc.) are preferred in the modelling. If intermediate (surrogate) endpoints are to be used in the model instead of clinical endpoints, this must be justified (e.g. HbA1c, LDL-c, SBP, PSA, etc.). Please also give references and discuss the available evidence which supports the ratio between the chosen surrogates and the relevant clinical endpoints. See the EUnetHTA's guidelines on the use of surrogate endpoints in health technology assessments for more details.
- For how long time period was the efficacy data applied? If this extends beyond the period for which clinical documentation is available, this must be justified and assumptions must be described thoroughly. Show the results in diagram form, e.g. using the Kaplan-Meier curve.

Variable	Value	95% confidence interval	Probability distribution (type and parameters)	Reference
Outcome 1				
Outcome 2				
Etc.

6.2.6 Use of epidemiological data in models

- The analysis should preferably be based on Norwegian epidemiological data as the source for background risk. If Norwegian epidemiological data are not available, data from countries that are considered to be as similar as possible to Norway in terms of the occurrence of diseases should be chosen.
- On occasions, a balance must be struck between study quality and transferability (internal vs. external validity). In such cases, advantages and disadvantages in connection with the various choices should be discussed. The control arm from an RCT can be used as a last resort, if it is not possible to find other sources of epidemiological data.
- Please complete the following summary table of the key epidemiological parameters used in the analysis:

Variable	Value	95% confidence interval	Probability distribution (type and parameters)	Reference
Probability of event X				
Probability of event Y				
Etc.		

6.2.7 The patient’s quality of life

- Quality-Adjusted Life Years (QALY) is the preferred objective for health. If QALY is not used in the analysis, this must be justified.
- How does the disease affect the patients’ quality of life? How is the patients’ quality of life expected to develop over time, with and without the currently established treatment? How do these developments compare with the developments for the rest of the population?
- Was quality of life data acquired in connection with the studies from which clinical data was obtained? If yes, describe in detail the method for valuing the patients’ quality of life and for acquiring this data. Include the time of measurement and the confidence intervals concerning the measurements.
- Specify the quality of life weightings which were used in the application in the following format:

State of health/health situation	Quality of life weighting	CI (95 %)	Source	Reason for the selection
State of health 1				
State of health 2				
Etc.				
Event 1				
Event 2				
Etc.				

6.2.8 Identification, measurement and valuation of resource use in the model

- This section is based on section 2.9 of the Norwegian Directorate of Health’s guideline.
- The applicant must also report the costs linked to each of the states of health and the events in the model:

State of health/health situation	Cost item	Unit cost	Quantity	Total cost	Sources
State of health 1	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
State of health 2	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
Etc.					
Event 1	Cost item 1				
	Cost item 2				
	Etc.				
	TOTAL				
Etc.					

6.2.9 Discounting

- It is recommended that both health effects and costs be discounted at the rate recommended by the Ministry of Finance for measures with a low to moderate systematic risk, currently 4% p.a. (see FIN 2005). See section 2.10 of the Norwegian Directorate of Health’s guideline for more details.

6.2.10 *Base case cost-effectiveness results*

- Overview of all treatments assessed in the analysis in ascending order with regard to total costs in the tables below. State the incremental cost effectiveness ratio (ICER) for each of the treatments in relation to the relevant comparator (see section 2.4 of the Norwegian Directorate of Health’s guideline for a description of the criteria for selection of the comparison alternative).

Measure	Total costs (NOK)	Total number of life years	Total number of QALYs	Incremental costs	Life years gained	QALY gained	ICER vs. relevant comparator (QALYs)	NHB (Net Health Benefit)
Treatment alternative 1								
Treatment alternative 2								
Treatment alternative 3								
Etc.								

6.2.11 *Sensitivity analyses*

- The uncertainty concerning the results of the analysis must be investigated, described and discussed via one-way and probabilistic sensitivity analyses, as well as scenario analyses. See section 2.12 of the Norwegian Directorate of Health’s guideline for a more comprehensive discussion of these methods.

6.2.13 *Interpretation of the analysis results*

- What does the applicant consider to be the key strengths of the analysis? And the key weaknesses?
- Are the results of the applicant analysis in accordance with the results of previously published analyses? If not, state the possible reasons behind the differences.

6.2.12 *Sub-group analyses*

- Is data available which indicates that the efficacy and/or costs associated with the health technology under consideration differ between sub-groups?
- If so and the measure has indication/CE marking for the treatment of these sub-groups, state whether the sub-groups were identified before the clinical study was conducted (a priori) or after the results of the study became available (a posteriori); describe the sub-groups’ characteristics; and finally report the model’s results for these sub-groups.

7 Budgetary consequences of the new technology

The manufacturers/applicants must provide/present an analysis of their technology's budgetary consequences. The Norwegian Knowledge Centre for the Health Services will then evaluate and possibly carry out own calculations where necessary.

The applicant must calculate and provide the budget implications on program category 10:30 of the National State Budget (Specialist health care services). The budget impact/implication is hereby defined as the additional costs incurred i.e. the total costs of introducing the new technology minus the total costs of not doing so.

These calculations/analyses are intended for the national level. Budget calculations at the regional or local level should be done regionally or locally.

The time horizon in relation to budget analyses of pharmaceuticals shall be five years. This is because it is assumed that the broad usage of new pharmaceuticals is well established after five years. For other technologies, the time horizon may vary depending on the economic life and/or depreciation of the technology.

Calculation of the additional costs shall be based on the following factors:

1. Costs incurred by the specialist health service during the calculation/analysis period.
2. The estimated market share of the new technology, in relation to the patient group the technology targets, in each of the relevant years after the decision to use the technology is made.
3. Deductions of: costs of competing technologies that will be completely or partially replaced by the new technology, any increases in patient payments and increments in user fees during outpatient treatment.
4. Other costs related to the technology assessment (change in bed-days, commodity costs, personnel costs, nursing costs, depreciation, travel expenses covered by the specialist health care service, administrative expenses, etc.) should only be included if there are significant differences between the competing technologies and/or if the differences constitute a large proportion of the additional costs.

The table below shows an example of how calculation of the additional costs can be done. Costs are calculated in two scenarios - one where the technology is introduced into the specialist health service (green table) and one where this is not the case (orange table). In each of the scenarios, costs are only presented for the indication that the new technology will cover. It is possible to provide where applicable; various treatment procedures, different measures, different pharmaceuticals used for treatment of the indication i.e. the new technology and several alternatives/comparators. It is also possible to have a scenario where a certain percentage of patients receive the new technology while a certain proportion of patients receive the alternative comparison technology.

Number or share of patients if the new technology is adopted						Number or share of patients if the new technology is NOT adopted					
	Year 1	Year 2	Year 3	...	Year x		Year 1	Year 2	Year 3	...	Year x
The New Technology						The New Technology					
Alternative/comparator A						Alternative/comparator A					
Alternative/comparator B						Alternative/comparator B					
Alternative/comparator C						Alternative/comparator C					

Cost (Yearly cost per patient * Number of patients per year)						Cost (Yearly cost per patient * Number of patients per year)					
	Year 1	Year 2	Year 3	...	Year x		Year 1	Year 2	Year 3	...	Year x
The New Technology						The New Technology					
Alternative/comparator A						Alternative/comparator A					
Alternative/comparator B						Alternative/comparator B					
Alternative/comparator C						Alternative/comparator C					
Total COST						Total COST					

Budget Impact	Year 1	Year 2	Year 3	...	Year x
+ Cost if the New technology is adopted					
- Cost without adoption of the New Technology, i.e. Current situation					
- Out-of-pocket charges during outpatient treatment					
- Payment by individual patients					
Total added cost					

Budget calculations/analysis should cover both the new technology and the competing technology(ies) if the extent of use is affected by the possible introduction of the new technology. This will in turn make it possible to calculate a total budget impact. The budget impact is the difference between the two scenarios in each of the relevant years of the analysis (tables below). Year 1 is the first full calendar year after a decision is made about introducing the new technology into the specialist health care service.

The budget impact calculations must show the following:

1. What proportion of the total additional costs is the result of an increase in patient numbers and what proportion is due to the transition to a more expensive technology
2. The basis for key assumptions in the calculations.

Additionally, the following calculations may apply in special cases:

1. Subgroup analyses such as in cases where it is prudent to prioritize giving the new technology to only a subset of the total population.
2. Analyses with added costs/impact on other patient groups not targeted by the new technology but whom none the less use the technology.
3. Sensitivity analyses where key assumptions and data are tested in order to check to what extent results and estimates used are sensitive to changes. This is particularly relevant if critical assumptions in the analyses are very uncertain.

8 References

Cochrane Handbook for Systematic Reviews of Interventions,

<http://handbook.cochrane.org/>

Consort statement website,

<http://www.consort-statement.org/consort-statement/flow-diagram0/>

EUnetHTA,

<http://www.eunetha.eu/outputs/new-application-hta-core-model-hta-core-model-rapid-relative-effectiveness-assessment-pharma>

Fornyings- og administrasjonsdepartementet (2005). Utredningsinstruksen.

<http://www.regjeringen.no/nb/dep/fad/dok/lover-og-regler/reglement/2005/utredningsinstruksen.html?id=107582>

Finansdepartementet (2005). Veileder i samfunnsøkonomiske analyser.

<http://www.regjeringen.no/nb/dep/fin/tema/statlig-okonomistyring/samfunnsokonomiske-analyser.html?id=438830>

Helse- og omsorgsdepartement, Meld. St. 10 (2012-2013). God kvalitet – trygge tjenester, kvalitet og pasientsikkerhet i helse- og omsorgstjenesten.

<http://www.regjeringen.no/nb/dep/hod/dok/regpubl/stmeld/2012-2013/meld-st-10-20122013.html?id=709025>

Helsedirektoratet (2012). Økonomisk evaluering av helsetiltak – en veileder.

<http://helsedirektoratet.no/publikasjoner/okonomisk-evaluering-av-helsetiltak--en-veileder/Sider/default.aspx>

Kunnskapssenteret (2009): Slik oppsummerer vi forskning. Håndbok for Nasjonalt kunnskapssenter for helsetjenesten.

<http://www.kunnskapssenteret.no/Verkt%C3%B8y/Slik+oppsummerer+vi+forskning.2139.cms>

Mednytt

<http://www.mednytt.no/>

NICE (2012), Specification for manufacturer/sponsor submission of evidence.

<http://www.nice.org.uk/aboutnice/howwework/devnicetech/SpecificationForManufacturerSponsorSubmissionOfEvidence.jsp?domedia=1&mid=97E2DC44-19B9-E0B5-D4F73F1DB153AA86>

PRISMA Statement – Checklist (2009),

<http://www.prisma-statement.org/statement.htm>

Statens legemiddelverk (2012), Retningslinjer for legemiddeløkonomiske analyser.

http://legemiddelverket.no/Blaa_resept_og_pris/soeknad_om_refusjon/retningslinjer_for_legemiddeløkonomiske_analyser/Sider/default.aspx



5 Recommendations and future work

More efficient use of money spent on health care will be highly prioritized by the Nordic governments in the upcoming years due to an aging population. There will be more need for health-care products and services and a higher demand for new and innovative solutions from the users.

On a European level, we see an increased focus on HTA evaluation of Medtech products. The progress and use of HTA in the Nordic countries are in very different phases, as described in the country-specific sections.

Today, there are very unclear incentives for Medtech suppliers to engage and put resources into HTA processes. This is mainly because there is no obvious link between a positive HTA and changes in treatment guidelines and increased patient access.

One of the key lessons in the project regarding HTA is that dialogue between stakeholders—governmental agencies, the health-care system, and suppliers—is important.

The project recommends

1. that there be continued collaboration between the health-technology industry in the Nordic countries in the established network to share best practice, experience, and information;
2. that one follow and use Medtech Europe's position on future EU cooperation on HTA March 2017 (see Appendix) and adapt it to local conditions;
3. that one continue to monitor the development of the EU commission's current work on a mutual HTA process;
4. that one continue the positive dialogue between stakeholders around HTA;
5. that one work to ensure that the HTA process will be an enabler of innovative solutions rather than a hurdle for patient access; and
6. that one work for an HTA process that is beneficial for all stakeholders—patients, health-care system, and suppliers.

6 Appendix:

1. Medtech Europe position paper
2. Swedish position paper on Medtech HTA vs Pharma HTA
3. Danish position paper on Medtech HTA vs Pharma HTA

**MedTech Europe position
on
future EU cooperation
on Health Technology Assessment
(21 March 2017)**

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Executive Summary

The European Commission is conducting an impact assessment on ways to strengthen the use of and cooperation on Health Technology Assessments (HTAs) at European level. The aim is to explore their potential in keeping healthcare systems financially sustainable while ensuring timely access to innovation that benefits patients.

MedTech Europe, the European trade association representing the medical devices and *in vitro* diagnostics (IVD) manufacturers operating in Europe, fully supports the European Commission's intent. However, we urge the Commission to ensure that its ongoing analyses and future proposals examine and incorporate the specific conditions of the market access model for medical technologies. A dedicated cooperation on HTA for medical technology could then be one of many initiatives contributing to the Commission's objectives, including Europe's 'Better Regulation Agenda'. The proposal needs to recognise the clear differences between medical technologies and pharmaceuticals, as reflected in the specific CE marking regulations for the medical technology sector, which differ from pharmaceutical legislations.

For medical technology, any cooperation on HTA in Europe should be built on the following principles:

- The demand for assessments should come from national and regional decision-makers.
- Member States that share a common unmet need should collaborate on a voluntary, non-legislative basis.
- Avoid compromising the existing well-functioning, distinct market access model for medical technologies, which delivers timely access to innovation.
- Focus on those medical technologies that are truly transformative.
- Identify the optimal point in time for performing HTAs in order to capture the full value of the technology.

Overall, there needs to be a conceptual shift that makes HTA cooperation in medical technology a constructive component of a value-based market access model.

For these reasons, MedTech Europe proposes a modern 'fit-for-purpose' HTA cooperation in Europe, which is suitable for medical technology.

The need for healthcare reform

Europe is in a time of transition. Ageing populations lead to a rise in chronic conditions, which puts a strain on budgets. At the same time, citizens rightfully expect continuous access to high quality healthcare and beneficial innovations. Healthcare systems will have to respond to this mounting pressure. Key questions are how to eliminate inefficiencies in current healthcare delivery, how to drive outcomes that matter to patients, and how to obtain the best value for money.

Our medical technologies already play an important role in optimising treatments and thus the use of scarce healthcare resources. Beyond that, we want to contribute as an active and constructive partner in the public debate. We believe that a shift towards a value-based healthcare model is a key step in addressing the public needs.

The role that HTA can play in the needed healthcare reforms differs significantly between pharmaceuticals and medical technologies: while HTAs of innovative medicines typically inform decisions about pricing and reimbursement, the same is not true for medical technologies, where a strategic link between assessment and decision is missing in many Member States. Discounting this reality would lead to a flawed solution.

Whilst we support the intent of future EU cooperation on HTA, we urge the European Commission and Member States to take this reality into account.

Our industry recognises that there needs to be some way of defining and evaluating the value of innovation. However, this definition needs to embrace a holistic view of value whilst acknowledging the specificities of different sectors.

The following pages explain our concerns and put forward recommendations and solutions for future cooperation on HTA for medical technology in Europe.

The medical technology industry's concerns on future EU HTA cooperation

The Commission aims to strengthen EU cooperation on HTA in a way that will efficiently and effectively contribute to the sustainability of healthcare systems, and simultaneously facilitate timely access of innovation to the benefit patients. MedTech Europe is worried that for medical technologies, the options outlined in the Commission's 'Inception Impact Assessment' would be detrimental to both of these goals as the current proposals use the pharmaceutical market access model as a basis - a model that cannot be applied to our industry.

In the pharmaceutical sector, the information generated in HTAs informs pricing and reimbursement decisions. In addition, the benefit of cooperation that are foreseen arise through preventing duplication of assessments at national level, potentially reducing costs and delays for all Member States.

However, the reality for medical technology is different and thus the above assumptions do not apply for HTAs on medical technology: In those few countries and limited cases (1% of technologies) where HTA is performed, it aims to inform Member State's specific, decentralised decisions at differing times and for differing purposes. The circumstances where all Member States will seek identical information to inform decisions on a medical technology at the same time are not the reality, based upon the analysis of the last three years. This means a low probability of realising the predicted efficiency gains.

On the contrary, up to now HTA cooperation on medical technology has been challenging in terms of finding common ground between member state demands. Cooperation still needs to prove its value in genuinely improving access to innovation for patients or in effectively addressing sustainability.

Moreover, there is a risk of further unintended consequences, if the specificities of the market access model for medical technology is not taken into account:

- **Significant delays in access** to medical technology innovation valuable to patients and health systems. This would have a particularly negative impact on countries that already struggle with unsustainable healthcare systems.
- **Added bureaucracy and costs**, running counter to the Commission's principles of better regulation. Especially the sizeable SME proportion of the medical technology

industry (around 95%) could be severely affected, with a risk of losing jobs and innovation potential in Europe.

- **Investment into medical technology and clinical research could shift out of Europe**, which would have a negative effect both on inward investment, and the development of technologies specific to European needs.

Moreover, using HTA inappropriately in access pathways may actually further **increase healthcare costs** by reducing **competitiveness**. It will thus lead to fewer choices available for personalised care and optimised care pathways.

There are other approaches and initiatives that may better serve the Commission and Member State objectives. One example is the value-based purchasing of medical technologies, in line with the EU Public Procurement Directive, which includes a comprehensive assessment of the value that medical technologies, services and solutions bring.

The industry recommendations for: “Modern ‘fit-for-purpose’ HTA cooperation in Europe for MedTech”

We call for the Commission, Member States, EU Institutions and stakeholders to ensure that the ongoing analyses and future proposals take into account the reality of the medical technology market access model. Any cooperation on HTA in Europe should recognise the clear differences between medical technology and pharmaceuticals in the same way as they do for regulatory approvals.

Any future proposal needs to recognise that the current market access model for medical technology is well-functioning and goes far beyond HTA. HTA is only performed in a limited number of countries for a limited amount of technologies (i.e. 1% of new technologies per year). For the vast majority, well established procurement systems at hospital, local, regional or national level determine the uptake and price. HTA cooperation should add value within this medtech reality.

For HTA cooperation to add value in this environment, **we recommend a fit-for-purpose fully separate modern HTA cooperation for medical technologies**, corresponding to the elements outlined below.

From a governance perspective:

HTA cooperation in Europe in medical technology should:

- Be structured as **voluntary collaboration**, that does not require new EU legislation,

- Operate in **collaborative groups of Member States**, smaller and more flexible than EU28, that can respond to shared unmet needs of specific countries at specific times, supporting effective, decentralised decision-making,
- Be **coordinated by a dedicated body within the European Commission** that understands the specificities of medical technology,
- Be primarily **funded by the EU** to support Member States and to reach the objectives of the European Commission.

From an implementation perspective:

HTA cooperation in Europe in medical technology should:

- Be **driven by demands of Member State decision-makers**, to allow the HTA cooperation to meet the specific needs of those who are responsible for the introduction, coverage, funding, adoption, and/or use of medical technologies.
- Use clear and predictable criteria for the **choice of technologies** undergoing an evaluation. We suggest focusing on 'transformative technologies', which address a high unmet need and involves a structural or organizational reform, leading to sustainable solutions in healthcare delivery.
- Identify, in collaboration with stakeholders, the **best time for conducting HTAs**. For medical technologies, this will not be at market entry since the true effectiveness and full value can only be assessed with the aid of real world evidence, by taking contextual factors into consideration, understanding the differing care pathways and diagnostic information, and the learning curve of professionals or patients using the new technology.
- Retain the focus of the HTA cooperation on further developing the concept and acceptance of **post-launch evidence generation** to capture the full value of technologies.
- Use **consistent methods, data requirements and outcome measures** that are able to capture the broader value that medical technology offers.
- Ensure close collaboration between HTA agencies, decision makers and stakeholders at all stages of the EU HTA cooperation.
- Feed into **a value-based access model for medical technologies**, where the **HTA genuinely informs decisions such as reimbursement**, funding and use in clinical practice **for transformative technologies**.

As a last but important note CE marking and HTA assessments must be maintained as separate processes with distinctly different purposes and should not be confused:

- The regulations of medical technologies (called CE marking) address the demonstration of the **safety, quality and performance** of a technology throughout its whole lifecycle.
- The concept of HTA aims to **inform** decision makers on questions such as the **use of technology in clinical practice, coverage, and funding**. It thereby often uses comparative, context-specific data and the information need to be fit-for-purpose for decision making.

In conclusion

The European medical technology industry supports the European Commission's objectives of assisting member states in making their healthcare systems sustainable and providing access to innovation for the benefit of patients. Cooperation on HTA for medical technologies may prove beneficial provided it fully recognises our reality of a well-functioning access model, with decentralised, localised decision-making, and is designed and implemented accordingly, and in response to decision-makers' common needs.

A fit-for-purpose, modern HTA cooperation needs to be seen in the context of a value-based market access model for medical technologies, where uptake and price for the vast majority of medical technologies is determined by well-established procurement processes at hospital, local, regional or national level. Otherwise, it will hinder rather than help achieving the stated objectives of the European Commission, and furthermore undermine Europe's dynamic, innovative, SME-driven, competitive medical technology sector.

We believe that the benefits of cooperation will only be fully realised if they take into account the specificities of the sector. This implies recognising and rewarding value with a focus on transformative technologies and solutions. This will be most effectively done by voluntary groups of collaborating Member States with a common need; and a 'fit for purpose' role for the HTA cooperation in informing their decisions. Such modern, 'fit-for-purpose' HTA cooperation will also make the most effective contribution to realising the European Commission's ambitions, ensuring timely access to innovation for the benefit of patient and support Member States to keep healthcare systems financially sustainable.

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Annex

Detailed Proposals on the Governance of HTA cooperation for MedTech in Europe:

Voluntary collaboration

- Any demand for HTA in medical technology will reflect specific situations in specific countries at specific times; plans for cooperation should reflect this reality. Such cooperation should not require new EU legislation.

Operating in collaborative groups

- Rather than seeking broad alignment between all EU Member States in spite of their very different needs and circumstances, several collaborative groups of Member States should identify shared needs and then collaborate on a voluntary basis, supporting national decision-making.
- These collaborative groups should be based on memoranda of understanding, mutual recognition agreements or similar, signed by participating Member States and those that will be informed by an HTA. This will foster national use of the cooperation outputs while supporting the subsidiarity principle.

Organisation and coordination

- A body, ideally within the European Commission, with dedicated expertise in medical technology should coordinate the voluntary collaborative groups of Member States.

Funding

- HTA cooperation in Europe should primarily be funded by the EU, helping to support EU and Member States in achieving their objectives of sustainable healthcare and supporting innovation.
- In case stakeholders such as industry want to ask participating bodies to perform a specific activity - like scientific advice - it is reasonable to expect a fee in return for such services. For SMEs, specific funding mechanisms should be considered, such as fee waivers.

Detailed Proposals on implementation of HTA Cooperation for Medtech in Europe:

Demand-driven

- The relevant decision-makers from collaborating Member States should determine the information they require, based on their shared needs. This will allow outputs relevant for informing the decisions at stake and contributing to a value-based access model.

- HTA cooperation in Europe should focus on generating post-launch evidence for evaluating the full value of medical technologies, services and solutions, taking the contextual factors into consideration.

Focusing on 'transformative medical technologies'

- Cooperating Member States need to agree on predictable criteria to identify medical technologies, services or solutions for common assessments.
- These criteria should guide the cooperating HTA agencies in selecting only the most relevant technologies for common assessments. Selecting products based on their value rather than risk directs resources to where they will make the biggest difference.
- The suggested criteria would be to focus on 'transformative' medical technologies. These are determined by:
 1. Their ability to address high unmet patients and/or healthcare needs (common to several Member States); and
 2. Imply a significant structural or organisational reform of healthcare delivery.Existing horizon scanning initiatives and industry can help identify these transformative medical technologies.
- The HTA Network of Member States and relevant stakeholders, including industry, should collaborate in the prioritisation process from the outset.

Capturing the full contribution of medical technology

- Decision-makers and HTA agencies need to agree on common and proportional evidence requirements that consider agreed standards of care, contextual factors, acceptance of data, evidence, and studies to demonstrate benefit and outcome measures.
- These criteria should be decided in advance, and used consistently within the collaborative groups.

Conducting HTAs at the right time

- Identifying the best time for performing an HTA on a medical technology is critical to assess its full value. Patients, decision-makers, healthcare professionals and industry need to be involved in this.
- Evaluating genuine value is a dynamic process, which needs to account for 'real life' conditions of use. These include continuous product modifications, the 'learning curve' of professionals using a new technology and differing care pathways depending on the diagnostic information.
 - Conducting assessments too soon in the life cycle of a technology risks failing to capture its full benefits. These include the genuine effectiveness, the socio-economic value, and outcomes that matter to patients

Samordnat Införande för medicinteknik

Inspel från Swedish Medtechs företagsgrupp gällande SKLs arbete medför samordnat införande av medicinteknik

Swedish Medtechs mål är att bidra till snabbare implementering av kostnadseffektiva och innovativa behandlingsmetoder i vård och omsorg. Vi vill förse vård och omsorg med bättre beslutsunderlag utan att hindra eller fördröja innovationer som kan komma vårdgivare, patienter och anhöriga till del och som kan bidra till jämlik vård i hela landet. Vi vill göra detta i dialog med relevanta myndigheter och aktörer som idag ser över en Ordnat Införande-process för medicinteknik. En process liknande den för läkemedel kan riskera att inte bara fördröja upptag, utan t.o.m. förbise viktiga effektiva medicintekniska innovationer. Medicinteknik är ett oerhört heterogent område, som innefattar allt från förbrukningsvaror som exempelvis absorberande inkontinens produkter till avancerade PET kameror. Därför är det svårt för medicinteknik att ingå i ett generiskt system för Ordnat Införande, och vi ser framför oss flera olika metoder/arbetssätt för snabbare upptag.

Företagsgruppen i Swedish Medtech vill här belysa några av anledningarna till varför vi anser att medicinteknik inte kan utvärderas med samma metod och efter samma kriterier som läkemedel.



Evidensgraden vid introduktion

- ✓ Medicinteknik har ett större kontextberoende p.g.a. bland annat operatörsberoende och inlärningstid.
- ✓ Det är ofta svårare och inte relevant att utföra randomiserade kontrollerade och blindade studier.
- ✓ Evidensgenerering och införandet av en medicinteknisk metod sker ofta parallellt efter godkännande enligt Medicintekniska direktivet, MDD.
- ✓ Värdet av medicinteknik visas ofta i klinisk vardag genom förbättringar i vårdprocessen och livskvalité hos patienter. Till exempel kortare handläggning, färre vård dagar, återgång i arbete, färre assistanstimmar.



Incitament för evidensgenerering

- ✓ Snabbare produktutveckling och kortare produktlivscykel för medicintekniska produkter gör att HTA och guidelines på produktnivå snabbt blir inaktuella.
- ✓ Patentsituationen är otydlig för medicintekniska produkter; ofta saknas patent-/exklusivitetsperiod.
- ✓ Studieresultat överförs ofta från en produkt till en annan.
- ✓ Det ställs olika krav på evidens i olika delar av landet, bl.a. kan HTA-processen se olika ut. Detta skapar osäkerhet och minskade incitament för evidensgenerering.
- ✓ Kunskapsunderlag påverkar idag sällan köpmönster eller utfall av upphandling.

Sundhedsøkonomisk evaluering af medicinsk udstyr

Både i Danmark og internationalt er der stigende fokus på anvendelse af sundhedsøkonomisk evaluering i vurderingen af nye teknologier i sundhedssektoren. De fleste retningslinjer for sundhedsøkonomisk evaluering tager udgangspunkt i lægemidler, hvilket er naturligt da de bærer størstedelen af udgifterne til nye teknologier¹.

Lægemidler adskiller sig imidlertid fra medicinsk udstyr på flere væsentlige områder og kommende retningslinjer og evalueringskriterier bør tage højde for forskellene. Ellers er risikoen, at vigtige fordele ved nye teknologier bliver overset og at patienter såvel som samfund ikke får gavn af nye innovationer². Det er derfor vigtigt, at forskellene mellem medicinsk udstyr og lægemidler indtænkes i kravene til sundhedsøkonomiske evalueringer af medicinsk udstyr.

Forskelle på evidens indenfor medicinsk udstyr og lægemidler

Lægemidler og medicinsk udstyr er først og fremmest forskellige i deres definition/funktion³, hvor medicin er kendetegnet ved den aktive ingrediens og medicinsk udstyr ved andre virkemåder.

Herudover tager evaluering af lægemidler typisk udgangspunkt i blindede, randomiserede og kontrollerede studier (RCT'er).

Der er dog flere grunde til, at der findes langt færre RCT'er for medicinsk udstyr i sammenligning med lægemiddelområdet⁴:

- 1) Der er ingen "steady state periode" på medicinsk udstyr, som ofte undergår kontinuerlige produktmodifikationer.
- 2) Den såkaldte "operator-device" indlæringskurve giver risiko for måling af forskelle i erfaring med udstyret i stedet for de egentligt produktrelaterede performance forskelle.
- 3) Medicinsk udstyr er ofte diagnostisk, hvilket kan give særlige metodiske udfordringer.
- 4) Det er oftere sværere eller umuligt at gennemføre blindede studier på medicinsk udstyr, fordi de fysiske forskelle er åbenlyse for brugerne (i modsætning til en aktiv ingrediens).
- 5) Medicinsk udstyr kræver CE-mærkning i modsætning til medicin-området, hvor nye produkter skal testes i RCT'er før godkendelse.

Udover metodiske forskelle er medicinsk udstyr kendetegnet ved langt flere produkter end lægemiddelområdet, hvilket giver en yderligere udfordring ift. evidensgenerering og evaluering. Indtil 2013 har FDA godkendt 1.453 nye lægemidler, mens der på device-området er blevet introduceret mere end 500.00 nye produkter⁵.

Som konsekvens af de grundlæggende forskelle mellem lægemidler og medicinsk udstyr og de anderledes regulatoriske krav er der behov for et bredere evidensbegreb til evaluering af nye innovationer på device-området.

¹ Tarn TY, Smith MD. Pharmacoeconomic guidelines around the world. Ispor Connections 2004; 10:5–12. Available from: <http://www.ispor.org/News/articles/aug04/PEGuidelines.asp> [Accessed April 3, 2008]

Sorenson C, Tarricone R, Siebert M, Drummond M. Applying health economics for policy decision making: do devices differ from drugs? *Europace* 2011. 13(Suppl 2): ii54–8

² Drummond MF, Griffin A, Tarricone R. Economic evaluation for devices and drugs. Same or different? *Value Health* 2009;12:402–4

³ Taylor, R. S. and Iglesias, C. P. (2009), Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?. *Value in Health*, 12: 404–406

⁴ Drummond MF, Griffin A, Tarricone R. Economic evaluation for devices and drugs. Same or different? *Value Health* 2009;12:402–4

⁵ Griffin, A. Incentivising Research into the Effectiveness of Medical Devices, presentation at ISPOR 2016 in Vienna, IP9, November 1, 2016

Forskel på sundhedsøkonomisk evaluering af medicinsk udstyr og lægemidler

Sundhedsøkonomi handler om systematisk sammenligning af omkostninger og effekter mellem forskellige teknologier. Mens opgørelsen af omkostninger ofte er sammenlignelig indenfor lægemidler og medicinsk udstyr, er der væsentlige forskelle på opgørelsen af effekter.

For at kunne sammenligne effekterne på tværs af teknologier og behandlingsområder kræver mange myndigheder, at sundhedsøkonomiske evalueringer baseres på en fælles måleenhed i form af såkaldte Quality Adjusted Life Years (QALY)⁶.

For at sikre at QALY'er bliver genereret på sammenlignelig vis stilles der krav om generiske instrumenter til måling af sundhedsrelateret livskvalitet, fx EQ-5D eller SF36. Der er imidlertid stigende erkendelse af, at QALY-metoderne kan være utilstrækkelige ift. medicinsk udstyr⁷:

- a) Generiske mål er ofte ikke i stand til at måle små, men over tid og for det enkelte individ vigtige ændringer i livskvalitet.
- b) Forbedringer forbundet med medicinsk udstyr er ikke altid direkte relateret til forbedringer i sundhedstilstanden, men til livskvalitet bredere set, fx ift. tidsforbrug for brugeren, bekvemmelighed, diskretion ol.

Pejlemærker for sundhedsøkonomisk evaluering af medicinsk udstyr i Danmark

Hvis der fremover stilles øgede krav om sundhedsøkonomiske evalueringer af medicinsk udstyr er det vigtigt, at retningslinjerne tager højde for de særlige aspekter vedrørende medicinsk udstyr.

Som en konsekvens af bl.a. de nævnte særlige karakteristika ved medicinsk udstyr har flere udenlandske myndigheder åbnet op for anvendelse af et bredere evidensbegreb på device-området. Det engelske NICE har fx åbnet op for at vurdere den eksisterende evidens fra område til område og dermed sikre hurtigere adgang til nye og innovative produkter⁸. På samme måde har TLV i Sverige mulighed for at inddrage forskellige metoder udover generiske spørgeskemaer til vurdering af behandlingseffekter, herunder willingness-to-pay og Time-Trade-Off-studier⁹. Den øgede anerkendelse af forskellene på medicinsk udstyr og lægemidler er dermed med til at sikre, at såvel borgere som samfund får hurtig og maksimal gavn af nye teknologier, samtidig med at producenterne tilskyndes til at forsætte udviklingen af innovative produkter.

Når den eksisterende evidens ikke er tilstrækkelig er der behov for drøfte andre evalueringskriterier med den førende faglige ekspertise på området. Ofte vil en del af de førende eksperter være ansat i industrien – både fordi udviklingen og dokumentationen går hurtigt og fordi der ofte er tale om nicheområder. Det er derfor afgørende, at industrien inddrages tæt i udviklingen af de fremtidige evalueringsmetoder – og kriterier.

For at få alle relevante perspektiver med bør det overvejes at inddrage patientorganisationer samt borgernes tid og andre sektorer end sundhedsvæsenet. Evalueringsperspektivet bør som minimum omfatte patienternes tid og både det regionale og kommunale sundhedsvæsen.

⁶ Taylor, R. S. and Iglesias, C. P. (2009), Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?. *Value in Health*, 12: 404–406

⁷ Wilkinson G & Drummond M (2015), Alternative approaches for assessing the socioeconomic benefits of medical devices: a systematic review, *Expert Review of Medical Devices*, 12:5, 629-648

⁸ National Institute for Health and Care Excellence (NICE). Guide to the Medical Technologies Evaluation Programme. Downloaded from www.nice.org.uk/mtmedia on January 15, 2016

⁹ Tandvårds- och läkemedelsförmånsverket (TLV), Handbok till Tandvårds- och läkemedelsförmånsverkets föreskrifter (TLVFS 2011:3) om ansökan om pris och subvention för förbrukningsartiklar, downloaded from <http://www.tlv.se/Upload/Foretag/Handbok-TLVFS2011-3-subvention-forbrukningsartiklar-sept-2011.pdf> on January 15, 2016

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