System Description

The National system for the introduction of new health technologies within the specialist health service

– For better and safer patient care

A working document from

- The Regional Health Authorities
- The Norwegian Medicines Agency
- The Norwegian Knowledge Centre for Health Services
- The Norwegian Directorate of Health

June 2013/January 2014

Version: 1.0
Date: 11 June 2013/23 January 2014

HELSE VEST HELSE SØR-ØST HELSE MIDT-NORGE HELSE NORD

Statens legemiddelverk
Norwegian Medicines Agency

kunnskapssenteret
Nasjonalt kunnskapssenter for helsetjenesten

Helsedirektoratet

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1.0 Summary

A national system for the introduction of new health technologies within the specialist health service is implemented. The purpose of this system is to promote better and safer patient care. This will be made possible through the systematic assessment of new health technologies with regard to effect, safety and consequences for patients, the health service and society in general. For the purposes of this document, 'health technology' means all interventions used to prevent, investigate, diagnose and treat diseases, (re)habilitation and the organisation of health services. A health technology assessment (HTA) is based on a systematic overview of research concerning effect and safety (a systematic overview) and an assessment of the consequences, usually in terms of health economics.

HTAs have been used for many years in numerous countries, including the USA, Canada, Australia, Sweden, England and Scotland, in addition to Norway. What is new in the Norwegian context is that HTAs are now being integrated into a holistic system with predictable and transparent processes for introducing new health technologies into the specialist health service. HTAs will be a tool for supporting appropriate prioritisation and decisions making in order to ensure that introduction of new technologies are proven as safe and effective (Figure 1). It will enable patients, health personnel and society in general to be certain that health technologies used in patient care are both safe and effective. The national system in its entirety will promote the rational use of resources within the health services.

As part of the new system, a new function for horizon scanning will be established. This feature will ensure the systematic acquisition of information relating to emerging health technologies at an early stage of their development. This will help health authorities and the health service to plan and establish structured processes for the introduction of new health technologies such that patients can gain access to them earlier.

The key elements of the new system are:

- Horizon scanning
- Health technology assessment
- Prioritisation and decision making
- Implementation

Predictable processes

Figure 1 *The key elements of the national system for the introduction of new health technologies within the specialist health service are horizon scanning, health technology assessment, prioritisation, decision and implementation.*

The systematic introduction of new health technologies within the specialist health service will be carried out as follows (Figure 2):

1. Locally, based on mini-HTAs carried out by individual hospital trusts.

2. Nationally, based on HTAs at the national level. HTAs at the national level will be conducted by the Norwegian Knowledge Centre for Health Services and the Norwegian Medicines Agency.

Mini-HTAs will be used for assessment of new procedures and new medical devices used in diagnostics and treatment by individual hospitals. It is anticipated that many topics of importance will be handled via HTA processes undertaken at the national level. For instance health technologies with a bearing on the entire health service, health technologies requiring health economic and socio-economic assessments, pharmaceuticals, highly specialised (tertiary) services and screening. The Regional Health Authorities (RHA) Forum for the commissioning of HTAs (*RHA Forum/Bestillerforum RHF*), which is anchored to the Regional Health Authorities, will prioritize which HTA applications should be commissioned at the national level. Suggestions and proposals about potential HTAs at the national level will be submitted to the RHA Forum via the Norwegian Directorate of Health which will have a secretariat function. A broad range of stakeholders such as the specialist health service, the Norwegian Directorate of Health, manufacturers, patient organisations, etc. will be encouraged to submit proposals on potential topics for HTA consideration. The RHA Forum will then prioritise and decide which HTAs should be carried out.

Decisions concerning the introduction of new health technologies within the specialist health service will be made within existing decision-making structures in the Regional Health Authorities, on the basis of completed HTAs. The Regional Health Authorities have a 'responsibility to ensure adequate provision of specialist health care to the population in their region' and a responsibility to ensure that decisions regarding the procurement of new health technologies are taken within established financial and professional frameworks. Decisions must be coordinated with the Norwegian Directorate of Health who hold the responsibility for the formulation (and maintenance) of national clinical guidelines.

The national system for the introduction of new health technologies presupposes involvement of professional expertise found within the specialist health service in both local and national processes. This professional expertise is vital for the system to function properly. User involvement is also an extremely important element in ensuring that the interests of patients and their families are safeguarded at all times in the organisation and realization of the objectives of the system. Important issues of principle, prioritisation-related issues linked to the system's method of operation and other thematic issues concerning the health technology area may be referred to the National Council for Priority Setting in Health Care for discussion. Questions pertaining to the introduction of a specific single health technology are not considered relevant for the council.

Establishment of the national system for the introduction of new health technologies within the specialist health service constitutes a significant development for both the health services and health authorities. It will require good coordination between the parties within the specialist health service and the authorities involved, transparent processes and interaction with users and patient organisations, the primary health service, innovators, research groups and the manufacturers of new technology. A secretariat function has been established

within the Norwegian Directorate of Health to contribute to coordination, follow-up, further development and assessment of the system. One of the roles of this function will be to act as the secretariat for national working groups, national reference groups and the RHA Forum.

This document describes functions and products of the new system, including the various forms of technology assessment and collaboration between the various actors involved, as outlined in Figure 2 and Table 1.

The document will be updated over time in light of new knowledge and experiences gained at local, national and international level.

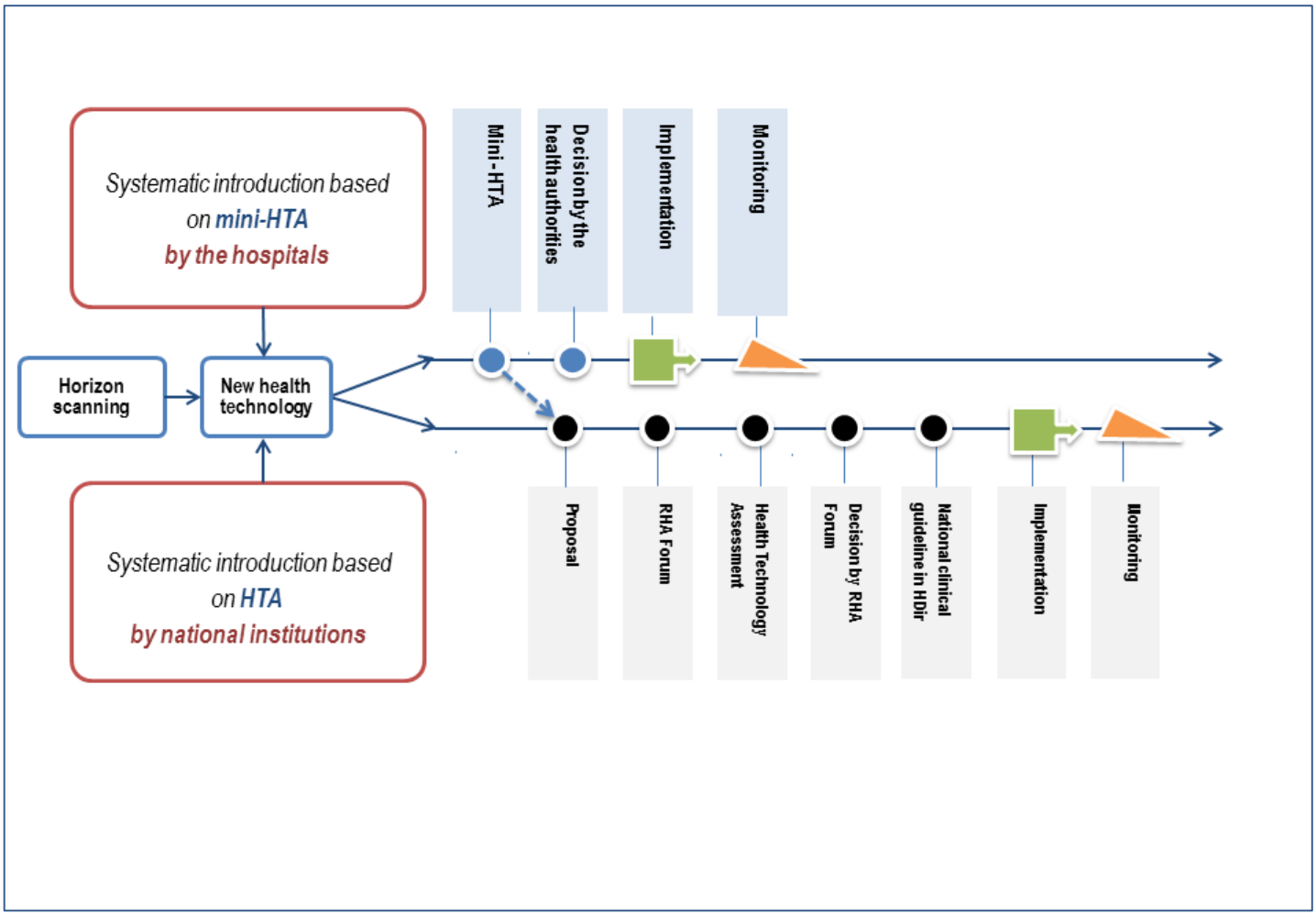

Figure 2 *Systematic introduction of new health technologies within the specialist health service based on (1) mini-HTAs by the hospitals (health authorities), or (2) HTAs by national institutions; the Norwegian Knowledge Centre for the Health Services and the Norwegian Medicines Agency. If appropriate, issues may be elevated from hospital level to regional level with the view of undertaking national HTAs and possible discussion within the National Council for Priority Setting in Health Care.*

Table1. Processes for the systematic introduction of new health technologies based on HTAs.

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.
2. Systematic introduction based on national HTAs	
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: 1. Single technology assessment (STA), an appraisal of a single health technology in relation to a particular area of use/indication, at an early stage. a. Medicines. Conducted by the Norwegian Medicines Agency. b. Other health technologies. Conducted by the Norwegian Knowledge Centre for Health Services. 2. Full health technology assessment (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.

2.0 Abbreviations

AdoptHTA	Adopting Hospital-based Health Technology Assessment in EU (EU project)
AGREE	Appraisal of Guidelines for Research and Assessment
CE marking	Conformité Européenne; product marking within the EU/EEA
CER	Comparative Effectiveness Research
DTC	Drug Therapeutic Committee
ECRIN	European Clinical Research Infrastructure Network
EMA	European Medicines Agency
EUnetHTA	European Network for Health Technology Assessment
EUROSCAN	International Information Network on New and Emerging Health Technologies
GRADE	Grading of Recommendations Assessment, Development and Assessment
HAS	Haute Autorité de Santé (France)
HA	Health Authority
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
ISF	Activity-based funding
LFH	"Leverandører for helse-Norge" (Norwegian trade association for health and welfare technology)
LIS	"Legemiddelinnkjøpssamarbeidet" (Drug Procurement Cooperation)
LMI	"Legemiddelindustriforeningen" (Association of the Pharmaceutical Industry in Norway)
Mini-HTA	Mini-health technology assessment
MOH	Ministry of Health and Care Services
MT	Marketing authorisation (concerning medicines)
MTA	Multiple Technology Assessment
NICE	National Institute for Health and Clinical Excellence
NOKC	Norwegian Knowledge Centre for the Health Services
NORCRIN	Norwegian Clinical Research Infrastructure
NOMA	Norwegian Medicines Agency
NPR	Norwegian Patient Register
NTA	Nordic Trial Alliance
RHA	Regional Health Authority
SBU	Swedish Council on Health Technology Assessment
SMC	Scottish Medicines Consortium
STA	Single Technology Assessment

3.0 Glossary

Medicine	Any substance, drug or preparation which 1) is issued as being suitable for preventing, curing or alleviating diseases, symptoms or pain, or influencing physiological functions in humans or animals, or which 2) can be used by or given to humans or animals in order to restore, alter or influence physiological functions through a pharmacological, immunological or metabolic effect, or to demonstrate a disease[1].
Medical devices	Any instrument, appliance, device, software, material or other object used either alone or in combination, including software which is intended by the producer to be used specifically for diagnostic and/or therapeutic purposes and which is required for correct use, etc.; see the complete definition in the Regulations on medical devices[2].
Health technology	For the purposes of this document, the term 'health technology' means all measures that are used to prevent, investigate, diagnose and treat diseases, as well as measures for the rehabilitation of patients and the organisation of health services. 'New health technology' means a health technology that has not previously been used outside clinical trials or has only been used on a small number of patients. A new health technology may also be the new use of an existing health technology for a new indication or a different patient group than that for which the health technology was first introduced. A health technology that is introduced in a health authority for the first time will be considered to be new within the authority concerned, even if it has been used by other authorities at an earlier date.
HTA	Health Technology Assessment (HTA) is a collective term for the various types of health technology assessment. An 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.
Mini-HTA	Mini-health technology assessment (mini-HTA) is a simplified HTA, generally based on systematically summarised research and used locally by the health authorities to support decisions in connection with an assessment 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

[1] Regulations on medicines, FOR 2009-12-18 no. 1839, http://www.lovdata.no/for/sf/ho/xo-20091218-1839.html

[2] Regulations on medical devices, FOR-2005-12-15-1690, http://www.lovdata.no/for/sf/ho/xo-20051215-1690.html

	effect, safety, costs, organisational consequences and ethical aspects linked to the introduction of the new health technology.
STA	Single Technology Assessment (STA) involves an assessment of effect, safety and cost-effectiveness. In the case of medical device and procedures, it may also be relevant to evaluate other consequences or preconditions for effective use. The documentation may be submitted by a manufacturer.
Full HTA	Full Health Technology Assessment (full HTA) is a more comprehensive systematic assessment of new or established health technologies which evaluates effect, safety and cost-effectiveness. An HTA also often covers issues relating to ethical, legal, organisational and social consequences.
Horizon scanning	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.
Organisational measures	Measures which define organisational structure and content, delegation of responsibility and tasks and interaction between the parties involved within and outside the specialist health service in order to ensure safetynd effectiveness in patient treatment.
Procedure	A procedure for use within prevention, diagnostics, treatment, rehabilitation, nursing and care which may consist of several stages in a particular sequence or as defined composite actions such as medical or surgical procedures. Procedures may integrate a number of other health technologies such as medical devices and medicines. The National Network for Professional Procedures defines professional procedures concerning medical and healthcare activities or processes within the health service [1].
Guidelines	Knowledge-based clinical guidelines contain advices and recommendations linked to prevention, diagnostics, treatment and/or follow-up within healthcare services; see the Guidance for the development of knowledge-based guidelines [2].

4.0 Approval and regulation of health technologies in the health service

Health technology	Regulatory system	Description of regulatory system
Medicine	Marketing authorisation (MA)	Authorisation of a medicine means that the manufacturer is issued with a marketing authorisation (MA), i.e. permission to sell the medicine. Authorisation largely takes place through the European collaboration of which the Norwegian Medicines Agency is part. Norway is involved in this through the EEA Agreement. A medicine can only be authorised for sale if the medicine has benefits that exceed the risks associated with its use. Assessment of the benefit/risk ratio of a medicine is based on documentation which the manufacturer must submit when applying for marketing authorisation. In the application, the manufacturer must document the medicine's pharmaceutical quality, safety and medical effect. Side effects and other unintentional effects of pharmaceutical use are monitored. In Norway, it is the Norwegian Medicines Agency that carries out supervision concerning trials, manufacturers, blood banks, importers, wholesalers, pharmacists and the marketing of medicines.
Medical device	CE marking	The manufacturer is responsible for declaring that a product complies with the applicable regulations and applies CE as a visible indication of this. Before the CE marking of all products (with the exception of those with the lowest risk), a technical control body must assess the device against the regulatory requirements and issue a certificate. These technical control bodies are independent third parties, appointed as an extended arm of the authorities. The requirements set out in EU Directives are implemented in Norwegian regulations. Basic and more specific requirements including requirements for clinical documentation. The Norwegian Directorate of Health carries out the supervision of technical control bodies, manufacturers and products on the market.
Procedures	None	-

5.0 Introduction

New health technologies can offer opportunities for health benefits, but can also present challenges linked to prioritisation and resource use. Ever stricter requirements are being imposed on the assessment of new health technologies to ensure patient safety in connection to their introduction and use. To date, there has been no provision for the consistent and systematic assessment of new health technologies within the specialist health service. For the purposes of this document, the term 'health technology' means all measures that are used to prevent, investigate, diagnose and treat diseases[3], as well as measures for the rehabilitation of patients and the organisation of health services.

A national system for the introduction of new health technologies in the specialist health service is implemented. The key aspects of this new system are described in "Nasjonal helse- og omsorgsplan *2011-2015"* [3] and "Stortingsmelding 10 (2012-2013), *God kvalitet – trygge tjenester"* [4]. This document presents a more detailed description of the various elements which make up the system. The Regional Health Authorities, the Norwegian Knowledge Centre for Health Services, the Norwegian Medicines Agency and the Norwegian Directorate of Health are working closely together as regards the tasks linked to the establishment and implementation of the new system.

Systematic assessments of effect, safety, costs and consequences for patients and society can be ensured through the use of various types of HTAs based on internationally established principles for HTAs and research summaries [5, 6]. In HTAs, systematic summaries of available research on effect and safety are prepared (systematic overview) and a cost-effectiveness analysis is conducted in relation to a health service initiative, often together with an assessment of issues relating to ethics, law and the organisation of health services [7, 8]. HTA was formally established in Norway in 1997 with the creation of the Norwegian Centre for Health Technology Assessment [9], and has a long history in many other countries, including the USA, Canada, Australia, England, Scotland, Germany, France and Sweden [10-14].

HTAs will provide a basis for qualified decisions regarding the introduction of new health technologies and will be carried out at various levels within the health service (Fig. 3). HTAs will act as pivotal tools for ensuring the safety and quality of patient care and sustainable development within the health services in the long term.

The development and implementation of health measures can be described as a life-cycle; from innovation and development to the introduction and establishment of new measures and possible withdrawal and replacement of measures that no longer meet adequate standards. During the course of such a life-cycle, there will be a need for various types of HTAs to support decision-makers in different phases and at various levels within the health service (see Figure 3). Many parties are involved in the various phases from the development of a new health technology to a decision concerning introduction or financing, development of guidelines and follow-up of service quality.

[3] Including somatic care, psychiatry and substance abuse

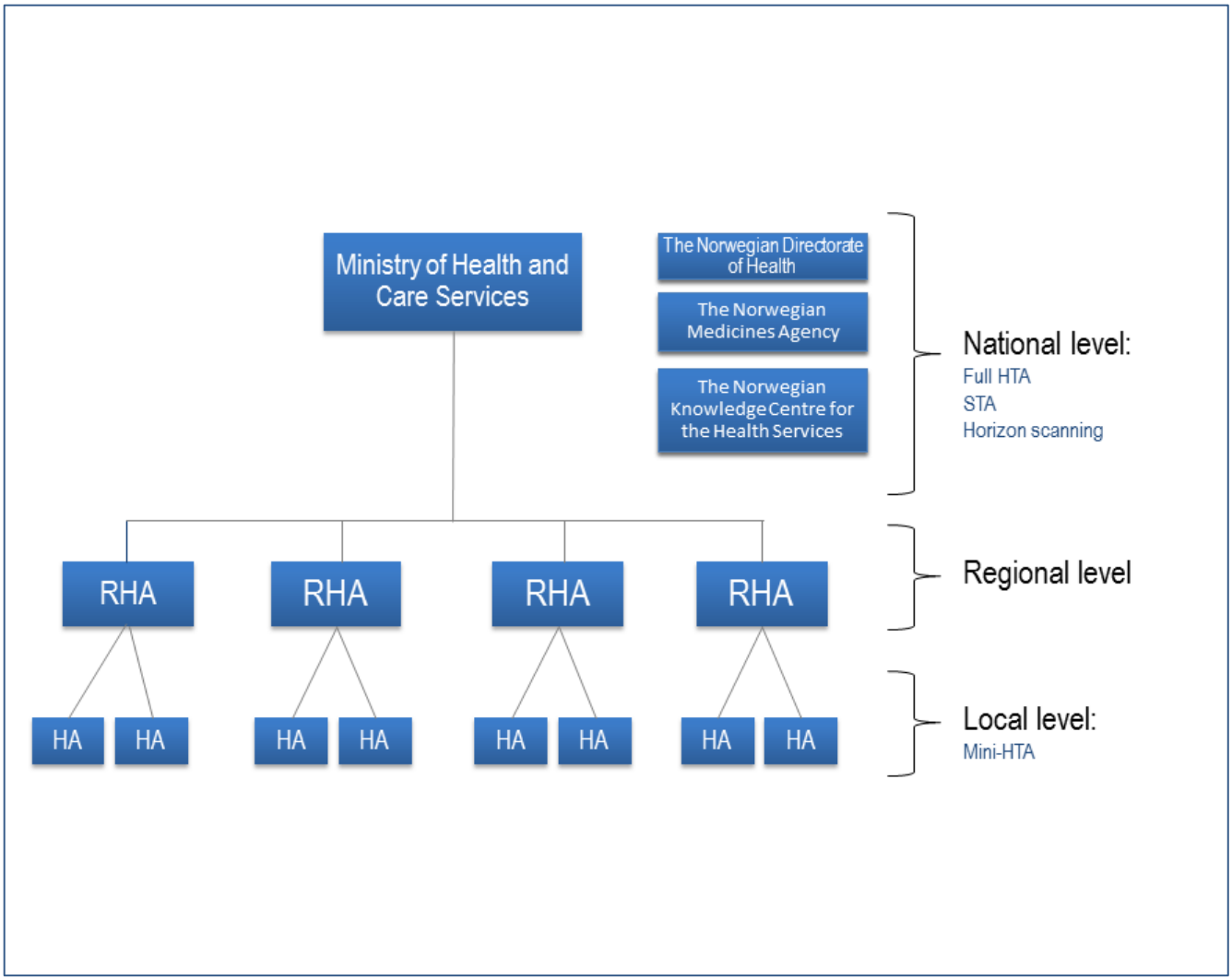

Figure 3 *HTA's at local, regional and national level. A mini-HTA is carried out at local level. If appropriate, issues may be channeled from the local hospital level through a regional level to a national process, in the form of a STA or full HTA. In particular cases the National Council for Priority Setting in Health Care may be consulted.*

Background for the national system:

- Medical and healthcare technologies change quickly
- Variation or absence of routines for health technology assessment within the specialist health service
- Differences in decision-making processes related to new health technologies within the health care system

The purpose of the system is to:

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

- Implement a predictable and systematic process for introducing new health technologies

The principal components of the system are:

- **Horizon scanning** which 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

- **HTAs** which ensure the assessment of health-related effects, safety and economics (costs, budgetary consequences and/or cost-effectiveness), and include relevant issues concerning ethics, law and organization of the health services. HTAs are available in different formats such as mini-HTAs, STA and full HTA.

- **Decisionmaking subsequently to HTAs**. Following mini-HTAs, decisions are made within the local health trusts. Following national HTAs, decisions are made within the Regional Health Authorities, and these decisions will be coordinated with the Norwegian Directorate of Health who holds the responsibility for national clinical guidelines.

- **Transparency**

Framework of the new system:

- Decisions on the introduction of new health technologies must be based on the same set of criteria; the severity of the disease, the benefits of the initiative and costs/cost-effectiveness
- Decisions must be based on transparent HTAs and documentation, and safeguard knowledge-based practice through use of recognised methodologies for HTAs
- The system must be in accordance with the responsibilities delegated to the health authorities and must be implemented within the framework of existing resources and financing system
- The responsibilities of the parties involved will not change.

6.0 Functions and appraisal of technologies in the national system for the introduction of new health technologies within the specialist health service

6.1 Horizon scanning

New health technologies which may become important for the health service can be identified at an early stage (one to three years) prior to their anticipated introduction with the aid of horizon scanning [15]. The information can be used to plan appraisals for HTAs and by decision-makers with responsibility for assessing financing, guidelines or major investments in the health service. In this way, horizon scanning acts as a tool for preparing authorities and the health service for the introduction of new health technologies. Ideally, horizon scanning will provide information on new health technologies one to three years ahead of their introduction, but may vary for different types of technologies (medicines, procedures, medical device).

A key recipient of horizon scanning will be the RHA Forum. Efficient interaction between the horizon scanning function and the RHA Forum will therefore be important for the functionality of the entire new system. This will help so that decisions and guideline processes are not delayed.

Horizon scanning will represent a new service for decision-makers within the Norwegian health service. To date, we have had individual assessments of new health technologies, ad hoc assessments when a new health technology is considered to be a challenge due to costs and assessments in the event of a need to discuss national coordination or ethical challenges. A horizon scanning function could reduce such 'surprises'.

A group under the national working group for the system has drawn up proposals for the development of a horizon scanning function in Norway. This document will provide a more detailed description of this function after the proposals have been considered.

6.2 Proposals for National Health Technology Assessments

Before HTA is carried out at the national level, qualified priorities must be drawn up to ensure that resources available for this purpose are utilised optimally. A national process is established which will handle incoming proposals for HTAs. The RHA Forum will decide which HTAs are to be prioritised and carried out. The RHA Forum consists of medical directors from the four regional health authorities and two representatives from the Norwegian Directorate of Health. The Norwegian Medicines Agency and the Norwegian Knowledge Centre for Health Services are participating as observers in the RHA Forum. The secretariat at the Norwegian Directorate of Health acts as secretariat for the RHA Forum and is responsible for case administration.

Product	Description	Duration	Knowledge base	Proposals	Executive responsibility	Decision-making responsibility
Horizon scanning	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
Mini-HTA	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
STA for medicines	Evaluation of effect, safety and health economics (manufacturer)	Up to 6 mths.	Clinical studies and medicine-economic analysis submitted by MA holder (manufacturer) Other published data	RHA Forum	Norwegian Medicines Agency	RHA[1]
STA for other health technologies	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]
Full HTA	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

National clinical guidelines	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

Table 2 *Overview of products/appraisal methods in the system for the introduction of new health technologies within the specialist health service.*

[1]Decisions following national HTAs are taken by the RHAs and coordinated with the Norwegian Directorate of Health's responsibility for national clinical guidelines.

[2]Can receive input from industry, provided there is transparency concerning all data. Full HTAs and STAs can be used to assess all types of health technology, while mini-HTAs are intended for use in the case of procedures, medical device and diagnostics. [3]Grading of Recommendations, Assessment, Development, and Assessment (GRADE) is an internationally established methodology for the quality grading of research and recommendations [16]. [4]Updating of guidelines will take less time, depending on the scope of revision.

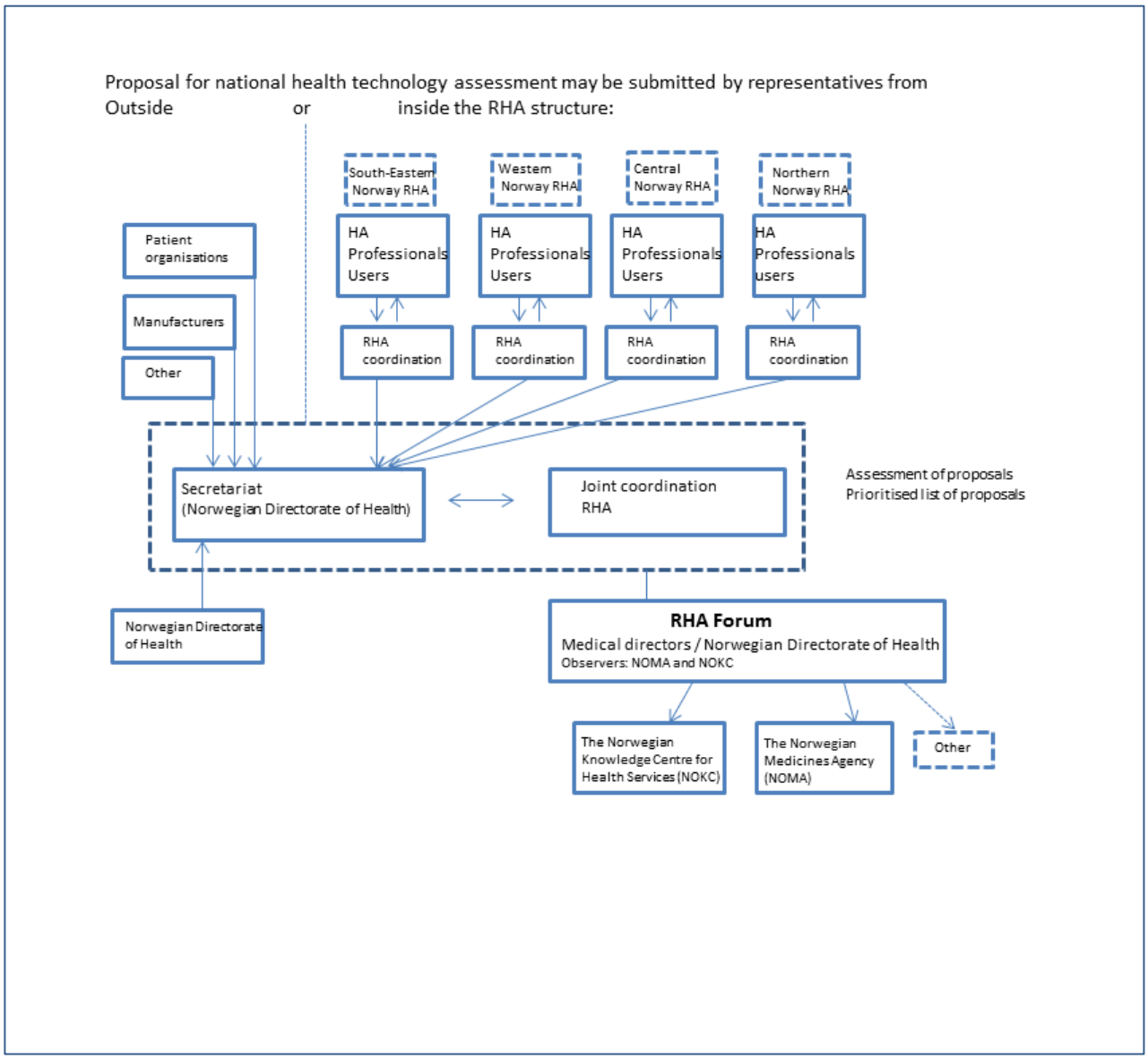

Figure 4 *Parties involved in the placement of national HTA orders.*

The appraisal proposal process passes through a number of stages before a decision on which proposals should be forwarded to the national HTA level (Figure 4). These stages cover:

1. Preparation of proposals for national HTAs

Proposals for national HTAs are prepared through the completion of a proposal form which is available on the Norwegian Directorate of Health's website (http://helsedirektoratet.no/helse-og-omsorgstjenester/system-for-innforing-av-nye-metoder/Sider/default.aspx). No further documentation should be enclosed with the completed proposal form at this stage.

Proposals may be prepared and submitted by:

- Specialist health service providers
- Manufacturers
- Patient organisations
- Norwegian Directorate of Health
- Primary health service providers
- Norwegian Knowledge Centre for Health Services
- Norwegian Medicines Agency
- Others

2. Receipt of proposal

The completed proposal form should be submitted to the Norwegian Directorate of Health secretariat via the following e-mail address: postmottak@helsedir.no and marked "Proposal for national health technology assessment" ("Forslag til nasjonal metodevurdering"). The secretariat will check to ensure that the form contains the necessary information and contact the sender if any information is missing.

3. Early assessment of relevance for proposals

Proposals for national HTAs are forwarded to the RHAs' coordinators, the Norwegian Medicines Agency and the Norwegian Knowledge Centre for Health Services. The Norwegian Medicines Agency and the Norwegian Knowledge Centre for Health Services carry out a quick evaluation (not more than 10 working days) of whether the proposal is relevant for HTA in either of the institutions, then report back to the secretariat at the Norwegian Directorate of Health.

4. **Proposal on how to prioritise**

Proposals will then be sent by the Norwegian Directorate of Health secretariat to Coordination Committee RHA, which consists of one coordinator from each RHA. The coordinators will then prepare a prioritised list of proposals for which are recommended for national HTAs and forward it to the RHA Forum[4].

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[4] **The Norwegian Knowledge Centre for Health Services order forum**

The roles that are described in the new system interface with the Norwegian Knowledge Centre for Health Services national responsibility to prepare knowledge summaries, including HTAs, in order to support the health service and administration. The Norwegian Knowledge Centre for Health Services has a separate order forum, which gives advice concerning the investigations which should be carried out by the Norwegian Knowledge Centre for Health Services (http://www.kunnskapssenteret.no/Artikler/1561.cms). Questions have been raised concerning the roles of the Norwegian Knowledge Centre for Health Services order forum in relation to RHA Forum and the new system. The Norwegian Knowledge Centre for Health Services order forum encompasses all health technologies in all sectors in the health service, while RHA Forum will handle new health technologies for the specialist health service. It is important that there is good collaboration between RHA Forum and the Norwegian Knowledge Centre for Health Services order forum, as health technologies which are not relevant to the system for new health technologies may be of relevance for assessment by the Norwegian Knowledge Centre for Health Services order forum, and vice versa

5. Decisions regarding proposals

The RHA Forum reviews and discusses proposals for national HTAs based on the submitted prioritised list of proposals from the joint coordination committee. The RHA Forum decides which proposals should be referred to the national HTA level and which type of HTA should be carried out.

6. Dissemination of national HTA assignments

After RHA Forum has reached its decision, assignments will be distributed as follows:

1. STAs to the Norwegian Medicines Agency when involving pharmaceuticals and the Norwegian Knowledge Centre for Health Services in case of other health technologies.
2. Full HTAs to the Norwegian Knowledge Centre for Health Services

6.3 Health Technology Assessments

New knowledge must rapidly be made available to the entire health service for utilization at local, regional and national levels. In the system, it is assumed that decisions concerning the introduction of new health technologies within the specialist health service can be taken at the lowest possible effective decision-making level. HTAs of different types (with regard to both scope and responsibility for preparation) have therefore been developed in order to support knowledge-based decisions and prioritization at different levels within the health service: mini-HTA, STA and full HTA (Table 3). Like other types of knowledge summaries, the core of an HTA is a systematic overview of effect and safety [17]. A full HTA also includes analyses of the consequences of introducing a new health technology or changing a practice. This could be analyses of economic, organisational, ethical and/or legal consequences for patients and society. In this way, HTAs can promote greater transparency regarding the basis for prioritisation and choice between different health measures.

	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***

	Mini-HTA	***STA***	***Full HTA***
Medicines		***x***	***x***
Medical devices	***x***	***x***	***x***
Procedures	***x***	***x***	***x***
Organisational initiatives			***x***
Screening			***x***
Highly specialised services			***x***

	Mini-HTA	*STA*	*Full HTA*
Single health technology	***x***	***x***	***x***
Several health technologies			***x***

Table 3 *Scope, content and use of the various HTAs in the system. Mini-HTAs will generally be based on an existing systematic overview concerning effect and safety, while STAs and full HTAs can be based on either existing or new systematic overviews.*

Knowledge summarises and special HTAs have been established to support national and regional decision making in an increasing number of countries (INAHTA.net). Evaluations of such organisations and systems have been conducted in many countries (including Norway), and confirm the need for this type of decision-making support [18, 19].

HTA groups in Europe are in the process of developing a permanent collaboration with support from the EU through the EUnetHTA collaboration [20]. Within this collaboration, a template has been developed for various HTA products with a view to apply them uniformly and reduce duplication. In an HTA, aspects dealing with effect and safety will in many cases be used across national borders, an approach which has long been used by the Norwegian Knowledge Centre for Health Services. Other aspects of a full HTA, the economic evaluations, organisational and ethical assessments will require national analyses or adaptations. The Norwegian Knowledge Centre for Health Services is involved in an EU-financed research project (AdoptHTA) concerning HTAs in hospitals and in projects aimed at improving ways of collating, grading and presenting research and recommendations (e.g. GRADE). These projects are important for the development of HTA as a field in the future.

6.3.1 Mini-HTAs

Mini-HTAs are a decision-making support tool that is used by hospitals when assessing the introduction of new health technologies [21, 22]. The process is intended to provide the management with a transparent, knowledge-based decision-making basis relating to the introduction of health technologies which encompass medical devices and procedure-related diagnostics and treatment. Medical devices are subject to a different regulatory system than medicines, while procedure-related diagnostics and treatment are not subject to any regulatory control. In cases where a mini-HTA would not provide an adequate basis for reaching a decision, the need for further investigations will be assessed at the next decision-making level.

Mini-HTAs are instigated by hospitals on the initiative of a professional group and/or management and are not dependent on a prior order process, as is the case with national HTAs.

A mini-HTA consists of a three-part form, as well as guidance [23, 24]. The guidance sets out criteria for cases where a mini-HTA should form part of the decision-making basis in relation to the introduction of new health technologies and cases where it is not necessary. Questions in the form consider circumstances linked to effect, safety, costs, organisational consequences and ethical aspects relating to the introduction of the new health technology. Different parts are completed by clinicians, financial staff, colleagues and management representatives.

Mini-HTAs are carried out when there is clinical uncertainty or professional disagreement concerning the effect or safety associated with a new health technology, or when the introduction of the health technology raises ethical issues. Clinical uncertainty concerning a health technology exists when the effect and benefits of the health technology have not been sufficiently clarified in good clinical studies with relevant end points.
Good clinical studies will ideally be randomised controlled studies (known as 'efficacy studies'), but may also be other controlled studies.

Roles in the system
A mini-HTA represents an important part of the decision-making basis for a hospital when deciding whether or not a new health technology should be introduced. If the introduction of a health technology cannot be carried out within the financial framework of the hospital or could result in such major health benefits that equal access to the new health technology should be ensured, the hospital should not introduce the technology. Further assessments and decisions are then directed to the regional or national level (Figure 5).

Mini-HTAs are not used for health technologies that are established in clinical practice or where the underlying knowledge concerning effect and safety has been adequately documented and evaluated.
A mini-HTA should also not be carried out if it is clear that the knowledge base concerning effect and safety is insufficient. In such cases, the health technology must be considered as not having been established and handled in accordance with the applicable research legislation or other relevant regulations. The process of carrying out a mini-HTA may also lead to the decision that the health technology is addressed through research studies. Mini-HTAs are not used for assessment of pharmaceuticals or health technologies in which pharmaceuticals are an important component.

The introduction of new screening technologies or technologies which should be made available as national services must always be directed to the national level through established systems. Where it has already been concluded that there is need for more thorough socio-economic or health-economic evaluation of the method, this must be carried out at the national level. The assessment of pharmaceuticals must also be conducted at the national level.

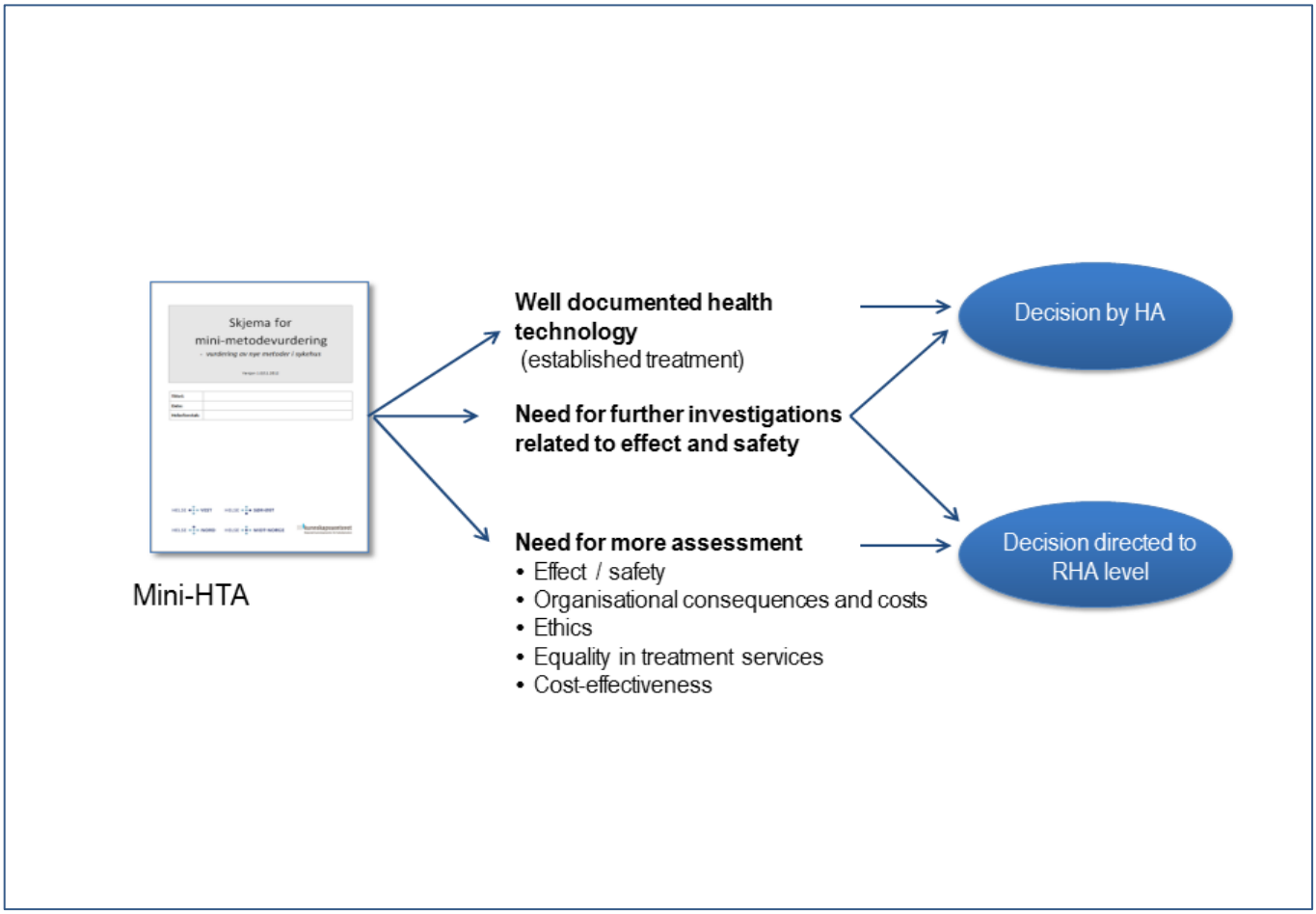

Figure 5 *The mini-HTA system and the criteria for reaching decisions or elevating decisions between the various levels in the health service.*

Support functions for mini-HTAs within the authority structure

In line with their 'responsibility to ensure', the RHAs must also make sure that they have (or have access to) the expertise that is necessary for carrying out mini-HTAs within the HAs. The objective is that whenever possible the hospitals should possess the expertise that is needed to conduct mini-HTAs without external assistance. It will therefore be necessary to establish support functions for mini-HTAs in each region. Such support functions should include method support, access to research librarians and analysis assistance of budgetary consequences.

National support functions for mini-HTAs

The Norwegian Knowledge Centre for Health Services has established and operates a national database for mini-HTAs [25]. All mini-HTAs that are carried out by individual HAs will be collated and published in this database. In addition, mini-HTA forms, guidance and other relevant information regarding mini-HTAs are available from these web pages.

The Norwegian Knowledge Centre for Health Services will also help to ensure appropriate national support functions for the use of mini-HTAs within the specialist health service. A national resource group for mini-HTAs has been established. This group consists of researchers, librarians, health economists and ICT professionals. The national resource group is tasked with providing teaching and practical training regarding completion of the mini-HTA form, particularly with regard to literature searches, assessment of research literature and cost assessments.

The group will provide support to the local and regional support functions and, together with the RHAs, further develop the mini-HTA form. In addition, the Norwegian Knowledge Centre for Health Services aims to contribute to information about the mini-HTA system at an overarching level together with the four Regional Health Authorities.

6.3.2 Single Technology Assessment (STA)

STAs involve the assessment of effect, safety, cost-effectiveness and budgetary implications. Additionally in the case of medical devices and procedures, it may be relevant to evaluate the need for training/expertise and organisational aspects.
STAs were introduced by NICE in 2005 [26]. The force behind this development was driven by the desire to establish a faster process for HTAs than had been the practice in relation to conventional full HTAs. STAs are carried out at an early stage. In the case of pharmaceuticals, a STA is carried out following the issuing of a marketing authorisation (MA), while in the case of medical devices; they are carried out after CE marking. In many European countries, new health technologies are subject to STAs before they are awarded funding or before a decision is made on whether to introduce the technology. In Norway, the Norwegian Medicines Agency has carried out STAs on all pharmaceuticals for which applications have been submitted for pre-approved reimbursement since 2002.

In the case of STAs concerning pharmaceuticals, the manufacturer normally prepares the documentation pack and the economic model, and the authorities critically assess the documentation that is submitted. The process is regulated by the EU's Transparency Directive, which gives a deadline of 180 days.

In the case of STAs as regards medical devices and procedures, there have so far been no EU regulations that authorities are required to follow. Additionally, the practice among the different European countries varies. Some countries use the EU's Transparency Directive on pharmaceuticals and use it to assess medical devices (e.g. HAS in France and to some extent also NICE in England). This has important consequences in regards to the choice of methodological approach, which in both countries is based on the manufacturer submitting documentation concerning effect, safety and cost-effectiveness. This is then critically assessed by one of the HTA groups, which also performs its own literature search and critically reviews the model.

The system assumes that STAs will fulfil EU requirements regarding transparency/openness in relation to documentation, assumptions and assessments, and will be carried out within defined deadlines – 180 days.
The introduction of STAs for new health technologies within the specialist health service is an entirely new function/feature in Norway and will encompass new medical devices, procedures, diagnostic methods and pharmaceuticals. STAs for pharmaceuticals will be conducted by the Norwegian Medicines Agency, while the Norwegian Knowledge Centre for Health Services will carry out STAs for other health technologies.

Within the EUnetHTA collaboration, a health technology guide is being developed which will be relevant for use in connection with STAs. This has initially been developed for pharmaceuticals, but will be tested for use on other health technologies. The guide covers the following [26]:

- Guideline on criteria for the choice of the most appropriate comparator(s)
- Guideline on composite endpoints;
- Guideline on surrogate endpoints;
- Guideline on applicability of evidence

• Guideline on direct and indirect comparisons
• Guideline on clinical endpoints
• Guideline on Health Related Quality of Life (HRQoL)
• Guideline on safety
• Guideline on internal validity

STA for medical devices, procedures and diagnostic methods

There are currently no requirements in place as regards the assessment of effect, safety and cost-effectiveness when introducing medical devices, procedures and diagnostic initiatives into the specialist health service. STAs involve an assessment and weighting of effect, safety, cost-effectiveness and budgetary consequences in order to enable qualified decision making. STAs also help to identify competency needs and whether there is a basis for division of functions. This will be particularly appropriate for new surgical procedures and implantation medical devices. STAs towards medical devices will often be based on a limited number of published studies because the new treatment or diagnostics are in early stage (Figure 6). Concerning medical devices, it may be necessary to carry out repeated assessments; as such technologies often have an incremental stepwise development process.

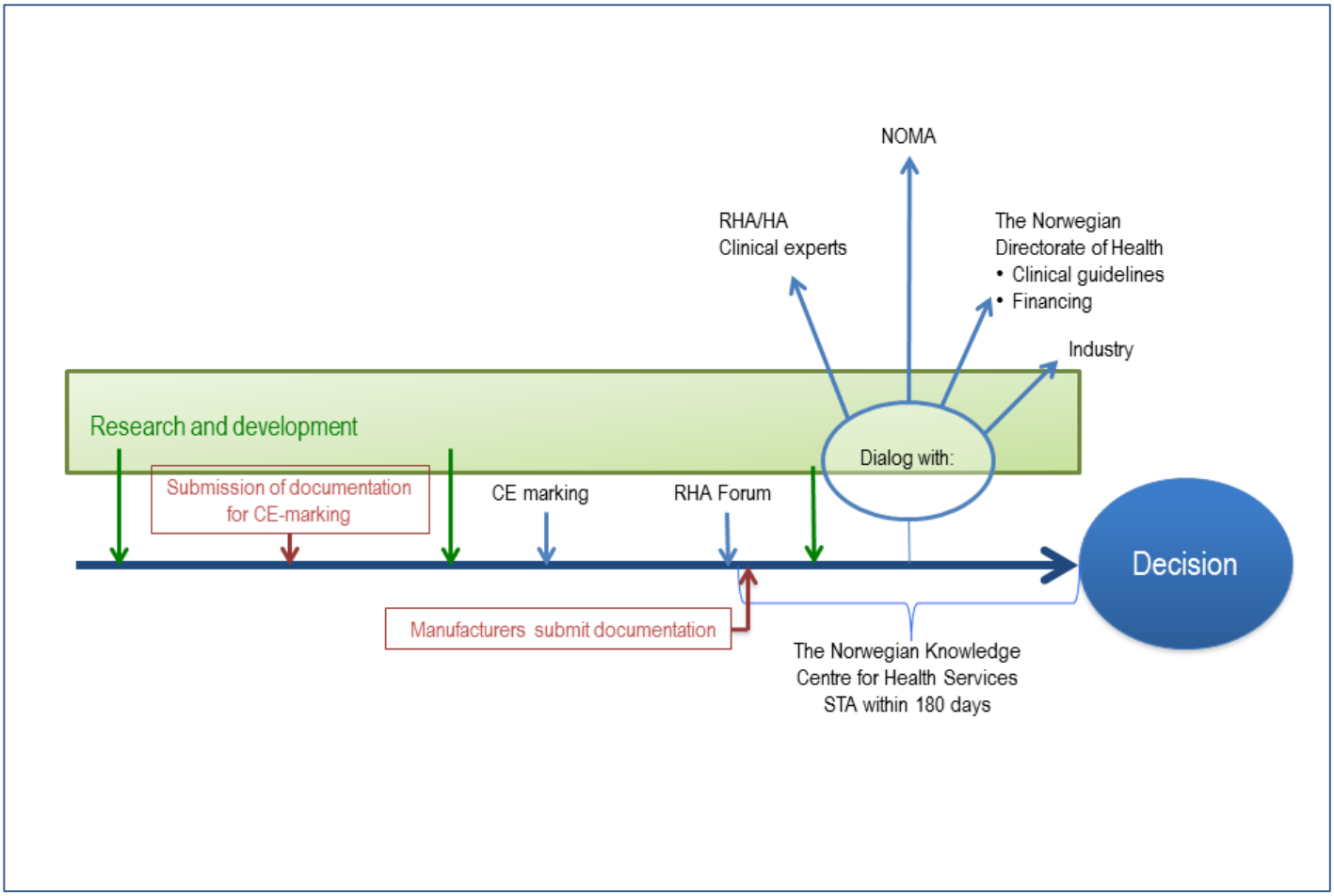

Figure 6 Medical devices and procedures involving medical devices. The process from research and development to CE marking and decision making

Roles and collaboration

The Norwegian Knowledge Centre for Health Services will carry out STAs of new medical devices and new diagnostic initiatives that have been prioritised by RHA Forum (Figure 6). It is vital to establish a close partnership with professional groups and manufacturers when preparing a STA. The Norwegian Knowledge Centre for Health Services and the Norwegian Medicines Agency will also benefit from a reciprocal collaboration in this work, both in general terms and with regard to individual cases where they may benefit from each other's expertise and experience.

STAs and new pharmaceuticals

Until the recent time, only pharmaceuticals that are applied for pre-approved reimbursement (the blue prescription scheme) [27] have been subject to systematic assessment. There is no requirement that new pharmaceuticals have to be better than existing ones in order to be approved. The clinical documentation that exists at the time of approval may therefore be insufficient for the subsequent assessment of cost-effectiveness. The Norwegian Medicines Agency will prepare STAs of new pharmaceuticals that have been prioritised by RHA Forum (Figure 7). STAs of new pharmaceuticals for use within the specialist health service will provide information on effect, safety, cost-effectiveness and budgetary consequences before a decision is taken. The analyses follow templates for STAs. This means that the industry (the marketing authorisation holder) must prepare all the necessary analyses and documentation.

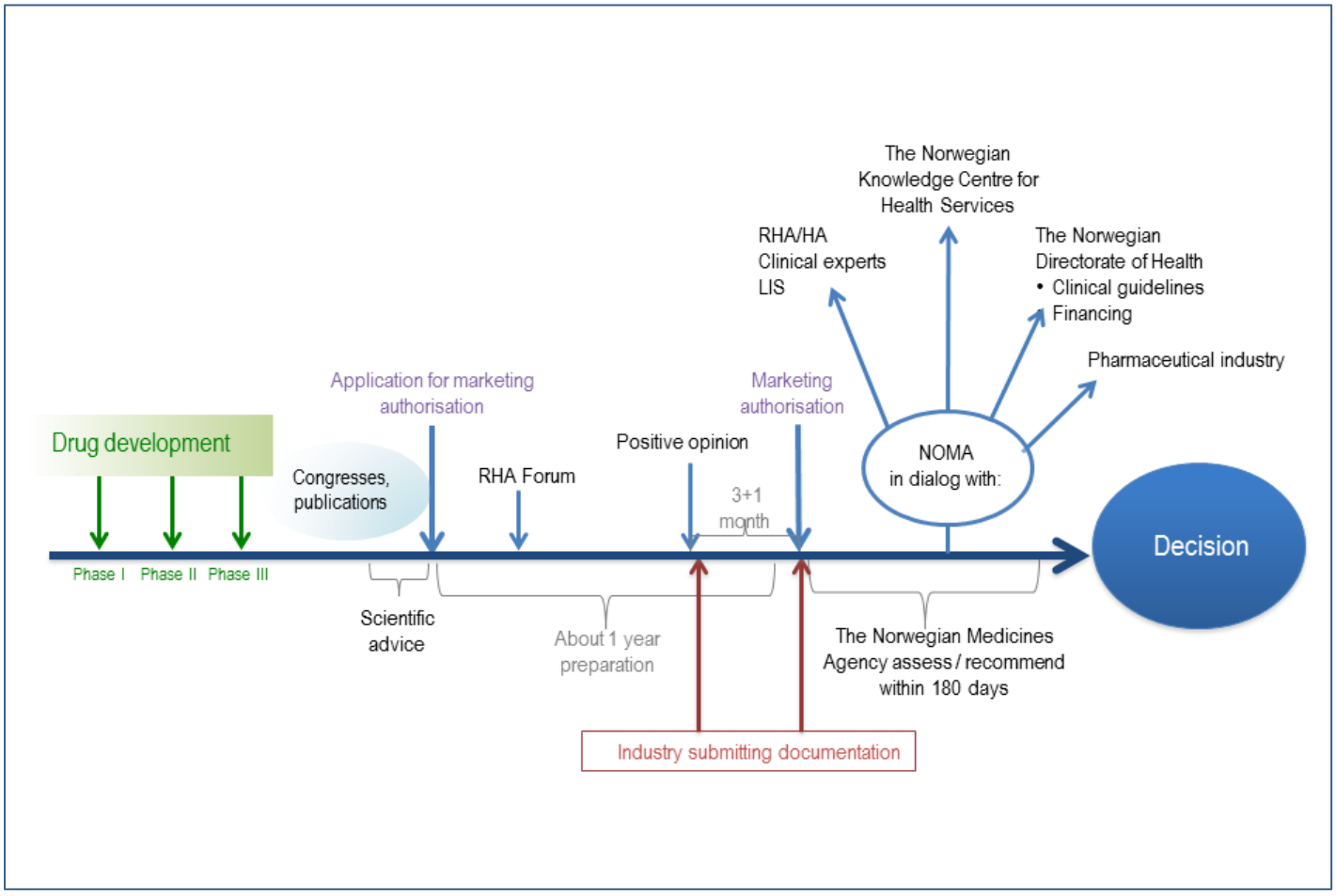

Figure 7 *Medicines; the process from clinical trial to use in hospitals*

To ensure that the assessment process is completed as quickly as possible, the Norwegian Medicines Agency will be prepared in advance with regard to the relevant pharmaceuticals. This mode of working saves both time and resources. It is important that the completed assessments are available about the same time as the launch of the pharmaceutical. It is vital that pharmaceuticals not considered to be cost-effective for hospitals are not adopted, whereas pharmaceuticals that meet the cost-effectiveness and other prioritisation criteria should be made rapid available.

Roles

The Norwegian Medicines Agency has the responsibility for assessment of new medicines, in the same manner as under the blue prescription scheme. Hence, the Norwegian Medicines Agency will carry out an assessment of whether the pharmaceuticals are cost-effective and whether the other prioritisation criteria are met. The Norwegian Medicines Agency will also include an analysis of the budgetary consequences. As part of its overall responsibility, the Regional Health Authorities must decide whether or not pharmaceuticals should be taken into use. The decision-making processes within the regional health authorities must be coordinated with the Norwegian Directorate of Health (which holds the responsibility for national clinical guidelines).

Collaboration

While carrying out health-economic evaluations of new pharmaceuticals, it is important that the Norwegian Medicines Agency works closely with the professional clinical groups at the hospitals. The Norwegian Medicines Agency will also collaborate with the Norwegian Directorate of Health, which is responsible for formulating and updating the national clinical guidelines and financing schemes. In all evaluations, the Norwegian Medicines Agency will work closely with LIS (Drug Procurement Cooperation) to ensure that pharmaceutical prices are as favourable as possible. If the regional health authorities wish to review established treatments in certain therapy areas, full HTAs should then be carried out by the Norwegian Knowledge Centre for Health Services.

6.3.3 Full Health Technology Assessment

A full health technology assessment (full HTA) is a systematic assessment of new or established health technologies where effect, safety, cost-effectiveness and budgetary consequences are evaluated. This also often covers issues relating to ethical, legal, organisational and social consequences [28]. A template for full HTAs has been developed within the EUnetHTA collaboration which is currently being tested [29]. A full HTA report is normally prepared by an independent institution which has no decision-making responsibility. In Norway, this is done by the Norwegian Knowledge Centre for Health Services, regardless of the health technology concerned. The time frame for a full HTA will be around 8-12 months.

Carrying out a full Health Technology Assessment

A full HTA can be used to analyse an issue from a broad perspective or to analyse broader issues than can be covered by a single health technology assessment. It may be appropriate to compare different alternatives in order to assess their effectiveness, side effects and complications, in order to select the most favourable alternatives for the patient and the health service. Such analyses are called “comparative effectiveness” analyses [30]. An example of this is a comparison of pharmaceuticals with different surgical procedures and/or lifestyle initiatives in the treatment of obesity. Another example is an assessment of the effect and side effects associated with various antipsychotics. A full HTA may also be appropriate for initiatives presenting different areas of application, and in connection with the assessment of health technologies that may be appropriate for withdrawal.

The Norwegian Knowledge Centre for Health Services will also prepare a full HTA where there is a need for an independent health-economic study or a broader assessment of consequences (ethical, legal or organisational consequences). A full HTA will also be relevant for the investigation of highly specialised services and screening programmes and in connection with issues relating to the introduction of new initiatives where an STA is inadequate in assessing the health technology or where there is no manufacturer to submit documentation.

Collaboration
The Norwegian Knowledge Centre for Health Services will prepare full HTAs of new health technologies for consideration at the national level, e.g. screening, highly specialised services, and in connection to the assessment of new health technologies as part of the formulation of national clinical guidelines. This will necessitate a close partnership with expert groups in the health authorities, the Norwegian Medicines Agency and the Norwegian Directorate of Health.

6.4 HTAs and the disinvestment of existing health technologies

The introduction of new health technologies within the specialist health service can change the basis for retaining existing health technologies or render existing health technologies redundant. There may also be other reasons to identify practices that no longer fulfil the required quality objectives and standards, or requirements in relation to cost-effectiveness. When introducing new health technologies, there is good reason to consider whether there are grounds for disinvestment of old health technologies. This has also been pinpointed by the National Council for Priority Setting in Health Care (see below).

A number of countries have established initiatives to identify areas where resources can be freed and made available for more appropriate use elsewhere in the health service. Some have been initiated by professional groups such as the 'Choosing wisely' campaign in the USA[31], others through government agencies such as NICE in Great Britain [32].

The need for disinvestment has been discussed within the National Council for Priority Setting in Health Care[5]:

'The National Council for Priority Setting in Health Care refers to the substantial increase in the development of new technology which could result in new diagnostic and treatment methods within the health service, and recognises that the systematic elimination of ineffective or less cost-effective methods could release resources for new initiatives. The National Council for Priority Setting in Health Care proposes that a set of criteria and a framework, including incentives for health personnel, be drawn up in order to eliminate less effective methods.

The National Council for Priority Setting in Health Care believes that to some extent the RHAs already wish to identify what can be disinvested. The National Council for Priority Setting in Health Care recommends that, in a new system for the introduction of new health technologies within the specialist health service, a systematic assessment be carried out focusing on the possible disinvestment of existing health technologies and that this assessment should be included in the assumptions relating to the introduction of health technologies above a certain cost threshold.

The National Council for Priority Setting in Health Care supports the standardization of procedures for the entire patient care process and asks that active consideration be given to what should be continued and what should be disinvested.

The National Council for Priority Setting in Health Care encourages everyone who prepares and systematically revises guidelines to explicitly consider what should no longer be part of the service.

[5] http://www.kvalitetogprioritering.no/Saker/Utfasing+av+metoder+i+helsevesenet.12891.cms

The National Council for Priority Setting in Health Care still wishes to discuss possible single technologies that should be disinvested and requests to be kept informed at all times of international developments."

There is need for systematic processes to identify and assess methods that should be disinvested by the health service. This will form an essential part of the system that needs to be further developed. Such assessments presuppose a broader assessment of both the therapy area and consequences for patients and the society in general. A full HTA assessing effect, costs, consequences for society and patients may therefore be an important tool in these instances [33]. From a quality and resource perspective, it is important that such HTAs also encompass potentially obsolete technologies in order to ensure a sustainable health service.

7.0 Decision-making processes

The system for the introduction of new health technologies within the specialist health service will ensure that processes for decision-making are transparent and separate from the processes for assessment and evaluation. The aim of conducting HTAs in the system is to provide an adequate basis for decisions that is adaptable to the various decision-making levels.

Decisions regarding the introduction of new health technologies will rely on existing decision-making structures within the Regional Health Authorities. The decision-making processes are anchored in the key principles of ensuring efficient resource utilization within the health services, including the prioritisation criteria for assessing severity, benefit and cost-effectiveness, as well as equality in treatment services for the patients.

At the local level, mini-HTAs will support decisions made by the hospital trusts. Issues may be referred through HTAs conducted at the national level, and in certain cases consultations in the National Council for Priority Setting in Health Care.

Upon completion, HTAs at national level will form the basis for decision-making processes within the Regional Health Authorities. The processes must be coordinated with decisions concerning implementation in the national clinical guidelines and recommendations in relevant areas. Further details about how the decision-making paths within this framework will be set are under way and will be disseminated later.

The Regional Health Authorities make decisions on the prioritisation of resource utilization within given budgets. The introduction of new health technologies must be covered within these budget limitations. In many instances, the introduction of new health technologies will take place in parallel to disinvestment of old technologies. These may allow re-allocation of resources to novel technologies. In many cases the new health technologies may supplement current treatment technologies and thus present major budgetary challenges.

As an important element in transparent decision-making processes, decisions not to introduce new health technologies must also be made public.

8.0 National clinical guidelines

Introduction of the national system for new health technologies within the specialist health service will be important for the work relating to national clinical guidelines. Appraisals involving HTAs before the possible

introduction of a health technology will act as the supporting knowledge base needed in relation to formulation of guidelines. It is assumed that decisions concerning the introduction of new health technologies within the specialist health service as a result of national HTAs will be coordinated with assessments of the need to update or amend national clinical guidelines. In some cases, it may also be necessary to formulate new national clinical guidelines as a result of decisions made on the introduction of new health technologies. In connection with the revision of national clinical guidelines, it may be relevant to carry out full HTAs, e.g. with a view to establishing comparisons and a running comprehensive reviews of available documentation about different treatment initiatives within a therapy area.

National clinical guidelines contain systematically developed, knowledge-based guidance and recommendations which in essence establishes a national standard for prevention, diagnosis, treatment and/or follow-up of patient groups, user groups or diagnoses groups within the health and care services. Recommendations in the guidelines are prepared against the background of knowledge-based practice and processes in accordance with the prioritisation criteria, which means that research-based knowledge, the wishes and needs of patients/users and experience-based knowledge are considered in the context of values, resource usage, prioritisation criteria, laws and regulations.

The review and formulation of the national clinical guidelines will be organised in projects and follow internationally recognised methodologies for guideline formulation, as described in the Norwegian Directorate of Health's Guidelines for the development of knowledge-based guidelines IS-1870 [2]. This follows international principles for the formulation of knowledge-based guidelines (AGREE) [30] and uses the system of Grading of Recommendations, Assessment, Development, and Assessment (GRADE) to grade the quality of the available documentation and the strength of the recommendations [34].

Key professional groups and service recipients are heavily involved in the work relating to guidelines. The Norwegian Directorate of Health strives to accommodate broad representation with regard to expertise, geographic distribution and the levels and bodies within the health and care services that are represented in the formulation of guidelines.

The formulation of national clinical guidelines must support objectives set by the Ministry of Health and Care Services. Review or formulation is often instigated under the auspices of the Ministry of Health and Care Service, on the initiative of the Norwegian Directorate of Health or at the request of a professional group/specialist group. Any initiative in relation to formulation of the guidelines must be approved by the Norwegian Directorate of Health before commencement, and the completed guidelines will be approved by the Directorate, following consultation and other processes. Factors leading to the formulation of new national clinical guidelines may include; instances where there is risk of patient safety failure, unacceptably wide variations in the type and form of services provided, a need for better coordination, intensive resource usage and issues affecting large patient groups. If appropriate, the Council may also be consulted.

National clinical guideline recommendations will be continually monitored and updated as new documented knowledge becomes available which indicates that a review of the basis for a recommendation is necessary. The HTA function will be an important tool in following developments with a view to ensuring that guidelines can be kept updated.

9.0 Implementation and follow-up during the introduction of new health technologies

Decisions leading to the introduction of new health technologies must be followed by implementation in accordance with national clinical guidelines and anchored in the decision gates of the Regional Health Authorities. Loyalty to decisions made is vital in ensuring good patient treatment, both for the health technologies that are to be introduced within the health service and those that are not.

Experience indicates that implementation of decisions made should be followed by specific initiatives to ensure adequate implementation. However, the implementation process is comprehensive and requires knowledge of how learning takes place within organisations. This can take place through the use of a range of initiatives encompassing general information, targeted training and competence initiatives at the group and individual levels, the development of decision-making support, the measurement of compliance with recommendations, updating or establishment of routines and procedures, etc.

Experience from the pharmaceutical area has shown that drug therapeutic committees (DTC) within the health authorities can play an important role in the introduction and follow-up of pharmaceuticals use, partly through the provision of pharmaceutical lists that are recommended for use. In the new system, it may be appropriate to clarify and specify the role of the drug therapeutic committees. Corresponding functions appropriate for other methods may also be initiated. For instance, it may be appropriate to establish committees responsible for medical equipment. The correct and cost-effective use of medical devices presupposes the training of those who will use the devices and it is important to have functions within the specialist health service which follow up such a need. It is important that experience and knowledge that is acquired relating to new health technologies is brought into a learning context within the specialist health service as part of an on-going quality development.

It is important to monitor and evaluate the processes in order to check and document to what extent new health technologies are being adopted. It is also necessary to monitor in clinical practice the results of new diagnostics and treatment methods. Systems for monitoring the functionality, results, safety (e.g. side effects of pharmaceuticals), actual costs and effectiveness of the new health technologies within the health services must be monitored and strengthened if necessary.

Follow-up trials and the use of clinical quality registries can be important tools for monitoring the effect of introducing new health technologies. It may be necessary to consider the establishment of new quality indicators or adjust existing ones as part of the on-going monitoring process. The re-evaluation of health technologies after a period of relative experience in clinical practice will be of considerable importance. This can be done through an updated HTA.

10.0 The four Regional Health Authorities

The Regional Health Authorities will play a pivotal role on behalf of the specialist health service in the system for the introduction of new health technologies. Inter-regional collaboration is important as examplified by existing collaborations such as the national clinical registries and the pharmaceutical procurement scheme through the LIS.

In the system, Regional Health Authorities will collaborate on many functions, e.g.:

- The RHAs' coordinators and joint coordination committee

- Running of the RHA Forum for the prioritisation of HTAs at the national level, including the coordination of proposal applications from the specialist health service

- Coordination of participation by experts/clinicians/professional networks working on various tasks within the system and ultimately in relation to:
    - The horizon scanning function
    - Proposals for national HTAs
    - Providing assistance in the form of clinical expertise in relation to formulation of national HTAs
    - Decision-making processes after HTAs are conducted
    - Participation in the process of updating and formulating national clinical guidelines.

- Collaboration and experience sharing in relation to the implementation of new health technology strategies within the specialist health service

- Contribute to the monitoring of new health technologies and side effects.

11.0 The National Council for Priority Setting in Health Care

Questions of a fundamental and prioritisation-related nature that are linked to the system's method of operation in addition to thematic issues that are linked to assessment of health technologies may be referred to the National Council for Priority Setting in Health Care for discussion. Questions concerning the introduction of a single health technology are not considered relevant for the council.

The National Council for Priority Setting in Health Care has an advisory role as regards issues touching on quality and prioritisation within the health service. The National Council for priority Setting in Health care's mandate states that it can consider issues such as those relating to the introduction of new and expensive technology/pharmaceuticals within the health care service and issues linked to the development of national guidelines within special areas in order to ensure a uniform range of high-quality health services.
According to its mandate, the National Council for Priority Setting in Health care must provide procedural advice with the view that the different actors involved develop a common understanding of situations and issues involved leading to good interaction. On such a basis, advice can be given regarding the further handling of pertinent issues.

12.0 Patient perspective and participation

Improved quality and safety in patient treatment is the pivotal objective behind the system for the introduction of new health technologies within the specialist health service. Safeguarding the patient's perspective is crucial in relation to both the introduction and the follow-up of new health technologies. Patients have a need for information regarding new health technologies and new treatments being introduced which is important for compliance. Patients will be able to contribute valuable information to the system based on their own experiences

regarding different treatments and treatment effects. This information can be used when placing orders for HTAs where patient-related aspects are to be reviewed and assessed. Patient organisations can place orders for HTAs. In line with this, it is important that the patient's needs and role in relation to the development of the new system are safeguarded. This can be partly ensured through user participation at various levels within the system.

13.0 Manufacturers, innovation and research groups

Pharmaceutical and medical technology industries play an important role in medical research. Effective, clear and focused collaboration between public sector hospitals, universities and the industry is essential. For hospital research departments, partnership with the medical industry is of considerable importance as regards expertise and mobilization of resources. Clinical trials are often carried out at the interface between research and treatment.

The new system underpins an important dialogue with the manufacturers of medical devices and pharmaceuticals at an early stage in the development and implementation of the health technology, i.e. before the product is brought into use (and financed) outside clinical studies.

When a new pharmaceutical is in the process of being introduced to the market, it is the pharmaceutical industry that is in possession of all the clinical data for the pharmaceutical concerned. The pharmaceutical industry can therefore prepare and produce documentation for pharmaco-economic analyses at an early stage in the development of the pharmaceutical. For the last ten years, the pharmaceutical industry has been preparing and providing such documentation for pharmaceuticals under consideration of pre-approved reimbursement (blue prescription). In this case, the industry (the marketing authorisation holder) has the duty to prepare and provide all necessary documentation and analyses.

In the new system, the Norwegian Knowledge Centre for Health Services and the Norwegian Medicines Agency will obtain the necessary documentation from the manufacturers when evaluating national HTAs.

14.0 Economics and financing

14.1 Economic evaluation of health initiatives

Economic evaluations carried out as part of HTAs will be done in accordance to guidance by the Norwegian Directorate of Health on economic evaluation of health initiatives [35]. This applies to both STAs and full HTAs. The aim of the guidance is to contribute to analyses of sufficient quality and uniformity such that they can be used in prioritisation assessments of new health initiatives within different treatment areas, between treatment areas and between treatment and prevention initiatives. The analyses should contribute to a decision-making basis which corresponds with the core prioritisation values and requirements about effective resource use within the health sector (FAD 2005).

14.2 The Regional Health Authorities' financing system

Need-based framework grants (basic grants) are the primary revenue source of the Regional Health Authorities. The basic grants are intended to cover many different types of costs, such as costs encompassing research,

professional development and education. Mental healthcare, alcohol and drug dependency care are largely financed through framework grants. Somatic services are financed through a component comprising approximately 60% basic grant and 40% activity-based financing. The budget framework, including how much money is to be allocated to the activity-based funding scheme, is made every year by the Norwegian Parliament. Thus the Regional Health Authorities have fixed budget frameworks within which they must prioritise their activities.

The activity-based funding component cannot provide a basis for the accurate pricing of individual services. The component sorts thousands of diagnoses and procedures into one of around 870 resource-based homogenous groups. The activity-based funding component is therefore generally only adapted to established treatments and will never be up-to-date in relation to new health technologies within the health service. The health authorities must take this into consideration when both income- and expense-related consequences are reviewed. Over time, new health technologies will be phased into the activity-based funding scheme as new health technologies become established treatment. See the regulations for activity-based funding 2012 for more discussion of the funding scheme (Norwegian Directorate of Health, IS-1945) [36]

In connection with the introduction of new health technologies within the specialist health service, it may in some cases be necessary to register activity and, if appropriate, implement national adaptations in the DRG system. See the report entitled "*Nye og kostnadskrevende metoder – forslag til system for håndtering av ny teknologi i helsetjenesten"* (Norwegian Directorate of Health, IS-1741) [37] for further discussion of the financing schemes and the provision of statistics in the Norwegian Patient Register (NPR) in relation to the testing of new health technologies. Some of the aspects covered in the report are:

- Generally it is recommended that health technologies not deemed to be established practice (uncertain beneficial effect) be financed through basic grants, i.e. such methods are not included in the activity-based funding scheme.
- Introduction of special temporary national codes for the early identification of new health technologies in cases where ordinary coding is not sufficient.
- System changes when updating the activity-based funding scheme. These changes involve the systematic use of prospective, rather than just empirically based, cost calculations as a basis for the determination of cost weights.
- A greater degree of national adaptation of the DRG system whenever necessary.

15.0 Significance for the primary health service

Although the system for the introduction of new health technologies in the specialist health service and the tasks therein are designed and limited to the specialist health service, there are similar needs for the primary health service. Decisions concerning the introduction of health technologies in the specialist health service may also have consequences and provide guidance for the primary health service. It is important to determine the economic consequences that the introduction of new health technologies within the specialist health service may impose to the primary health service.
Appropriate forms of collaboration between the primary health service and the specialist health service should be identified when introducing new health technologies. Information requirements within the primary health service are one such example. This could be decisive as regards implementation and follow-up of health technologies. The

primary health service can also contribute valuable input in relation to placing orders for HTAs and through experience sharing and dissemination of results following the introduction of new health technologies.

16.0 Monitoring and further development of the national system for the introduction of new health technologies

The new system will be continually under development. An important task will be to monitor implementation, coordination between the parties involved, user participation, transparency, experiences, functionality, risk assessments and handling, and in particular the results of the holistic system for the assessment of new health technologies in Norway. Evaluations of the system including its different sub-functions are essential. The system will also be further developed based on the experiences that are gained locally, nationally and internationally, and the system description will be updated in line with such developments.

The following initiatives will help to ensure that the above tasks are accomplished:

1. **The national working group** continues with its mandate. This group consists of representatives from the RHAs, the Norwegian Medicines Agency, the Norwegian Knowledge Centre for Health Services and the Norwegian Directorate of Health, as well as observers from the Ministry of Health and Care Services. The group has primary responsibility for updating of the system description and associated appendices which provide a more detailed description of the products/appraisal initiatives in the system.

2. **The reference group** with representatives from manufacturers, professional associations, patient organisations, the universities, etc.; shall be an essential arena for input linked to the system's function and method of operation.

3. **The secretariat at the Norwegian Directorate of Health** shall:
   - Enhance good coordination between parties involved in the system
   - Contribute towards further development of the system
   - Contribute towards monitoring of the system
   - Draw up proposals for evaluation initiatives
   - Perform the role of secretariat for the RHA Forum, national working group and reference group.

17.0 Knowledge gaps and the instigation of clinical studies

The system for the introduction of new health technologies will help to identify existing knowledge gaps both through mini-HTAs and HTAs at the national level. This can act as the starting point for new research. The database for mini-HTAs and the national HTAs will act as a source of information regarding research needs. There is a need to discuss how identified research needs can best be channelled to research projects, both with regard to the need for coordination of projects encompassing the same issue as well as to help ensure that the best possible research methodology is used.
New infrastructures and research networks are in the process of being constructed at the national level (NORCRIN), at the Nordic level (Nordic Trial Alliance; NTA) and at the European level (European Clinical Research Infrastructure Network; ECRIN). Such networks may become important tools for executing clinical studies in an effective manner, e.g. in areas where knowledge gaps have been identified.

18.0 Participation in international collaborations

Active participation and experience sharing at the international arena as regards functions of the new system for the introduction of new health technologies in the specialist health service is considered as a key component towards quality assurance and further development of the system. There is particular reason to emphasise the European EUnetHTA collaboration [20], which has the aim of developing a common approach to products and processes, and hence making it easier to use studies conducted by other countries. EuroScan, the international network for health technology assessment (horizon scanning) and the early assessment of new health technologies [15], is another important forum. During the formulation of guidelines, it will be important to ensure alignment with the Guidelines International Network.

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