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LÄKEMEDELSFÖRMÅNSVERKET

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Health Technology Assessments of Medical Devices

For a more evidence-based knowledge and equitable use

Final report

The Swedish Dental and Pharmaceutical Benefits Agency, December 2014
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Preface

On April 4, 2012, the Swedish Dental and Pharmaceutical Benefits Agency (TLV) was commissioned by the Swedish Government to conduct health technology assessments (HTAs) of medical devices. The project was carried out on a trial basis and a final report was published on November 5, 2013. The final report included HTAs of selected groups of medical devices that had been evaluated and summary of how a permanent function might be structured.

On October 17, 2013, TLV was granted a renewed commission by the government to continue and expand the work with HTAs of medical devices. An interim report on the commission was presented on April 30, 2014 and this report represents the final presentation

In preparing this report, TLV consulted the Medical Products Agency (Läkemedelsverket), the Swedish Council on Health Technology Assessment (SBU), the National Board of Health and Welfare (Socialstyrelsen) and VINNOVA. We have also discussed with patient representatives, healthcare authorities and the medical technology sector.

Stockholm 17 December 2014

Sofia Wallström
Director General

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Summary

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) was commissioned by the Swedish Government in April 2012 to conduct health technology assessments (HTAs) of medical devices. The project was carried out on a trial basis and initiated to aid the county councils in making more informed decisions regarding medical devices. Another objective was to perform HTAs, at the national level, which would enable uniformity and equal healthcare.

A report on the first government commission was presented in November 2013. Prior to this, TLV was assigned a renewed government commission to continue and expand the project until the end of 2014. The objective with this commission was to evaluate the possibility to perform HTAs in early stages of product life cycle. An interim report on the commission was presented in April 2014, and the final report was published in December 2015. Once again TLV has been commissioned to continue evaluating medical devices throughout 2015.

HTA of medical devices should be performed at the national level
Each year, approximately SEK 20 billion is invested in medical devices in the Swedish healthcare system. This investment is comparable to the annual spending on pharmaceuticals in the benefits scheme. According to Swedish law, investments in healthcare should involve a reasonable relationship between costs and effects. This means that patients should receive the best possible health benefits from tax money spent on medical devices. However, decision-makers rarely perform an HTA of medical devices where all costs and effects, regardless by whom they are incurred, are included (i.e. a societal perspective). In previous reports TLV has concluded the need for HTAs regarding medical devices and that the assessments should be performed at national level.

Limited scientific data in early stages of the product life cycle
A CE-marked medical device must have sufficient evidence of the product's safety for intended use. The scientific data, concerning effect in relation to cost, used in HTAs are generally not comprehensive for medical devices. This may result in varying degrees of uncertainty of the analysis. HTAs always imply a certain degree of uncertainty. Therefore, it is particularly important to be transparent when describing and working with uncertainty in an economic evaluation, but it should not in itself be an obstacle in carrying out HTAs. When the product is CE marked and available on the market, the decision makers need to decide whether they should buy the product or not.

HTAs regarding medical devices can be conducted in a similar manner as pharmaceuticals

HTAs regarding medical devices may be conducted in a similar manner as pharmaceuticals but may present particular challenges. Besides having less comprehensive scientific data compared to pharmaceuticals, medical devices often have a shorter product life cycle and undergo minor incremental changes, making it more difficult to assess patient benefits. Medical devices are also to a large extent affected by the circumstances under which it is used. HTA need to include factors, which influence use. For example, the requirement for organisational changes, follow-up and possible re-evaluations.

Not optimal to perform an HTA prior to CE-marking

During 2014, TLV chose to assess three different innovative products in the area of cardiovascular disease: thumb-ECG, Stroke prevention CDS and Strokefinder. It is important to point out that the assessments do not evaluate the products but rather their use in clinical practice. All products were considered to have major potential for improved public health as well as offering the possibility of reduced costs for society. The project provided a deeper understanding of when in the product life cycle it is possible and most appropriate to conduct an assessment. TLV concluded that to gain most impact assessments should be conducted as soon as possible following CE-marking.

A novel and iterative approach to HTAs early in the product life cycle

The purpose of HTAs is to aid decision makers prioritising among new medical devices introduced in healthcare. In Sweden there is no systematic process for the introduction of new products at the national level. County councils make such decisions without the support of HTAs from a societal perspective.

TLV's final report proposes a four-step model for HTA of medical devices. By visualizing the various steps in the evaluation process it is made transparent and raises awareness among medical device companies and decision makers on how to conduct HTAs. By increased knowledge base, the four-step approach allows us to increase the accuracy of the decision.

In the first step, it is important to identify intended use of the product and currently available treatment options. The next step involves collecting data on costs and effects. The third step involves estimating the cost-effectiveness ratio with, for example, the use of decision-analytic modelling. The final step is follow-up of results from real life data, if available. This is, therefore, an iterative process. Every step involves identification of knowledge gaps and describes the uncertainty of parameters important for the HTA.

The future of medical device introduction into public healthcare in Sweden

During the collaboration with the county councils, TLV has seen that there is a real need for a national body that performs HTAs. TLV also concludes that these HTAs must be based on best available information and that it is possible to conduct these HTAs even in the early stages of the product life cycle. The county councils are, when appropriate, responsible for implementing the assessed products in healthcare. Among the medical device companies there is also a need for greater awareness of how to produce high quality economic assessments. TLV has, therefore, established an advisory function for this purpose. To ensure cost effectiveness, it is vital to continue developing methods for evaluating medical devices. This will make the Swedish healthcare sector better prepared when medical devices start to play an even greater role in healthcare than today.

Terminology and concepts

Evidence – scientific proof which serves either to support or oppose a scientific theory or hypothesis. Such evidence is expected to be empirical and adequately documented in accordance with the scientific methods applied in respective scientific field. Reference to evidence in the report means, unless otherwise stated, the scientific data on which the HTA is based and *not* the scientific data on which a CE marking is based on.

Consumables – medical devices required by a patient to be able to take a medicine and be able to check levels of medication. For example, test sticks used to check level of glucose in the blood.

Health benefits – benefits for the patient gained from the use of the medical device evaluated in terms of an individual's improved health and quality of life. Health benefits are measured as QALYs gained.

Healthcare perspective – means that all costs and effects incurred by healthcare (by, for example, county councils, municipalities and the state) should be included.

Innovation – involves new or better methods of creating value for society, companies and individuals. Innovations are new solutions which meet needs and demands in everyday life and worldwide. The value arises from making use of and applying ideas. The value created can take many forms – for example, economic, social or environmental values[1]. An innovation is, therefore, a new solution or idea resulting from a development process and meets a market need.

Clinical data – a scientific body of evidence on effects and costs to be used in economic evaluations.

Knowledge base – systematic collection of clinical data takes place throughout the product life cycle of a medical device. This includes clinical testing before CE marking, and all knowledge generated following CE marking, until the product is withdrawn from the market.

Quality-adjusted life years (QALYs) – QALY is defined as number of years an average patient is expected to live, multiplied by a quality of life weight.

Medical devices – products used to: diagnose, prevent, monitor, treat or alleviate symptoms of a disease; diagnose, monitor, treat, alleviate or

[1] The national innovations strategy.

compensate symptoms resulting from injury or disability; investigate, alter or replace anatomical structures or physiological processes; regulate fertility.

Product life cycle – The product life cycle may, according to Kotler's definition[2], be broken down into four phases: introduction, growth, maturity and decline. In this report, TLV has chosen to call the first phase the development phase since CE marking takes place *between* the development and growth phases.

Randomised controlled trial (RCT) – a trial in which participants are randomly assigned to different groups. The trial can be blind (i.e. either of the participants or researchers do not know to which group the participants belong) or double blind (i.e. neither the researchers nor participants know to which group the participants belong).

Risk categories – medical devices included in the Medical Device Directive are divided into categories: Category I, Category IIa, Category IIb and Category III. This categorisation is based on the risks to which the human body may be exposed. The risk categorization depends on the intended use of the product.

Societal perspective – means that all costs and effects, regardless by whom (county councils, municipalities, the state, patients, relatives) they are incurred should be included. In 2014, TLV reviewed how to estimate costs and effects from a societal perspective.

[2] Kotler P, 1999, Principles of Marketing – Second European edition.

1 Starting principles

Summary of chapter
The market for medical devices is similar in size to that of pharmaceuticals within the benefits scheme, approximately SEK 20 billion annually. Yet, medical devices are not assessed at the national level to the same degree as pharmaceuticals. There is a clear demand for economic evaluations (or Health Technology Assessments, HTAs) from county councils and the medical technology sector.

Due to the size of the market, it is not possible to assess all medical devices. It is, therefore, crucial to find and select the medical devices that can make the most impact on healthcare. The three products TLV chose to evaluate during 2014, were all in early phases of their product life cycles. An important reason for the choice of products was to investigate how early assessments may be conducted.

The clinical data required before medical devices can be sold (i.e. be CE-marked) can, generally speaking, be less comprehensive than for pharmaceuticals. The data exclusively concerns the product's performance and safety and there is generally no clinical data to support an economic evaluation. A shorter product life cycle for medical devices than for pharmaceuticals present extra challenges in conducting HTAs.

1.1 The medical device market is large, but use is not always cost-effective

Healthcare authorities invest approximately SEK 20 billion in medical devices each year. This is roughly the same as the state budget for pharmaceuticals within the benefits scheme. According to Swedish healthcare laws, a reasonable relationship between costs and effects for investments in healthcare must exist. This increases the likelihood that patients and users gain the best possible health for the tax money spent on medical devices. Despite national regulation, county councils and municipal authorities do not generally conduct Health Technology Assessments, HTAs, of medical devices.

Health authorities and medical device companies have expressed that HTAs of medical devices be carried out in a similar manner to those already employed for pharmaceuticals. To achieve the best possible utilisation of public resources, the basis for TLV's work is that medical devices should be assessed to a greater extent than it is at present.

If the assessments are conducted by TLV, rather than by individual county councils or municipalities, better utilisation of existing resources is achieved. This also means that county councils and municipal authorities will have access to the same HTAs when deciding on procurement and use, which will promote more equal care and better public health.

1.2 Government commission

In April 2012, TLV was granted a government commission, to carry out HTAs of medical devices on a trial basis. The party bringing the product into use, for example, the healthcare sector must follow the National Board of Health and Welfare's regulations (SOSFS 2008:1). Within the first government commission, TLV presented, in 2013, HTAs on four groups of medical devices (1-4), an interim report (5) and a final report (6)

The renewed and expanded government commission awarded to TLV in 2013 (7), directs the authority to develop methods allowing the economic evaluation for new and innovative medical devices not yet introduced on the Swedish market, and for which there are no validated data. TLV's HTAs will be made available, allowing county councils and municipalities to take them into consideration before procuring the evaluated devices. TLV will, in this respect, specifically collaborate with the National Board of Health and Welfare and the Swedish Council on Health Technology Assessment (SBU) to ensure an effective utilisation of resources and expertise as well as concurrence between national guidelines and HTAs. In conjunction with making assessments available, TLV will propose how to carry out ongoing follow-ups.

Medical devices used for treating chronically ill patients often require gathering of additional data (e.g. from healthcare quality and health records) in order to be included in a decision model. In this regard, differences in clinical practice among county councils, as well as how the product is used in healthcare, are important for assessing data to be used in economic evaluations. The HTAs produced by TLV will consider the treatment context and clearly point out cases where cost-effective use requires changes in healthcare and treatment procedures.

Within the expanded government commission dated 2013, TLV presented an interim report (8) in April 2014. The interim report was a summary of experiences gained up to that date. The report presented herein, is a final report for the expanded government commission.

1.3 Medical devices and pharmaceuticals are regulated differently

Pharmaceuticals have an approval process clearly regulated by the authorities. There is no equivalent approval process for medical devices, instead a so-called "new approach" is used. This means that the products should be CE marked when released on the market. A product CE marked in one country, has access to the entire EEA market. It is the manufacturer's responsibility to ensure that a medical device complies with current legal requirements regarding CE marking. It is also the manufacturer that grants CE marking for the product. CE marking does not mean authority approval of the product. In cases where products are associated with specific risks for patients, the manufacturer must engage an independent party (a so-called notified body) to participate in the assessment and to confirm that the product fulfils the imposed requirements.

The clinical data required before medical devices can be sold are, generally speaking, less comprehensive than for pharmaceuticals, and the data exclusively concerns product performance and safety[3]. CE marking means that the manufacturer guarantees that product design and documentation fulfil regulatory performance and safety requirements for intended use, and that products brought to market fulfil such requirements. The information required should, therefore, illustrate product benefits in relation to risk involved when using the product. CE marking also means that the manufacturer applies systematic risk management, as well as follow-up and feedback on experiences gained from products brought to market.

However, HTAs require clinical data indicating effects and costs related to the product. The amounts of clinical data vary substantially between different medical device groups and depend on to which risk category the product belongs and where in its product life cycle the product is. In this report, reference to clinical data means information on effects and costs that may be used in HTAs.

1.4 Short product life cycle

A specific feature of medical devices is their short product life cycle. A product life cycle (see Figure 1) is, according to Kotler's definition (9), usually divided into four phases: introduction, growth, maturity and decline. We have adapted the product life cycle to medical devices and CE marking and have chosen to rename the first phase the “development phase”. The development phase ends with CE marking, and the product is not introduced to the market during this phase. The four phases, according to TLV’s definition, are:

[3] LVFS 2003:11 2 §.

Development: A period of slow growth with respect to the use of the product. Use of the product in this phase consists of use in clinical trials required for obtaining CE marking.

Growth: After it is CE marked, the product is transferred to the growth phase. The use of the product consists of sales and use in clinical trials to generate further clinical data. In this phase companies are still establishing the knowledge base for the product. This means that the data regarding product effects and costs are not necessarily publicly available.

Maturity: Growth slows down as the product is well known and accepted among a majority of potential buyers. Randomised controlled trials may be carried out as the patient base is larger and further clinical data may be gathered.

Decline: Use decreases. The level of knowledge about the product reaches its peak in this phase.

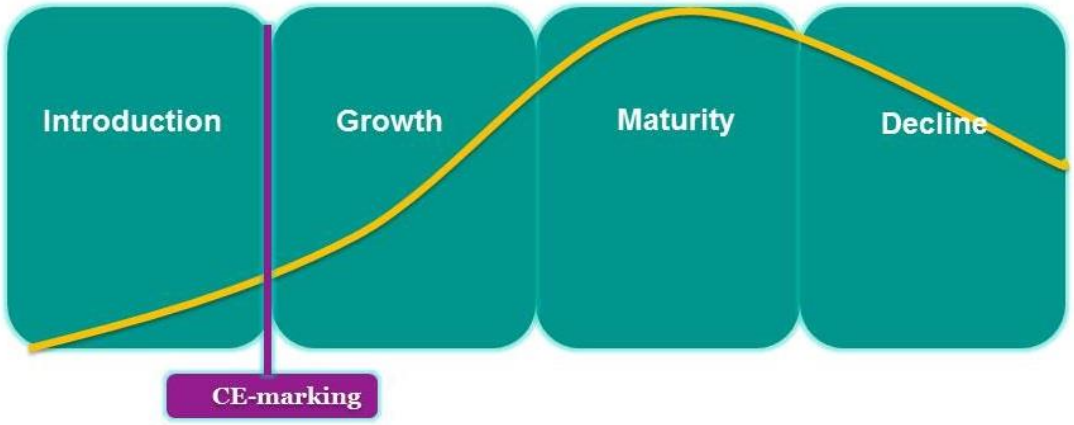

Figure 1. The figure shows the four phases and use of the product during the product life cycle. The figure is inspired by Kotler (9) *. The yellow line shows how the changes of use shifts during the four phases. As an addition to Kotler's original figure of the product life cycle, TLV indicates where CE marking takes place and has chosen to call the first phase the "development phase" instead of Kotler´s original name "introduction phase". Prior to CE marking the product is not available on the market.*

Medical devices comprise a heterogeneous collection of products. They differ from each other with respect to complexity, degree of competition, rate of development etc.

One example to illustrate how short product life cycles may be for medical devices is glucose sensors for CGM (continuous glucose monitoring). Between September 2009 to February 2014, three new glucose sensors from the same product line were included in the benefits scheme. The three glucose sensors are further developments of previous products ("Sof" sensor and "Enlite" sensor from Medtronic AB). Generally, when a further development of a

glucose sensor has been included in the benefits scheme, the previous glucose sensor has been withdrawn at the request of the company. The product life cycle for such products is, thereby on an average two years and three months.

A product category (for example, insulin pumps) also has an overall product life cycle. Insulin pumps were introduced on the Swedish market as early as the 1970s and are still in the maturity phase since their use has not decreased over time. Contrary, further growth may be required for certain patient groups.

1.5 Access to clinical data is a challenge

The county councils have the highest demand for HTAs for medical devices not yet purchased where a decision has to be made whether or not to purchase the product, and where current assessments conducted by the National Board of Health and Welfare and Swedish Council on Health Technology Assessment (SBU) do not offer sufficient support for the county councils' decisions on procurement and use. The county councils primarily request HTAs derived from best available scientific data, not recommendations. Even the medical devices sector requests national HTAs.

At present, it is difficult for companies with innovative medical devices to reach the healthcare sector and start generating sales. This is because the healthcare sector finds identifying and assessing innovative products problematic. Also, short term budget considerations among county councils and municipalities may risk delaying the introduction of innovative and cost-effective medical devices.

A delayed introduction due to a lack of HTAs may cause failure to generate health benefits for patients and reduced productivity in healthcare. It is, therefore, crucial that HTAs are conducted at the right time and in a format that may easily be used by county councils and municipalities. HTAs offer the greatest benefits to society, when they should be conducted soon following CE marking.

1.6 The importance of finding a method for product selection that will make a difference in healthcare

The expanded government commission stipulated that TLV should assess new and innovative products as well as products for the chronically ill. The choice of medical devices/methods to assess was, in that respect, to a certain extent dictated by the commission. TLV aimed to identify medical devices having a potential major impact on resource consumption in healthcare for patient groups with unmet clinical needs.

In the first government commission, TLV proposed a list of criteria to facilitate a more transparent and predictable prioritisation of medical devices to be assessed in a possible future permanent commission. The following six criteria were identified:

- Resource usage
- Severity of the disease
- Disease epidemiology
- Unmet clinical needs
- High/low clinical effect (innovation/obsolescence)
- Non-equitable use

The number of medical devices is very large, approximately half a million products. TLV finds that it will be difficult to assess all medical devices on the market. It is, therefore, crucial to find and select the medical devices most urgently in need of assessment from a societal perspective.

1.6.1 HTA selection process during 2014

In 2013, TLV made it possible to submit proposals for medical devices that might be suitable for assessment. The proposals from the public, county councils, patient associations, companies and others, were submitted via TLV's web site. Out of forty proposals submitted in 2013, approximately one-half were submitted by county councils. The former Swedish Handicap Institute (Hjälpmedelsinstitutet)[4] submitted two proposals and the Swedish Association of the Hearing Impaired (Hörselskadades riksförbund) one proposal. Other proposals were submitted by companies, authorities and private individuals.

TLV carried out preliminary evaluations of the proposals that were suitable for an HTA stipulated by the government commission. Among the proposals submitted were methods that had already been assessed in whole or in part by SBU and were, therefore, not appropriate for assessment by TLV. Based on the preliminary studies, remaining proposals were prioritised and county councils, authorities and Swedish Medtech and the Association for Medical Technology in Sweden, were given the opportunity to express their views on the proposals with respect to said prioritisation. The majority of the submitted proposals lacked data on which to form an opinion regarding suitability for an HTA.

Among the proposals considered high priority in the selection process were a number of proposals concerning cardiovascular disease. TLV, therefore, chose to focus on this area, particularly stroke, mainly because the disease concerns a rather large group of chronically ill patients, and there was a clear potential for improvement in healthcare. Patients affected by stroke require extensive healthcare resources, it is a severe condition, clinical requirements are inadequately met, and available healthcare is unequal throughout the country.

[4] The Swedish Agency for Participation.

At the same time, there are a number of innovative medical devices intended to improve prevention, diagnosis, etc. that have not yet been introduced.

1.6.2 At which stage may and should HTAs be carried out?

It is not, as previously stated, until a product is CE marked that it is ready to be introduced into healthcare in a manner other than within the framework of research and development. Even following CE marking there may remain major uncertainties regarding the effect of the product in everyday clinical use.

TLV selected three products for assessment in 2014: Strokefinder, Stroke Prevention CDS and primary preventative screening of atrial fibrillation with thumb-ECG. For a more detailed description of the products see Chapter 2.1.2. All products/methods are considered to be innovative and, as mentioned earlier, they are all intended for use in the area of stroke. Moreover, they are all in the development or growth phases of the product life cycle (see Figure 2 below).

Two of the products (Strokefinder and Stroke Prevention CDS) lacked CE marking when they were selected by TLV. The product with CE marking (primary preventative screening of atrial fibrillation with thumb-ECG) was being used in a new area of application in healthcare covered by the existing CE marking. A great deal of variation was found in available clinical data regarding the effects of the selected products.

An important reason for choosing two of the products, Strokefinder and Stroke Prevention CDS, was to determine how early HTAs could be conducted. Although Stroke Prevention CDS lacked CE marking when the assessment began, the company had progressed further in its product development than Strokefinder. The two products were hence at different stages in the development phase of the product life cycle.

By choosing three products in the development and growth phases of the product life cycle, we have also been able to begin the process of developing health economic methods for new and innovative products.

The four HTAs published by TLV in November 2013 represented products in the growth or maturity phases of the product life cycle.

Figure 2 illustrates where the various assessed products are in the product life cycle. The illustration aims to give a general description of the different assessments and does not claim to specifically define which product is placed where.

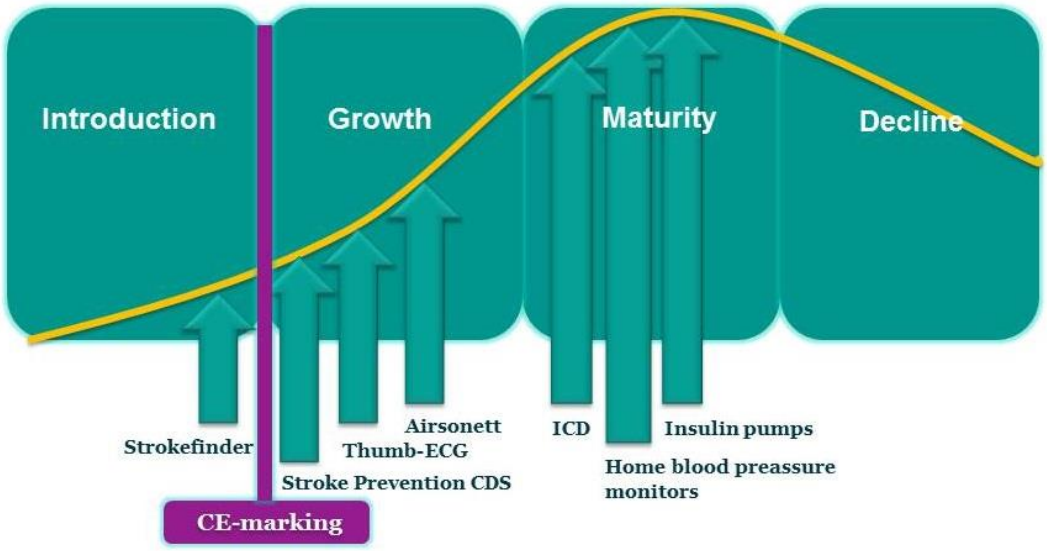

Figure 2. The figure illustrates where the assessed products stipulated in the government commission were in the product life cycle when the assessments were published.

1.7 The HTAs are based on the ethical platform

TLV has proceeded on the assumption that the criteria applied to pharmaceuticals in accordance to Section 15 of the Act on Pharmaceutical Benefits (2002:160)[5] , should apply in the evaluation of medical devices. The application of such criteria must be adapted to the special conditions that apply to medical devices. TLV has also worked with the assumption that there will be the same willingness to pay for medical devices as there has been so far for pharmaceuticals included in the benefits scheme. The assumption is in agreement with the limits of willingness to pay reported by the National Board of Health and Welfare (10). TLV does not make any claims whether this concurs with the county councils' actual willingness to pay.

TLV´s assessments are based on the ethical platform[6], laid down by Parliament and which contains three principles:

The principle of human dignity is a general principle maintaining that all humans are of equal value and have equal rights to healthcare, regardless of

[5] A prescribed drug should be covered by pharmaceutical benefits and, in setting the purchase price and sales price for the drug, it is assumed that the costs of using the drug, in observance of the stipulations in 2 § Healthcare and Medical Services Act (hälso- och sjukvårdslagen) (1982:763), appear to be reasonable from the medical, humanitarian and socioeconomic perspectives, and that there are no other available pharmaceuticals or treatment methods which, in balancing the intended effect against harmful effects as considered in Section 4 of the Medicinal Products Act (Läkemedelslagen) (1992:859), are adjudged to be significantly more suitable for the intended purpose.[6] Priority setting in healthcare (Prop. 1996/97:60).
[6] Priority setting in healthcare (Prop. 1996/97:60).

personal characteristics and functions in society. The principle, thereby, stipulates what factors should not affect priority setting in healthcare (for example, ability, social standing, income, age or gender).

The principle of needs and solidarity maintains that if priority setting of different methods is necessary, more healthcare resources should be allocated to those with the greatest need, those with the most severe conditions and those with the worst quality of life. The principle aims to ensure that the outcome of healthcare is as equal as possible. In addition, it implies a specific responsibility for people who are unable to defend their own rights and it requires that particular attention is paid to the needs of those who are the weakest in society. This includes children, elderly with dementia, those who are unconscious, and others who, for various reasons, are unable to communicate with those around them.

The principle of cost-effectiveness maintains that when there is a choice of measures to implement, a reasonable relationship should be sought between cost and effect, measured in improved health and quality of life.

The principle of human dignity could be said to be a framework where priority-setting decisions in healthcare. The two other principles are less absolute in the sense that a balance between them ought to be achieved. The principle of cost-effectiveness deals with the level of health benefits created per SEK invested and the principle of needs and solidarity maintains that the health benefits created should be fairly allocated - in particular, more healthcare should be provided to those who have the worst state of health.

Cost-effectiveness is, therefore, one of those aspects that should be taken into account when deciding on priority-setting decisions (i.e. on which treatment strategies within healthcare should be based). In “Priority setting in healthcare”, the principle of cost-effectiveness stipulates that there should be a reasonable relationship between costs and effect in healthcare investments.

A conflict between the principles arise if a greater total health benefit may be achieved by providing higher priority to a patient group with moderate health loss, than to a patient group with major health loss. Therefore, a compromise must be reached between the principle of needs and solidarity and the principle of cost-effectiveness. In order to prioritise without risking sub-optimisation, a societal perspective is preferable. TLV accepts lower cost-effectiveness (less benefit per SEK invested) the more severe the illness is.

1.8 Basis for the expanded government commission

In the interim report published April 2014, TLV presented the basis for conducting the continuing work. An overall description is listed below.

1. **HTAs should be based on the best data available**
   Assessing a product at an early stage may sometimes mean that the HTA is conducted before studies relating to clinical data are published. TLV believes that an HTA should be based on the best available clinical data and, if county councils required it, assessments could be updated when more data became available.

2. **Distinctions between different authorities were unclear**
   It is important to aim for transparency and predictability, as well as to define TLV's role in relation to other authorities who assess medical devices with different methods. TLV's permission to receive and classify confidential material from companies means that we are better prepared than healthcare authorities in general to conduct HTAs on medical devices.

3. **Do HTAs of medical devices present challenges not found in HTAs of pharmaceuticals?**
   Lack of clinical data and short product life cycles makes it necessary to develop methods specifically adapted for HTAs of medical devices.

4. **An HTA can be conducted early in the product life cycle, but when is it too early?**
   A starting point in the work was looking at the possibility of evaluating medical devices before the product is CE marked, or in connection with the product being CE marked.

5. **TLV has identified a demand for HTAs to also include factors affecting use**
   The HTAs should not be limited to a cost-effectiveness analysis. The first part of the HTA is an economic evaluation. The second part comprises further information and an impact analysis. TLV noted that ethical, legal, organisational, economic (such as budget effects) and environmental aspects should be included in the second part of the HTA. Suggestions on how assessments and follow-ups should be designed should also be included in order to strengthen level of knowledge of the products with respect to their future use. The patient perspective is also considered in this second part.

6. **Managed introduction**
   To examine the possibility that medical devices being assessed should, to a certain extent, be introduced in an organised manner, similar to that for pharmaceuticals. Using managed introduction, it could be

possible to increase the level of knowledge regarding effects of a product, provided treatment results are schematically collected, for example, in a national register.

7. **Information and advisory services for the medical technology sector**
   TLV has identified a demand for additional clinical data. TLV may, through advice, offer companies assistance to produce the clinical data required to conduct a cost-effectiveness analysis with less uncertainty. TLV, therefore, started to provide the medical technology sector information through advisory services.

The above items have now been examined and additional experiences gained are presented in Chapters 2 and 3 of this report.

2 Gained experiences from conducted HTAs

Summary of chapter
TLV's work is deemed to have contributed to increased awareness among county councils regarding the possibilities for, and the benefits from, conducting HTAs in the area of medical devices. There is an explicit role for TLV and a demand for its HTAs of medical devices. Even though other authorities also conduct assessments of medical devices, the efforts of the various authorities in this area complement each other.

All seven HTAs published by TLV within the government commission have provided experience regarding how early it is possible, and appropriate, to conduct HTAs of medical devices. For a complete economic evaluation sufficient clinical data must be available. An assessment should not be published before the product has been CE marked. An HTA is of greatest benefit if it is introduced at the right time; when clinical data is available, but before the product has been launched on a broad front.

HTAs in an early phase of the product life cycle are conditioned upon the ability to classify company material, as well as other unpublished study results. One should also consider the possibility that data is not gathered at a sufficient rate, which may result in the assessment not being published. Unpublished data may be associated with greater uncertainty. It is, therefore, important to update HTAs as new data becomes available and when county councils so requests.

2.1 Assessed products

In the first government commission (11), TLV assessed four medical devices or methods:

- insulin pumps and continuous glucose measurement (CGM) (4),
- temperature-controlled laminar air flow in the treatment of allergic asthma (Airsonett) (2),
- measurement at home with automated blood pressure monitors (1); and,
- implantable defibrillators for the treatment of heart failure (ICD) (3).

TLV chose to evaluate these as they are in different phases of the product life cycle. The choice was, among other things, aimed at assessing the suitability of different health economic methods for assessing medical devices. The four

selected medical technologies offered different types of comparitors and varying amounts of available clinical data. TLV also initiated an attempt to compare different products within the same product group. For this purpose we collaborated with various agencies[7] to determine what type of clinical data was available to other agencies, or could be produced by them.

2.1.1 Experiences from the first government commission

TLV deems it possible to assess specific products and methods. Most importantly, the HTAs consider a specific use rather than the product itself. For example, it cannot be stated whether an X-ray equipment is cost-effective if the context in which the equipment will be used is not known. To determine whether the medical device is cost-effective requires an assessment of each applicable area for which the product may be considered.

During the evaluation of insulin pumps and home blood pressure monitors, it was found that it is not appropriate for a national authority to conduct HTAs with the purpose of comparing products in the same product group. This type of assessment is better suited to be conducted within the procurement framework of the county councils.

In the HTAs published in 2013, TLV used different health economic methods. TLV found that the same health economic methods may be used for medical devices as for pharmaceuticals. The only limitation is the amount of available clinical data. For medical devices, the cost-effectiveness of the method often depends on a number of parameters such as, for example, the skill of the user, healthcare organisation and clinical workflow. In the government commission of 2014 we have decided to clarify said parameters of the HTAs.

Finally, we found that the HTAs of products in the maturity phase of the product life cycle (insulin pumps and home blood pressure monitors) did not make a big impact among county councils because many of these products were already routinely used in healthcare. On the other hand, ICD was in the growth phase of the product life cycle and sales increased after TLV published this HTA (3). It is, however, difficult to comment to which extent TLV's HTA affected the increase. Airsonett was in the growth phase of the product life cycle and the HTA for this method made the greatest breakthrough both nationally and internationally. In April 2014, Stockholm county council initiated a managed introduction of Airsonett, which led to an increase in prescriptions and several other county councils followed suit. In the National Guidelines for Care in Asthma and COPD [Support for Governance and Management - Consultation version (12)], the National Board of Health and Welfare gave Airsonett a recommendation of five on a scale of ten, for patients

[7] The Center for Medical Technology Assessment at Linköping University, KTH Royal Institute of Technology (Kungliga Tekniska Högskolan) in Stockholm, the Medical Products Agency (Läkemedelsverket), the National Board of Health and Welfare (Socialstyrelsen), and SBU.

(adults and children ≥ 6 years) with severe, uncontrolled (despite stage 4 treatment) allergic asthma.

2.1.2 Experience gained from the expanded government commission

Based on the experiences gained during the first government commission, TLV realized the value of determining how early in the product cycle it was possible and desirable to conduct HTAs. In the expanded government commission, therefore, we decided to assess, products in the development and growth phases with potentially significant impact on healthcare.

The three medical devices that were assessed in 2014 were, in different ways, intended to improve the screening, diagnosis, and treatment of individuals who were at risk of suffering, or had already suffered, a stroke:

1. **Primary preventative screening of atrial fibrillation with thumb-ECG**, a portable unit for measuring ECG in the home.
2. **Strokefinder**, an item of diagnostic equipment which differentiates between clotting-induced strokes and bleeding strokes.
3. **Stroke Prevention CDS**, a computer-based tool for clinical decision making in evaluating the risk of stroke and in preventative treatment.

To our knowledge, none of the products mentioned above have an exact equivalent on the Swedish or international markets; at least not with regard to the uses being assessed. All the products are deemed to have major potential for improving public health, and at the same time the use of the products may lead to a reduction in healthcare costs.

Thumb-ECG is regarded as being in the growth phase, while Stroke Prevention CDS and Strokefinder are in the development phase of their product life cycles. Neither of the latter two products had CE marking when we began the HTA. Before this work began, the manufacturers of the products stated that CE marking was planned for 2014.

All the products were targeted at patients who had suffered strokes or were at risk of suffering strokes. By focusing the assessments on a specific disease area, we assumed that synergy effects could be achieved. By, among other things, working with third parties, collaboration with other authorities could be facilitated and negotiations made more effective. SBU recently conducted work in the area of atrial fibrillation and the National Board of Health and Welfare produced preliminary national guidelines for stroke. In retrospect, we see that collaboration with and among external parties, such as healthcare providers, patient associations and other authorities, has been facilitated. The collaboration has also improved the possibility of highlighting care needs, consequences of silo budgeting, changes in clinical workflow and/or treatment. Focusing on one or a few therapy areas at the same time may therefore be preferable in ongoing work.

2.2 HTAs should not be carried out before CE marking

All medical devices that are marketed within the EEA should be CE marked and fulfil the requirements of the European directives[8] concerning medical technology incorporated via medical technology laws[9], medical technology ordinances[10] and the Medical Products Agency's regulations[11]. Medical devices are divided into three risk categories. Allocation to categories is based on the risks on which the human body may be exposed due to the product's design, method of manufacture or use. When a medical device is CE marked, it means that the manufacturer ensures the stated product performance and that the product's side effects are not disproportionate to its clinical benefits when used for its intended purpose and in the prescribed manner.

A product cannot be sold on the market before it has been CE marked. It also means that neither the product's intended use, nor its safety in relation to its benefits, have been established. TLV has, therefore, found that it is not desirable to publish assessments for a product before it has been CE marked. Furthermore, TLV ascertains that it is not possible to assess a use not covered by the product's CE marking since such use is not legal.

Because Strokefinder had not yet been CE marked during 2014, no HTA was published for the product. If TLV is granted an extended government commission in the area of medical devices, we intend to recommence the assessment of Strokefinder and expect to publish an assessment at a later date. Provided, however, that the product is CE marked.

To begin developing an HTA before the product has been granted a CE marking is possible, because there is always value in identifying decision problems and compiling treatment strategies (see Appendix 1). Work on the HTAs for Strokefinder and Stroke Prevention CDS began before CE marking. Conducting assessments at such an early stage involves certain risks; however, it was necessary in this research project in order to gain experience on how early an assessment may be started. One risk in the evaluation is that we may assume an intended use which, at a later stage, is not covered by the CE marking. Another risk is that product development may cease and the product never actually achieves CE marking, which would waste society's resources. Therefore, an assessment should only be started before CE marking if the product expects to be granted CE marking and if its future intended use

[8] Council Directive 90/385/EEC of the 20 June 1990 on the approximation of the laws of member states relating to active implantable devices.
Council Directive 93/42/EEC of the 14 June 1993 concerning medical devices.
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
[9] The Medical Devices Act (1993:584).
[10] The Medical Devices Ordinance (1993:876).
[11] LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7.

is clearly stated. There should also be specific reasons for starting an assessment at such an early stage; for example, a potential social benefit, no other available treatment alternatives, or a high demand from healthcare.

2.3 In which phase of the product life cycle are HTAs of greatest potential benefit

As stated earlier that uncertainty surrounding clinical data is greatest during the development phase of the product life cycle and decreases in subsequent phases. The less material available, the more assumptions have to be made. Such assumptions may, at a later stage, prove to be incorrect.

We have been able to publish assessments for two of the three selected products: the assessment for primary preventative screening for atrial fibrillation with thumb-ECG and for Stroke Prevention CDS.

Stroke Prevention CDS gained its CE marking during the Autumn of 2014. There was only one ongoing, and therefore unpublished, clinical trial being conducted by the company. The clinical trial could not serve as a basis for our assessment as TLV believes that an incomplete trial, with few patients, should not serve as basis for an economic evaluation. TLV, therefore, chose to carry out a scenario analysis based on assumptions derived from best available knowledge. This means that TLV conducted an HTA without any demonstrated clinical effect. Due to the government commission deadline, we published the HTA even though it presented a greater degree of uncertainty than if we had waited for the results from the clinical trial. This demonstrates that it is possible to conduct HTAs of new and innovative products not yet introduced on the Swedish market. TLV, however, believes it would be of greater value for the healthcare sector to obtain HTAs based on clinical data with higher quality than this. On the other hand, one major advantage with this type of scenario analysis is that it becomes applicable to all similar products in that product area available on the market and is thus more universal.

Thumb-ECG is already used by healthcare in secondary preventive screening, that is to say, for patients who have already suffered a stroke. The use which TLV assessed was primary preventive screening for atrial fibrillation with thumb-ECG. This is an innovative use of an existing product, not yet adopted by any county councils, though several county councils are planning to introduce such use of the product in routine healthcare. The basis of the clinical data for the HTA is a large randomised controlled trial (approximately 13,000 individuals). The trial had not been published in a scientific journal when TLV's HTA was published in 2015.

2.3.1 It is very important that the HTA is published at the right time

HTAs are valuable in healthcare, as healthcare providers require knowledge in order to make legitimate decisions. It is important to prioritise which medical devices should be assessed in order to economise with public resources. To maximize the benefit and value of TLV's assessments, the assessments should be carried out at the right time; not too early, and not too late. Of the assessments that TLV has published so far, we believe that the assessments concerning Airsonett and thumb-ECG were those with best timing. Airsonett was introduced in healthcare after the assessment was published, which confirms the previous statement. It is also confirmed by the fact that the National Board of Health and Welfare is considering evaluating whether screening for atrial fibrillation may be included in the national screening programme.

TLV concludes that the processing times for HTAs are not the only important issue, but rather the time when county councils obtain the assessment. One experience from the government commission is that, during a permanent commission, there should be a greater number of ongoing HTAs to allow for the fact that it takes time (and sometimes more time than anticipated) to generate sufficient clinical data to perform an economic evaluation. The objective must be to publish assessments when they generate greatest benefit.

2.4 HTAs made during the growth phase of the product life cycle demand specific requirements

The growth phase of the product life cycle is a knowledge-generating phase. This means that the product has not reached its full potential. Scientific studies are generally produced also after the product has been CE marked. Not all available data is, however, published. The scientific publishing process may be long and unpredictable. To gain access to unpublished data, it must be possible to classify the material as confidential until it is published.

Published data are obviously preferable, as such are examined by researchers before publication. However, to rely solely on published data would mean that county councils may not obtain guidance early enough before making important decisions. TLV, therefore, believes it is better to proceed based on the best available information for each individual case, rather than conducting no assessment at all. Unpublished data may be associated with great uncertainty and, therefore, it is important to update assessments as new data becomes available and upon the request by county councils.

Unlike SBU and the National Board of Health and Welfare, but like the Medical Products Agency, TLV is able to request and classify unpublished data as confidential and use such data in the assessments. If TLV had not

been able to classify business material and results of trials as confidential, we would not been able to complete any of the three HTAs conducted in 2014.

Clinical trials comprise a more selective choice of patients than subsequent routine use; the results, therefore, do not necessarily reflect clinical reality. An expanded use can alter the perceived effectiveness and, consequently, also the cost-effectiveness of the product.

2.5 Experiences from the development of health economic methods

The expanded government commission stipulates that TLV shall develop methods to allow evaluation of cost-effectiveness for new and innovative medical devices not yet introduced on the Swedish market and for which validated data is unavailable. One objective has, therefore, been to determine how early in the product life cycle a medical device may be assessed.

2.5.1 How may HTAs contribute to decision making in healthcare?

Society's resources are limited and there are always alternative choices in which areas to use them. It is, therefore, important for decision makers to prioritise resources to be used in the best possible manner. It becomes particularly important in situations where there are several treatment alternatives from which to choose.

The basis of TLV's work has been to meet the demands of county councils for HTAs at a national level and in a coordinated fashion. The main objective of HTAs is to provide a basis and guidance for decision makers in healthcare. To apply a societal perspective is an important basis for all of TLV's work. This means that all costs and effects, regardless by whom they are incurred (county councils, municipalities, the state, patients or relatives) should be included. This differentiates TLV’s work from that generally conducted by county councils.

2.5.2 Differences between medical devices and pharmaceuticals – specific challenges

When conducting an HTA, effect and cost data for the medical device are required. Even if HTAs of medical devices are fundamentally no different from assessments made of other interventions in healthcare, there are specific challenges to be considered. Medical devices often have a shorter life cycle than pharmaceuticals and also undergo small incremental alterations throughout the entire product life cycle. This means it may be more difficult to assess benefits of a medical device.

A medical device may also have more areas of intended use than pharmaceuticals. The focus of an HTA should be the evaluation of specific

areas of use. Neither a medical device nor a pharmaceutical may be considered cost-effective in itself; it is always a specific use of the product that is evaluated in an assessment. In the HTA regarding screening with thumb-ECG, the evaluation concerned screening for primary preventive purposes, which is an example of a new area of use for the product. Therefore, it is important that TLV's reports clearly state what intended uses are being assessed.

In many cases, it may prove difficult to carry out scientific studies in the area of medical devices. Development of new medical devices are often done in small companies without sufficient resources to conduct large scientific studies aimed at collecting clinical data that may serve as basis for cost-effectiveness analyses (that is to say, effects and costs).

Another challenge is that some medical devices are non-therapeutic and used in diagnosis, monitoring or screening. An HTA of non-therapeutic medical devices must also consider how cost-effective the subsequent treatments are. Products should be chosen so as to offer cost-effective treatment for the disease for which the medical device is used. There is also an ethical dimension here; namely, that a subsequent treatment should always be available should one choose to screen or diagnose a disease. In the assessments for screening with thumb-ECG and Stroke Prevention CDS, the purpose is to diagnose or detect atrial fibrillation for which there is a cost-effective pharmaceutical treatment.

2.5.3 Conducting HTAs in all phases of the product life cycle is beneficial

As mentioned above, one experience from this government commission is the importance of HTAs being published at the right time. It is not unusual for clinical trials to be delayed; plans to be changed or that additional data is required in order to conduct an HTA; all of which have been challenges in our work.

TLV's basis has been that assessments are of greatest usefulness, and are most needed, when decision makers in healthcare make their decisions. It is better to base decisions on the best available material; that is to say, with sufficient clinical data to form the basis of an HTA. Deferring decisions while waiting for better material, or making decisions without best available material, are also an option. Waiting for reliable clinical data may, however, prevent the product from being introduced to healthcare and, thereby, not generating health benefits or new knowledge. TLV believes that HTAs made in the early phases of the product life cycle should be revised when more clinical data becomes available. It is important to note that an assessment may also find that a product is not cost-effective and should not, therefore, be introduced on the market, or should be withdrawn if it has been introduced.

If there is significant potential for saving lives, enhancing quality of life and reducing future healthcare costs (which is the case with atrial fibrillation and

the preventive treatment of strokes with anticoagulants), it may still be wise to begin screening despite the risk that the method may not demonstrate as much potential as expected in a later phase. This may, for example, be the case regarding thumb-ECG.

2.5.4 The importance of highlighting the stages of an HTA

An important experience from the government commission is the importance of highlighting how HTAs may be conducted in relation to the product life cycle. One element in this work is to clearly define decision problem and treatment options.

In an assessment conducted at an early stage of the product life cycle, it is important to remember what questions are answered by available evidence. In the example of Stroke Prevention CDS, available evidence answers the questions regarding what potential benefits are offered by stroke risk prevention. That is to say, how many additional patients, with atrial fibrillation, are actually given the right drug treatment with the help of the decision support. In this way, parameters important for cost-effectiveness are highlighted.

While waiting for relevant data regarding effect, an evaluation conducted at an early stage may contribute by highlighting potential benefits. However, the uncertainty is so high at this early stage, that TLV believes the HTA should not be conducted at such stage in a future permanent commission.

2.5.5 Managing uncertainty

To identify uncertain parameters is the first step in managing uncertainty and should always be included in an HTA. Sensitivity analyses are used to illustrate how robust results are; that is to say, how variations affect results and the conclusions that may be drawn. In addition to this type of sensitivity analysis, models may also be used. Models cannot substitute missing data, but then case scenario analysis, as carried out in the assessment of Stroke Prevention CDS, may be used instead.

A decision-analytic model as well as a number of sensitivity analyses, were used in the HTA regarding thumb-ECG. In said assessment, TLV conducted sensitivity analyses for nine different scenarios in order to determine whether screening with thumb-ECG was cost-effective, even if our basic assumptions were not applicable. All sensitivity analyses illustrated that screening with thumb-ECG appeared to be cost-effective.

By mapping out available clinical data in an early phase of product development, a systematic compilation of scientific knowledge may be established in order to identify knowledge gaps.

2.6 HTAs may generate knowledge

New methods that may offer major benefits in healthcare should be made available to patients as early as possible, while taking into account uncertainties and risks that may be involved. On the same token, a delayed introduction could mean no health benefits and reduced productivity in healthcare. In addition, it is very important to monitor development of the products that TLV is assessing. TLV will also include in the HTAs, proposals on how a new HTA may be conducted. By identifying the knowledge gaps, TLV will, therefore, support generation of knowledge.

In the HTA for Airsonett, TLV proposed that a register of patients who use the product should be created. A prospective study called ATLAS was, therefore, started by the company in August 2014. So far, patients from ten clinics in Sweden have been included in the register. The idea is that clinical data generated in the study will constitute the basis for a future national register. The register can then be used if the HTA for Airsonett needs to be updated.

In carrying out the government commission TLV works in close collaboration with the academia. In a collaboration with KTH, TLV has produced scientific material on the user friendliness of insulin pumps and CGM, which will give rise to a chapter in a scientific anthology (13).

2.7 HTAs may contribute to a more equitable healthcare

It follows from the government commission that TLV's HTAs may contribute to:

- better information on which to base clinical decision making and the procurement of medical devices,
- greater transparency concerning cost-effectiveness and prices of medical devices,
- better utilisation of existing resources for scientific evaluation, with assessments being conducted by a national authority rather than by healthcare authorities; and,
- a more knowledge based and equitable use of medical devices throughout the country.

2.7.1 Better material on which to base clinical decision making and the procurement of medical devices

According to the government commission, the HTAs should be targeted at, among others, procurement officers in county councils. The material published so far by TLV has not been targeted at procurement officers, but rather at decision makers in healthcare as a tool in their decision making. In

this respect, TLV's HTAs has served a function at a stage prior to when procurements are generally conducted and it is at this stage county councils are in greatest need of HTAs. TLV's objective has been to try and provide for the needs of procurement managers. However, the objective could not be achieved in this situation as we found that it is not appropriate, due to reasons of competition, etc. for a state authority to compare manufacturers' products with each other. Nevertheless, we have tried to adapt assessments so that procurement officers also can benefit from them.

2.7.2 Greater transparency concerning cost-effectiveness and prices of medical devices

Companies may have a number of different pricing models and these may vary significantly among different products. With respect to thumb-ECG and Stroke Prevention CDS, TLV has made calculations based on county councils leasing such products from the company. The advantage of this is that county councils only pay for patients who are actually screened and that costs are, therefore, more predictable. The county councils may also purchase the product from the company. This would require other calculations. It is, therefore, important that companies inform TLV which remuneration models they intend to provide, otherwise the assessments will not offer county councils the support they request.

2.7.3 Assessments being conducted by a national authority rather than by county councils offers better utilisation of existing resources

TLV acts as support for county councils, develops HTAs from a societal perspective and generates new knowledge, which many county councils do not have the wherewithal to do themselves. In this way, resources are utilised more effectively and we provide conditions for a more equitable healthcare. Economic evaluations aim to highlight benefits and costs, making it easier for county councils to make decisions based on the best available information.

2.7.4 A more knowledge-based and equitable use of medical devices on the national level

As long as no recommendations or decisions are concluded on the basis of TLV's HTAs, county councils will be free to address such matters themselves. Simply producing HTAs will probably not in itself lead to equitable use. A more knowledge-based and equitable use presupposes a recipient organisation within the county councils. An organisation which has a mandate, expertise and is capable of making decisions based on TLV's assessments, something which as yet we do not have. Even better would be if there was a national player to make said decisions in order that all county councils act on the same basis, creating conditions for a more equitable healthcare.

2.8 Strengthened contacts with the healthcare providers

An important part of the commission is identifying the recipient of assessments in the county councils. The county councils have different structures and organisations and do not, therefore, possess the same functions overall. Nor, for example, do heads of medical technology units in different county councils have the same job assignments and responsibilities. This has resulted in that neither TLV nor the county councils have been able to identify how to communicate with each other in the best possible manner. It also meant that at the start of the commission, it was a challenge to find a platform for collaboration with the county councils.

TLV requested that the county councils select an individual, on a strategic level, from each county council to act as representative and be TLV's communications contact in matters of medical devices. All county councils appointed one contact person and TLV has now established a network of contact persons. Collaboration with the county councils and network of contact persons will gradually be developed and assessed as more experience is gained.

To maintain the county councils' expert knowledge in medical devices, TLV also created a reference group comprising four heads of medical technology units. The group has broad experience and substantial knowledge in the area of medical devices and, at the same time, they represent a cross section of the country from both large and small county councils.

In addition, TLV has an ongoing dialogue with Ledningsnätverket för Medicinsk Teknik (LfMT) (the Management Network for Medical Technology) to obtain opinions and to pass on experiences gained from the project. LfMT is a joint forum for healthcare authorities for collaboration, development and exchange of experiences in the area of medical technology. Participants of LfMT are representatives of county councils. Along with business representatives, LfMT will, in the area of medical technology, contribute to the attainment of high level of patient safety, good quality, cost-effectiveness, standardisation, cooperation between regions, and development in the environmental area.

TLV is also involved in other activities with county councils; for example, participation in the investment process of the Kalmar County Council in 2013. The aim was to learn from each other and to contribute with a health economic perspective. We have since maintained ongoing, close dialogue and for the investment process of 2015, Kalmar County Council decided to adopt a health economic approach throughout the entire process which provided them with a prioritisation tool. TLV also provides training in the area of health economics for Landstingsnätverket för upphandling (LfU) (County Councils Network for Procurement) comprised of heads of procurement for

the county councils/regions. LfU has undertaken to provide TLV proposals on how the second part of the assessments may be designed in order that the information also provides the procurement officer necessary support prior to purchasing the medical device.

All county councils were given the opportunity to express their opinions on TLV's final report, and those responding offered positive feedback on TLV's commission. Sveriges Kommuner och Landsting (SKL, Swedish Association of Local Authorities and Regions) believes that the government commission on medical devices should be made permanent and that sufficient resources should be reserved to ensure a qualitatively and quantitatively appropriate level of the work.

3 Collaboration with other parties

Summary of chapter
Concerns have previously been expressed over the risk that TLV's HTAs of medical devices will lead to duplication of work or to differing assessments of evidence etc. among the authorities. TLV's work in the area of medical devices supplements the work of other authorities. It has therefore been vital to clarify TLV's commission so that the demarcation lines between it and the commissions of other authorities are made clear, and so that the forms of collaboration can be developed further in the future. This has allowed the resources and expertise within the various authorities to be utilised in a cost-effective manner. It is vital to ensure that this is carried out by a national authority as the county councils have expressed their substantial need for guidelines and useful assessments in making decisions on procurement and use in the areas where there is currently some uncertainty. It is important to consult with other authorities, particularly the National Board of Health and Welfare, SBU, and the Medical Products Agency. It is also of great value to involve patient and user organisations in the work.

As no specific requirements had previously been imposed on HTAs of medical devices, companies are not optimally equipped to produce this type of material. In order to contribute to the generation of knowledge TLV has, together with VINNOVA, set up an information and advice service for companies. TLV has also taken part in international advice exchange with other European HTA authorities.

3.1 Patient and user organisations contribute important perspectives

The overall starting principle of the commission is the Healthcare Act stipulation of good and equitable healthcare for patients. It is, therefore, of utmost importance to involve patient and user organisations in the work. In TLV's assignment during 2014, all state supported patient and user organisations were asked if they wished to participate in dialogue during the development of the HTAs. As we focused on the cardiovascular area, we decided to send a special invitation to the two patient organisations in this area: STROKE-riksförbundet (Swedish Stroke Association) and Riksförbundet HjärtLung (the Swedish Heart-Lung Foundation).

These organisations have contributed important views. They have been able to examine the information material and have been given the opportunity to suggest improvements. We also hosted a consultation meeting with patient

organisations in August 2014. In addition, twice a year TLV organises a dialogue forum to which all member associations within the Swedish Disability Federation (Handikappförbunden) are invited. At the autumn forum, TLV presented the government commission.

TLV has circulated this final report for comments among all patient organisations associated with the umbrella organisation of the Swedish Disability Federation. Many of the patient organisations within the Swedish Disability Federation chose not to respond. The majority of the patient organisations that did respond were favourable to TLV being awarded an extended commission to conduct HTA of medical devices.

3.2 Clarification of the commissions of different authorities

TLV's commission regarding medical devices has been developed gradually. As this commission is relatively new compared with existing commissions of other authorities, it has been important to hold ongoing discussions regarding the boundaries of the commissions and to identify risks of duplication and lack of definition. It has, therefore, been crucial, as more experience is gained, to clarify TLV's commission so that boundaries between it and commissions of other authorities are made clear, and that the forms of collaboration can develop. This will allow optimal utilisation of resources and expertise within the various authorities. It is vital to ensure that HTAs are carried out by a national authority as the county councils have requested guidelines and useful assessments for making decisions on procurement and use in areas of prevailing uncertainty.

An obvious starting principle in TLV's work is its objective of further cooperation between the authorities in the area of healthcare. This is necessary to ensure quality and coordinated knowledge management by the state.

TLV has had ongoing dialogues with the authorities affected by this commission: the Medical Products Agency, SBU, the National Board of Health and Welfare, and the Public Health Agency of Sweden (Folkhälsomyndigheten). TLV has, in various ways, consulted with said authorities in order to benefit from their experiences in the area of medical devices, to avoid duplication in efforts and to prevent the authorities producing conflicting results. Contribution from the authorities has been an important element in the project's development. For example, SBU has provided TLV with systematic literature reviews, while the Medical Products Agency has contributed with information and support for clinical evaluations and CE marking of medical devices. In addition to said authorities, TLV has collaborated with the National Board of Health and Welfare and, to some extent, the Public Health Agency of Sweden. All authorities have examined the

reports prior to publication and have been offered the opportunity to provide opinions and comments.

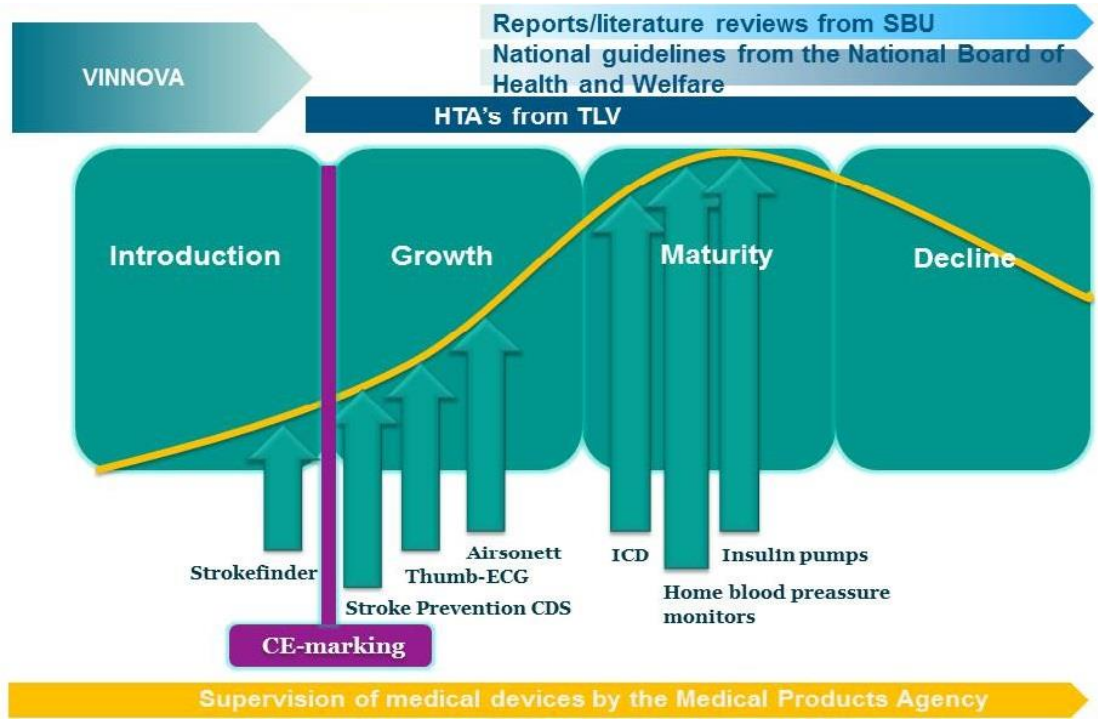

Figure 3. The figure illustrates that various authorities in the area generally enter the product life cycle either through economic support of Swedish companies with innovative products (VINNOVA), the supervision of medical devices (the Medical Products Agency), HTAs (TLV), national guidelines (the National Board of Health and Welfare, SoS) and reports/literature reviews (SBU).

All the above-mentioned authorities have been able to express their opinions on the choice of products for assessment by TLV. The HTA that lies closest to the sphere of responsibility of another authority is the assessment of the method for primary preventive screening for atrial fibrillation using thumb-ECG. Said assessment has enabled us to draw important conclusions regarding particular conditions that are especially applicable to screening and diagnosis. Particularly, crucial in this area is consultation with the National Board of Health and Welfare. As the National Board of Health and Welfare has special responsibility for recommendations on national screening programmes, its knowledge should in the future serve as a guide when deciding whether or not TLV should assess a medical device used for screening purposes. In 2013, TLV also assessed implantable cardioverter defibrillators (ICD) in treatment of heart failure. The ICD's were recommended in the national guidelines of the National Board of Health and Welfare's; however, TLV noted underutilisation and a wide variation in the extent to which county councils used ICD, despite use being cost-effective.

The above-mentioned authorities have provided valuable opinions on TLV's work. Among the issues raised are: importance of considerations to patient safety; the fact that authorities are increasing their collaboration (in part through the selection process); and, a more visible involvement of the medical profession. With regard to the design of assessments, the authorities have expressed the importance that TLV henceforth develop its management of uncertainty, and the issue surrounding TLV's handling of unpublished clinical data was also raised. We intend to take such opinions into consideration wherever possible.

3.3 Collaboration with VINNOVA

The government commission requested that TLV conduct HTAs on new and innovative medical devices. VINNOVA is an authority commissioned to support Swedish companies developing innovative products. TLV and VINNOVA have, therefore, begun collaboration and VINNOVA has submitted proposals on innovative products that have come to their attention. In addition, TLV also participates in VINNOVA's Research & Growth Programme which supports Swedish companies with promising innovative products. In addition to the programme just mentioned, there are a number of programmes in different areas for products in the development phase of the product life cycle.

TLV's participation in VINNOVA's programme processes involving medical devices means that we become aware of upcoming promising medical devices and methods. It also allows TLV to contribute an economic perspective at an early stage which is beneficial to companies. In addition, through funding by VINNOVA, society can encourage, at an earlier stage, development of medical devices which can be cost-effective (or cost saving) and avoid investment in products that may probably never be cost-effective. This may, hopefully, lead to cost-effective innovative products being introduced in healthcare more quickly and thereby reducing suffering for patients.

3.4 The requirements and challenges of the medical technology sector

There are two trade associations for medical technology, Swedish Medtech and Swedish Labtech, with whom TLV has hosted several meetings resulting in important contributions to TLV's work. In addition to continuous discussions regarding which products should be assessed, which sets of information should be used, and how the authority should obtain access to such, the trade associations have also served as a link between TLV and companies.

TLV has also met with a number of companies, both within the framework of the HTAs, and at advisory meetings in preparation for a prospective upcoming permanent commission; as well as various meetings initiated by the medical device branch associations. During the implementation of the government commission, it has, thereby, become evident that different conditions apply to medical technology and pharmaceuticals.

Swedish Medtech believes TLV should be further commissioned to assess new medical devices and treatment methods made possible by such devices. Swedish Medtech is also of the opinion that when TLV's commission to assess medical devices is made permanent, it will be important that adequate resources are allocated. The volume of new developed medical devices is much greater than for pharmaceuticals and, if development of healthcare is to gain momentum, TLV should not become a bottleneck.

Swedish Medtech asserts that the lack of national HTAs may have an adverse effect on the introduction of medical devices on the Swedish market. Swedish Medtech also states that the county councils need a recipient organisation, which the association believes is currently lacking.

3.5 TLV has expanded support to companies manufacturing medical devices

No actual requirements have previously been imposed on HTAs for medical devices at national level. During the government commission, TLV noticed that companies are neither ideally equipped to produce clinical data that can serve as a foundation for HTAs, nor to carry out economic evaluations. TLV has also noted that companies see national HTAs as a resource for the future. TLV, therefore, decided to expand the support to medical device companies by establishing an information and advisory service. TLV already run similar advisory services in the area of pharmaceuticals, partly in collaboration with the Medical Products Agency but also internationally. The circumstances are, therefore, favourable for expanding the advisory service into the area of medical devices. Within the framework of the government commission there are, of course, limits to how much advice may be offered and, because resources are limited, priorities need to be set. The approach is, therefore, to offer the type of advice which best advances knowledge for the sector as a whole. Assuming that the government commission is extended, TLV intends to achieve this by further developing its advisory activities.

3.5.1 Joint authority advice for companies

During the course of its work, TLV has offered advice to companies as we have observed a substantial demand for this. Advice has included fundamental information on health economic methods and what data is required for an analysis.

As a complement to the advisory service above, we have also started a joint authority advisory service together with VINNOVA. The purpose has been to allow companies to obtain information from both authorities (TLV and VINNOVA) at the same time and, thereby, streamline the authorities' dissemination of information. This is a pilot project currently under development and procedures are yet to be fully established. TLV is responsible for the supply of joint authority advice since the main focus of this advisory service is health economics.

A handful of companies have been provided advice concerning products in the development and growth phases of the product life cycle. The advice has mainly been aimed at enabling companies to become aware of, and at an early stage identify, important parameters for a possible future HTA.

3.5.2 International advice

On an international level, collaboration has been initiated between European authorities. Within the framework of such collaboration, TLV has participated at a meeting in Paris organised by HAS (Haute Autorité de Santé, the French National Authority for Health), the French equivalent of TLV. This meeting was a part of the SEED consortium which, in project form, assesses and implements early dialogue between Health Technology Assessment (HTA) bodies in Europe and developers of innovative healthcare products. During the year, the SEED consortium conducted ten advisory sessions, three of which concerned medical devices.

The advisory session in which TLV participated concerned a medical device which used ultrasound in an entirely novel way. This was the first advisory session for a medical device conducted jointly by the European HTA authorities. The product is in a very early phase of the product life cycle and CE marking is planned in 2017.

4 The importance of HTAs of medical devices, now and in the future

Summary of chapter
Medical technology is a growing market. HTAs of medical devices have therefore become an important prerequisite for equitable and cost-effective healthcare in the future. This requires that municipalities and county councils increase their awareness of the value and potential of HTAs and obtain support by gaining access to assessments of medical devices.

TLV has for a long time been conducting HTAs of pharmaceuticals in the benefits scheme and has for some time also been assessing clinical drugs. The assessments are conducted with a societal perspective and it would be reasonable for medical devices to be assessed in the same way as pharmaceuticals. It is also important that medical devices are prioritised in accordance with the same model used for a managed introduction. It is not possible to assess all medical devices, therefore it is important to continue developing a transparent and appropriate selection process.

It is vital to continue developing methods for evaluating medical devices to ensure the cost-effective use of medical devices in the future. To continue conducting HTAs of medical devices will make the Swedish healthcare sector better prepared as medical devices start to play an even more important role in future healthcare than they already do today.

4.1 HTAs of medical devices are a prerequisite for good and equitable healthcare in the future

The report *Empati och high tech* - Delresultat från LEV-projektet (*Empathy and high tech* - Interim results from the LEV project) (14), describing healthcare in 50 years, includes the statements *"new technology will be the catalyst that makes possible a new way of thinking in healthcare and elderly care*" and *"productivity development [in healthcare and elderly care] is insufficient when viewed from the taxpayer's perspective. By productivity development we mean that patient value, in the form of the health outcome per krona that is actually achieved, must increase."*

Healthcare providers spend billions each year on medical devices and, moreover, this turnover is expected to increase over time. Few of these investments are preceded by HTAs. For the billions that are invested in medical devices to have the greatest impact on public health, a national player

is needed to assess cost-effectiveness of the products in such a way that county councils are offered better and more standardised HTAs before deciding on purchase and use. This means, the councils will purchase the most cost-effective products and use such correctly. In some cases it may also lead to cost savings for society, while in other cases, costs may increase.

TLV has been commissioned to conduct HTAs of medical devices. It has become evident that there is a large gap between currently available HTAs of medical devices and the requirements of healthcare, companies and patients. TLV has, therefore, developed a model allowing this gap to be filled by conducting HTAs for medical devices. The model may be used, even if the body of information is limited. The HTAs can serve as a basis for priority setting by county councils prior to purchasing decisions, and, thereby, contribute to a more equitable healthcare.

TLV believes that to offer maximum benefit, the HTAs should generally be conducted in the development and growth phases of the product life cycle. This means the assessments will become available at the right time to have greatest impact. The HTAs should be based on best available data. TLV believes it is better to conduct an HTA containing elements of uncertainty, rather than introducing a product into healthcare without any HTA at all. Even when TLV finds that a product, or method, does not appear cost-effective, the assessment is of greatest benefit at an early stage, before the product has been introduced into routine healthcare.

We realize that it will be necessary to update the assessments whenever more data become available. This probably means that the earlier in the product life cycle the HTAs are done, the greater will the need for updates be. It also means that TLV will need to have different designations or names for the HTAs. An HTA at a very early stage is, if anything, a description of the decision problem and should be designated accordingly (for example, "early HTA"). An assessment at a later stage is a complete cost-effectiveness analysis, with less uncertainty, and should, therefore, be designated differently (for example, "complete HTA"). It might also be useful for different types of assessments to have further differential designations. This would further clarify how TLV's assessments differ from reports of other authorities.

4.2 Knowledge regarding HTAs among municipalities and county councils is gradually increasing

HTAs are helpful tools for priority setting in healthcare. TLV's assessments can create conditions for a more knowledge-based and equitable use of assessed medical devices. As already mentioned, not all medical devices may be assessed. However, with respect to medical devices, the effect of increased focus on health economics is thought to have a positive impact on the

purchasing and investment processes of county councils and municipalities. TLV has already seen this sort of development in some county councils.

Many county councils have requested further assistance with, for example, health economic models, prioritisation matrices, purchasing tools, etc. Within the government commission, it has not been possible to meet such requests so fat. However, it is conceivable that assistance may be offered to county councils and municipalities in the future should the commission be made permanent.

If TLV continues to conduct HTAs, as well as disseminate information and awareness of the possibilities for HTAs, it may eventually make a major impact on greater health return on money spent. It also means that innovative and cost-effective products are able to generate sales. The medical device market, therefore, needs to be monitored to see what effect TLV's work and assessments have on the healthcare sector. We plan to follow-up, by, among other things, conducting focused opinion surveys, accessing sales statistics and examining usage.

4.3 TLV's knowledge and experience

TLV has been conducting HTAs of pharmaceuticals within the benefits scheme for a long time, and has, thereby, gained extensive experience and a broad knowledge base in the areas of health economics and healthcare. Besides, TLV also decides which consumables should be included in the reimbursement scheme and determines the sales prices of these products. These are consumables patients need for taking a drug or regulating their own medication (for example, diabetes aids and inhalation devices for asthma, etc.) and are classified as medical devices. TLV assesses such devices in the same manner as pharmaceuticals because the same legislation covers both drugs and consumables.

TLV has also been assessing clinically administered pharmaceuticals for about two years[12]. This means that TLV already provides county councils with HTAs in the case of most pharmaceuticals. It also means that TLV already have expertise, processes and prioritisation tools that can be developed and also applied to medical devices. Within the framework of the government commission, TLV has gained unique experience and developed further expertise.

TLV conducts HTAs of pharmaceuticals from a socio-economic perspective and it would be reasonable to assess medical devices in the same manner as

[12] Drugs used in inpatient care.

pharmaceuticals, as well as to prioritise the products in the same way. It is, in the end, the same money and same patients.

4.4 A managed introduction of pharmaceuticals is ongoing

The project Managed Introduction in Collaboration (Ordnat Införande i Samverkan, OtIS) was a sub-project in the National Pharmaceutical Strategy (NLS) for which SKL was responsible. One objective was to find proposals on structures for developing a joint process for county councils and other involved parties to implement managed introduction of new pharmaceuticals. During the project, the issue of managed introduction of new medical devices was also relevant. The OtIS final reported stated that: "*It is desirable that pharmaceuticals and medical devices be assessed in a similar manner and under similar conditions. Certain elements of the proposed processes for pharmaceuticals can also be used for medical devices whereas others, for example horizon scanning, need to be developed specifically for the area of medical devices.*"

The Pharmaceutical Benefits Board (Nämnden för läkemedelsförmåner) at TLV decides which drugs should be included in the pharmaceutical benefits scheme. With respect to clinically administered pharmaceuticals, TLV develops HTAs and then NLT (New Drug Therapies Group) (15) provides a recommendation on whether such pharmaceuticals should be used by the county councils.

A proposal has been raised for a joint collaboration among the county councils in the area of pharmaceuticals. The medical delegation of SKL (Swedish Association of Local Authorities and Regions) has decided to recommend that county councils participate in and support the collaboration model for pharmaceuticals. As of January 1, 2015, the commission of the NLT group will be reassigned to NT-rådet (16), as part of the county councils' collaboration model for pharmaceuticals.

4.5 A managed introduction of medical devices is needed

How new medical devices should be introduced into healthcare in a structured manner is not described on a national level, and, without such, our HTAs will only have limited penetration. The risk is that as long as this shortcoming persists, the assessments will not generate maximum benefits and will not lead to equal healthcare. It is also important that the county councils are involved in the development of, and that they create a structured process for, managed introduction of medical devices.

It is important to point out that a managed introduction of medical devices is not necessarily a broad introduction in healthcare. It may also mean that a product is introduced in a few county councils with the aim of generating more knowledge before it is introduced on a broader front. TLV, therefore, believes that a body is needed to give national recommendations based on the HTAs produced by TLV, similar to what the NT group caters for pharmaceuticals. Ideally, medical devices and pharmaceuticals would be prioritised in the same manner, as the county councils have requested. It may be possible to develop this process and body further in the future. One possibility is that a national player, such as NT-rådet (New Therapies Council), decides, based on the HTAs produced by TLV, for both pharmaceuticals and medical devices. To bring this about, the composition of NT-rådet should be adapted accordingly and also include expertise in the area of medical devices.

The collaboration between TLV and county councils in the area of pharmaceuticals is a good prototype for a developed collaboration in the area of medical devices and could support a more equitable healthcare with respect to medical devices.

4.6 Increased collaboration among authorities and prioritisation of what should be assessed

TLV understands there is an explicit will and ambition among other authorities in healthcare and VINNOVA, to increase and intensify collaboration in the area of medical devices. One of the most important areas for collaboration is the selection process; that is to say, which medical devices TLV should assess and which products would be better suited for assessment by other authorities.

The government has proposed that eight state authorities be linked through a new strategic board for state management of knowledge: the National Board of Health and Welfare, the Swedish eHealth Agency (E-hälsomyndigheten), the Public Health Agency of Sweden (Folkhälsomyndigheten), the Swedish Research Council for Health, Working Life and Welfare (Forskningsrådet för hälsa, arbetsliv och välfärd - Forte), the Health and Social Care Inspectorate (Inspektionen för vård och omsorg - IVO), the Medical Products Agency, SBU and TLV. All eight authorities will sit on the board which has been named Kunskapsstyrningsrådet (Knowledge Management Council). The government will also establish an advisory body, comprised of elected representatives from municipalities and county councils, Huvudmannagruppen (Administrators' Group), to provide support to the Knowledge Management Council. These boards could also lead to better synergies in medical devices and, in turn, presenting a future possibility of further expanding collaboration between authorities. This is all aimed at efforts invested should make the greatest possible difference. County councils have requested a joint

information channel to and from the authorities. The county councils have also suggested what the authorities should examine, a list for which Myndigheternas samverkansgrupp (MSG) (the Authorities' Collaborative Group) is responsible. MSG includes TLV, the Medical Products Agency, SBU, the National Board of Health and Welfare and the Public Health Agency of Sweden.

4.6.1 Collaboration with the Medical Products Agency

In order to conduct clinical trials with products that are not CE marked, a notification is generally required to be sent to the Medical Products Agency who in turn responds with a decision whether or not the trials should begin; the information is usually confidential. If TLV is to base its HTAs on data from clinical trials, it is very important that TLV knows that the Medical Products Agency has given approval for the clinical trials to start. TLV can then request information from the company which confirms said approval, and forward to the Medical Products Agency for verification. TLV also needs to be aware of marketing prohibitions, recalls and corrections to products in order to update the assessments when such becomes appropriate.

One other possibility may be collaboration in the selection process. This is best done separately from the Medical Products Agency's supervisory work. Collaboration between TLV and the Medical Products Agency needs to be discussed based on the context of the authorities' mission statements. In addition, the consequences of how the distribution of responsibilities between the authorities develops need to be examined. TLV and the Medical Products Agency have found that joint information efforts for, for example, medical technology companies, could present an opportunity for improving knowledge of medical technology regulations and benefits of HTAs.

4.6.2 Collaboration with SBU

SBU can conduct systematic literature reviews for products or areas of therapy that will be assessed by TLV. SBU generally uses the GRADE scheme for grading evidence, but can also provide data without evidence grading. In such cases, it is up to recipients to use the material as they think best. In order to optimize TLV’s use of the results, a form of evidence grading more appropriately tailored to the area of medical devices should probably be used rather than the GRADE scheme. In addition, it is also important to strengthen contacts among the authorities as SBU also possess health economic expertise that can be of greater help to TLV than is currently the case.

4.6.3 Collaboration with the National Board of Health and Welfare

Within the framework of its assessment of thumb-ECG, TLV has initiated collaboration with the National Board of Health and Welfare, since the Board is responsible for decisions on recommendations for introduction of new national screening programmes. When the clinical data, on which TLV's assessments are based, is published the method may be used for assessments within the framework of the National Board of Health and Welfare's work

with the national screening programme. In the future, similar situations may present themselves in which TLV and the National Board of Health and Welfare will interface significantly.

4.7 The future of HTAs of medical devices in Sweden and internationally

In implementing the government commission, TLV has identified a major demand in Swedish healthcare for HTAs of medical devices. TLV has also observed that the medical devices sector is not exclusively a Swedish issue but, as with the pharmaceuticals sector, is becoming ever more global.

TLV, therefore, perceives a demand for expanded international collaboration in a permanent government commission. One example of possible international collaboration is horizon scanning. Just as for pharmaceuticals, there is a need for horizon scanning of medical devices. In the final report from the OtIS Project (17), it was noted that it is more difficult to conduct effective horizon scanning for medical devices than for pharmaceuticals. This is, according to the report, due in part on the fact that medical device manufacturers are generally based outside Europe and that medical devices on the Swedish market are supplied by smaller retailing companies. TLV shares this view and believes that horizon scanning would be best conducted on at least a European level, since the medical technology market is global, and development is rapid.

In the future, it might also be justifiable that clinical trials required for CE marking are conducted on a European level in order to ensure a large enough patient base. This is currently presented as a problem within both the pharmaceutical and medical device areas. This would increase the possibility of obtaining robust clinical data as basis for CE marking.

TLV has suggested earlier that assessed new innovative medical devices may need to be monitored, especially during the growth phase. This means updating HTAs as further clinical data becomes available. TLV has also suggested that it should be possible to conduct a managed introduction of medical devices, where individual county councils test a product in routine healthcare after CE marking; gathering new knowledge which can be used to provide healthcare assessments with greater certainty. If there are no county councils in Sweden able to test products in routine healthcare, it would be desirable to examine the possibility of managed introduction of medical devices at European level.

HTAs of medical devices in early phases of the product life cycle have been discussed in international scientific literature. The international scientific community has usually settled for pointing out that HTAs in early phases are difficult and to indicate the problems caused by these difficulties. In this

report, TLV has presented proposals on how the health economic methods can be further developed to support decision-making in different phases of the product life cycle (i.e. development, growth, maturity and decline phases). Provided a permanent commission, TLV would be well-equipped to continue driving the development of the health economic method in the area of medical devices, both nationally and internationally, offering the potential to become a world leader; assuming, however, that the funding for such achievement were made available.

Healthcare authorities invest approximately SEK 20 billion each year in medical technology, which is comparable with the annual Swedish state budget for pharmaceuticals in the benefits scheme. Moreover, the LEV Report (14) states that medical devices will become increasingly significant in the future. Medical devices will in the future have an increased role in treating patients, replacing pharmaceuticals to some extent. It would therefore be reasonable to assume that resource investment in medical devices will increase and may eventually exceed that in pharmaceuticals.

Despite major investments in medical devices, they are currently rarely assessed from a health-economic perspective. Within the government commission, TLV has also realised that the need for assessments of medical devices is great among the county councils. To ensure cost-effective use of medical devices in the future, it is vital to continue developing methods that will form the basis for HTAs of such devices. Continuing with HTAs of medical devices will better equip the Swedish healthcare sector as medical devices play an increasingly important role in future healthcare.

Against this background, TLV has proposed the authority's commission to assess medical devices to be extended and given opportunity to develop gradually, in order to better meet the needs of the patients, the medical devices sector and county councils.

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