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# **Economic evaluation of medical devices**

Final report

You are welcome to quote Swedish Dental and Pharmaceutical Benefits Agency, but please remember to indicate the source: the report's name, year and the Dental and Pharmaceutical Benefits Agency.

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## Preface

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In April 2012, the Dental and Pharmaceutical Benefits Agency (TLV) was commissioned by the Swedish Government to undertake economic evaluations of medical devices. The commission was conducted in the form of a trial commission and the final report was presented in November 2013. This mandate was subsequently extended on several occasions. The final report of the current commission shall be submitted to the Government by 31 December 2015, which is thus done via this report.

During the Government commission, TLV has actively collaborated with patient representatives, county councils, government agencies and trade associations. This collaboration has been crucial for how TLV has developed the process of evaluating medical devices.

In the appropriation directions for 2016, TLV received a renewed mandate that runs until December 2016. During the coming year, it is of great importance to maintain the network of contact representatives already built up, at same time as our work is further developed together with, among others, providers.

Stockholm, 21 December 2015



Sofia Wallström  
Director General

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## Summary

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Each year, healthcare providers in Sweden invest about 22 billion SEK in medical devices. This amount increases each year since the supply and use of these products is continuously increasing. It is reasonable to assume that medical devices will become even more important in the healthcare sector, and that they will also assume a more therapeutic function. In this sense it is possible that medical devices can, to a certain extent, take over the role of pharmaceuticals. It is therefore conceivable that the resources invested in medical devices will increase, and in the future, exceed the resources spent on pharmaceuticals.

The Health Care Act (1982: 763) states that there should be a reasonable relationship between the costs and effects of a healthcare intervention. Healthcare providers do not usually carry out economic evaluations of medical devices. One consequence of this is that medical devices are purchased without establishing if they are cost-effective. In order for healthcare providers to be able to make as informed a decision as possible, and to get the most health for the money invested, a well-planned Health Technology Assessment (HTA) that illustrates the cost-effectiveness of a medical device is crucially important. All county councils having access to the same HTA's as a basis for decisions about the purchase of medical devices also contributes to national coordination and is a step towards a greater equality in care.

As well as TLV, a number of agencies and local health technology assessment organisations already make HTA's of medical devices. However, it is rare that these actors make their evaluations in the early phase of the product lifecycle, and also include economic aspects. There is, therefore, a great demand from both county councils and medical device companies for HTA's of medical devices early in the product lifecycle.

TLV's HTA's of early-phase medical devices is based on the best available knowledge. The economic evaluations also have a societal perspective. Conclusions found in the HTA's are not binding for county councils and a HTA is not to be regarded as a recommendation. The HTA's are intended for use by county councils to contribute to their information for making decisions prior to making purchase decisions.

During 2016, TLV has evaluated six medical devices that were selected in consultation with county councils. This year we have chosen to make different types of HTA's; a complete HTA's, an update of a previous year's HTA's, a cost comparison, and one HTA based on a previously made evaluation. In addition, we also published a rapid review. The purpose of

making various types of HTA's is to see what opportunities are available and to best meet the needs of the county councils. In making these evaluations, TLV had close cooperation with county councils, patients, governmental agencies and companies. TLV also had a dialogue with the county councils regarding the development of a managed introduction of medical devices at a national level. TLV has understood that this ambition will be realised and that the county councils will work with this in 2016.

The Swedish Agency for Health and Care Services Analysis (Vårdanalys) has evaluated TLV's work concerning medical devices in a report published in March 2015. Vårdanalys found that medical device practices have a central and growing importance in the Swedish healthcare system. Vårdanalys sees a great potential for TLV to create value for patients and county councils in the field of medical devices and further notes that county council representatives, patient organisations and companies are positive about TLV's commission to evaluate medical devices. Vårdanalys believes that TLV's HTA's can be a useful tool in healthcare since few evaluations of medical devices are done and those that are done often have a healthcare perspective. Furthermore, Vårdanalys finds that mutual development efforts by TLV and the county councils regarding medical devices and HTA's are necessary, and should be long-term and systematic.

Since the publication of Vårdanalys' report, TLV's working methods and processes have developed. In order for TLV's work to be as cost-effective as possible, it is important to continue to develop the process surrounding the production of HTA's. TLV has determined that the process should, among other things, be developed through further collaboration with both county councils and patients to reduce the challenges of making early economic evaluations of medical devices. TLV has therefore developed a proposal for a new process. In light of the proposed process, TLV has also conducted a legal impact analysis. The process will continue to evolve during 2016.

TLV can state that the government commission, which has run since 2012, has now developed to a point where identified short-term improvements and established measures are implemented or initiated. Vårdanalys' evaluation has confirmed this picture. TLV deems that the government commission needs to be made permanent in order to develop further. This will create the long-term sustainable continued development that is necessary to respond to the demands and needs expressed by county councils and hence to achieve a sufficient impact within county councils. During 2016, TLV intends to further specify requirements for continuing with economic evaluations of medical devices in order to lay a solid foundation for a decision on a long-term sustainable commission.

## Terms and concepts

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**Decision problem** – is the selection of one or more comparable treatments for the same condition and the same group of patients for the medical device product that the economic evaluation is assessing.

**Evidence** – scientific proof that 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.

**Consumables** – relatively simple, less costly products with a limited lifespan that can be included in the benefits system if the product is needed to: administer a pharmaceutical to the body or for patients to be able to control their medication. One example is a test strip that is used to check blood sugar levels.

**Health Technology Assessment (HTA)** – evaluation of technologies in healthcare using the method of systematically evaluating scientific publications regarding diagnosis, treatment and care and summarizing what consequences the methods have. Evaluations may but need not necessarily include economic aspects. HTA reports, however, can take different forms and are therefore difficult to compare.

**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 (quality-adjusted life years) gained.

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

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<sup>1</sup> The national innovations strategy

**Cost-effectiveness** – a treatment is cost-effective if the patient benefit / effects bear a reasonable relationship to the cost of treatment. If evidence regarding the effect is lacking, it is not possible to know if the treatment is cost-effective.

**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.

**Pharmaceutical benefits** – pharmaceuticals included in the pharmaceutical benefits scheme are subsidised and included in the cost ceiling arrangement.

**Medical devices** – products used to: diagnose, prevent, monitor, treat or alleviate symptoms of a disease; diagnose, monitor, treat, alleviate or compensate symptoms resulting from injury or disability; investigate, alter or replace anatomical structures or physiological processes; regulate fertility.

**Managed introduction** – is a common process for the introduction of new pharmaceuticals where all county councils, several authorities and pharmaceutical companies cooperate in order to achieve an equitable, cost-effective and efficient use of new pharmaceutical across the whole country.

**Product life cycle** – the product life cycle may, according to Kotler's definition<sup>2</sup>, 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 categorisation 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.

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<sup>2</sup> Kotler P, 1999, Principles of Marketing – Second European edition.

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

# 1 Background

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## 1.1 Medical devices are a large and heterogeneous group

The definition of what comprises a medical device is found in the Act (1993: 584) concerning medical devices. This states that a medical device is a product to be used alone or in combination with others to detect, prevent, monitor, treat or alleviate illness in people. The product's primary intended effect shall not be achieved by pharmacological, immunological or metabolic means. This means that the concept of a medical device covers a diverse flora of products ranging from plasters and bandages to patient record systems and advanced robotics.

There is no register or other compilation showing how many medical devices are found on the Swedish market. In Italy, however, there is a database of all medical devices sold in the Italian market. This database contains about 700,000 products (1). It is reasonable to assume that the number of products in Sweden is of similar magnitude.

In Sweden the healthcare providers consists of many actors. Sweden has 21 county councils that provide healthcare to the inhabitants in the county. Other healthcare providers include 290 municipalities, a number of private operators, and caregivers who use medical devices.

Each year, healthcare providers in Sweden invest large sums on medical devices, and this amount increases each year as the range of products continues to grow. The volume of the sales turnover of medical devices has not previously received attention.

TLV's interim commission report, *Economic evaluation of medical devices* (April 2014) (2), estimated the healthcare providers costs for medical devices in 2012 to be just over 20 billion SEK (2).

In the latest report, TLV has estimated healthcare providers' costs for the year 2013. Similarly to TLV's previous estimate for 2012, the consolidated expenses are largely based on the most recent data available (2013) from Statistics Sweden and the Swedish eHealth Agency.

Based on data for 2013, the amount healthcare providers paid for medical devices is estimated to approximately 22 billion SEK. This amount is comparable to Sweden's yearly cost of pharmaceuticals within the benefits scheme. It is concluded that medical devices are a significant cost for healthcare providers, but that it is difficult to determine exactly how large it

is. Compilations for 2012 and 2013 indicate the value of the market in Sweden rather than describe the development of the market or which segments are increasing or declining.

#### 1.1.1 Pharmaceuticals and medical devices are evaluated to different degrees

The Healthcare Act (1982: 763) states that there should be a reasonable relationship between the costs and effects of a healthcare intervention. In theory, this means that patients and users should get the most health for the money invested. Nevertheless, healthcare providers do not usually conduct cost-effectiveness analyses of medical devices.

Since 2015, pharmaceuticals have had a managed introduction into the Swedish market. This aims to contribute to a more equitable and cost-effective utilisation of pharmaceuticals for all patients throughout the country (3). Pharmaceuticals that are expected to provide patient benefit in relation to the societal value should reach patients via a managed introduction without undue delay. All county councils and regions have agreed to this cooperation model, which leads to collaboration regarding pricing, introduction and monitoring of pharmaceuticals. Currently, there is no corresponding managed introduction of medical devices in county councils, but an initiative has been taken to explore the possibilities of this, see Section 6.6 (4).

The benefits scheme includes less costly medical devices with a limited lifespan, so-called consumables (5), for example, syringes, needles and ostomy pouches. These medical devices have a turnover of approximately one billion Swedish kronor per year in the benefits scheme. Just like pharmaceuticals, medical devices must be cost-effective to be included in the benefits scheme (5).

Other medical devices sold and used in Sweden but not included in the benefits scheme are not included in other similar schemes. The vast majority of medical devices used in healthcare are not assessed in a systematic and comprehensive way, but usually procured on the basis of product price. Certain county councils do, however, employ a procurement procedure where other decision-making criteria are included, such as quality and price per unit of time.

## 1.2 Swedish HTA actors that evaluate medical devices

The basis for assessing technologies in healthcare, Health Technology Assessment (HTA), is a systematic review of scientific literature to find out what evidence exists.

A number of actors in Sweden evaluate medical devices, see Figure 1, for example the Swedish Council on Health Technology Assessment (SBU) (6). To some extent, the National Board of Health and Welfare also assesses medical devices within the scope of its work on national guidelines (7). In the past ten years, SBU has made about 140 health technology assessments of medical devices (6). Most of these do not contain economic evaluations, but focus instead on comparing their effects.

Several county councils and regions in Sweden now also have their own units for health technology assessments of medical devices and they produce assessments covering a wide range of medical devices and methods in the healthcare sector. The reports' scope varies. They may sometimes comprise compilations of scientific literature, but most often the reports deal with the opportunities for, and consequences of, an introduction into their own region.

Since 2007, there is also a Swedish HTA network that is coordinated by SBU. Its purpose is to coordinate HTA work in Sweden, to develop common methods for assessment, to transfer knowledge from other HTA organisations to county councils, and to disseminate regionally conducted assessments for use in Sweden (6). For example, in the past nine years, the Västra Götaland regional HTA group, Programme and Prioritization Council (8), has produced about 80 different reports many of which concern medical technology. These reports do not usually contain any cost-effectiveness analysis.

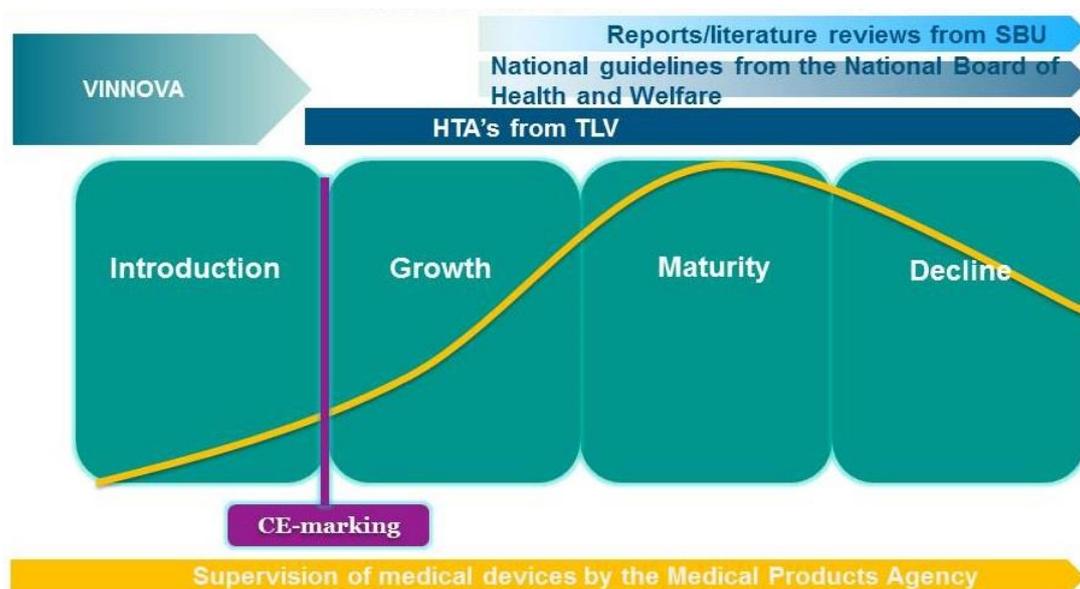


Figure 1. A medical device's life cycle has four phases; the different actors mentioned are active in different phases.

If county councils are to be able to make as informed a decision as possible, well-performed HTA's that illustrates the cost-effectiveness of medical devices is a necessity. For practical and resource reasons, it is not feasible for each caregiver themselves to produce HTA's since there is a large amount of medical devices and technological progress moves quickly (4). This leads to a need for updating HTA's when new procurement decisions are to be made.

Healthcare providers have therefore requested HTA's in conjunction with medical devices being CE marked (4). Assessments of products that are early in their product lifecycle have, however, so far been rare (4).

In April 2012, TLV received a Government commission to conduct economic evaluations of medical devices. This mandate was subsequently extended annually (4). The commission TLV received in 2013 included that TLV, within the framework of the commission, was to develop methods that make it possible to evaluate the cost-effectiveness of new and innovative medical devices that have not yet been introduced onto the Swedish market and for which validated data is lacking.

The Government deemed that the economic evaluations are expected to contribute to a better basis for clinical decisions and procurement of medical devices, greater transparency concerning medical devices' cost-effectiveness and prices, better use of existing resources for evaluating knowledge (since assessments are made by a national authority and not by all the healthcare providers individually), as well as more knowledge-driven and equitable use of medical devices throughout Sweden.

## 2 Opportunities and challenges of medical devices

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### 2.1 Medical devices will be more significant in the future

The demographic development in Sweden is a challenge for the future (9). According to a report from 2010 (10), the average life expectancy for a 65-year-old in 2050 is expected to increase by 2.6 years from 84.4 years to 87 years. Health is also expected to be better in the future, which in turn will reduce healthcare costs per individual. If a quarter of the population is aged 65 or over in 2050, both more elderly care as well as more general healthcare will be needed (9).

It is quite reasonable to assume that medical devices will become more important in healthcare. Medical devices are also likely to have a more therapeutic function. In this way, it is possible that such products may to some extent take over the role of pharmaceuticals (9). It is therefore conceivable that the resources spent on medical devices will increase and, in the future, exceed the resources spent on pharmaceuticals.

Developments in e-health and IT systems within healthcare, which can also be classified as medical devices, mean that the need for HTA's will increasingly expand (9). These systems are often very poorly validated (11), and frequently result in high start-up and running costs. However, where these systems are used properly, it is likely that both e-health and similar IT solutions could bring significant benefits for society (9, 12).

### 2.2 Many actors in the market

Today, there are approximately 580 different medical device companies in Sweden with at least five employees and net sales of over one million SEK. Approximately 180 of these companies conduct research and development in Sweden. In addition to these companies, there are a large number of companies with up to four employees (13), as well as foreign companies that sell products in Sweden, even if they do not have any distributor in the country.

All medical devices to be purchased by the governmentally funded healthcare providers must be procured via a tendering process. Nevertheless, healthcare providers have no common process for this. The 21 county councils in

Sweden sometimes work together in small groups to purchase certain product types such as Fyrlänsgruppen (12). The most common is, however, that each county council manages its own contracts. Some counties also have decentralised procurement. In Stockholm County Council, for example, each hospital has its own purchasing unit, and procurement has so far not been synchronised between hospitals within the county (14). In addition to county councils, there are also 290 municipalities and many private operators and caregivers who use medical devices. Municipalities must, like county councils, procure the medical devices to be used via a tendering process. The same does not apply to private operators and caregivers.

The lack of a national process for making evaluations and recommendations concerning the introduction of new medical devices in healthcare has had consequences. This is apparent both in the difficulty to gain market access in any other way than approaching individual healthcare providers, which is both time and resource intensive, and when healthcare providers produce duplicate assessments and risk coming to different conclusions. The overall risk is that it becomes more difficult for innovative new medical devices to reach the Swedish healthcare system.

## 2.3 The societal perspective and more equitable care

Each Swedish krona spent on medical devices should deliver the most benefit for the money invested. During an economic evaluation of medical devices, it is advantageous to use a societal perspective (4). This means that effects and costs are taken into account wherever these occur in the community. Using a societal perspective avoids silo budgeting (restricting the choice of medical devices to those with a cheap purchase price), budgetary perspectives and faulty decision incentives, and instead focuses on what is best for the patient and society (4).

All county councils having access to the same HTA's as a basis for making decisions about procuring medical devices can reasonably be seen as a step in the right direction towards more equitable care in Sweden.

## 2.4 Access to evidence early in the product life cycle

Compared with pharmaceuticals, one of the challenges with evaluating medical devices is that there is usually fewer high quality studies on their effects (4). Pharmaceutical companies have a clear approval process regulated by authorities that requires clinical studies (15). There is no corresponding approval process for medical devices, which have instead been assigned what is called 'the new approach' (4). This means that the products must be CE-marked before being introduced into the market. A product that is CE-

marked in one European Economic Area (EEA) country has access to the entire EEA. It is the responsibility of the manufacturer of a medical device to ensure that it conforms to the relevant regulatory requirements.

Furthermore, it is also the manufacturer that CE-marks the product, which means that the company is required to show that the risks are proportionate to the benefits. When a medical device has received CE-marking, it is possible to conduct studies to acquire more knowledge about the effects and costs associated with the product.

As the healthcare system works today, new medical devices are introduced when the products have been CE-marked, regardless of whether or not an economic evaluation has been made. Therefore, it is usually not an option to delay the introduction of new medical devices in healthcare until high quality studies are available (4). In view of this situation, it is important that an evaluation of the state of knowledge is based on the best available data and made as early in the product life cycle as possible (4). If this is not carried out, medical devices that are not cost-effective risk being introduced into healthcare while innovative and cost-effective medical devices that reduce patient suffering risk not being introduced early enough.

However, evaluating a medical device at an early phase, before clinical evidence of high quality exists, means that the uncertainty of the conclusions increases (4). A further factor to consider is that information regarding effects can usually only be provided by the manufacturer or other unpublished documentation. This, in turn, could increase the level of uncertainty further. Nevertheless, the option of refraining from evaluating medical devices at an early phase on a national level leads to an even higher uncertainty (4), while individual healthcare providers are forced to make decisions with only limited and uncertain information which increases the risks of healthcare providers making different decisions.

## 2.5 Medical devices undergo rapid step-wise development

Although it is more challenging to evaluate medical devices, it is not impossible to do so, as TLV has already determined (4). In an economic evaluation of medical devices, other challenges nevertheless exist compared with pharmaceuticals. Among other issues, medical devices often have a shorter product life cycle, and also undergo small step-wise changes regarding their practical functioning (4). This means that it can sometimes be difficult to collect evidence since each product update is in use for a shorter period of time compared with pharmaceuticals (4).

Medical devices are also influenced by the context in which they are used, to a greater extent than pharmaceuticals, which means that the evaluation also

needs to include factors such as the need for organisational changes and follow-up (4).

## 2.6 Robotic surgery example

Robot-assisted prostatectomies (surgical removal of the prostate) are carried out in Sweden (16). The purchase cost of the robots is around 20-30 million SEK each.

The first robot was purchased in 2002 (17) and a local HTA organisation evaluated the robotic practice in 2006 (16). The overall assessment of the state of knowledge existing then was that the scientific basis for the technology was inadequate. SBU took the view that even in the year 2009, there was insufficient scientific evidence to assess whether robot-assisted surgery was better than normal surgery (16).

Only in 2013 was SBU able to publish an economic evaluation of the robots, when it deemed that the clinical effect was uncertain and therefore difficult to assess the cost-effectiveness of robot-assisted laparoscopic surgery (18). Nevertheless, SBU was able to state that seven robots were sufficient to meet the total Swedish demand for prostatectomies (18). It should be added that the robots can also be used for other surgical procedures, such as hysterectomies (surgical removal of the uterus) (18). Despite this, there were a total of 18 robots in Sweden at that time (18). According to the report, the healthcare sector in Sweden had purchased eleven robots too many at a cost of 220 million SEK up to 2013.

Despite the SBU report, the number of robots continues to increase in Sweden, and today about 25 robots can be found. Note also that as recently as October 2015, yet another county council decided to invest in a surgical robot despite the need for additional robots having long been filled according to the SBU report (18). This highlights the problem that although there is a government agency that produce HTA's, in this case SBU, the assessments do not necessarily have an impact on healthcare. It is not, however, reasonable that cost-effectiveness is first evaluated ten years after a new technology has been introduced.

## 2.7 Business intelligence

To carry out economic evaluations in a timely manner, it is necessary to remain updated about developments that are underway and about which new medical devices are expected to be introduced on the market.

Business intelligence and horizon scanning are two terms used for the same thing. In this report, TLV has chosen to use business intelligence regarding the medical device sector in order not to confuse this with horizon scanning, which is done in the pharmaceutical sector. Unlike pharmaceuticals, medical devices are not covered by the so-called Transparency Directive (89/105/EEC). Before a medical device has been CE-marked and has reached the market, it is not certain that the public is aware that the product is under development. For this reason, the opportunity to work with business intelligence (or horizon scanning) does not arise. However, this does not mean that it is impossible.

As previously mentioned, there are many medical devices that have different characteristics. Because of this very large scope, no government or organisation alone can carry out this monitoring. Instead, it can be considered likely that international cooperation is necessary in order to achieve an as up-to date and relevant business intelligence as possible, and to cover as much of the sector as possible.

## 3 International perspective

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Ever since TLV was awarded its first medical device commission in 2012, the agency has worked actively to spread knowledge about the commission in particular, medical devices in general and also about cost-effectiveness issues. Initially, this was done on a national level. In recent years, however, TLV has increased its international cooperation in several ways. This has occurred through business counselling within the EU, contact with sister authorities in other countries, international HTA projects and the evaluation of medical devices marketed by international companies. To extend its international reach, TLV has also chosen to translate its final reports and certain supporting information that is of international interest. A prerequisite for TLV's ability to carry out the government commission as cost-effectively as possible is the importance of drawing lessons from developments taking place internationally and implementing relevant aspects of this into the existing Swedish system.

### 3.1 Definitions of different types of HTA reports

The international scientific literature has drawn up definitions of different types of HTA reports (19). There are primarily three established types of HTA reports; complete HTA, mini-HTA and rapid review (19).

The definition of a complete HTA (19) is that the report should always describe the product and its current use, evaluate its safety and effectiveness, determine cost-effectiveness through economic modelling (if appropriate), provide information on costs, economic impact and discuss organisational considerations. In addition, a full HTA report should always contain an exhaustive systematic literature review, critically review the evidence base and preferably discuss ethical, social and legal considerations.

A mini-HTA (19) should always describe the technology and its use, evaluate safety and effectiveness, and offer information regarding costs and economic impact. A mini-HTA should also include a comprehensive systematic literature review and critically evaluate the quality of evidence.

A rapid review (19) should always describe the technology and its use and evaluate safety and effectiveness. It often contains a high-quality overview of the evidence or recently published studies. The literature search can be restricted to one or two databases. Critically evaluating the quality of the evidence, and providing information on costs/economic impact is optional.

Irrespective of the type of HTA report, there is no standardised way of expressing the results of the assessment, which can lead to difficulties in comparing HTA reports.

### 3.2 Health technology assessments in Europe

Economic evaluations, within the framework of HTA, are used in several countries in Northern Europe for pricing and reimbursement matters, and to determine the recommended use of new medical devices (20). In southern Europe, the situation is completely different. There, effect comparisons form the core of the evaluation (20).

In 2015, the World Health Organization (WHO) assisted Hungary in evaluating five European countries' systems for HTA of medical devices (21). Of the five countries surveyed (Britain, France, Germany, Italy and Sweden), only the United Kingdom and Sweden conducted cost-effectiveness analyses (21). In addition to the United Kingdom and Sweden, some other countries (Ireland and the Netherlands) made use of cost-effectiveness analyses (20).

Other countries, such as France and Germany, only look at the direct clinical benefit of the treatments or the additional clinical benefit that a treatment brings. The discussion of whether a new product should be reimbursed and at what price is based on this information (20). France has the ability to conduct cost-effectiveness analyses but has not yet done so (21).

As an example of this situation, it can be noted that several countries have evaluated PAVR (percutaneous aortic valve replacement). The majority of these evaluations did not include an economic dimension and the recommendations emanated only from clinical aspects (20).

### 3.3 Sweden has a well-developed system for economic evaluations

In 2011 (22), 15 different countries' HTA organisations were assessed. The assessment focused primarily on pharmaceuticals and it is only in France, the Netherlands and Sweden where an HTA is a formal part of decisions taken on price and subsidy (22). The assessment was based on 15 criteria (23) proposed by an international group of HTA researchers as a way to compare different HTA programmes independently of the organisation and the perspective used. The results showed that TLV's counterparts in England and Canada (NICE and CADTH respectively) are the best, followed by the organisations in Australia, Germany and Sweden (22).

According to the report, only a few countries, including England, the Netherlands and Sweden, also offer formal scientific counselling to pharmaceutical manufacturers (22). Sweden, together with the Netherlands, occupies a special position regarding the use of a societal perspective for decision-making (22).

As TLV produces HTA's within the medical device commission in the same way as for pharmaceuticals, the assessment made for pharmaceuticals (22) must, therefore, be regarded as also being valid for the medical device commission.

### 3.4 NICE in England

NICE must be deemed to have made the most progress regarding the evaluation of medical devices. NICE has a healthcare perspective in its evaluations (24), which means that it only takes into account the costs and effects that impact healthcare, unlike TLV, which applies a societal perspective. The evaluations NICE carries out can generally be divided into four components (24).

1. *NICE guidelines* correspond to the National Board of Health and Welfare guidelines in Sweden.
2. *Technology appraisal guidance* is a recommendation where the impact and cost-effectiveness of pharmaceuticals and medical devices are evaluated. Health services must comply with the recommendation within three months of it being published. This type of evaluation allows all patients within the National Health Service (NHS) to receive equal treatment and be given access to the most cost-effective treatments once the evaluation has been published.
3. *Medical technologies guidance, diagnostics guidance and interventional procedures guidance* enables healthcare providers to start using cost-effective technologies quickly and on equal terms. If NICE believes that the new technology can be introduced, it has deemed that it offers advantages for patients and the healthcare sector.
4. *Medtech Innovation Briefing* contains a description of the product, how it is used and its potential role in treatment. In addition, a description of the state of knowledge and the potential costs associated with the use of the product are included.

NICE also has a programme known as the Health Technologies Adoption Program (HTAP), whose primary purpose is to support care providers during

the introduction into the healthcare system of therapies recommended by NICE (24).

### 3.5 HTA organisations outside Europe that evaluate medical devices

A study from 2015 (25) identified 36 HTA organisations from 20 different countries outside the EU that evaluated medical devices. Of the 36 organisations identified, 75 percent had their own organisational structure or specific procedures for evaluating medical devices.

As part of the study, the authors conducted interviews with representatives from 36 organisations concerning, among other things, the challenges that existed with conducting HTAs for medical devices (25). The challenges highlighted were, as earlier research has shown, that evidence for medical devices was found to be poorer than for pharmaceuticals and there were difficulties in relating the results of a medical device from one environment to another (25). The effect of the learning curve, skills and experience of, for example, the operator as well as the problem of identifying relevant comparative alternative, were further challenges that were mentioned in the study (25).

Several of the organisations (69 percent) had different kinds of methodology documents for evaluation or policy documents for what was to be submitted as a basis for evaluation. However, the documents were normally not specific for medical devices, even though representatives from the organisations had identified several challenges that were specific to medical devices. Despite this, none of the organisations had for planned methodology documents for medical devices and only one organisation had developed specific methodological guidelines for medical devices, the HTA organisation in Brazil (the Department of Science and Technology).

A report mentioned earlier (22) studied 15 countries including some outside the EU. Among other things, the report concluded that although many countries had an HTA system with a mandate to include items other than pharmaceuticals, such as medical devices, seven of the countries had not evaluated medical devices at all during the year that data collection took place (in 2009) (22). For the other countries, a smaller proportion (about two percent to about 40 percent) of HTA reports dealt with medical devices. Among the many countries that published HTAs of medical devices, their extent was less than 20 percent of the total number of HTA reports except for Poland and Sweden, both of which had about 40 percent representation (22). However, with regard to Sweden, this appears to be misleading as SBU, according to their website (6), published a small number of evaluations in the medical device field in 2009, which was before TLV had received its commission to evaluate medical devices.

### 3.6 EU collaboration in the medical device field

At EU level, cooperation between European HTA authorities, EUnetHTA, has been initiated. This cooperation is conducted with partial funding from the European Commission and Member States in a Joint Action (JA). An example of this cooperation is the SEEDS consortium that has taken place within the EUnetHTA's JA 2. The SEEDS consortium, carried out as a project, evaluates and implements early counselling between HTA agencies in Europe, developers of innovative medical devices, and pharmaceuticals. Within the framework of this cooperation, TLV participated in a business counselling session in Paris organised by the Haute Autorité de Santé, which is TLV's counterpart in France. During 2014, the SEEDS consortium conducted ten consultations, of which three dealt with medical devices. TLV was also invited to participate in business counselling concerning medical devices in 2015 but could not attend, partly because one of the companies in question required a confidentiality agreement that TLV could not accept.

During 2015, preparations have been made for continuing EUnetHTA collaboration in a third JA. Some sixty HTA agencies have expressed an interest to the EU Commission to take part in the work of JA 3.

Preparations for JA 3 include plans to for more in-depth cooperation via early joint scientific counselling in SEED, where medical technology is named as a particular priority. Furthermore, pilot projects to see how better evidence can be generated following a product's approval, both for medical devices and pharmaceuticals. The JA 3 project has a special mandate to see how cooperation can be made permanent after the project ends in 2019.

## 4 Health technology assessments can support healthcare providers and contribute to equality of care

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Pharmaceuticals are mainly evaluated on a national level, which creates the basic conditions for the provision of equitable care. However, the need for national coordination, equitable healthcare and effective evaluation also applies to medical devices (4).

Health technology assessments can support healthcare providers by contributing to national coordination and thereby creating the conditions for equitable care by giving county councils access to the same HTA's, thereby enabling policy makers to make as informed decisions as possible regarding the priority setting and implementation of new medical devices in healthcare (4).

### 4.1 TLV's health technology assessments

TLV's HTA's consists of two parts. The first comprises a statement of clinical efficacy, costs and an assessment of cost-effectiveness, as well as of the uncertainty in the assessment. The second part consists of ethical, legal and organisational implications plus the financial impact arising from the possible introduction of the medical device (4).

HTA's are based on the best available knowledge, and assume a societal perspective, but their conclusions are not binding and they are not to be regarded as a recommendation. Instead, the HTA's are intended for use as decision support for healthcare providers (4).

#### 4.1.1 TLV's work is based on the ethical platform

TLV has assumed that the evaluation of medical devices should be based on an application of the same criteria used for pharmaceuticals in § 15 Act (2002: 160) on Pharmaceutical Benefits, etc. (4). The application of these criteria must nevertheless be adapted according to the special conditions that apply to medical devices (4). All of TLV's economic evaluations are based on the ethical platform, which comprises three principles.

*The human dignity principle* is an overriding principle that everyone has equal value and the same rights to healthcare regardless of his or her

personal characteristics and roles in society. The principle thereby sets down what should *not* determine priority setting in care, such as intelligence, social status, income, age or sex. This principle can be seen as a framework within which priority setting decisions must always be made.

*The needs and solidarity principle* means that if priorities must be made between different treatments, more healthcare resources are to be allocated to the most needy, i.e. those individuals with the most severe conditions and the poorest quality of life. The principle implies, in addition to the desire that the outcome of care should be as equal as possible, a special responsibility towards individuals who are unable to defend their rights and to especially reflect the needs of the weakest. These include children, elderly with dementia and individuals who otherwise might have difficulty communicating with their surroundings. The needs and solidarity principle does not mean that all resources must go to those most in need.

*The cost-effectiveness principle* means that when choosing between different treatments, a reasonable relationship between cost and effect measured in improved health and higher quality of life should be sought after. Cost-effectiveness is thus one of the aspects that must be considered when setting priorities, such as deciding which treatment strategies should be developed in healthcare.

If a greater overall health benefit can be achieved by prioritizing a patient with moderate health deficiency instead of a patient with serious health deficiency, a conflict between principles arises. This means that a balance must be struck between the needs and solidarity principle and the cost-effectiveness principle. TLV handles this balancing act by accepting a lower cost-effectiveness – less health benefit per Swedish krona invested – the more severe the disease is.

#### 4.1.2 Published when they have the greatest impact

In an earlier report (2), TLV found that it is not normally appropriate to assess medical devices that are not yet CE-marked. One reason for this is that the authorised use is not determined before the CE-marking has been done. Before use is established, it is thus difficult to establish which comparative alternative would be relevant in the economic evaluation (4).

According to TLV, HTA's have their greatest impact if the economic evaluation is done as soon as possible after CE-marking (4). The reason is that the potential purchase of the medical device being evaluated has in all probability not yet taken place, and the assessment can thus be used as a basis for purchasing decisions.

Apart from TLV, SBU is the only body in Sweden that makes HTA's of medical devices at a national level. However, in comparison with TLV, SBU typically carries out its evaluations at a later stage in the product life cycle, see Figure 1 (4). TLV's HTA's can therefore be considered to fill a previously unmet need (4).

## 4.2 An evaluation of TLV's commission has been made

TLV's government commission has successively been developed over the years, a development that has been assessed by the Swedish Agency for Health and Care Services Analysis (Vårdanalys), whose report was published in March 2015 (26). TLV's development of the commission in 2015 is thus not covered by the evaluation. Vårdanalys has consistently used the term *medical device method* in its report (26) and in the paragraphs that concern this report, TLV uses their terminology.

In its report (26), Vårdanalys notes that medical device practices have a central and growing role in Swedish healthcare. It further notes that, with regard to the short period of time that TLV's commission has been conducted, only a limited number of HTA's have been developed, and that there are particular challenges associated with work on HTA's within the field. It is thus much too early to fully evaluate the actual effect of this work (26). Instead, Vårdanalys focuses on the potential of the economic evaluations as a tool for a more cost-effective implementation of medical device practices in healthcare.

Vårdanalys sees great a potential for TLV's work to create value for patients and county councils (26). It notes that county council representatives, patient organisations and companies are positive to TLV's commission. The few county councils that conduct HTA's do so only from a county council perspective, while TLV evaluates at national level. Sweden's municipalities do not conduct economic evaluations at all (26). Based on these aspects, Vårdanalys concluded that decision-makers are largely only referred to an individual doctor's assessment of a medical device method's clinical effect. The consequence of this is that the economic aspect is often omitted (26). Furthermore, Vårdanalys believes that economic evaluations can be a useful tool in healthcare, but that this will require mutual development from TLV and the county councils regarding the economic aspects of medical device practice, which cannot be expected to happen overnight.

Vårdanalys notes that county councils decide differently regarding which medical devices practices are to be introduced and that this could lead to inequitable care (26). Despite the fact that both SBU and the National Board of Health and Welfare conduct economic evaluations of medical device methods, county councils report a lack of sufficient national support

regarding decisions to introduce medical device practices (26). In addition, most county councils lack sufficient resources and the necessary competences to carry out economic evaluations (26), despite the fact that they have an explicit need for increased economic support in their decision-making. Vårdanalys therefore felt that higher requirements should be set regarding structured efforts related to evaluation and decision-making about which medical device methods are considered appropriate.

One purpose of Vårdanalys' evaluation was also to make improvement suggestions for how TLV's work with the commission could be further developed to ensure cost-effective, high-quality care. However, the improvement proposals directed at TLV had to a large extent already been recognised by TLV itself and accounted for in published reports. The improvement proposals (26) are presented below.

Vårdanalys considers that the presentation of TLV's assumptions, estimates and uncertainties in the HTA's has development potential (26). Vårdanalys finds, for example, that greater clarification is needed on how TLV has validated data and models in the HTA's. TLV has developed this further and the results of its efforts are presented in Chapter 5.2.7.

Vårdanalys also finds that TLV should develop processes for economic evaluation in close cooperation with county councils, healthcare professions and patients. This is partly because it is important that TLV further develops the selection, formulation, and communication of HTA's. This is also partly because collaboration with county councils regarding the use of HTA's are considered central (26). TLV has developed these processes, which are presented in Chapter 6.3. Vårdanalys also believes that it is important that TLV, in an appropriate manner, involves patients in selection and evaluation (26). TLV has already begun work regarding these issues and this is presented in Chapter 6.3 and chapter 6.6.2.

TLV intends to conduct a detailed legal investigation to clarify the possible implications of European Union law and the administrative law's provisions on decisions and decision appeals and to consider how work with the commission needs to be developed and adapted according to these regulations. Vårdanalys agrees and believes that this should be included as part of the ongoing commission (26). TLV's work is presented in chapter 6.5.

## 5 Development of TLV's work on economic evaluations during the year

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In addition developing even more user-friendly HTA's, TLV has worked on two main issues during 2015. Partly to strengthen collaboration with county councils and partly to further develop TLV's selection and work processes for evaluating medical devices (4).

Below is an account of how the selection of products to be evaluated in 2015 was conducted.

### 5.1 Products that TLV has evaluated during 2015

This year's government commission contained no specific directives concerning which products should be evaluated or which patient groups should be covered. Hence, TLV asked which needs existed and received a number of suggestions for products, primarily from county councils and medical technology companies. These proposals were different in nature, partly regarding how much information was provided about why the evaluation would be necessary, and partly because there was a broad spread in the type of products proposed for evaluation; everything from needles to surgical procedures. The number of proposals was higher than in previous years. All proposals were compiled and sent to the county councils in order to provide them with opportunities to prioritise what they felt was the most urgent for TLV to evaluate.

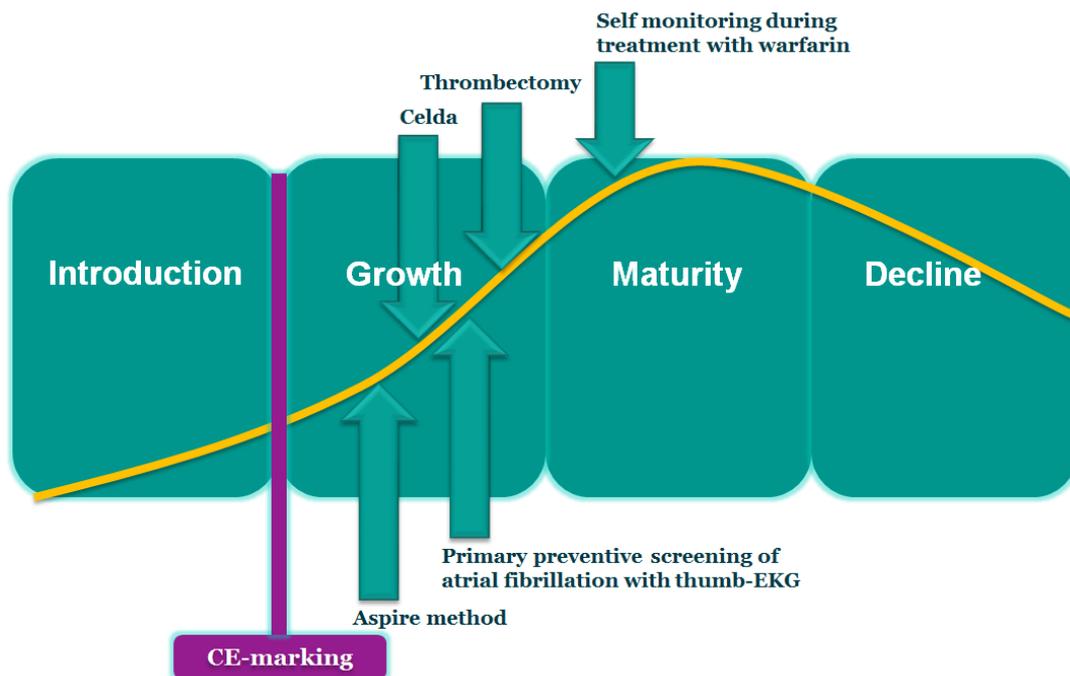
TLV has a business intelligence function that consists of several parts and that affects different partners. One example is the cooperation with Sweden's innovation agency VINNOVA and the business counselling that is part of this (4). TLV also cooperates closely with the industry association for medical devices, thereby gaining a better insight into the innovations that can be introduced onto the market. Additionally, TLV has other national and international contacts that enable business intelligence (4). One of this year's evaluated products, see chapter 5.2.1, was discovered by these latter means.

TLV has previously noted that a product should be evaluated in the appropriate phase (4), and this has been an important factor in the 2015 selection. In addition, TLV tries to identify products to evaluate where equitable care has been a challenge. Availability of data to enable assessment has also been a prerequisite.

The situation can change even after TLV has selected a product to evaluate. For example, a company may not CE-label their product as planned or a necessary trial might be delayed (4). Because of this, TLV therefore started more evaluations than it intended to complete during 2015. A total of six evaluations were started. Of these, three have been completed during the year and the remaining three will be published in 2016.

## 5.2 This year's health technology assessments and the lessons learnt

All medical devices evaluated during the year, except for one example, are located in the growth phase of the product life cycle, see Figure 2. To some extent, the respective positioning in the product life cycle also depends on external circumstances. Such circumstances could, for example, be that other treatment methods have reduced the demand for and sales of the product.



**Figure 2.** HTA's positioned within the product life cycle based on the products' market development until now.

### 5.2.1 Thrombectomy for the treatment of stroke

Thrombectomy with stent retrievers is a method of treatment for acute ischemic stroke that mechanically removes a blood clot from a larger vessel in the brain by inserting a catheter in an artery at the groin. In Sweden, stroke is the third most common cause of death and the leading cause of permanent physical impairment in adults. Stroke thus affects patient quality of life. Good evidence regarding clinical effect and increased benefit for patients treated with thrombectomy is available. In view of this background, TLV chose to evaluate thrombectomy.

TLV noted early in the evaluation that the county councils were in need of an HTA regarding thrombectomy. To provide a relevant HTA as soon as possible, TLV chose, in consultation with the county councils, to publish the first part containing the economic evaluation (27) in 2015 and to wait until 2016 to publish the second part which will comprise of a thorough organisational and ethical analysis of the product. To accelerate work on the HTA, and to avoid two agencies performing the same work, TLV collaborated with the National Board of Health and Welfare concerning the literature review of medical evidence of thrombectomy. For this reason, TLV published the board's resulting literature review as an attachment to its HTA (27). This literature review of medical evidence had not been published previously. In turn, the board will use TLV's HTA in its revision of the national guidelines, which are expected to be published in 2017.

TLV has also collaborated with the National Programme Council for Stroke at the Swedish Association of Local Authorities and Regions (SKL), Region Skåne and companies that market products used for thrombectomy.

### 5.2.2 Self-monitoring of treatment with warfarin

Patients with an increased risk for blood clots may need to be treated with anti-coagulant drugs (warfarin). This treatment requires careful and regular monitoring with blood tests. Testing is carried out within routine healthcare at an anti-coagulation clinic or in primary care. Self-monitoring of treatment with warfarin means that the patients themselves test if the pharmaceutical dosage is correct (self-testing) and, in some cases, even adjust the dosage (self-care). Self-monitoring means that patients do not need to travel to a clinic to test pharmaceutical levels to the same extent as routine medical care. Thus, they become less bound to healthcare services.

In this instance, TLV chose to base the HTA on other national and international HTA organisations' previously conducted analyses. This was done in order to streamline processes and to evaluate if this method is a viable alternative in the future to base HTA's on previously completed evaluations in some cases.

The economic evaluation was based on a report with a cost estimate from the Norrbotten County Council in Sweden. An HTA analysis from NICE in England was also used to validate the results.

The HTA regarding self-monitoring of treatment with warfarin may be considered to fall within the maturity phase of the product life cycle, as the treatment has been on the market for some time and already used in certain counties.

### 5.2.3 The Aspire method

The Aspire method is a method for treating obesity where a tube is placed in the stomach. The patient then uses the tube to drain about 30 percent of the contents of the stomach after each main meal, which reduces nutrient intake and leads to weight loss. Because obesity increases the risk of several disease complications, an effective obesity treatment can lead to both large health gains and cost savings in healthcare.

One clinical study of the Aspire method has been completed in Sweden and the results after six months of treatment have been published. The results after two years of treatment are expected to be published shortly. Another Swedish comparative study is in progress. In the US, a small pilot study has been published, and a further study is ongoing. However, the completed studies included only a few patients and TLV believes, therefore, that it is not possible to comment on the effect of the Aspire method. It therefore decided to only implement a cost comparison and not an effect comparison.

### 5.2.4 Primary preventive screening for atrial fibrillation with thumb-ECG

Measuring ECG can determine whether a patient has atrial fibrillation, which is a risk factor for stroke. If more patients with atrial fibrillation are identified, stroke prevention treatment can be initiated, with the result that fewer people will suffer a stroke. The healthcare costs of stroke in the community would thus decrease accordingly.

The method of primary preventive screening for atrial fibrillation with 'thumb-ECG' means that patients can measure their ECG by placing their thumbs on the device. Patients can thus perform this measurement themselves without having to visit a healthcare facility. TLV has previously evaluated thumb-ECG and published a HTA in the autumn of 2014.

In previous reports, TLV has discussed the possibility of updating the HTA's as new data is published or as needs for updates arises from the county councils or other bodies. Thumb-ECG meets both of these criteria since the study, on which the cost-effectiveness analysis was based, has now been published. Thus, the HTA now contains less uncertainty regarding the

results. Furthermore, following the publication of the TLV's HTA, the National Board of Health and Welfare received a government commission to evaluate primary preventive screening for atrial fibrillation based on the board's model for evaluating national screening programs. This requires analyses other than those initially made by TLV. Thus, there is an even greater need of updating the HTA and TLV therefore chose to begin this task.

TLV has assisted the National Board of Health and Welfare with additional analyses needed to evaluate a possible future national screening program. Even SBU is participating in this cooperation by contributing with a systematic literature review. TLV has, therefore, chosen not to publish an updated HTA yet. This will allow the results of the systematic literature review to be incorporated in TLV's updated HTA, thereby leading to the national healthcare providers being able to deliver a more consistent message.

#### 5.2.5 CELDA

CELDA is a medical device that, in a structured and automated manner, measures and analyses the pressure and flow of spinal fluid. Its primary aim is to investigate if a patient has the disease idiopathic normal pressure hydrocephalus (INPH). INPH leads to great suffering in patients from symptoms such as, memory loss, urinary incontinence and impaired walking ability. Nevertheless, suffering can be reduced or completely avoided if patients are diagnosed quickly and accurately. TLV believes that CELDA is an innovative product that can hopefully make a big difference in healthcare if more data is collected to support the effect of the treatment.

While working on the HTA for CELDA, TLV encountered several challenges. There are, for example, different ways to diagnose the disease and there is no consensus on which of these ways is the most accurate. In addition, regional differences risk leading to unequal treatment. TLV has published a rapid review regarding CELDA. Its work on the HTA is already underway and will be published in 2016.

#### 5.2.6 Strokefinder

Strokefinder is a medical device that can be used during the examination of stroke to determine whether the stroke is caused by a clot or haemorrhage. TLV has previously initiated an evaluation of the product because of its high degree of innovation and its potential to reduce patient suffering. However, it appeared that both the CE-marking of the product and the clinical trials were delayed, which made publication impossible. The product has not yet received CE-marking and a HTA will most likely be published during 2016 if the product gets CE-marked.



## 5.3 Development projects in which TLV has participated during the year

During 2015, TLV also participated in various ways in a number of development projects, some of which are accounted for below.

### 5.3.1 Swedish Medtech's HTA project

In earlier reports (2, 4, 28), TLV has established that medical device companies experience that county councils are not active regarding the introduction of new medical devices. One reason for this slow progress can be that the county councils usually lack information when making decisions. This means that they will likely be positive to evaluations of medical devices that demonstrate relationships between cost and benefit. In addition, companies are seeking a structured, transparent and effective approach for introducing valuable new medical devices in healthcare while minimising regional differences in the introduction of new medical devices. In this respect, evaluations of medical devices will benefit both patients and healthcare.

As part of its efforts to strengthen the evaluation of medical devices, Swedish Medtech has initiated a research project called 'Medical technology for the future - Basis for decision on the introduction of medical technology'. This project has a steering committee in which TLV, SBU, VINNOVA and Swedish Medtech participate. One of the aims of the project is to standardise the way economic evidence should be presented to make it easier for industry and healthcare.

### 5.3.2 Method development project

One of the challenges regarding the evaluation of medical devices is that the products' benefits are often difficult to determine using the health-related quality of life measures generally applied to pharmaceuticals. For patients using a medical device, other benefits beyond the clinical effect tend to have great significance for how their physical, mental and social well-being is affected. Today, general methods for measuring such benefits are lacking.

One current method development project in this area is conducted by Nordic Health Economics AB in Gothenburg. The aim is to develop a standardised survey instrument to measure the benefits of medical devices seen from the patient's perspective. Development work is conducted as an innovation project with certain financing support from, among others, the European Regional Development Fund and ALMI / VINNOVA.

TLV has provided feedback at various stages of the project. The development of the instrument is now in its final phase and the work was presented in a scientific format at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) congress in Milan in November 2015 (29).

## 6 Future work

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TLV has gathered comments during the early stages of this report from healthcare providers, patients, government agencies, trade associations and SKL as part of the development work. General comments about the continuation of the mission are given below.

SKL has stated that the government commission is of great value to county councils and regions and that it is vital that its activities continue. SKL also supports the use of TLV's HTA's in a process for the managed introduction of medical devices, as TLV has itself suggested. According to TLV, it is vital that the county councils are involved in a clear and concrete manner in the evaluation process of medical devices for the results of the work to be as successful as possible. The trade association for medical technology companies (Swedish Medtech) has also proposed that the commission should be made permanent and given adequate funding.

### 6.1 The effect of the government commission

As mentioned previously, Vårdanalys has noted that it is too early to fully assess the actual effects of TLV's activities (26). TLV, however, has seen that its work has led to several important results, both with external actors and within TLV itself.

TLV's external network of contacts has been expanded. This is reflected in, among other things, TLV being invited to a number of international conferences and meetings where TLV has not previously been represented. This is an expression of the fact that TLV has become an actor worthy of attention both nationally and internationally. This has in turn meant that TLV is involved in a variety of research and development projects, which are already initiated or planned, see chapter 5.3.

The medical device commission has led to TLV's work with consumables being developed and, to some extent, changed. Consumables are included in the benefits scheme and, following the government commission, the way they are dealt with has become more stringent and now more closely resembles the way that TLV deals with pharmaceuticals. The work of evaluating medical devices has also had other effects on TLV's activities. Ethical issues for example, have been highlighted and continued further development work has started internally.

TLV plans to further develop its work by following up the effect that the medical device evaluations have as well as the impact that published HTA's have within healthcare.

To increase the understanding of how TLV's HTA's are used, as well as the benefits they bring to healthcare, their impact must be studied. This applies regardless of whether or not a managed introduction of medical devices is created. This means that when TLV henceforth selects products to evaluate, key indicators must be identified to make possible studying the impact of HTA's as a basis for further develop work to maximise impact.

## 6.2 Identified challenges with economic evaluations of medical devices in their early phase

Different challenges related to economic evaluations of early-phase medical devices arise depending on how the HTA is used in practice. The most obvious challenges are the risk that new, cost-effective medical devices are not introduced into healthcare, or that they are implemented differently in different counties without a clear implementation process. This could risk leading to inequitable treatment. However, a managed introduction of medical devices is planned which could reduce this risk, see 6.4.1.

Another challenge is that TLV's economic evaluations in an early phase of the product life cycle risk becoming a gatekeeper that decides whether there is sufficient evidence to determine the cost-effectiveness of an innovative product; since the product still can begin to be used. TLV believes that it is better to base a HTA on the best available data, thereby gaining an understanding of the cost-effectiveness despite the uncertainties arising from the data's quality and reliability. TLV believes that not making an early economic evaluation poses a greater risk to society.

An additional challenge is the risk that different authorities in healthcare make different assessments and have different methods of ranking evidence. This risk is reduced by TLV actively working to reduce process duplication. Authorities now also cooperate more actively regarding individual HTA's, for example thrombectomy, which reduces this risk. A future managed introduction of medical devices can lower this risk even further.

Finally, there is concern that making economic evaluations will become a requirement and that this demand will increase costs for companies and delay the introduction of innovative medical devices on the market. TLV could never demand this and has not charged for services rendered. County councils can, however, make such requirements on companies but TLV believes that the risk that this will become a general problem is low since the field encompasses such a large number of products.

TLV finds that the risks identified in implementing economic evaluations in an early phase have been reduced by the process that has been developed. This process is presented below.

### 6.3 TLV's process has been further developed

It is imperative to continuously review and develop the process so that TLV's work is as cost-effective as possible. The main aspects of the work processes in 2015 are still valid, but it is reasonable that further developments arise from collaboration with both the county councils and patients and to reduce identified risks regarding early economic evaluations of medical devices, see 6.2. Hence, TLV has developed a proposal for a new process, see Figure 3. The parts of the process that involve other actors (primarily county councils) will be developed appropriately. The process will thus continue to evolve during 2016.

The proposed process consists of twelve different aspects; of which several are unrelated to the production of HTA's. These aspects are necessary in different ways to produce the HTA's.

#### 1. *Business intelligence*

The value of business intelligence, as previously discussed, see chapter 2.7, is that TLV can be ready to make an evaluation in the most appropriate phase when it is known that the product is being introduced on the market.

#### 2. *Business counselling*

TLV has held a large number of business counselling sessions during the entire period of the government commission. It has emerged that there is a need for companies to receive guidance as to what type of economic evidence is required in order to suffice for the county councils and authorities. TLV therefore intends to continue with this important work.

#### 3. *Proposals for products to evaluate*

Healthcare representatives, patients, companies and the general public have the opportunity, via the TLV website, to submit suggestions as to which medical devices the proposer believes that TLV should evaluate. In addition to the proposal, a number of questions should also be answered such as which use of the product should be evaluated, why the product should be evaluated, as well as the comparative alternatives proposed. These questions must be answered for a proposal to be considered complete and progress to the next step in the selection process. Twice a year, TLV collects the proposals received and the selection process begins.

#### *4. Categorisation of the proposed products*

The proposals are compiled and categorised according to the selection criteria, see 6.4.1. These criteria are intended to provide guidance to further the work of selecting products to evaluate.

#### *5. County council and authority collaboration*

TLV sends the consolidated list of suggestions of products to evaluate to the county councils and government agencies in order to give them the opportunity to consider the proposals. County councils then suggest which medical devices on the list they consider suitable for evaluation based on the selection criteria. Government agencies are also able to advise about ongoing or planned evaluations. As a minimum requirement for TLV to proceed with a proposal and conduct a preliminary assessment, it is reasonable that several county councils consider that a need exists and that the product should be evaluated.

#### *6. Preliminary assessment*

TLV intends to perform preliminary assessments of all products that have been selected in the previous step. The preliminary assessment charts the available data for the product in order to determine whether it is possible and appropriate for TLV to carry out an evaluation. When TLV has conducted a preliminary assessment of a product, it then publishes a short summary of the state of knowledge on TLV's website.

#### *7. Consultation*

In order for TLV's resources to be used in the best way, it is important to consult with county councils, patients and healthcare providers. This consultation is based on the selection criteria identified. At this stage, stakeholders should propose products that they consider TLV should evaluate. This ensures that the selection is as transparent and appropriate as possible and avoids duplication.

#### *8. Decision to start an evaluation*

The decision to begin an evaluation is made by TLV's Director General. Any deviations from the products proposed as a result of the consultation process concluded should be reasonably justified and reported back to the interested parties who are involved in the consultation process in step 7.

#### *9. Economic evaluation*

The HTA is produced in consultation with scientific experts, county councils, patients, other government agencies and companies.

### 10. Publication

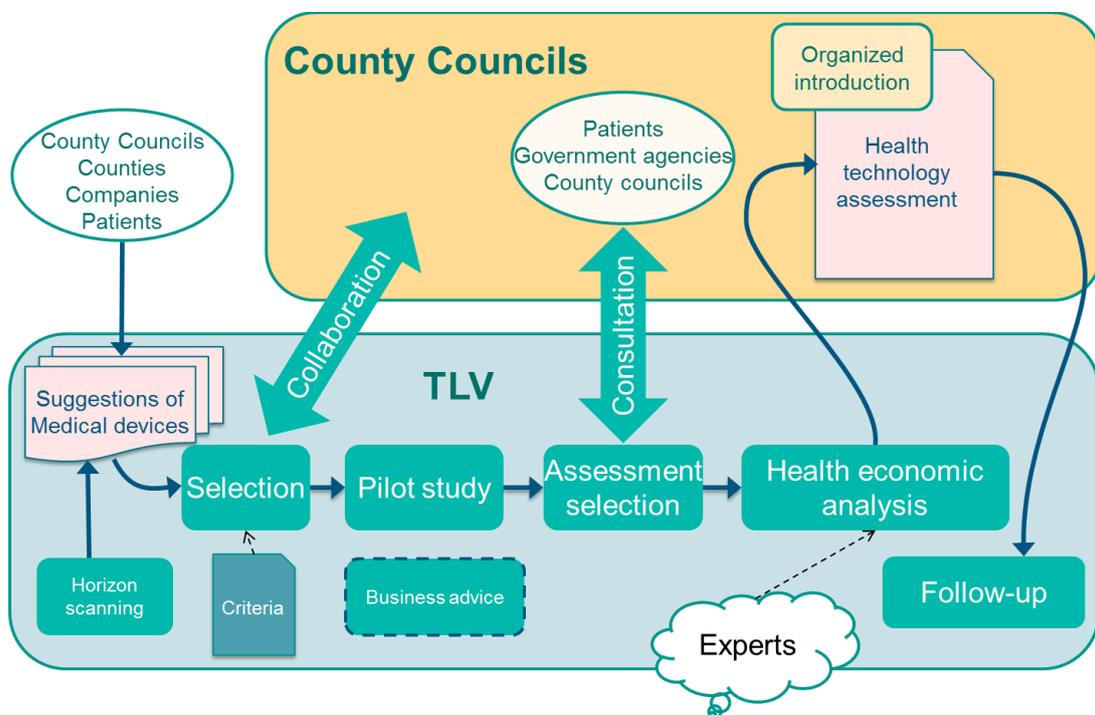
The HTA is published on the TLV website and also sent out to relevant stakeholders such as scientific experts, county councils, patients, other government agencies and companies.

### 11. Managed introduction

TLV believes that a process of national managed introduction of medical devices in healthcare is desirable. Nevertheless, this lies outside the scope of TLV's process.

### 12. Follow-up and evaluation

When a certain period of time has elapsed, TLV intends to seek input from healthcare authorities regarding the need to update HTA's. The HTA's that are to be updated are prioritised according to the selection criteria, see chapter 6.4.1. TLV finds that follow-up and evaluation of the product in question is desirable. Nevertheless, this lies outside TLV's process for developing HTA's.



**Figure 3.** Overview of TLV's future process

## 6.4 Selecting a medical device

The benefit of a medical device is always dependent on the context in which it is used, and as such, an assessment cannot be made solely on the basis of the product without considering how it is used and by whom. In terms of the evaluation, it is therefore more appropriate to evaluate medical device methods.

In its final report for 2013, TLV suggested selection criteria for the selection process (28). Some minor adjustments of these criteria were made during 2014. During 2015, TLV continued its developmental work regarding the selection criteria.

The selection criteria are used in TLV's selection process and should relate to the purpose of the HTA. The overall aim is that TLV's resources are used where they have the most benefit. The objective with the HTA is to create a necessary basis for making informed decisions in healthcare to achieve a good and equitable care across the country. To accomplish this, as elsewhere in healthcare, the therapies prioritised are those intended for the most severely ill patients or for patients who risk becoming seriously ill if untreated. Differences in local or regional situations need not rule out an evaluation. On the contrary, they may constitute a reason to initiate an evaluation.

The proposals that TLV has drawn up so far are presented below.

### 6.4.1 Selection criteria

TLV is currently working on seven selection criteria, see below. Efforts to further develop selection criteria will continue during in 2016.

1. Resource impact
  - a. Resource impact resulting from the disease
  - b. Resource impact resulting from the introduction of the medical device.
2. Unequitable use
3. Disease severity
4. Number of affected patients
5. Clinical need
  - a. The disease area relevant for the product has inadequately met needs
  - b. The disease area has already been evaluated by TLV and an update of an existing knowledge base is not in question
6. Clinical efficacy
7. Innovation (that provides substantial value to healthcare)

One issue that TLV has worked on during 2015 is how the criteria should be applied and how they can be assessed against each other. For example, it must be determined which criteria are considered to be most significant separately or in combination with each other. As work progressed, we have found that such weighting is difficult. The ambition, therefore, is that in the future, TLV will further clarify how the criteria relate to each other and how they are best applied.

## 6.5 Legal impact analysis of the selection process

In the light of the proposed selection process, TLV has conducted a legal impact assessment.

To ensure that TLV fulfils Sweden's commitment to the Medical Devices Directives (30-32), its selection criteria must be transparent and objective. Furthermore, selection should take place at predetermined time points (as already proposed).

Despite the fact that TLV's commission is to produce HTA's that can be used as a basis for healthcare providers' decisions, it does not mean that only the latter can submit suggestions for product groups to evaluate. Patients, companies and the general public also have the opportunity to submit proposals to TLV. It should be stated that TLV's assessment of the product groups is intended to compare a current treatment alternative with another treatment alternative. This means that TLV does not evaluate a specific company's medical device other than that the product itself may be part of the evaluated method.

TLV sends out all the proposals received, categorised according to the selection criteria, for the county councils to consider. County councils may then assess and suggest which product groups they consider appropriate for evaluation. It may be the case that several county councils are deemed to represent all the council's need of evaluation of a method. In terms of the purpose of TLV's commission, the county councils' proposals should primarily carry the greatest weight.

TLV believes that there are no regulatory requirements or other discriminatory practices that exclude or prevent foreign operators from making suggestions as to which product groups should be evaluated. TLV should, of course, actively seek ways to reach out to the European Union's market to obtain proposals.

The purpose of a formalised consultation is to gather views on the proposals submitted to TLV based on conducted feasibility studies. The involvement of trade associations and companies in the consultation does not, in TLV's view,

constitute an exchange of information that in turn could lead to inappropriate business practices in the market. The reason for this view is that the information that can be shared with trade associations or companies is exclusively public information. Every industry organisation and business is, of course, responsible for ensuring that their recommendations and other actions are consistent with the rules of competition. From a transparency point of view, the criteria applied in the proposed formalised consultation process should be objective, transparent and pre-determined. TLV should actively seek ways to obtain views on proposals from actors in the European Union market.

TLV's cooperation with VINNOVA in respect of which products should be evaluated could, however, be problematic from an EU legal perspective. Unlike TLV, VINNOVA promotes Swedish companies and its activities are based on an exemption from EU legal principles.

The decision to carry out an HTA is taken by TLV's Director General. It cannot be excluded that TLV's decision not to evaluate a product in a product group constitutes an appealable decision in the administrative legal sense.

TLV's objective with the HTA's is to provide county councils with information from an economic perspective primarily pertaining to new, innovative medical devices prior to the county councils' purchases of such products. It cannot be excluded that the HTA's published by TLV will be of significant importance for the county councils' purchases of medical device products.

The basic provisions concerning state aid are contained in Articles 107-108 in the Treaty on the Functioning of the European Union TFEU (33). The purpose of the provisions is to ensure that Member States do not to unduly favour certain companies. According to the EU Court of Justice, four conditions, which are cumulative, must be fulfilled for a measure to qualify as state aid. It is required that the action, of any kind whatsoever, granted by a Member State or through State resources, favours certain companies, distorts or threatens to distort competition and affects trade between Member States. Examples of state aid may be grants, loans on favourable terms, guarantees, warranties, rental reductions or reduced government fees and taxes. According to established Community case law, it is not the objective of a measure nor the donor's costs for the support that are relevant for assessing whether it constitutes state aid, but the impact that the measure has for the beneficiary.

As stated above, the intent of the HTA is to give healthcare providers access to decision support for the purchase of medical devices. The question of whether or not producing an HTA could constitute State aid to a business primarily requires an assessment as to whether the business whose products are included in the product group assessed, receives economic benefits and whether the business would have not obtained these benefits under normal

market conditions. The purpose of TLV's HTA is not that it will make recommendations or dissuasions about acquiring the evaluated product in the product group. The aim is rather that the HTA should provide a basis for the county councils' decision. County councils themselves decide which medical devices they should buy, and they should subject their respective purchases to a competitive public tendering process according to the public procurement law.

In conclusion, TLV deems that there are no legal obstacles that hinder it continuing to conduct its government commission as carried out today.

## 6.6 National cooperation is crucial

During 2015, TLV interacted with several stakeholders; county councils, patients, governments and companies. TLV interacted through various types of meetings and also gave stakeholders the opportunity to comment on the HTA's produced during the year. Some suggestions about how this cooperation can be further developed are given below.

### 6.6.1 County council collaboration

TLV collaborated both with individual county councils and with SKL during 2015. An important part of TLV's commission has been to identify the recipient of the HTA's at the county councils. County councils differ from each other regarding their structure and organisation; not the same or even similar functions can be found in all counties. This has resulted in neither TLV nor the county councils initially being able to identify how cooperation and communication between the parties should take place in an optimal way.

In order to establish a more systematic cooperation with county councils, TLV in 2104 asked healthcare authorities to designate a person at a strategic level within each county council with a mandate to represent the council in contact with TLV and to be TLV's communication partner concerning medical device issues. All county councils have appointed a contact person and TLV have set up a network of contact representatives in the county councils.

During 2015, however, TLV concluded that the network of contact representative's mandate needed clarifying. TLV also noted that it must work in a different way with the network. It became apparent that the HTA's produced have not been dealt with in a systematic manner regarding their introduction in the county councils. To improve the interaction between the agency and the county councils, it is therefore necessary that the work tasks and forms of collaboration between the parties be further clarified and

formalised. This can form part of any future managed introduction of medical devices.

### 6.6.2 Patient collaboration

A general premise for the government commission is the Health and Medical Services Act (1982: 763) statute for good and equitable healthcare for patients. Involving patient and user organisations in this work is therefore of utmost importance. Within TLV's work, all patient and user organisations receiving government funding have been contacted with a request to participate in a dialogue during the development of HTA's and reports.

Vårdanalys deemed that TLV should develop their processes for HTA's in close cooperation with patients (26). Through this work, it has become clear that patients want to be involved at an earlier stage in TLV's processes for developing HTA's. Patient organisations have therefore been able to examine the HTA's and been given an opportunity to suggest improvements in an earlier stage than before, which has resulted in valuable feedback. During 2016, TLV will involve patients in the proposed process earlier and with increased transparency see 6.3.

### 6.6.3 Collaboration with other government agencies

TLV has enjoyed good collaboration with other government agencies, which is evident from 2015 year's evaluations when it interacted primarily with the National Board of Health and Welfare and SBU. TLV has also had good cooperation with the Swedish Medical Products Agency via meetings and information dissemination. TLV has also collaborated with VINNOVA. It continues, among other things, to be part of VINNOVA's call for proposals Forska & Väx (Research & Grow). The purpose of this call is to support Swedish companies that have promising innovative products.

TLV's participation in VINNOVA's call processes concerning medical devices increases its knowledge regarding future medical devices, and can thus be considered to constitute a form of business intelligence. This results in TLV being able to contribute with a health economic perspective at an early stage, from which businesses can thus benefit. It also means that society, via VINNOVA's funding, can at an earlier stage stimulate the development of medical devices that can be cost-effective and thereby avoid investing in products likely never to be cost-effective. This will hopefully lead to cost-effective innovative products reaching healthcare faster.

#### 6.6.4 Regular information to interested parties

As has been stated, it is primarily county councils, patients and companies that have a need for more information about TLV's activities regarding medical devices. As part of these activities, TLV will in the future inform stakeholders about the work being done at the agency concerning medical devices and other significant events in the field. The aim of this information initiative is to increase national collaboration and commitment to economic evaluations and medical devices. The information initiative will initially consist of an information letter, of which the first will be distributed to interested parties early in 2016.

#### 6.7 The public sector's willingness to pay per gained health unit should be clarified by county councils

The conclusion of TLV's economic assessments in its HTA's is often a cost per QALY or a cost estimation of treatment methods. TLV does not recommend county councils to introduce or not to introduce a new medical device into their organisation. However, TLV does state whether this is a high or a low cost per QALY in cases where this is relevant. Nevertheless, this is not the same as a cost-effectiveness threshold based on willingness to pay, but it does offer guidance to county councils.

In its HTA's, TLV has so far assumed that the county councils have the same willingness to pay regarding medical devices as has so far existed for pharmaceuticals in the benefits scheme to determine if this is a high or a low cost per QALY. This assumption is based on the fact that it applies to the same individuals and that medical devices, like pharmaceuticals, are funded by tax revenue. This is broadly consistent with the limits for what the National Board of Health and Welfare finds to be is a high or respective low cost per QALY.

However, it is not possible for TLV to comment on whether this is consistent with the county councils' or public sector's actual willingness to pay. One of the areas for development within the county councils is therefore that they should decide which willingness to pay prevails for medical devices if this differs from pharmaceuticals. TLV can assist county councils in this work.

#### 6.8 Identified needs for further development

TLV has identified a need to further develop the government commission to be able to involve municipalities and to make HTA's more accessible by varying the extent of their scope.

### 6.8.1 Involvement of municipal authorities

In previous reports, TLV has noted that some of the investments made concerning medical devices in Sweden today are made by municipalities. The municipalities' knowledge of economic evaluation and the use of health economic considerations in investment processes are even less common compared to county councils. For these reasons, municipalities are still not involved in TLV's processes for medical devices. This is something that TLV intends to remedy in the future.

### 6.8.2 The evaluations should vary in scope to best meet the needs

As stated earlier, medical devices are often introduced into healthcare before there is a complete scientific basis on which to make decisions. HTA's can therefore be required before it is possible to carry out a full HTA. TLV can thus state that it is appropriate for HTA's to have different scopes because the evidence on which they are based will itself vary in extent, and this should therefore be reflected in the HTA's. This will also make producing the knowledge bases as cost-effective as possible.

TLV believes that it is reasonable to have three different levels of HTA's. The most extensive type is a complete HTA. The second type is a shorter and less comprehensive product. This kind of HTA can still form the basis for a decision on the introduction of a product into healthcare, despite an increased uncertainty in the results. The third and final HTA type is a short knowledge briefing designed to provide an understanding of product's capabilities and limitations. Thumb ECG is one example of the first type of HTA, while the Aspire method is an example of the second type. The third type of HTA has been tested in conjunction with the evaluation of CELDA.

## 6.9 National managed introduction of medical devices

TLV believes that early HTA's should be linked to a managed introduction of new and innovative medical devices in healthcare. A managed introduction will allow further knowledge acquisition in a controlled manner, which could reduce uncertainty before a new and innovative medical device is introduced on a broad front.

Hence, TLV has initiated several meetings with county councils for preliminary discussions regarding how HTA's of medical devices can be used

to a greater extent in the county councils and in the future managed introduction of medical devices<sup>3</sup>.

In December 2015, SKL and the government agreed that SKL, together with county councils and regions, should during 2016 conduct a preliminary study on the managed introduction of medical devices. This study aims to find ways for the county councils to collaborate and coordinate a more managed and systematic introduction of medical devices and methods. In addition, the study will map the county councils' need of HTA's and the way in which they will use them in the implementation process of medical devices. In parallel with this, the government intends to review how government agencies' HTA's in this field could be better coordinated, and to analyse the agencies' future roles in this field.

## 6.10 The government commission is ready to be made permanent

Vårdanalys found that national HTA's of medical devices have the potential to create value and that TLV, despite limited resources, has succeeded in developing the agency's processes (26). Vårdanalys also highlights the fact that stable working conditions are important for the project to be given the opportunity to develop further (26). Despite this, Vårdanalys finds that the government commission should not be made permanent, but rather be further extended for a limited period, for example, three years (26). Vårdanalys' report was published in March 2015 and is based on TLV's work carried out in the years prior to this (26).

In the appropriation directions for 2016, TLV has been instructed to continue the government commission with economic evaluations of medical devices carried out according to the earlier government decision (No. S2013 / 7195 / FS). This includes presenting a plan for how products are selected as well as what selection criteria form the basis for selection, plus a legal analysis of the implications that union law and administrative procedure regulations regarding decisions and appealing against decisions have on its activities.

TLV can constitute that the government commission, which has been in operation since 2012, has now developed to the point that identified short-term improvement and establishment measures are implemented or under start up. Vårdanalys' evaluation confirmed this picture. TLV deems that in order to develop further, the commission needs to be made permanent. This is needed to create sustainability for ongoing development that is necessary

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<sup>3</sup> Efforts to improve care for people with chronic diseases, etc. An agreement between the Government and the Swedish Association of Local Authorities and Regions 2016

to respond to the demands and needs expressed by county councils and to achieve a sufficient impact. During 2016, TLV intends to further specify the necessary basis for continued operations with the aim of laying a sound foundation for a decision concerning a long-term sustainable commission.

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