Piecing the puzzle together

Getting a medical device reimbursed is critical for its market adoption. In Europe, the complex and highly fragmented reimbursement landscape presents itself as a major challenge to medtech companies of all sizes. In this report, IBI analyst Phil Greenfield offers a guide to piecing together the reimbursement puzzle and an overview of reimbursement in the five major EU markets

Speak to experts on medical device reimbursement in Europe, and a couple of things become clear. Firstly, the processes for gaining reimbursement are not homogeneous: there is a great deal of heterogeneity among countries in terms of healthcare policy, physician practices and costs, and how technologies are assessed, as well as great variation between different product types, in terms of the requirements for gaining reimbursement. Secondly, many manufacturers, particularly the smaller ones, fail to plan how they intend to gain reimbursement for their products early enough in the product lifecycle.

What's more, as a result of the heterogeneity, most generic reports on the subject of European reimbursement are of limited use to manufacturers, or, at worst, are meaningless.

However, there are some useful tools to help manufacturers. For example, case studies provide a useful way to learn about different product sectors, and there are some general rules that can be applied by companies when building a reimbursement strategy into their product lifecycles. Experts also predict that applying for, and gaining, reimbursement across Europe will become easier in future. This executive briefing is intended to provide a guide to some of the lessons that can be learned from others navigating the European reimbursement minefield.

A complex picture

Unlike with medical device regulation, there is no pan-European process for medical device reimbursement. Most countries use diagnosis related groups (DRGs) to set a price for a particular patient treatment, including the procedure and any products that are used in that procedure.

The authorities often use health technology assessment (HTA) to decide which products will be formally approved for use in the procedure, ensuring that only those medical devices shown to be clinically and economically effective are reimbursed.

However, the decision on which medical devices will qualify for reimbursement (and often what price will be paid) by the government or patient's health insurance provider is driven by national government healthcare policy. As a result, there is often considerable variation in the medical device reimbursement approval process and data requirements between different countries. Additionally, the processes can be subject to regular change, as countries reform their respective healthcare systems and budgets in line with their current policies. All products, however, must be CE marked before reimbursement is approved.

According to Corinne Lebourgeois, managing director of Swiss market access consulting firm MedC Partners, a lot of companies are still not fully aware of changes to reimbursement compared with the situation 10 years ago, when reimbursement was simpler. Now reimbursement is a major strategic issue that can determine the success or failure of a company.

One of the main changes over the past decade has been the emergence of the health technology assessment (HTA) agencies, which have opened all over Europe to determine what is needed to reimburse a product and put it on the market, says Ms Lebourgeois. "Historically pharma products had to prove effectiveness and devices had to demonstrate safety and functionality. That was the main philosophical difference." In other words, the past reimbursement for devices was determined by whether a product was CE marked; but because the CE mark also covers non-medical products, devices typically only had to show what they did, not how they affected health. Now HTAs are requesting effectiveness data; and how to assess effectiveness poses problems for manufacturers because they are not used to providing it.

What's more, there are considerable differences between national HTA systems. For example, the UK's National Institute for Clinical Excellence (NICE) was the first HTA body to rigorously assess scientific evidence. However, some believe that it has failed to adapt and is now seen as inflexible for device companies. In Germany, the Institute for Quality and Efficiency in Health Care (IQWIG, see below) is now seen as having one of the most progressive and sophisticated HTAs.

The considerable differences between how HTAs assess new products present a major problem for manufacturers, who potentially have to submit a variety of data in different forms before gaining reimbursement across the EU. In January 2010, the European Commission, in its exploratory process on the future of medical devices, revealed a consensus among industry as to the "lack of European vision" in relation to the measurement of value of medical devices and, in particular, to the differences in the use of HTA systems within and between EU member states.

The methodologies and the evidence requirements for the HTA processes, the European medtech industry believes, are more easily applied to pharmaceuticals and do not always sufficiently consider the specificities of medical devices, eg the importance of the learning curve of health professionals for the effective use of a product.

The assessment of the value of a medical device, the industry feels, often lacks a holistic approach, such that it does not always consider the whole clinical pathway and the full lifetime of a product.

"It is a challenge to take into account the impact of the different and variable clinical applications of relative importance of the same medical device. Other aspects such as non-monetary improvements linked to societal aspects (eg quality of life, reduced hospital stay for patients, social inclusion, etc) are rarely considered," said the industry consensus.

One issue is that the requirements for clinical evidence in order to obtain CE marking were not designed for HTA purposes and, therefore, emphasised the need for developing "standardised, predictable and common criteria for HTA methods appropriately designed for medical devices".

The problem remains that if a device satisfies HTA requirements in one country, it gives no guarantee that HTA agencies in other countries will also judge the device to be clinically and economically effective and recommend reimbursement. Ms Lebourgeois says: "To my knowledge, HTAs in different countries don't communicate enough with each other, although a NICE appraisal is recognised by Germany, France etc and vice versa. But no agencies are talking to each other in a formal way."

Comparative effectiveness

Ms Lebourgeois says she has also seen cases in France where reimbursement has been denied because clinical efficacy data were not "excellent" despite the French Supreme Health Authority (HAS), which has ultimate decision-making power over which medical procedures and products are reimbursed, saying the data were as good as those for other devices on the market. "Basically they were saying that they already have good devices on the market, they don't want to add more because they don't want to/can't afford to pay for the products. You now have to prove with comparative studies that your product is better."

There have also been cases of de-reimbursement, where the agency has refused to continue reimbursing a device.

Figure 1. Types of HTA model

Model	Characteristics	Countries
Integrated	One or more agencies operating in a national framework integrated within the decision making process	UK, France, Germany, Denmark, Sweden
Integrated	One or more agencies producing scientific HTA reports and appraisals to support decision making without explicit integration in decision making process	Norway, The Netherlands, Finland, Belgium
Federal	Different agencies operating at national, regional or provincial level	Spain
Network	Different agencies co-operating at national, regional, provincial level and local (organisational level) with a multilevel framework	Denmark, Italy

Source: adapted from presentation by Marco Marchetti, Unitàdi Valutazione delle Tecnologie Policlinico Universitario "Agostino Gemelli", Università Cattolica del Sacro Cuore., International Conference on Applied Health Economics and Mathematics, May 2010

For example, in France, HAS is reviewing the Tarif Interministeriel des Prestations Sanitaires (TIPS) – the former French reimbursement system – list product by product, brand by brand (it recently looked at urethral stents and hernia meshes). This process is also happening in Belgium, Germany and Switzerland, according to Ms Lebourgeois. "A similar thing happened in 1993 when CE marking was introduced – companies with products already on the market got CE marking but then a review had to prove safety and efficacy."

In the US, the FDA is going the same way with the comparative effectiveness process. There is the example of one company that filed for 510(k) clearance and tried to get a higher price for its product. However, the FDA and Centers for Medicare and Medicaid Services (CMS) talked to each other and as a result the CMS decided that the company could not get higher reimbursement for a product that was deemed to be equivalent to other, cheaper products.

A good example of how a company can fall foul of the increased focus on effectiveness, if it does not have a thorough reimbursement plan in place, is the case of Given Imaging's bid to gain French reimbursement for its PillCam capsule endoscope.

Case study – the French capsule endoscope saga

The following is from a presentation by Given Imaging at a meeting of the HAS in December 2009.

PillCam is a disruptive imaging technology that has had a tortuous regulatory path on its way to market.

It was CE marked in August 2001. The French regulatory process began in 2002, with the listing of the device on the LPPR (list of reimbursable products and procedures); and the creation of a new procedure within CCAM, the common classification of medical procedures.

The French society of digestive endoscopy sent the LPPR dossier to the CEPP, the products and services evaluation committee, in 2002.

In May 2003, CEPP confirmed the strong potential of the technique, and the need for more clinical trial data.

In June 2003, Given established a work programme based on CEPP's recommendations, getting the additional trial data in 2003 and securing reviews in many major publications. It sent the second dossier to CEPP in December 2004, only to have it summarily rejected in January 2005 as a result of a decree change (in December) stating that devices which do not remain in the body for at least 30 days cannot be listed on the LPPR. Result: 18 months of work and €60,000 wasted, no regulatory route and a legal vacuum.

In the meantime, the French DRGs (the T2A, a DRG-like scheme) and the HAS were formed. In September 2005, the latter took on the dossier. In May 2006, it reported that there was no ready reimbursement path for Pillcam. In June 2006, it transferred the dossier to UNCAM, where it stayed for 14 months awaiting attention. In September 2007, UNCAM sent the file to CHAP, the procedures reimbursement costing body, which accredited the "video capsule procedure", in December 2007.

A solution was at last at hand: in early 2008, the social security department and UNCAM said the device fell under the video capsule procedure. But there was then a wait until November 2008 until the wording of the decision was finalised and accepted, so the product could be introduced under the CCAM.

Given Imaging's criticisms of this long route to market

It is impossible to assess costing, there is a lack of transparency, and start-ups and SMEs are squeezed out, with R&D threatening to become concentrated among only a handful of big companies. Patients are denied access to new treatments; there is insufficient return on investment for the innovator (a company can work for seven years on a major technological advance only to see it fail); and delays in the cost benefit to the healthcare system.

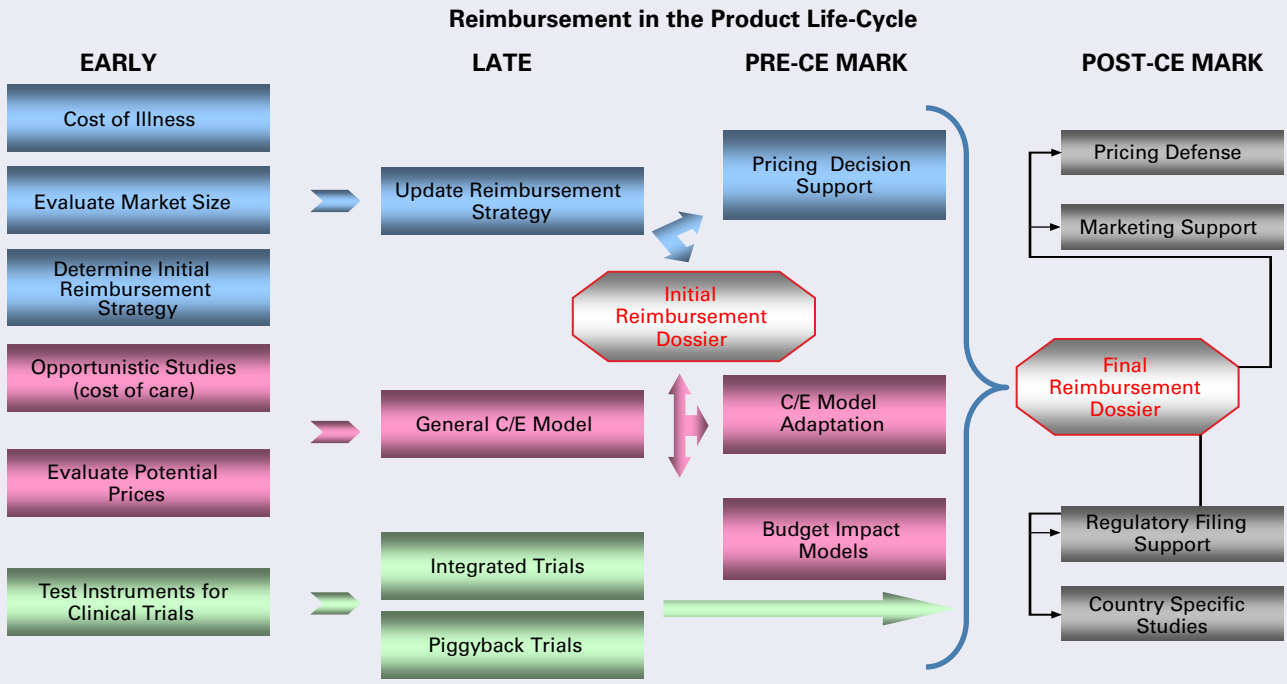
The proposal of Given Imaging's CEO is the creation of a document that states clearly which reimbursement path to take; and, if none exists for the product in question, the means by which this is to be addressed (and by whom). In short, he suggests a three-phase application procedure should be established, allowing the product to be integrated as a reimbursed product/service within five years:

- Phase 1: two years – the CE-marked device begins the necessary clinical trials for reimbursement (it is debatable whether clinical trials for reimbursement should be started before or after CE marking);
- Phase 2: two years – the device is accepted on a temporary/provisional basis by the HAS, which looks at possible application; and
- Phase 3: one year – HAS validates the product; tariffs are set by UNCAM.

Differences in clinical practice

Another problem for manufacturers is the fundamental differences in how patient care is delivered, such as whether through primary or specialist care. For example, the delivery of ophthalmology services is heterogeneous. Ms Lebourgeois explains: "In France, Spain and Italy, only ophthalmologists are able to touch patients' eyes, but in the UK, Germany and the Netherlands, an optometrist is allowed to work on the eye. This difference in who is the potential end-user for a device has major implications for reimbursement and means that the reimbursement approach will be 'cluster specific'."

Figure 2. The ideal timing of reimbursement steps in a product's life cycle



Source: Dr Jenifer Ehreth

Practical help for manufacturers

Dr Jenifer Ehreth set up the reimbursement team at Medtronic Europe and now runs a consultancy; working primarily with small companies with up to five products. She says: "The first thing I need is to know what clinical data they have – what scientific evidence do they have of the efficacy of a product? A lot of [small] companies don't do these scientific studies." She adds that this scientific evidence needs to be compared with what, at the time of application for reimbursement, they have to offer government (or a health insurance company). The data may need to be analysed in different ways, or additional data gathered, to help decide when the company can go for reimbursement. "You have to look at [the data] the same way as the government looks at it".

"If you want to charge a price greater than the competition then you will need to show a significant advantage in terms of clinical benefit or cost-saving. And you can't even begin these discussions unless you have the CE mark."

In the past, companies were totally ignorant of reimbursement timing. "This is still a big problem as they simply don't have the expertise. By the time they come to me it's often too late. The first conversation we have is usually depressing for them."

Figure 2 describes the ideal timing of different reimbursement steps in the life cycle of a product. It clearly demonstrates the need to integrate reimbursement and economic thinking into early development to avoid:

- Poor decisions about which products to develop
- Under or over-valuing the product
- Delays in getting access to the product

It also stresses the need to adapt the reimbursement and economic plans to new information obtained during product development to be able to respond to current payer needs.

The colour coding is to distinguish the activities that are dependent on each other from those that can be done separately.

While, the diagram is applicable to any health product where licensing and reimbursement are involved, the time-lines vary from product to product. For example, for medical devices, the time-line ranges between 2-5 years, whereas with pharmaceuticals, it is between 8-15 years.

The future

While the path to reimbursement has become more complex in recent years, the future looks to be brighter for companies. Dr Ehreth predicts greater homogeneity among European markets in the next few years. "Applying for reimbursement and decisions around pricing will be easier than today", she says. Dr Ehreth believes this will be driven by economic necessity and the fact that there is more information sharing, including the creation of a central HTA database, more informal meetings, learning from each other. "Five years ago the countries' [governments and HTAs] didn't talk to each other, but this is changing," she says.

Dr Ehreth continues: "At some point, maybe not in the next five years, but perhaps 10, there will be EU-wide guidance to HTA. This has been discussed by the HTA community. While there are certain pockets of expertise in countries, at the moment the backgrounds of those working in the HTAs don't allow them to have an educated discussion on technical parts of the guidance."

With reimbursement, homogeneity is much further down the line, says Dr Ehreth, as there are fundamental differences in the approaches by each country. Countries like the UK think there is a need for full assessment before a rational decision can be made to reimburse, she says, while in other countries, such as Germany, they say the product needs to be on the market for a while before the decision to reimburse can be made.

"There will be more and more articles [on reimbursement] over the coming years that will lead to standardisation.

I'm working on a book on device reimbursement and economics; when it comes out it will be used by companies as guidance. There is a lot of information in it on what expected in terms of clinical evidence."

Ms Lebourgeois agrees that there will be more homogeneity in reimbursement. "While in five years there will probably be little change in terms of more homogeneous reimbursement landscape, there may be a full implementation of a common HTA system. Spain used to have an HTA agency in each region; now it is looking at a national system. There is willingness for HTAs to collaborate at a European level. This would be very beneficial to manufacturers, as they could do an assessment in France and submit at European level for approval/acceptance across the EU. At the moment you can build the 'core dossier' but you have to customise for each country."

Ms Lebourgeois believes that DRGs will play a critical role in improving homogeneity and providing a benchmark for the cost of treatment of patients throughout Europe. "With DRGs, you have to ensure the definition of patient treatments is the same. For example, a consensus across Europe that varicose vein treatment requires 'x' amount of time to undertake, length of stay in hospital etc. However, the cost of a nurse of doctor will still be different across countries. There will also be a more homogeneous approach to coding."

"With the DRG system, the concept is the same, but the implementation is still country-specific. At least there will be a clear way to benchmark costs of treatment. At the moment, it costs around twice the amount to implant a drug eluting stent in Switzerland as it does in France. And there is a cost differential of 25-30% across Europe for all treatments."

A country-by-country summary of the reimbursement systems in main EU markets

Germany

Germany operates a dual health system with statutory health insurance (SHI) and private health insurance. All German residents are obliged to take either statutory health insurance or private health insurance. Almost 90% of the population is insured by the SHI system, with the remainder opting for private health insurance.

The reimbursement system is divided into two types: reimbursement of medical devices dispensed in the form of inpatient care (in hospitals and other health institutions); and outpatient care – reimbursement of medical devices prescribed by physicians through pharmacies and retail outlets to patients who are not receiving hospital care.

The reimbursement of medical devices dispensed to hospitalised patients is regulated by a DRG system. The introduction of this system in 2003 also saw the introduction of a special reimbursement process specifically developed for new health technologies.

In Germany, policymakers, regulatory authorities and the statutory health insurance funds are increasingly bringing medical devices under the HTA umbrella

The hospital receives a fixed amount that is set-up by the DRG system for the entire treatment of the patient. The DRG system does not set prices for the medical devices which are used for the treatment of the specific diagnosis covered by the DRG. Medical device prices are negotiated between the hospital and the respective medical device manufacturer according to the specific device used to treat the patient subject to the relevant DRG.

The reimbursement of all physician-performed out-patient care treatments is subject to a schedule (standardised assessment factor) which determines the content of all billable benefits. Benefits not listed in this schedule cannot be billed to the statutory health insurance system by health care professionals. The Joint Federal Committee (G-BA) has to determine whether a specific benefit is billable to the SHI prior to the benefit being discharged. Therefore, treatments which involve the use of a novel medical device but which are not listed in the Standardised Assessment Factor schedule cannot be billed to the SHI.

The German DRG system is open to novel devices which are not listed in the current DRG scheme. According to German trade group BVMed, there are several ways to include novel medical devices in the reimbursement scheme for hospitals to ensure that new medical devices can be used in hospitals without becoming bogged down in red tape. However, the application for the inclusion of a medical device as a new treatment should be filed as soon as possible, as the new treatment needs to be assessed prior to its embedding in a DRG. This assessment can be time-consuming and take up to three years depending on the treatment at stake. Nevertheless, the use of any novel technology (stem cells, for instance) is not restricted unless a negative decision regarding its efficacy has been made by the competent authorities.

SHI-reimbursable medical products must satisfy a number of minimum standards, such as CE-marking, information supporting product functional suitability, safety, quality, and – if necessary – medical or nursing care benefits, in order to be included in the therapeutic appliance schedule (Hilfsmittelverzeichnis) of approved medical devices, complied by the central SHI association. Medical devices included in this directory can then in principle be prescribed, with the cost being borne by the SHI funds.

A package of reforms to the Act on Medical Devices is intended to reduce bureaucracy and fostering increased transparency and deregulation within the reimbursement process.

So-called fixed amount groups exist for specific, easy-to-compare products. A maximum payable sum to which these aids can be reimbursed is set for these therapeutic appliances. The fixed amount groups concern only the following products: orthotics, hearing aids, incontinence aids, compression therapy aids, visual aids, and ostomy aids.

In Germany in particular, policymakers, regulatory authorities and the statutory health insurance funds are increasingly bringing medical devices under the HTA umbrella. IQWIG (the German Institute for Quality and Efficiency in Health Care), an executive arm of the G-BA, became a full HTA agency in 2010, assessing not only the benefits, but also the costs of drugs and devices.

There is one important factor in Germany that could put devices slightly ahead of drugs in the HTA arena in terms of the speed of assessment, and thus speed up the route to reimbursement. Whereas a drug is obliged to be the subject of clinical trials before it can be considered for pricing and reimbursement by the statutory health insurance funds, certain medical devices can simply skip this

ordeal. Germany operates a system of "permission with the right to ban" for medical devices in the hospital sector.

What this means is that an innovative medical device can be used in a hospital setting to treat a patient, without needing to undergo a clinical trial. Of course, it is not reimbursed by the statutory health system at this point and such devices are used on a case-by-case basis. Proponents of this scheme point out that it is an innovation driver, as new devices are not held back from the market due to trials. There are those who cite possible safety issues as a reason for more vigorous testing prior to the introduction of high-risk medical devices into the patient arena, but to date the system has served both the health service and the industry very well.

Manufacturers would do well to exploit this system by considering the use of a new device in a hospital setting as a clinical trial. If this attitude were adopted, the manufacturer and hospital could work together to generate data that could be used to support the device as it exits the hospital environment and is obliged to undergo HTA before it can be considered for reimbursement by the statutory health insurance funds.

This means that a device that appears for assessment in front of the G-BA and IQWiG could effectively have an advantage over a drug in a similar position and would perhaps enjoy a faster route towards reimbursement.

France

Recent changes to the French system seek to harmonise the arrangements for the public and private sectors, under the same scheme: the T2A. The French acronym for DRG is GHM, Groupe Homogene de Malades: a GHM describes the patient group. In most cases, one GHM corresponds to one GHS, Groupe Homogène de Séjour (a standard patient stay): the GHS represents the tariff of the GHM. Allocation to a GHM is mainly based on the diagnosis and on the existence of a medical or surgical procedure performed during the patient stay (if any).

Procedures and their tariffs are listed on the CCAM. CCAM is the common classification of medical acts; a medical procedure naming and charging system for both the public and private sectors. Products paid under CCAM are those bought by the physicians for their daily practice and include some of the larger medtech systems, like X-ray machines, for example. Other devices such as instruments bought by the hospital are paid on the GHS budget. CCAM is the common coding system for all physicians, but only private sector physicians get paid on the CCAM basis.

CCAM tariffs only apply to private physicians' activity to date, although the system is ultimately intended to be used also in the public healthcare sector.

An increasing number of procedures in the French private and public sectors, and in both the traditional hospital and "day hospital" (up to 48 hours) settings, rely on the case-mix healthcare accounting system. With this system, it is up to purchasers to make a decision about what products they will buy within their diagnosis-related group (GHM) budgets.

There are a number of very innovative, or very expensive, products which are paid for "en sus", or separately to the DRG system.

To receive reimbursement for these products that are on the "en sus" list, the products need to be registered on the LPPR, the list that historically was used to indicate products that could be reimbursed when used in the private sector, and that has now been whittled down to reflect the growing number of products that have been transferred and assumed under the GHM.

This means that the list of products which are paid for "en sus" in the context of the T2A case-mix payment system extends across both the public and private sectors.

The HAS has ultimate decision-making power over which medical procedures and products are reimbursed. It assesses which products and procedures benefit which patients, under what conditions they should be reimbursed and how they fit with other medical techniques.

A commission within the HAS, the CNEDIMTS, is responsible for the evaluation of medical devices. It assesses the medical benefit of an individual medical device and accords it with a reimbursement rating of 1 to 6 according to its perceived value and innovation, with 1 and 2 reflecting innovative products with the highest perceived value, as part of the registration process.

If these level 1 and 2 technologies also involve a new procedure, they are assessed by the CEAP, a commission that provides scientific opinion concerning the definition of medical procedures, to assess their utility.

Once this is complete, the economic committee for healthcare products, the CEPS, establishes a tariff for the product, and the sickness insurance association, the CNAM, determines the tariff for the procedure and whether, when and under what circumstances the product and new procedures should be paid for, following discussions with the relevant doctors associations.

This can be a very lengthy procedure. It can often take between three to five years to make a decision. This can spell ruin for some companies, and severely disable others, according to a recent article in *Clinica*. For example, Lyon-based company EDAP has been waiting five years to have its ultrasound device for prostate treatment reimbursed within the context of the relevant procedure (www.clinica.co.uk, 20 July 2010). This company has been able to keep going, thanks to sales of its lithotripsy products, although these devices have not been spared either; there has been a 30% cut in the reimbursement levels for lithotripsy.

UK

In the UK, there is no positive reimbursement list onto which a medical device has to be accepted before it can be bought by either the public or private sector, with the exception of those products that are borderline substances or are drug/device combinations and fall under the Drug Tariff. The Drug Tariff applies to prescriptions in the community and also includes drugs. Otherwise it is sufficient for a device to be CE-marked. NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

NICE does not approve devices for listing. Its Technology Appraisals Programme looks at how well the technology works compared with standard National Health Service (NHS) practice and how much a given course of action costs compared to standard practice in the NHS, and measures the cost per quality adjusted life year. The Technology Appraisals Programme considers drugs,

devices, and biotech, and if it approves the use of a device, funding of that device is mandatory. However there is in practice no formal method for requiring NICE to look at any technology, and it only looks at a limited number of products, so most drugs and devices are not considered by NICE.

Apart from NICE guidance, there is no official barrier or procedure for assisting acceptance of innovative products in the UK market

Meanwhile, its Interventional Procedure Programme (IPP) looks at the efficacy and safety for patients of innovative procedures and medical technologies when these form an integral part of the procedure (which is quite common since many new procedures become possible because there is a new device). It does not look at cost-effectiveness, or make statements about the comparative effectiveness of procedures (unlike the technology appraisals programme which does look at cost effectiveness), nor suggest which hospitals should perform which procedures.

The focus of the IPP is whether the procedures and technologies are safe and efficacious for routine use in the NHS with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately.

The IPP has a significant impact on which procedures can be carried out within the NHS, which clearly has a bearing on the devices that are needed, but unlike Technology Appraisals, this does not bring with it a requirement for obligatory funding. But within those procedures, whether a product is actually bought or not will be more influenced by individual clinician choice, by guidance to clinicians, and by the amount that is allocated as a tariff to each Healthcare Resource Group (HRG) under the Payment by Results (PbR) scheme, effectively a diagnosis-related group scheme.

NICE technology approvals are still few and far between, and not available for most technologies.

The private sector tends to follow the lead given by the NHS, for example by relying on NICE guidance. In short, UK decisions regarding medical device purchasing policies are neither highly transparent nor formal.

Apart from NICE guidance, there is no official barrier or procedure for assisting acceptance of innovative products in the UK market. The process is market-driven. Indeed, there is a general professional obligation not to introduce a procedure outside a clinical trial unless there is good evidence as to its effectiveness and safety. The NICE IPP programme underpins this 'clinical governance' system and hospitals cannot have reimbursement under PbR unless an appropriate HRG can be identified. And an HRG can only be identified if there is an appropriate procedure code. If the device involves a new procedure, the manufacturer must apply for a new code.

The Department of Health in England will consider extending its "innovation pass" scheme to medical devices "at an appropriate time in the future". The scheme is currently applicable only to promising new medicines.

Italy

The Servizio Sanitario Nazionale (SSN) – Italy's national healthcare system – provides healthcare coverage to the Italian population. Although it is the responsibility of the Ministry of Health, the system is decentralised, resulting in three levels:

•National level: The Ministry of Health formulates a healthcare plan (Piano Sanitario Nazionale, PSN) every three years that determines healthcare policies.

•Regional level: 20 regions implement the PSN with their own resources and can adjust to region-specific needs. As a consequence, geographic disparity in terms of healthcare access or the level of co-payments exists.

•Local level: Local health units (Azienda Sanitaria Locale) provide the health care services – eg primary medical services and co-ordinate all non-emergency admissions to public hospitals.

Medical devices in Italy are not subject to pricing and reimbursement negotiation at the central level, thus funding must be queried at the local level, according to a briefing document from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (see http://www.ispor.org/htaroadmaps/Italy/Italy_MDD.asp).

The decision-makers in reimbursement are:

- Agenzie Sanitaria Regionale (regional health agencies): their role is to plan hospital and ambulatory resources in the region according to population needs, to implement national health plans at regional level, to contract with hospitals for optimising provision of health care to the population and negotiate hospital budgets for the part not financed by the DRGs. Part of the contracts are related to appropriate utilisation of costly drugs and medicals devices. Regional Health Agencies may also play a role in defining appropriate funding (extra payments) for expensive medical devices, whose technical value is supported by adequate clinical and economic evidence, which may not be sufficiently covered by the specific DRG tariff.
- Commissione Regionale Dispositivi Medici (regional medical device committees). According to local specificities, the regional and local units may envisage the need to set up technical committees with the aim to evaluate devices and issue recommendations on their use.
- Commissione Prontuario Terapeutico Ospedaliero (CPTOs). These are hospital drug committees in all hospitals that monitor drug prescription consumption and delivery, to decide which drugs are on the hospital formulary. For some, but not all, medical devices CPTOs monitor use and decide on listing/purchase of medical devices. As the cost of devices falls into the hospital budget, and with the hospital being funded through DRG tariffs, the responsibility of the local committees in the acquisition process may be much greater for devices, but this largely depends by regional legislation.

CE marking ensures that medical devices are in accordance with these European directives and represents the only mandatory step to market access in Italy. However, as this does not guarantee any specific SSN reimbursement, funding of medical devices is related to the capability of local providers to effectively manage hospital admissions or outpatient treatments within the predetermined tariffs.

According to the ISPOR, funding of medical devices appears

largely unregulated and purchase decisions are in practice left to individual providers (hospital committees and managers).

If a new device is used in the course of a new procedure (ie a procedure for which diagnosis and/or procedure reimbursement codes are not available) an appropriate code that most closely resembles the characteristics of the new procedure, especially in terms of resources consumption, is used; this may be done by representatives of a scientific society, group of physicians, or patient association or manufacturers and should be done in collaboration with the regions. Afterwards, the new procedure may be listed in the National Formulary List at the time of the next revision (for DRGs the List should be updated by the Ministry every two years).

Assobiomedica has rejected the idea of either applying single reference prices to devices, or of centralising purchasing

If the new device is used as part of an existing procedure, the willingness of purchasers to fully adopt the new technology will ultimately rest on its price level; in fact, depending on the weight of the price, versus the DRG or Ambulatory tariff, two funding mechanisms would eventually apply:

Since January 2006, diagnoses and procedures are coded using the Italian version of the US 2002 ICD-9-CM classification, 9th revision, which contains a total of 15,327 codes: 11,745 codes for diagnoses and 3,582 for procedures. As a result of this update, the current list of DRGs contains a total of 521 DRG codes, 506 of which are operative.

It is very difficult to make changes to the Italian DRG list at a national level. Modification at the regional level is, however, possible. If regions add new procedure codes to reflect the uptake of new technologies in their territories, they can either increase the corresponding DRG tariff or allow extra-DRG reimbursement. In all cases, these additional costs must be covered by the regional budget and cannot be passed onto the SSN.

This means that a manufacturer wishing to introduce a new technology must consider the regional DRG listings.

The Italian medtech industry has advocated increasing the cost-efficiency of the health system and the Italian government has announced austerity measures worth €24bn over 2011-12, or about 1.6% of GDP. As a result there is a major drive to make medical device purchasing more cost-effective. This may include a greater focus reference pricing and centralised purchasing.

Italian trade association Assobiomedica has rejected the idea of either applying single reference prices to devices, or of centralising purchasing. "It has finally become clearly evident [that] reference prices, purchase centralisation and any excessive attempt to save at any cost, are pointless," according to the association.

"Without careful planning, [centralised purchasing] could do great harm. In general terms, the tendering process must at least guarantee complete accessibility to all players," it added. "Average unit prices are not valid indicators of cost, and can actually create distortions of the market".

"We must therefore accept as inevitable that in order to guarantee appropriate care, we must first define the diagnostic and therapeutic pathways involved," said Dr Fracassi. "Only in such a system can health technology assessment [HTA] deliver its full potential.

Spain

Spain consists of 17 autonomous regions with their own regional health services and which are responsible for the health care management within their territory. The national ministry of health has health care management powers for Ceuta and Melilla (two autonomous cities), through the National Health Management Institute.

The national health care basket includes all services, procedures and technologies that all autonomous regions must provide. In addition to this, an autonomous region can choose to add extra services, technologies or procedures to their own regional health care basket. These extra services must be financed by the regions themselves.

The funds needed for the public health care system are mainly raised by general taxation (94%) and are included in the regions' general budgets. The system offers full coverage to all Spanish citizens. However, for some services such as pharmaceuticals and prostheses the patient is charged a co-payment. In 2007 public health care expenditures amounted to €60bn and total health care expenditures was 8.5% of GDP.

Every year the national ministry of health publishes an updated DRG list, including cost weights and tariffs for the specific DRGs. This list is however not used for the overall reimbursement and funding of public hospitals. Instead public hospitals are mainly funded by global budgets. Since health care is regionalised the funding mechanisms can differ from region to region. In Andalusia for example, DRGs are an important factor when negotiating the allowed annual growth of a hospital's budget.

In Spain, DRGs remain mainly a management tool and are not the main basis of hospital funding.

The national Spanish hospital activity recording system (CMBD) allows documentation of cases using ICD-9-CM diagnosis and procedure codes, and subsequent grouping of these episodes into the 653 DRG codes currently in use.

Until the end of 2005 coding was done using version 4 of the Spanish ICD-9 coding manual. Version 5 of the manual was due for implementation in 2006. An updated coding manual is now available from the Ministry of Health (the body responsible for managing the coding system), but full implementation of v5 in public and private sector hospitals is still ongoing.

Coverage of inpatient episodes is now relatively complete and consistent, although there are still concerns regarding the accuracy of procedure coding. By 1998, 97% of all public hospital inpatient episodes were covered by the system, as well as approximately 25% of private hospital inpatient episodes. Data from the autonomous communities (ACs) are forwarded to the Ministry of Health. However, coverage of outpatient activity, ambulatory surgery and other day hospital episodes such as chemo- or radiotherapy sessions remains erratic, and varies widely from one AC to another.

In addition, two similar types of DRG coding system are used for inpatient activity, but they are considered sufficiently close to enable national activity compilation. This was last undertaken in 2002, using the full CMDB, Configuration Management DataBase, dataset from 1999. Subsequently, national activity data have been made available only in the form of basic statistics by DRGs.

Recruiting the right reimbursement professionals

For companies with the resources to recruit their own reimbursement staff, the challenge is to find professional economists who are able to communicate on the same wavelength as government officials and private insurers. Clinica spoke to Gerard Fulconis of headhunting firm HTI-Paris, and former reimbursement specialist for Medtronic, about the specific requirements for the role.

"The basic requirement is a degree in health economics and the ability to size all the components of the function. Also, membership of ISPOR, the professional body, is essential for anyone serious about reimbursement and health economics. It has 8,000 members, mostly from an economics background. All the top guys have been part of ISPOR. After gaining a degree, people normally start as a junior reimbursement exec, then given country-level responsibility, which expands to groups of EU countries, then EU-wide."

He continues: "When I first talked to Medtronic Europe in 2000, they had no-one in reimbursement, only regulatory affairs people. Jenifer [Ehreth] started in 2000 and began to staff it properly and now it has moved to 15-20 people. This gives you an idea of the speed at which a company has taken the necessary steps. This is more of a strategic approach to market success. Medtronic copied Johnson & Johnson, which was really the first to apply health economics in the device area due to its affiliation with the pharmaceutical industry, the early adopter. I know of one very famous medtech company that still does not have a reimbursement person. Instead, they rely on a country-specific regulatory affairs or country manager to make reimbursement decisions. Small companies tend to go through consultants.

"More companies are starting to have in-house reimbursement/health economics professionals. We placed around 10 last year. Timing of decision to set up internal group depends on number of products – the trend is to claim that very early in the clinical process you incorporate reimbursement," (ie together with safety, efficacy, security, evidence of quality, include fundamental health economics in that stage, not after approval).

"There is a big difference between pharma and medtech – in pharma, you normally have a junior person who can work their way up in the organisation. In medtech, the person has to take full responsibility for the product direction. People from a marketing background don't tend to do well in reimbursement roles. You need someone with the right cultural background. Experts in countries talk to health agencies. The agency guys have the same educational background as the reimbursement people in the private sector; they challenge the reimbursement guy with difficult questions, based on their involvement in a number of files. Therefore companies need to recruit the best people to work in this environment – the negotiation on an approval of a concept on the ability to pay takes place between two experts on the same subject. A pharmacoeconomics degree or equivalent is crucial, hence a marketing background not ideal."

Phil Greenfield is a principal analyst at Informa Business Information, the publisher of Clinica Medtech Intelligence.