ADI Medical

Healthcare Systems and Reimbursement for Medical Devices in Europe

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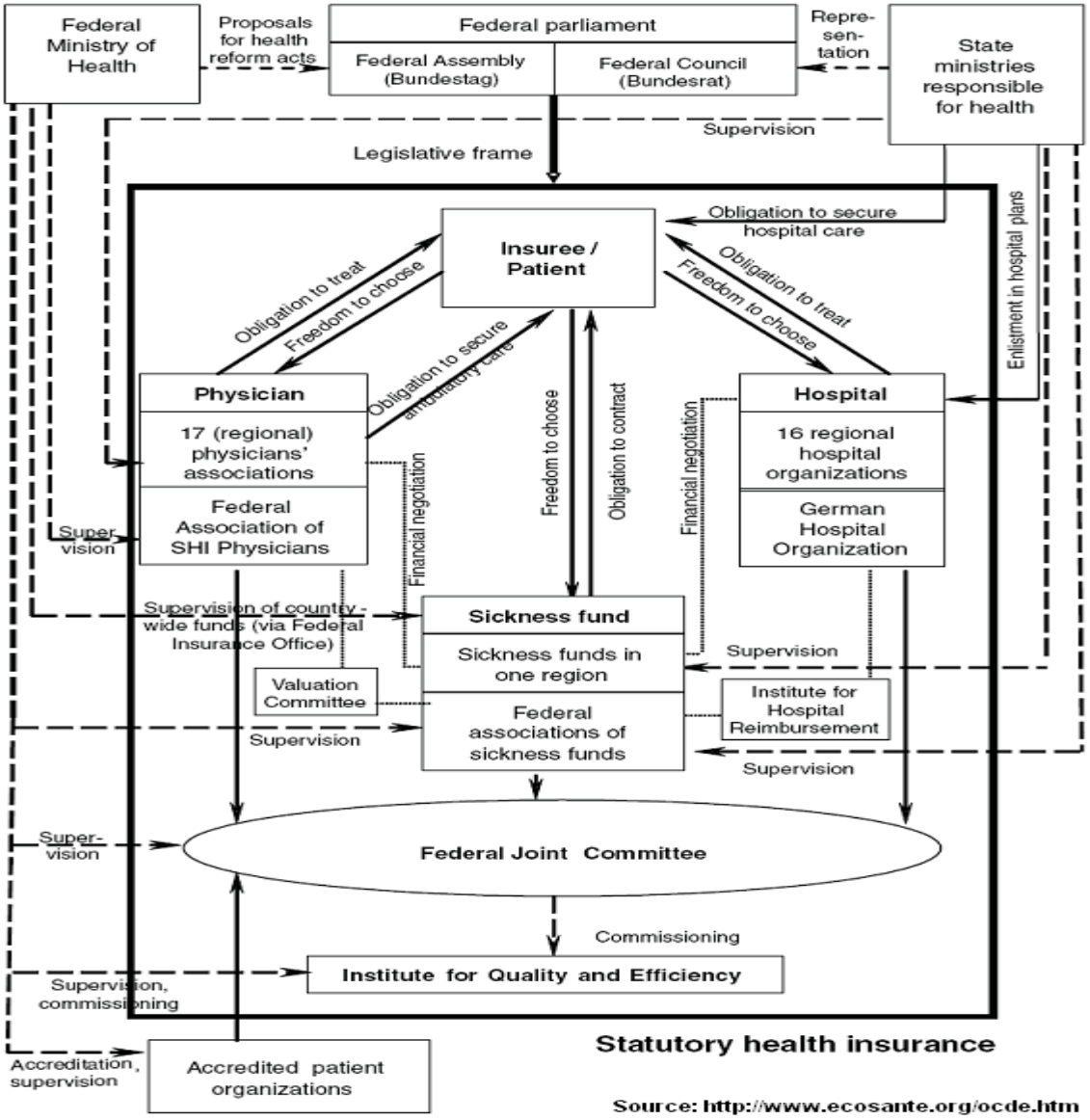
1. Introduction

The European Union currently consists of 27 member states, with recent inclusion of Eastern European countries and the Baltic States; additionally Cyprus and Malta join Greece from the south of Europe.

Add to this the non EU, advanced markets of Norway and Switzerland, together with the original and added to members since the inception of the community and the initial 6 members in 1950 is the basis of this report. Focus is on Healthcare systems and particularly relevant to the markets within Europe for Medical Devices.

3.1 Germany

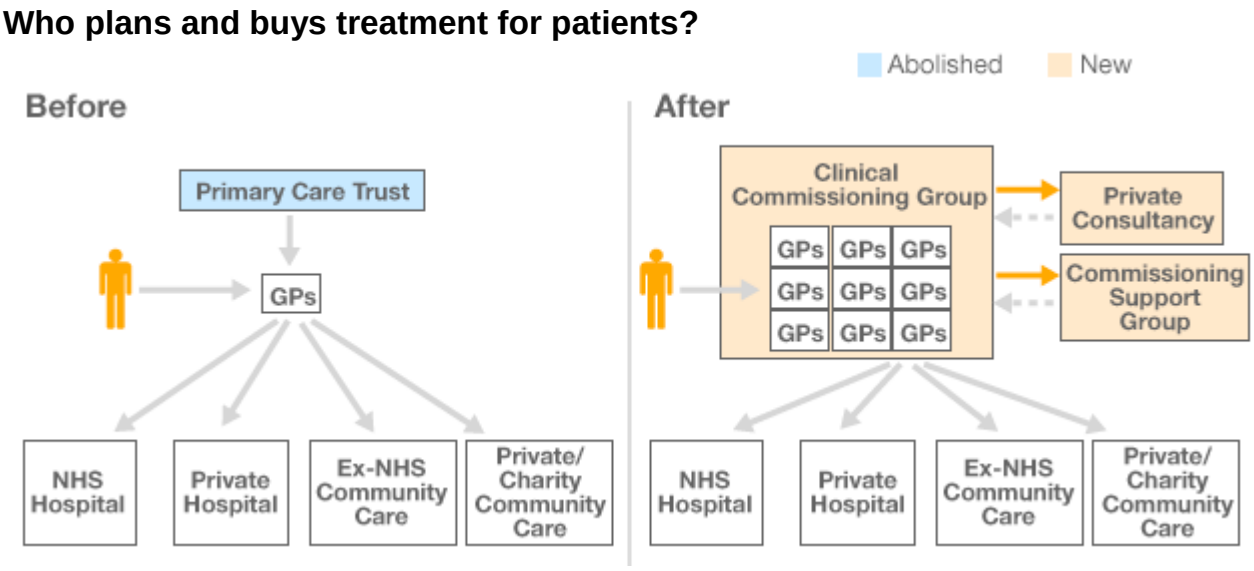
Germany has Europe's oldest universal health care system, with origins dating back to Otto von Bismarck's Social legislation, which included the Health Insurance Bill of 1883, Accident Insurance Bill of 1884, and Old Age and Disability Insurance Bill of 1889. As mandatory health insurance, these bills originally applied only to low-income workers and certain government employees; their coverage, and that of subsequent legislation gradually expanded to cover virtually the entire population.



3.3 UK

The NHS provides the majority of healthcare in England, including primary care, in-patient care, long-term healthcare, ophthalmology and dentistry. The National Health Service Act 1946 came into effect on 5 July 1948. Private health care has continued parallel to the NHS, paid for largely by private insurance: it is used by about 8% of the population, generally as an add-on to NHS services. In the first decade of the 21st century the private sector started to be increasingly used by the NHS to increase capacity. According to the BMA a large proportion of the public opposed this move.

The NHS is largely funded from general taxation (including a proportion from National Insurance payments). The UK government department responsible for the NHS is the Department of Health, headed by the Secretary of State for Health. Most of the expenditure of The Department of Health ($153 billion in 2008-9) is spent on the NHS.



2. Reimbursement Systems

Unlike medical device regulation, there is no pan-European process for medical device reimbursement. Most countries use a system of Diagnosis Related Groups (DRGs) to set a price for a particular medical procedure, including any products that will be used in that procedure.

The authorities 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 concerning which medical devices will qualify for reimbursement (and often also what price will be paid) by the government or patient's health insurance provider is driven by local government health care policy. As such, there can be 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 health-care systems and budgets in line with their current policies.

The analysis of reimbursement policies in respective countries is therefore critical to successful marketing strategy implementation for medical device manufacturers and here we review the basis of systems for each of the countries.

4.4 Italy

In Italy, the general conditions of the reimbursement system are established on a national level and implemented at a regional level by governmental bodies. When marketing authorization is granted either by the European Medicines Agency (EMEA) or the Italian Medicine Agency AIFA (Agenzia Italiana del Farmaco), the company may apply for reimbursement on the National Pharmaceutical Formulary PFN (Prontuario Farmaceutico Nazionale). A product can be assigned to Class A, H or C.

- Class A includes essential products and those intended for chronic diseases and are fully reimbursed by the NHS.
- Class H includes products that are only fully reimbursed in the hospital
- Class C includes other products which do not have the characteristics of Class A and are not reimbursed.

Besides the possibility to apply for a price premium for an innovative product, recently a new ranking system has been introduced for these types of products. First, AIFA will allocate the product into one of three classes (in decreasing order of importance):

I. Treatments for serious diseases - those which cause death, require hospitalisation or endanger life or permanent disability (e.g. neoplastic diseases, Parkinson's disease, AIDS).
II. Treatments that reduce or eliminate the risk of serious disease (e.g. hypertension, obesity and osteoporosis).
III. Treatments for non-serious diseases (e.g. allergic rhinitis).

For each of the three above classes, the degree of innovation will be investigated, looking 1) availability of existing products and 2) extent of therapeutic benefit. Subsequently, scores will be allocated for the availability of pre-existing treatments:

A. Drugs, Devices, Procedures for the treatment of diseases with no adequate treatment to date (this is the case of many orphan drugs for the treatment of rare diseases) or aimed at sub-groups of patients with absolute contraindications for using the drugs already on the market and for whom the new drugs represent the only feasible therapeutic option;
B. Drugs, Devices, Procedures designed for the treatment of diseases in which sub-groups of patients are resistant or non-responders to first line therapy (this is the case of anti-HIV drugs and some anticancer drugs);
C. Drugs, Devices, Procedures for the treatment of diseases for which recognized treatments already exist.

In the case of C-grouping (sufficient treatment alternatives already exists), a product will be allocated to one of the below 3 subgroups:

- C1. Products offering better safety and efficacy or a better pharmacokinetic profile.
- C2. Products that represent a pharmacological innovation - such as a new method of action - but no improvement over existing therapies.
- C3. Products offering a technological innovation but not a therapeutic advantage over existing products.

Then, when the extent of a new treatment's therapeutic benefit is considered, AIFA looks at principal and surrogate clinical endpoints and uses three classifications:

A. Major benefits on clinical end-points (reduction of mortality and morbidity) or on validated surrogate end-points

B. Partial benefit on the disease (clinical end-points or validated surrogate end-points) or limited evidence of a major benefit (non-conclusive results).
C. Minor or temporary benefit on some aspects of the disease (for example, partial symptomatic relief in a serious disease).

Scores on each of these scales are combined to determine whether a product represents an important, moderate or modest therapeutic innovation.

On top, the authorities can decide to put restrictions in place for certain products or product classes, which are known as “note AIFA” (“note CUF” in the past).

If a manufacturer seeks for reimbursement, the price for the product will be set through a negotiation between the manufacturer and the Pricing and Reimbursement Committee CPR (Comitato Prezzi e Rimborso). Among criteria used during the negotiations are:

- Cost-effectiveness for pharmaceuticals where no effective therapy exists
- Risk-benefit ratio compared to alternative pharmaceuticals for that indication
- Therapy costs per day in comparison to products of the same efficacy
- Evaluation of the economic impact on the national health system
- Estimated market share of the new pharmaceutical
- Prices and consumption data in European countries

The prices for products included in category C (non-reimbursable by the SSN) are free.

According to the Directive 89/105/EEG, the pricing & reimbursement process should not take longer than 180 days. However, various studies in the past years indicated that it is not unusual that it takes the Italian authorities longer to get to a decision.

Although the Italian healthcare system is decentralized, pricing & reimbursement of products is mainly decided on the national level and published in the official journal (Gazetta officale). Regions, however, can decide upon patient copayments resulting in price difference of devices for patients across the country.

The main problem that medical device companies have to face in Italy is that the Italian national health service has been consciously and markedly underfinanced for many years and yearly deficits are paid slowly and partially. This delay of payments gives rise to stressful relationships between the public administration and suppliers. Shows the trend in outstanding payments from January 2000 to May 2006, according to data collected by Assobiomedica

from 37 companies; the payment terms have progressively increased, reaching almost 350 days in 2006.

In May 2006 the new Government took power and a significant debate has begun between the Government and the regions on how to deal with the financial gap that has opened up. But, in view of the financial situation in Italy, a solution seems remote.

4.6 Sweden, Denmark

Sweden

Reimbursement for devices established in the Swedish market follows the following pathways:

Decision makers and influencers

Health Technology Assessment Organization
Statens beredning för medicinsk utvärdering (SBU): Swedish Council on Technology Assessment in Health Care

Organizations who determine reimbursement
Tandvårds- och läkemedelsförmånsverket (TLV): Dental and Pharmaceutical Benefits Board **MPA:** Medical Products Agency

Decision making process:

The HTA to support reimbursement decisions is conducted by an expert board at TLV with advice from a board from the 18 county councils. The county councils provide health care, are responsible for the local health care budget and conduct HTA for recommending the device to local hoapitals and formularies.

Recommendations from the National Board of Health and Welfare, the Swedish Council on Technology Assessment in Health Care (SBU) and the Medical Product Agency and other experts may also be consulted.
The National Corporation of Swedish Pharmacies is the distributor of primary care devices and provides some public information about the therapeutic use of drugs.
In Sweden, the key organization involved in Reimbursement and Pricing processes is the Dental and Pharmaceutical Benefits Board (Tandvårds- och läkemedelsförmånsverket), or the TLV, formerly the Pharmaceutical Benefits (Läkemedelsförmånsnämnden). TLV is an

independent government agency established in 2002 and is most commonly referred to by its previous Swedish acronym LFN.

TLV makes national pricing and reimbursement decisions on which pharmaceutical and health technology products should be covered by the Pharmaceutical Benefit Scheme. The decisions pertain to primary, secondary and out-patient care. Reimbursement decisions made by the TLV at a national level are mandatory and are therefore always adopted at the local level by the county councils. However the degree and rate of adoption may vary between counties due to individual budget planning mechanisms, differing interpretation of TLV recommendations, or variable access to specialist physicians. Budget planning, health economic modelling and cost-effectiveness evidence are therefore important at the local level as well as the national level. However, device companies can chose to seek coverage via local county councils or through the TLV.

In order for a product to be reimbursed as part of the national Pharmaceutical Benefit Scheme, the TLV must approve its inclusion. However, if TLV rejects a device at the national level, a county council may still decide to fund it, as long as specific criteria are met (e.g. if a cost-effective treatment fulfils an unmet need, in a severe disease, where there are only a few patients who have no other treatment alternatives). Furthermore, patients can opt to pay for devices privately that are not reimbursed by the National Health Service.

TLV does not negotiate on the price of products; the company has to apply for reimbursement at a proposed price. The decision by TLV is thus a joint reimbursement and price decision.

TLV has a remit to review all newly licensed prescribed products however, it is currently also conducting a review of the entire list of products that were eligible for reimbursement when the new Pharmaceutical Benefits Scheme came into force in October 2002. TLV also decides on what dental care ought to be covered by the society, at which cost. If a submission is rejected, the manufacturer may re-submit with a different drug price or with new evidence, however the new submission will enter the process from the beginning, potentially delaying market access. The Swedish government has requested that TLV should aim to announce reimbursement decisions within 120 days of submission.

The Medical Products Agency (Läkemedelsverket) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing, and sale of pharmaceuticals and other medicinal products. MPA is primarily involved in the regulatory process of some drugs and interventions. In cases where the MPA has been involved in the regulatory decision, they produce a product monograph detailing the effectiveness and safety

of the product. MPA has no involvement in the pricing and reimbursement process of a product; merely it's safety and efficacy, or the use of the product in practice.

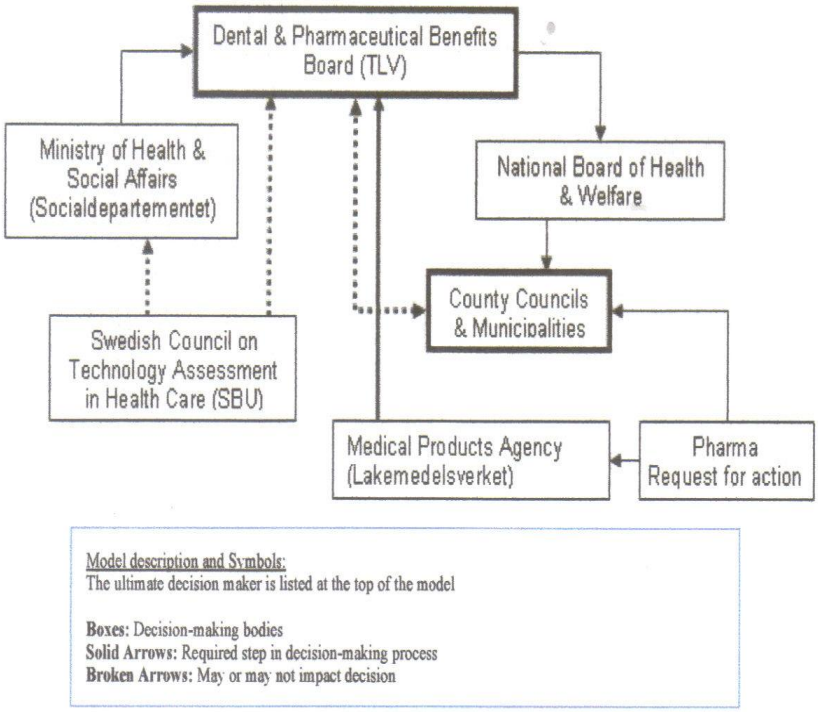


Figure 1 - Reimbursement Processes, Sweden

5.3 Summary

This report demonstrates the importance of understanding the differences, nuances and complexities of European Healthcare. The important final points to note are:

- Preparation and ensuring compliance with the latest introductions to the Medical Devices Directives
- CE Mark attainment and compliance is only the start of the marketing process

- Healthcare and medical device technology continues to evolve and develop at a fast pace. Individual and collective governments are increasingly unable or unwilling to support new introductions without clear cost benefit assessments
- To this end, Health Technology Assessment is driving everything
- Opportunities do and always will exist in Europe for the marketing of medical devices that benefit healthcare. Understanding the systems, requirements and constraints of individual countries will benefit supplier and lead to more cost effective product marketing and introductions.