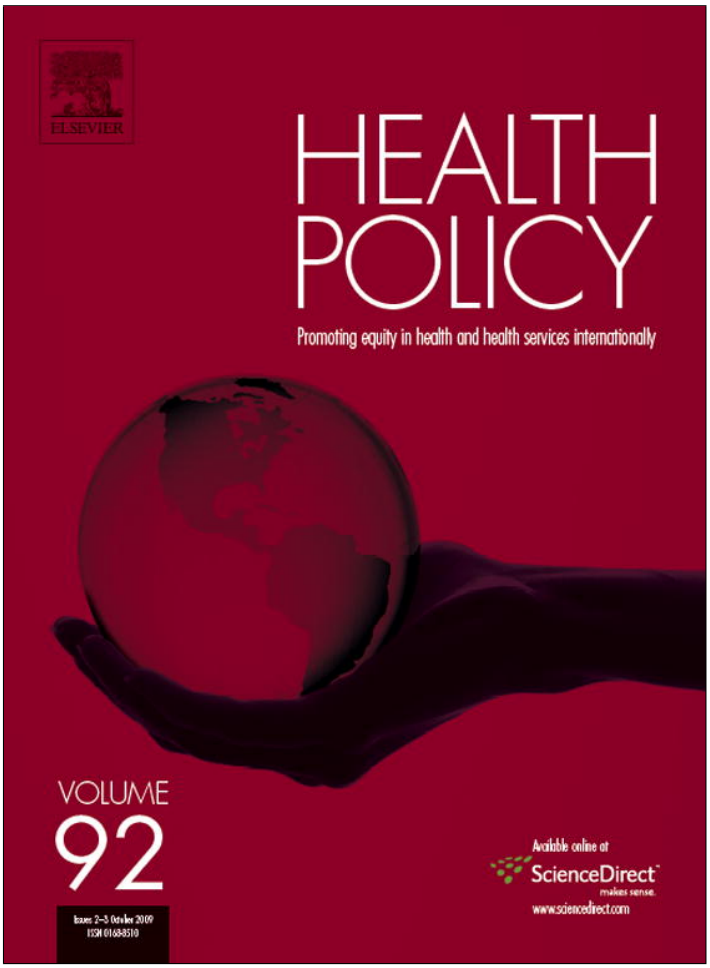

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# Balancing adoption and affordability of medical devices in Europe

Jonas Schreyögg[a,b,c,*], Michael Bäumler[b], Reinhard Busse[b]

[a] Department for Health Services Management, Munich University, Schackstr. 4, 80997 Munich, Germany
[b] Department for Health Care Management, Berlin University of Technology, Germany
[c] Helmholtz Zentrum München, P.O. Box 1129, 85758 Neuherberg, Germany

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ABSTRACT

Dramatic increases in health expenditures have led to a substantial number of regulatory interventions in the markets for devices over the last years. However, little attention has been paid thus far to the regulation of medical devices and its effects. This article explores the policies pursued by European countries to find the right balance between improving access to new medical devices and restricting market forces to contain costs and ensure affordability. We outline the medical device policies of the four European countries with the largest expenditures on devices: Germany, France, Italy, and the UK. Subsequently, we discuss how these policies attempt to balance technological adoption and affordability by illustrating two case studies from Italy and Germany. We find that reference prices, if defined as maximum reimbursement levels, can help to achieve balance, because they are supposed to contain costs effectively, but do not necessarily act as a hurdle for the adoption of innovations. We also find that policy tools that encourage technological adoption should be used carefully since the benefits of a new technology are often difficult to predict. Finally, we draw a number of policy implications based on our observations.



There is broad evidence that access to preventive and therapeutic health interventions is associated with the dramatic improvements in life expectancy observed in industrialized nations in recent decades [1–3]. At the same time, it cannot be denied that technological change has accounted for a large part of health expenditure increases in Europe and the United States during this same period. Numerous studies in Europe and the US have concluded that technological change related to medical devices and pharmaceuticals is a much stronger driver of health spending growth than the trend towards aging societies [4,5]. Indeed, dramatic increases in health expenditures have led to a substantial number of regulatory interventions in the markets for devices and pharmaceuticals. However, although numerous studies have analyzed regulatory interventions aimed at containing pharmaceutical spending, little attention has been paid thus far to the regulation of medical devices and its effects [6–8].

This article explores the policies pursued by European countries to find the right balance between improving access to new medical devices and restricting market forces to contain costs and ensure affordability. The aim of this article is to describe and discuss current policies for regulating devices in Europe. To do so, we first outline the medical device policies of the four European countries with the largest expenditures on devices (Table 1): Germany, France, Italy, and the UK. These four countries are exemplary of the two most common types of healthcare systems in Europe: (1) social health insurance (SHI) systems, like those in Germany and France, that are based on mandatory payroll deductions and matching employer contributions and (2) tax-financed systems like those in Italy or the UK. Subsequently, we compare the policy approaches in Europe to similar policies in the US and discuss how policies of European countries attempt to balance technological adoption

* Corresponding author. Tel.: +49 89 2180 3845; fax: +49 89 2180 16547.
*E-mail address:* schreyoegg@bwl.lmu.de (J. Schreyögg).

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**Table 1**
Total health expenditures (THE) and expenditures on medical devices (EMD), in absolute numbers and as percentages of gross domestic product (GDP) in 2003/2004.

| Country | THE (billion €) | THE as % of GDP | EMT (billion €) | EMT as % of THE | EMT as % of GDP |
|---|---|---|---|---|---|
| Europe total/average | 1034.4 | 8.7 | 63.6 | 6.3 | 0.5 |
| Germany | 232.2 | 10.3 | 20.0 | 8.6 | 0.9 |
| France | 172.6 | 10.5 | 10.0 | 5.8 | 0.6 |
| Italy | 126.0 | 8.8 | 7.0 | 5.6 | 0.5 |
| UK | 148.3 | 8.4 | 6.7 | 4.5 | 0.4 |
| Spain | 67.3 | 7.4 | 5.5 | 8.2 | 0.6 |
| Netherlands | 44.7 | 8.9 | 2.5 | 5.6 | 0.5 |
| Switzerland | 11.6 | 11.6 | 1.6 | 4.7 | 0.5 |
| Sweden | 25.5 | 8.9 | 1.3 | 5.2 | 0.5 |
| Denmark | 17.6 | 8.5 | 1.0 | 5.7 | 0.5 |
| Norway | 21.9 | 9.2 | 1.0 | 4.6 | 0.4 |
| Belgium | 27.6 | 9.2 | 0.9 | 3.3 | 0.3 |
| Poland | 12.6 | 6.5 | 0.9 | 6.9 | 0.4 |
| Austria | 22.6 | 9.1 | 0.8 | 3.7 | 0.3 |
| USA | 1440.5 | 15.3 | 79.4 | 5.5 | 0.8 |

*Source*: Calculations based on OECD Health Data 2006 and Eucomed "Competitiveness and Innovativeness of the European Medical Technology Industry. Evaluation of the Survey Results," May 2007, http://www.eucomed.be/sitecore/shell/Controls/Rich%20Text%20Editor/~/media/pdf/tl/2007/portal/publications/compsurvey.ashx (accessed 28 April 2008).

and affordability. Finally, we draw a number of policy implications based on our observations.

## 1. The market for medical devices

The market for medical devices in Europe (€63.6 billion) is nearly as large as that in the US (€79.4 billion) (Table 1). Both markets include items as diverse as medical aids (e.g. wound-care products), artificial bodyparts (e.g. hip endoprostheses), and technical equipment (e.g. MRIs) and are thus very heterogeneous. Devices are used for diagnosing, preventing, monitoring, treating, or alleviating disease. In contrast to pharmaceuticals, however, they do not achieve their principal intended action by pharmacological, chemical, immunological, or metabolic means, although they can be assisted in their function by these means.

## 2. EU directives on medical devices

Market access for manufacturers of medical devices has been regulated in most European countries by three EU directives since the 1990s. On March 21, 2010 the new directive 2007/47/EC, updating and amending directives 90/385/EEC, 93/42/EEC and 98/8/EC, will come into effect. One of its main goals is to increase transparency, better coordination and communication of market surveillance activities [9]. An EU directive is a legislative act that requires member states to achieve a particular result without dictating the means of doing so. In practice, this involves transposing the directive into national law according to a certain timetable, in this case until December 21, 2008. The three EU directives on medical devices specify a range of requirements, such as safety standards, that a product must meet in order to gain marketing approval, i.e. being licensed. They also create mechanisms for national authorities to supervise implementation of the directives or to intervene in the market as required. If a product is approved in any one EU country, it can be marketed in all other 26 EU countries. The directives are meant to speed up the process of adopting a product and, at the same time, provide a uniform definition for medical devices within the EU. Unlike the US Food and Drug Administration (FDA), however, the EU currently does not require clinical data on medical effectiveness in the sense of producing a health gain [10], even though the new directive will require clinical data for all new devices. Thus, manufacturers did usually not provide information on effectiveness as it was not required for receiving the CE mark as sign of being licensed for use within the EU. However, in recent years most EU-countries have specified additional regulation on national level for coverage in the national benefit baskets which usually requires data on effectiveness or even cost-effectiveness, creating a dilemma as manufacturers have not been required to provide such information for the licensing decision.

Each member state has its own agencies for regulating medical devices. These agencies are responsible for supervising manufacturers to ensure that incidents are reported correctly and appropriate action is taken; moreover, the agencies may pursue whatever measures they feel are most appropriate to ensure patient safety.

## 3. Decisions on coverage, reimbursement, and pricing

Although the three EU directives may give the impression that the regulation of medical devices is uniform throughout the EU, many regulatory decisions – especially those dealing with coverage, reimbursement, and pricing – are made at the level of the individual EU member states (Table 2). Indeed, with some countries, such as Italy, having devolved certain powers to their regions, there are possibly 100 different approaches to regulating devices in the 27 countries of the EU. In the following section, we present the main policies on coverage, reimbursement, and pricing in the four largest EU countries: France, Germany, Italy, and the UK.

France and Germany are exemplary for social health insurance systems. The French healthcare system is based on a national social insurance system complemented by

**Table 2**
Regulatory mix in European Union.

| | Level at which decisions are made |
|---|---|
| Licensing regulation | EU regulation (medical devices directives), transposed into national law |
| Actual licensing decisions | Notified bodies in 27 member states (but decisions are also valid in all other 26 countries) |
| Coverage (public benefit basket) | EU member states, usually at national level, either through government or through self-governing bodies |
| Decisions on pricing | Left to manufacturers or set/limited by national government |
| Reimbursement rates | National or sub-national, either through government or through self-governing bodies |
| Steering the usage (restricting or promoting technological adoption) | National or sub-national, either through government or through self-governing bodies |

*Source*: Authors' own analyses.

elements of tax-based financing (especially the General Social Tax, CSG) and complementary voluntary health insurance (VHI). The health system is regulated by the state (parliament, the government and ministries) and the statutory health insurance funds. Germany's financing system is characterized by three co-existing healthcare financing schemes. The majority of the population is covered by statutory health insurance based on income-related contributions while 10% of the population are covered by private health insurance or governmental schemes (4%). The healthcare system is characterized by federalism and delegation to nongovernmental corporatist bodies as the main actors in the social health insurance system.

Italy and the UK are exemplary for tax-financed systems. The Italian healthcare system provides universal access to a uniform level of care throughout the country, financed by general taxation. The state has exclusive power to define the basic benefit package (Livelli Essenziali di Assistenza, LEA) that must be provided throughout the country. The 20 regions have responsibility for the organization and administration of the healthcare system. There are large differences in healthcare and health expenditure between the regions. The United Kingdom has devolved healthcare responsibilities to its constituent countries: England, Northern Ireland, Scotland and Wales. All these countries fund healthcare mainly through national taxation, deliver services through public providers and have devolved purchasing responsibilities to local bodies.

### 3.1. Coverage policy

Decisions on the coverage of medical devices in France and Germany are made by self-governing bodies. In France, devices must be shown to be cost-effective in order to be classified as reimbursable. Devices that fulfill this requirement are included in a positive list. In Germany, health benefits are defined by the Federal Joint Committee consisting of representatives from health service providers and SHI funds. This committee may take into account assessments that have been prepared by the Institute for Quality and Efficiency (IQWiG). Decisions on the coverage of medical aids are made by the Federal Association of SHI Funds. Medical aids that have been approved are included on a positive list, currently containing around 15,000 products. In the UK, decisions on medical device coverage are made centrally by the NHS Business Service on behalf of the Department of Health. The National Institute for Health and Clinical Excellence (NICE) serves as a clinical and economic advisory board. Devices suitable for use within the NHS are listed in a catalogue. In Italy, the national authorities are responsible for setting a regulatory framework; the real decision-making power, however, is located at the regional level. As a result, medical device policies vary from region to region.

### 3.2. Reimbursement and pricing

Regulations on reimbursement and pricing in Germany, France, Italy, and the UK are grouped according to three categories of medical devices, which are summarized in Table 3 and described in greater detail below.

*Category I*: Medical aids (e.g. wheelchairs and incontinence products). In all four countries, relatively strict reimbursement levels have been set for outpatient care. In general, these levels do not apply to a particular product, but to a category of products. The mechanisms for setting reimbursement levels vary between the four countries.

In France, and for some categories in Germany, reference prices are used to cap the amount that may be reimbursed from public sources. It is important to note that these reference prices are not necessarily identical to the actual selling prices. If the selling price of a device exceeds the reimbursement cap, patients must pay the difference. Reimbursement levels for categories that are not subject to reference pricing in Germany are derived from competitive bidding. Even for medical aids with a reference price, competitive bidding is an opportunity. Nevertheless, these tenders have been implemented very rarely so far.

A similar approach is used in the UK: Part IX of the *Drug Tariff*, a monthly UK publication that serves as a catalogue of NHS prescription costs, sets maximum reimbursement levels for these medical devices. In Italy, depending on

**Table 3**
Reimbursement regulations in Europe.

| Category of medical devices | Common regulations for reimbursement of medical devices |
|---|---|
| I: Medical aids | For outpatient care: reimbursement limits, competitive bidding<br>For inpatient care: included in case fees |
| II: Implants and other artificial body parts | Included in case fees; additional payments for certain innovative and/or expensive technologies |
| III: Technical equipment for professionals | Running costs included in case fees; capital costs often covered differently |

*Source*: Authors' own analyses.

the region and product category in question, different approaches are used, including competitive bidding.

*Category II*: Implants and other artificial body parts (e.g. total joint replacements, implantable defibrillators, stents). In the majority of cases, this category is associated with inpatient care. Similar to Medicare and other large insurance providers, most reimbursement systems for inpatient care in Europe are based on case fees. France, Germany, and Italy use diagnosis-related groups (DRGs) to determine these fees, whereas the UK uses DRG-like health-care resource groups (HRGs). Although these groups are generally meant to reflect actual costs, the degree to which they do so differs considerably between the countries: in Germany, for example, the case-fee system is updated each year, but in some regions of Italy, the last update was made several years ago [11]. Case-fee payments establish a basic framework for the pricing of medical devices. However, most countries allow additional payments to be made to hospitals to cover the costs of certain high-priced devices that represent an advance in medical technology. These add-on payments are defined at different organizational levels and can result from: direct negotiations between providers and payers; directives issued by regional authorities (e.g. in Italy); or legislation or directives that set uniform payments for an entire country (e.g. so-called pass-through payments in the UK). Add-on payments are usually set for a limited period of time and can encourage the diffusion of innovative technologies.

*Category III*: Technical equipment for professionals (e.g. diagnostic imaging devices, therapeutic devices such as equipment for laparoscopic surgery). Case fees are in general meant to include running costs. In Germany, as in other countries, disposable or reusable devices as well as costs associated with using the technical equipment are included in the applicable DRG, whereas long-life equipment that can be viewed as a capital investment is not reimbursed by SHI. These investments are funded by the federal states.

## 4. Balancing adoption and affordability

### 4.1. Different policy approaches in Europe and the US

Medical device policy generally involves the attempt to reconcile two contrary goals: cost-containment and ensuring access to medical devices. To this end, the US and Europe follow different approaches. Manufacturers must prove the effectiveness of their products before these can be licensed in US, but they do not need to do so in Europe. Moreover, in the US, the Center for Medicare and Medicaid Services (CMS) may decide to cover a device and other large insurers may follow suit. In Europe, however, manufacturers must seek coverage from individual public payment systems in each country. Even if manufacturers receive coverage for a product in a given European country, they are then faced with a variety of country-specific post-coverage regulations, such as reference prices or volume limits.

The main difference between US and European approaches is that licensing and coverage decisions in the US are used, in addition to some post-coverage regulations, as key instruments to help limit adverse selection. Adverse selection problems occur when licensing bodies are uncertain about the claims that a manufacturer makes regarding the characteristics of a given product that may be licensed and finally reimbursed by public payers. For instance, licensing bodies may be unsure if a new medical device (e.g. a radioactive stent) provides a more effective treatment than other already existing treatment options. One solution to reduce this problem of information asymmetry is that the less informed party (i.e. the licensing body) requires the better informed party (i.e. the manufacturer) to provide effectiveness information.

In contrast, European countries do not require prove of effectiveness for licensing but rely mainly on coverage decisions in each country. Of these two approaches to balancing adoption and affordability, the latter is probably the more restrictive, potentially limiting access to certain medical devices. At the same time, most European countries have lower expenditures for devices as a percentage of GDP (cf. Table 1).

Evidence-based coverage policy is clearly preferable to post-coverage market regulation to reach these goals, because the effects of the former are more predictable. However, even the best evidence-based coverage policy requires a certain amount of post-coverage regulation. In principle, there are two situations that might require post-coverage regulation to establish or re-establish the balance between technological adoption and affordability. First, there may be high volume market segments with rising prices to which cost-containment measures could be applied in order to generate savings that can be used for other market segments. The key, of course, is to do so without establishing any substantial hurdles for new innovations. Second, encouraging the adoption of new technologies may increase access, but at the same time lead to a sharp rise in expenditures, necessitating post-coverage cost-containment measures. The first situation is discussed in the case of medical aids in Germany, while the second situation is presented in the case of drug-eluting stents in Italy.

### 4.2. Price regulation of medical aids

With the aim of limiting spending for medical aids in high-volume categories, a nationwide reference price (RP) system was adopted in Germany in 2005 for six out of 33 medical aids' categories. Non-nationwide RPs had already been adopted previously for visual and hearing aids (in all states) and for some other categories (in several states).

As described above, German RPs are not fixed prices per se, but rather serve as a cap on the amount that may be reimbursed from public sources. Any difference between the selling price and the reimbursement cap must be paid by the patient. RPs aim to mobilize efficiency reserves and encourage effective price competition. Patients willing to spend more money – for example, if they perceive the quality of a given product as being higher than another – are able to do so by paying the difference. Thus, if manufacturers are able to convince the consumer that their products are worth the extra payment, the German RP system does not act as a hurdle for adopting innovations. Incentives for research and development are more likely to be retained in this flexible

RP system than they would be under a fixed-price regime in which the RP constitutes the maximum selling price.

In Germany, defining and setting RPs are a two-step process. First, the Federal Association of SHI Funds creates RP groups for products of the same or equivalent function and effectiveness within each category [12]. Second, it determines RPs for each group. At both stages of the process, associations of the manufacturers and of the handicapped may issue statements, which must be taken into consideration. RPs are reviewed at least once a year and adjusted to actual market conditions at appropriate intervals. The ability to adjust RPs regularly, the well-defined classification of product groups, and the stipulation that the manufacturers' and users' concerns be considered are three important factors that contribute to maintaining the balance between adoption and affordability.

The effects of RPs on medical aids expenditures can be observed in data of the Gmünder Ersatzkasse, one of the largest German SHI funds, with a total of 1.6 million insured [13]. Per-capita expenditures for medical aids' categories that were not subject to RPs on a nationwide basis before 2005 decreased by up to 26% in the first two years after national RPs were introduced – with the exception of incontinence products, which showed increased expenditures. The decrease correlated with the number of federal states with RP setting before 2005, i.e. the fewer RPs before 2005, the larger the decrease. In contrast, expenditures for medical aids without RPs have increased since 2004.

The cost-containing effects of RPs on medical aids were rather moderate compared to those that have been observed in the context of pharmaceuticals [14]. This difference can potentially be attributed to the influence that certain interest groups exert on the process of defining RP groups and setting RPs. However, as mentioned above, this influence can also be regarded as a balancing feature within the price-setting process.

Although competitive bidding clearly plays an inferior role in RP groups in Germany, it is used for non-reference-priced groups in that country, as well as in some regions of Italy. Although competitive bidding may represent a better solution for cost-containment, it can potentially lead to oligopolistic or monopolistic prices in certain categories. Additionally, competitive bidding might eliminate incentives for innovations that are preserved in reference-pricing schemes. Under competitive bidding competition is reduced to price-competition and differentiation according to product quality only plays a secondary role. This implies lower incentives for R&D since manufacturers will focus on the reduction of production costs rather than investing into the development of innovative products with a potentially higher quality as there might be no market for these products. In the long run, this might result in a barrier for innovations and may lead to an unfavorable situation for patients. If in addition the respective products are associated with learning-curve-effects or economies of scale competitive bidding may in the long run lead to a substantial increase in market share for one or few manufacturers with the lowest costs. Consequentially, the number of competitors would decrease and manufacturers may be able to increase selling prices again.

### 4.3. Reimbursement of new technologies

Innovative medical devices are usually evaluated in relatively small clinical trials and have thus not been tested in large numbers of patients. As a result, estimates of the efficacy or even cost-effectiveness of innovative technologies are often still vague at the point when decisions on coverage are being made. Moreover, the use of innovative technologies can lead to higher costs for providers long before DRGs or other reimbursement mechanisms have been adapted to the new technologies. Clearly, this can slow down the process of adopting innovations. By the same token, creating economic incentives for healthcare providers to use these innovative technologies can lead to a sharp rise in expenditures, thus taking resources from other parts of the healthcare system where they might have led to greater benefits. This is a dilemma faced by every healthcare system.

Reimbursement policies for drug-eluting stents (DES) in Italy provide a good example of an approach designed to speed up the adoption of new technologies and, at the same time, take aspects of affordability into account. In 2002, DES became available in Italy as an alternative to bare-metal stents (BMS). Although long-term studies were not yet available, DES appeared to be an effective treatment option at the time. However, in 2002, the DRG associated with percutaneous transluminal coronary angioplasty (PTCA) did not draw any distinctions between different types of stents, thus providing no incentive for providers to use the more costly DES. Shortly after DES were introduced to the Italian market, seven out of 19 regions adopted different programs to encourage their use. Of these regions, Emilia-Romagna, with its four million inhabitants, can be seen as a pioneer in speeding up the adoption of DES [15,16].

Emilia-Romagna was the region with one of the highest numbers of PTCAs performed per inhabitant. To provide information on the effects of the reimbursement policy in effect there, a regional registry was established. In addition to reimbursement policy and the PTCA registry, the regional Cardiological and Cardiosurgical Commission developed guidelines, based on clinical evidence and cost-considerations that defined people with a high risk of restenosis as the target-population for DES. Negotiations between the regional health authority and DES manufacturers led to significantly lower prices for DES [17].

All data from this region that were associated with the use of DES were collected after the introduction of the special reimbursement system. The proportion of patients who received a DES instead of a BMS almost tripled within three years [18,19]. Although this approach led to an increase in the number of DES sold, the substantial price reductions that had been achieved through negotiations (i.e. of up to 40%) resulted in a certain balance in overall expenditures.

This example illustrates the classical trade-off facing regulators between aggressive and defensive strategies. The aggressive strategy emphasizes the early adoption of innovative technologies and is accompanied by rapidly decreasing prices, but increased utilization. The defensive strategy emphasizes cost containment (e.g. no separate DRG for DES), but can lead to higher prices and delayed technological adoption. However, even if the first approach

is able to balance adoption and affordability, it carries with it the risk that the medical device in question may not be as effective in the real world as predicted by clinical trials. In other words, strategies that encourage the early adoption of a technology represent an investment accompanied by considerable uncertainty. Today, in the case of Italy, the pioneering region of Emilia-Romagna has adapted to other Italian regions and provides one DRG for coronary stents which covers both bare metal stents and drug eluting stents. At the same time, the proportion of DES implanted as a percentage of the total number of stents has now fallen below the Italian average.

Although Italy was one of the first countries to introduce programs to encourage the rapid adoption of DES, many other countries, including the US, introduced similar programs shortly thereafter (i.e. the CMS introduced separate DRGs for DES in 2003). From today's perspective, a more careful strategy toward DES may have been more appropriate.

Today most European countries have developed standardized approaches to deal with new technologies in a balanced way. DRG systems pay additional reimbursement components (e.g. for wage differences, teaching status, or the use of new technologies or drugs), which account for a substantial share of the overall inpatient expenditure (i.e. up to 30%). After a new medical device is launched, it is often covered by additional reimbursement components at first and, if sufficient evidence for effectiveness is provided (e.g. Germany), later incorporated as a separate DRG into the DRG systems [11]. This approach facilitates, but does not force, the adoption of innovative medical devices. Moreover, although price decreases under this approach may occur more slowly, expenditures tend to be more predictable and controllable.

## 5. Conclusion

Governments all over the world are faced with the dilemma of facilitating the adoption of medical devices while ensuring their affordability. Without reimbursement, many patients would be unwilling or unable to pay for the devices. As a consequence, many manufacturers would have little incentive to develop new products, and providers and payers would be unable to offer innovative technologies. Thus, insurance providers and governments have the responsibility to balance technological adoption and affordability, thus creating a favorable market environment for medical devices tailored to the unique features of each country [20].conclusion, certain lessons can be drawn from the presented approaches of regulating medical devices: Reference prices, if defined as maximum reimbursement levels and based on groups of products with comparable effectiveness and quality, can help achieve balance, because they are supposed to contain costs effectively, but do not necessarily act as a hurdle for the adoption of innovations. In contrast, competitive bidding procedures that can be observed in several European countries may require additional instruments to encourage technological adoption.

Moreover, policy tools that encourage technological adoption tend to show a strong preference for a particular technology over others. Such tools should be used carefully (e.g. on a trial basis in the early stages of technological diffusion), since the benefits of a new technology are often difficult to predict, may lead to market distortions and to sharp rises in expenditures.

## 6. Policy implications for the future

It can be observed that markets for medical devices do often not work without problems due to asymmetric information. In this situation policy makers should try to make use of coverage policy as the chief instrument for regulating medical devices. Coverage decisions should be taken by governmental or self-governmental institutions in each country but require some kind of evidence for the cost-effectiveness of the products. Thus, manufacturers should be required to provide evidence for the cost-effectiveness of their products according to very transparent country-specific criteria. Due to different preferences of European countries it will not be possible to define European-wide cost-effectiveness criteria, at least in the short-to-medium-term. Evidence should be evaluated by outside experts who have a high degree of independence while the details of coverage should be worked out by the respective governmental or self-governmental institutions. Moreover, as innovations emerge coverage policy for existing products on the market should also be reviewed using the same approach. This approach would give manufacturers a financial incentive that is aligned with best-practice and cost-effective health care.

Clearly defined standards for coverage policy can influence payers' costs but are usually not sufficient to achieve cost containment. Thus, post-coverage instruments dealing with reimbursement prices or limits on volumes, which have less predictable effects, may be used as a second best option for cost-containment. When choosing instruments for post-coverage policy pricing, i.e. definition of reimbursement rates should be preferred to other instruments such as volume control or global budgeting tools. Fixed reimbursement rates (e.g. reference prices) might be able to increase the efficiency of allocation since it encourages price competition and at the same time avoids rationing induced by volume control or global budgeting tools (e.g. physician spending caps for medical aids). Reimbursement rates should be defined based on actual costs rather than on politically driven considerations (e.g. to encourage the use certain technologies). Actual treatment costs can be obtained by defining a sample of providers (e.g. hospitals) that regularly submit their costs on a voluntary basis calculated according to defined standards. Finally, as a last resort, if cost containment goals can still not be achieved, global budgets or provider specific spending caps could be used to control costs, but these may constitute access hurdles. The presented framework should be able to ensure a cost-effective allocation of resources and achieve cost containment at the same time.

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