GERMANY'S STRUGGLE WITH PRICES FOR PATENT-PROTECTED DRUGS

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Introduction

In 2008, the German statutory health insurance funds (SHIs)[1] that provide health insurance to about 90 percent of the population spent almost one fifth (EUR 29.2 billion) of their total EUR 160.8 billion budget on pharmaceuticals (Schwabe 2009). Only hospital and ambulant care took up larger shares of their total spending. Meanwhile, expenditures on pharmaceuticals have been increasing at an average annual growth rate of more than 5 percent over the last decade, and thus more rapidly than overall healthcare spending (Beckmann et al. 2010).

The increase in pharmaceutical spending is primarily driven by patent-protected drugs (PPDs). With revenues growing by 15 percent from 2008 to 2009, this segment was responsible for 35 percent of all pharmaceutical spending in 2009 (IMS Health 2010). Ten years earlier, the PPD spending share had amounted to 27 percent (Beckmann et al. 2010; Schwabe 2009).

Germany is one of the few countries in the European Union where manufacturers can freely determine drug prices. For many years SHIs were required to fully reimburse these prices for PPDs, the argument being that full reimbursement is a precondition for pharmaceutical innovations.[2] Only recently has new legislation permitted deviations from this full reimbursement rule.

Manufacturers use the full PPD reimbursement to employ so-called skimming-price-strategies. By setting high PPD prices they seek to recoup their research investments and generate maximum profits before the patent expires and price-competition through generic drugs sets in (Guminski 2008). In many cases German prices also form benchmarks for public price setting in countries where pharmaceutical pricing is not left to the industry (Pirk 2008). This creates additional incentives for high-pricing strategies in Germany. Unsurprisingly, a recent study by Brekke et al. (2010) finds that PPD prices in Germany exceed those in other comparable European countries (see Figure 1).[3]

The pharmaceutical industry justifies the high PPD prices with high research and development spending paired with an excessive risk for innovations to fail. Manufacturers report that only 1 in 10,000 tested substances becomes a marketable product – on average 14 years after the initial trials (DiMasi 1995). DiMasi et al.'s (2003) analysis of United States pharmaceutical industry data suggests that development costs per newly launched drug amounted to more than USD 800 million in 2001 (in USD 2 billion). The validity of DiMasi et al.'s method and of the industry-provided R&D data, however, has been questioned. For instance, the US consumer protection advocacy group Public Citizen (2001) proposes that the average R&D costs for drugs launched in the US between 1994 and 2000 were as low as USD $100 million.

A question of basic relevance for the pricing and reimbursement of a PPD is whether or not it offers additional therapeutic value[4] over existing treatments,

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[1] Health insurance is obligatory in Germany and provided either through 166 SHIs or through private insurers. The SHIs are public-law corporations that are financially and organizationally independent. Contributions to SHIs are income dependent. Private health insurance can be bought by civil servants, the self-employed and employees who earn more than EUR 49,950 per year. Private insurance contributions depend on individual health risk.

[2] Exemptions to the general reimbursement rule for prescription drugs apply for drugs used in the treatment of minor health disorders, so-called lifestyle drugs, and for "non-economical drugs" that form part of a negative list of about 2,500 pharmaceuticals with unproven therapeutic value.
[3] To rule out that their results are driven by cross-country differences in the taxation of pharmaceuticals, all calculations by Brekke et al. (2010) exclude value-added tax.
[4] A new drug provides additional value by being more effective, having lesser side-effects, or by being less costly at equal effectiveness as existing drugs.

and thus deserves the advantages of patent-protection in the first place. Figure 2 from Fricke and Schwabe (2009) shows the total number of drug launches in Germany between 1992 and 2008 and how many of the launches represented improvements or actual innovations over existing therapies. The so-called me-too-drugs – PPDs without relevant clinical advantages over already available medications – form the gap between the total number of launches and the sum of improvements and innovations. Me-too drugs made up over 42 percent of all launches during the 1992–2008 period. Schwabe (2009) calculates that expenditures on me-too drugs have increased from EUR 2.3 billion in 1999 to EUR 5.1 billion in 2008 and that an annual EUR 1.7 billion could immediately be saved if me-too-drugs were replaced by generic drugs with equal therapeutic value.[5] The high prevalence of me-too-drugs reflects the longstanding absence of systematic effectiveness testing in the German healthcare system. With the introduction of the Institute for Quality and Efficiency in Healthcare (IQWiG) in 2004, this situation has only recently begun to change. Until today, the market admission of PPDs by the Federal Institute for Pharmaceuticals and Medical Products (BfArM), which automatically leads to full SHI reimbursement, does not require a proof of increased effectiveness over existing drugs (Paris and Docteur 2008). Post-launch studies also rarely compare the effectiveness of one drug relative to others. Furthermore, the pharmaceutical industry's involvement in academia and scientific publication often puts into question the independence of academic pharmacological research (Relman and Angell 2002; Angell 2004). In sum, whether or not a PPD provides additional clinical value remains widely opaque to both doctors and SHIs (Beckmann et al. 2010).

In the past Germany has made various attempts to control and increase the efficiency of PPD

spending, resulting in a variety of regulations from patient co-payments and reference pricing, to physician spending caps and incentives for the import of cheaper foreign pharmaceuticals. Cost-effectiveness research and economic evaluations form more recent regulatory inventions. Because of the myriad of regulations in place, it is hard to distinguish the effects of individual measures on PPD expenditure. What is known, however, is that the combination of regulations in place has failed to put overall PPD expenditure under control (Schwabe 2009).

The new minister of health, Philipp Rösler, has developed guidelines for pharmaceutical sector reform. A main building block is the strengthening of price negotiations between SHIs and pharmaceutical manufacturers. Before discussing the new proposal and its possible consequences on PPD prices we in the following describe and evaluate existing direct and indirect PPD price regulations.
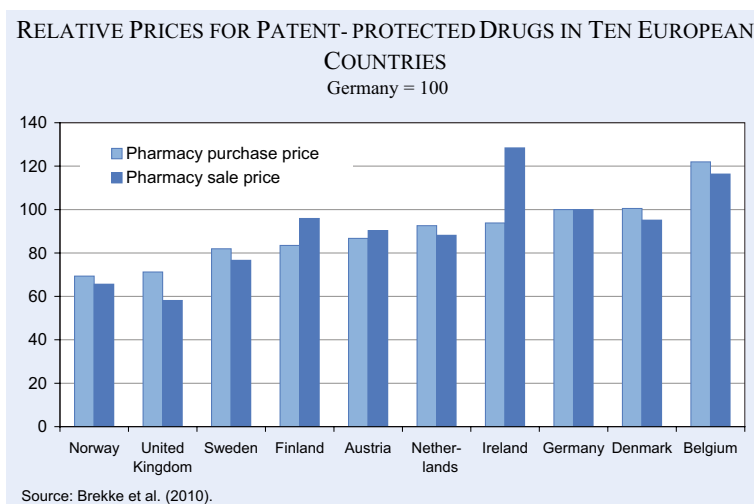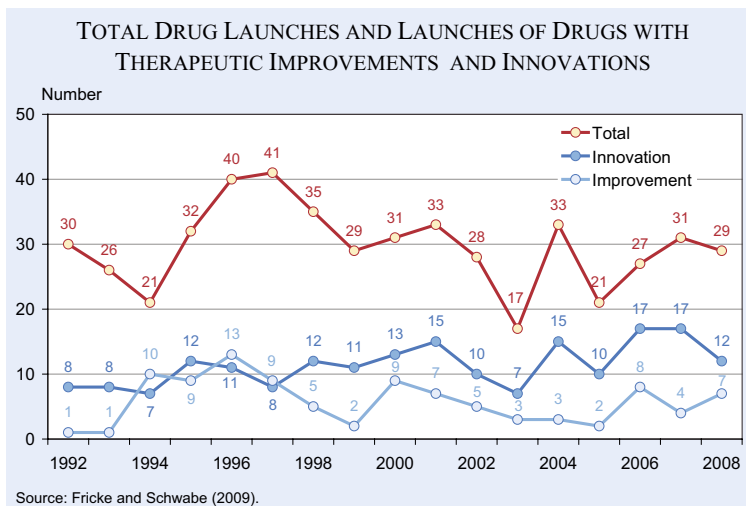
Figure 1

RELATIVE PRICES FOR PATENT- PROTECTED DRUGS IN TEN EUROPEAN COUNTRIES
Germany = 100

Source: Brekke et al. (2010).

Figure 2

TOTAL DRUG LAUNCHES AND LAUNCHES OF DRUGS WITH THERAPEUTIC IMPROVEMENTS AND INNOVATIONS

Source: Fricke and Schwabe (2009).

[5] The case of the statin-drug Inegy® is cited as a compelling example. Inegy is 13 times more expensive than the existing generic drugs (Schwabe 2009).

Patient co-payments and reference pricing

Standard co-payments in the SHI system cannot exceed EUR 10 per prescription. An important exception to the co-payment limit rule, however, applies to drugs subject to reference pricing, a policy first introduced in Germany in 1989. Its basic principle is the establishment of a reimbursement ceiling for medical indications for which enough equally effective therapies exist to form a reference group. Drugs in a reference group either a) contain the same active substance, b) have similar active substances, or c) display comparable efficacy. Reference prices are set as follows (also see Figure 3). Within the reference group, the average selling price of the three most and the three least expensive drugs is calculated. The reference price then corresponds to the average price of the three least expensive drugs in the reference group plus one third of the difference between the high and low price averages. If physicians prescribe drugs that are more expensive than the reference price, the patient has to pay this difference plus EUR 5 to 10 out of pocket.[6]

While not interfering with the principle of free pharmaceutical price setting directly, reference groups create substantial price pressure by involving patients in the payment of high-priced drugs. The pressure is particularly high in reference groups that include cheap generic drugs – their introduction regularly leads to price drops of the original and formerly patent-protected drugs of between 30 and 50 percent (Fricke and Schöffski 2008).

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[6] Furthermore, there are provisions to promote continuous competition in the low-price segment of reference groups. For example, drugs priced 30 percent below the reference price are exempt from any patient co-payment. The reference price level is adjusted regularly to accommodate overall price changes.

Figure 3

THE PPD REFERENCE PRICING SYSTEM IN GERMANY

At least three PPDs with
- the same active substance, or
- similar active substances, or
- comparable efficacy

Producer price

A
Average price of 3 most expensive drugs in group

Reference price

1/3 of difference between A and B

B
Average price of 3 least expensive drugs in group
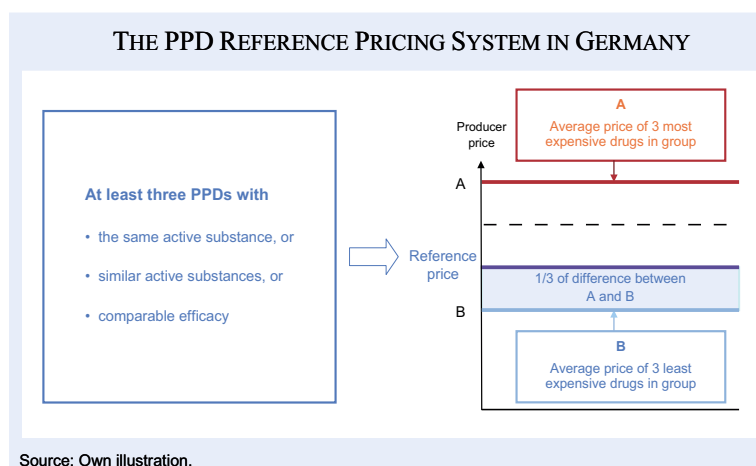
Source: Own illustration.

The initial 1989 legislation permitted the inclusion of PPDs in the reference price system but in 1996 PPDs were excluded. Aimed at encouraging pharmaceutical innovation, the exclusion decision instead boosted the launch of pricey me-too drugs (Busse et al. 2005). In 2004, reference pricing for PPDs was reintroduced. To be subject to reference pricing, a PPD has to qualify as a me-too drug by not offering relevant therapeutic value over existing therapies. Whether or not such therapeutic value added exists is determined by the Federal Joint Committee (G-BA) – an institution formed by healthcare service provider associations and SHIs that has substantial regulatory competencies in the German healthcare system.

A severe limitation to PPD reference pricing is that it is applicable only if a reference group that at least includes three PPDs can be formed. This is rarely the case in practice. Thus, in stark contrast to the effect of reference pricing for non-PPDs, the 2004 legislation has not led to meaningful PPD price reductions or overall savings (Nink and Schröder 2009).

Spending caps and individual target volumes

Spending caps and individual target volumes for physician spending coupled with financial liability for overspending are instruments to generate cost awareness among providers. Ideally, they could lower prescribed volumes to therapeutically required levels and put pressure on the prices of PPDs. The latter expectation builds on the assumption that if overall prescription values are limited, physicians will be less likely to prescribe high-priced drugs – in particular where cheaper alternatives are available – and that the industry will respond to this by lowering prices.

Germany first passed legislation requiring individual physician spending targets in 1989. A lack of data to calculate individual budgets, however, impeded the implementation of this legislation for years. Instead, in 1993 a national pharmaceutical spending cap was introduced. From 1994 to 1997, the national cap was replaced by regional spending caps to be negotiated between the regional physician and SHI associations. These were abolished in 1998 – only to make a quick comeback from 1999 until
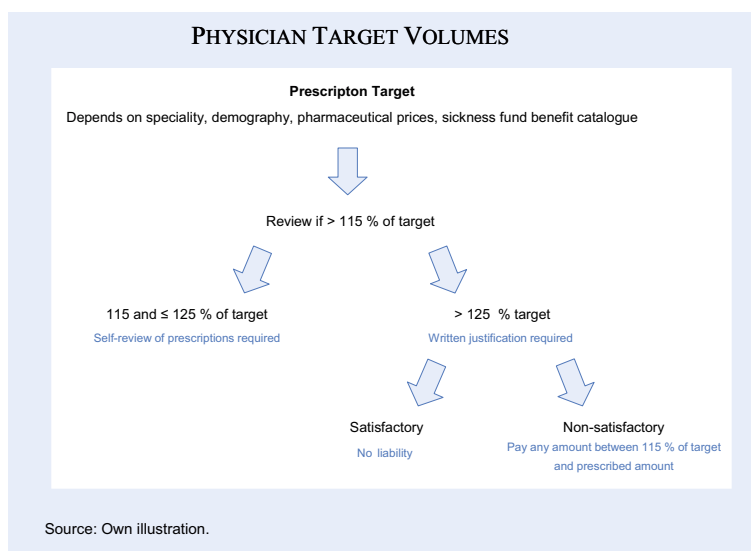
2001. The regional capping policy stipulated that SHIs could reclaim their payments from the pharmaceutical industry and from Germany's 23 regional physicians associations if spending exceeded the respective regional cap.

National and regional caps helped to contain pharmaceutical expenditure. In the first year after the 1993 reform, for instance, a decrease in the number of prescriptions and a rise in the use of generics reduced SHI expenditures by over EUR 1.5 billion (Busse et al. 2005). A major problem of the caps, however, was that financial liability could not properly be enforced. Physicians associations successfully refused the payments, claiming that a lack of data impaired their capacity to efficiently manage regional expenditure. In addition, legal concerns were raised over the mechanism of collective liability that imposed financial fines on physicians irrespective of their individual prescription behavior. The ongoing legal uncertainty lead to the abolishment of the regional caps in 2001. In response, overall drug expenditure increased by 10 percent in the first half of that year to again reach the level it had assumed before the caps were first introduced (Breyer 2002).

While the 2001 legislation abolished collective liability, it introduced individual physician prescription target volumes that remain in place to date. Today's target volumes consider the medical specialty in which physicians are active, the demography of their patients and changes in pharmaceutical prices and to the SHI benefit catalogue (Paris and Docteur 2008). Physicians who exceed their target by over 15 percent are advised to review their prescription practices. Overspending by more than 25 percent requires a written explanation. If the explanation is judged insufficient, physicians have to pay back to the SHIs the difference between 115 percent of the target and their total spending. The spending cap mechanism is summarized in Figure 4.

While there is good evidence that spending caps and target volumes have reduced prescriptions by physicians, it is less clear to what extent such rationing strategies are in the public interest. Critics of spending caps argue that capping may lead to inefficient

Figure 4

PHYSICIAN TARGET VOLUMES

Prescripton Target
Depends on speciality, demography, pharmaceutical prices, sickness fund benefit catalogue

Review if > 115 % of target

115 and ≤ 125 % of target
Self-review of prescriptions required

> 125 % target
Written justification required

Satisfactory
No liability

Non-satisfactory
Pay any amount between 115 % of target and prescribed amount
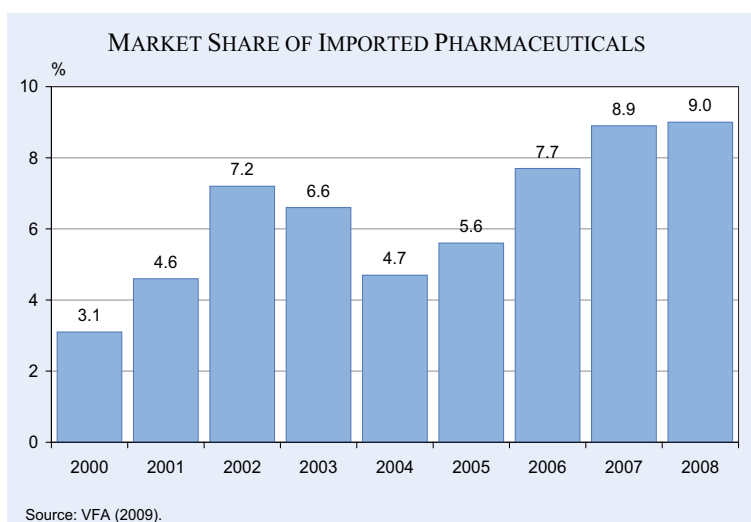
Source: Own illustration.

rationing and unwanted substitution effects in other healthcare sectors (Drummond and Jönsson 2003; Schreyögg and Busse 2005). For instance, Henke et al. (1994) and Schulenburg (1997) found evidence that physicians seek to avoid surpassing their individual budgets by shifting patients to specialists and hospitals. Schöffski (1996) calculated that this substitution inflicted an additional EUR 700 million in costs per year on the SHIs. To what degree spending caps and target volumes have affected price setting strategies for producers of PPD is not known.

Promotion of pharmaceutical imports

Since 1989, German pharmacies have been legally obliged to substitute locally marketed drugs with imports if identical imported drugs are available at a lower price. Since this is the case for many drugs, the substitution regulation had a potentially large impact. Monitoring, however, varied considerably by region and overall implementation levels were low. In 1996, the substitution-obligation was repealed altogether, only to be re-introduced in 1999.

In 2002, new legislation established minimum import sales quotas for pharmacies, requiring that 5.5 percent of revenues charged by pharmacies to each SHI had to come from imports. This quota increased to 7 percent in the following year. At the same time, targets for the use of imported drugs were set in negotiations between regional SHI and physician associations. The reform caused an immediate increase in the market share of imported pharmaceuticals to a 7.2 percent peak (VFA 2009, see Figure 5).

Figure 5

MARKET SHARE OF IMPORTED PHARMACEUTICALS

%

Year	Value
2000	3.1
2001	4.6
2002	7.2
2003	6.6
2004	4.7
2005	5.6
2006	7.7
2007	8.9
2008	9.0

Source: VFA (2009).

In 2004, however, the bar for pharmaceutical imports rose. The pharmacy import quota was again reduced to 5 percent and the price difference between non-imported drugs and imports required to trigger obligatory substitution was increased from 10 to 15 percent (or a minimum of EUR 15). As a consequence, the market share of imported drugs decreased while overall expenditures rose.

The negative effect of the 2004 reform was temporary, however, as in 2008, the market share of imported pharmaceuticals reached a record 9 percent (VFA 2009). For 2006, the Association of German Pharmaceuticals Importers (VAD) estimated that further increases in the use of imported drugs would have lowered pharmaceutical expenditures by up to EUR 200 million per year (Prognos AG 2006).

Overall, the obligation to sell imported products has put considerable pressure on the price of PPDs. Pharmaceutical manufacturers have therefore sought to avoid this regulation by hindering the free operation of pharmaceutical importers in the past (Geller 2008) and by lobbying against import quotas (VFA 2010).

Manufacturer price moratoriums and compulsory rebates

To tackle the continuing increase in PPD expenditure, German policymakers have on several occasions diverged from the basic principle of free price setting and imposed price freezes and compulsory rebates on the industry.

In 1993 and 1994, pharmaceutical manufacturers were for the first time obliged to give SHIs a 5 percent re-bate for drugs outside the reference price system. Moreover, newly introduced drugs were subjected to a price moratorium during those two years.

Obligatory rebates on PPDs almost made a comeback when new health minister Ulla Schmidt attempted to introduce a 4 percent rebate for 2002 and 2003. Savings projections for the rebates ranged as high as EUR 960 million (Busse et al. 2005). The price cut was however stopped at the last minute by extensive lobbying that instead led to the pharmaceutical industry paying the SHIs a lump sum of EUR 200 million. Not only did the industry save up to EUR 760 million in revenue but it also avoided a negative price signal for countries referencing their pharmaceutical prices to those in Germany.

In 2003, however, the mounting cost pressure finally led to a 6 percent obligatory rebate on all non-referenced price drugs including PPDs. The rebate was further increased to 16 percent in 2004. In 2005, it was again reduced to 6 percent, where it remained until June 2010. In addition, a price moratorium was imposed on all prescription drugs from April 2006 to March 2008. For 2009, recent data suggest that overall obligatory manufacturer rebates to SHIs amounted to EUR 852 million (IMS Health 2010).

Surprisingly, the newly elected center-right coalition government continued on this path in 2010. Its first major piece of healthcare legislation again increased the rebate on non-reference-priced drugs to 16 percent. This was accompanied by an unprecedented price freeze with retrospective effect from August 2009 to December 2013. Figure 6 provides an overview of compulsory rebates and price moratoriums in Germany since 1993.

Clearly, price moratoriums and compulsory rebates are effective short-term measures to control pharmaceutical prices and expenditure. However, they are ineffective when it comes to new drugs as the manufacturer can still set prices freely when the drugs are launched. A further problem is that prices are cut across the board. There is no discrimination based on a drug's therapeutic value added. This again highlights the need for economic evaluations, which have only recently been introduced in Germany.

Figure 6

PRICE MORATORIUMS AND COMPULSORY REBATES IN GERMANY
1993–2010

Moratorium   — Rebate in %

Source: Own illustration.
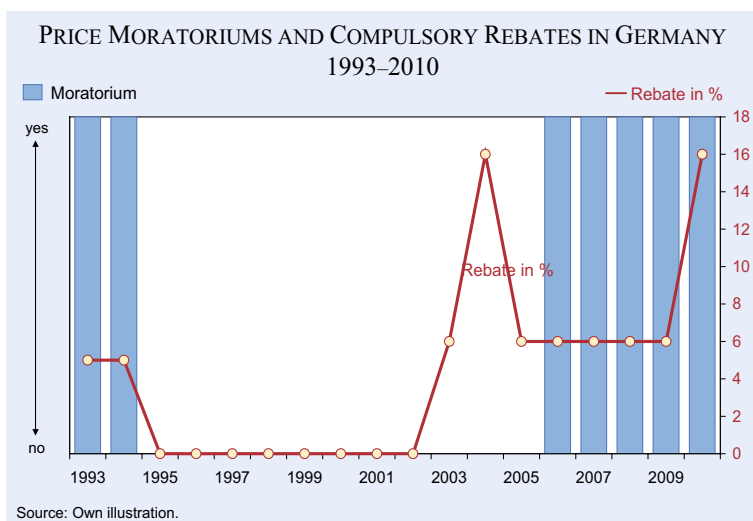
Economic evaluation of therapeutic value

In 2007, the principle of full reimbursement of PPDs for which no reference group could be formed was eliminated. Instead, reimbursement ceilings for these drugs were now permitted. If the manufacturer charges a price that exceeds the reimbursement ceiling, the difference must be paid out of pocket by the patient. The level of SHI reimbursement is determined on the basis of an economic evaluation by IQWiG. However, because no such evaluation has been concluded to date, reimbursement ceilings as a potentially important instrument of PPD price control have yet to be put to use. This delay in implementation is mainly a result of IQWiG choosing to develop an entirely new method for economic evaluation instead of using established methods like cost-benefit and cost-utility analysis (see Zweifel et al. 2009 for an overview).

Figure 7

EXTRAPOLATION OF THE EFFICIENCY FRONTIER BY IQWiG

Source: Own illustration.
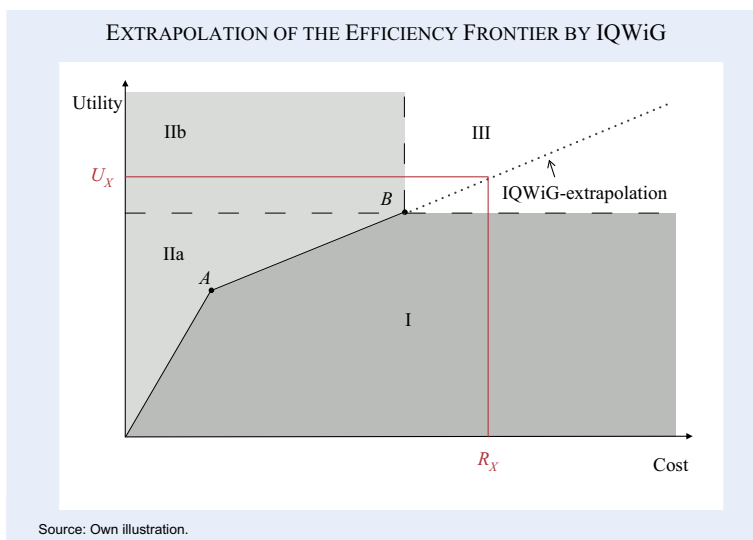
IQWiG's key methodological concept is the "efficiency frontier" (IQWiG 2009). In a cost-utility diagram, the frontier is defined by the combination of therapies that yields the maximum utility at a given cost level. IQWiG has opted to measure utility by indication-specific indicators. To determine the frontier, the cost and utility of all existing therapies in an indication must be assessed. Therapies which are both more costly and less effective than others are classified as inefficient. Moreover, if a combination of two therapies – one less costly and less effective and one more costly and more effective than a third therapy – creates more total utility at lesser cost than a third therapy, the third therapy is also graded inefficient by the principle of extended dominance (Weinstein 1990).

Figure 7 shows the efficiency frontier for an indication with two efficient drugs A and B. The connecting lines represent combinations of these therapies. Based on this frontier, an economic evaluation is performed. If a new PPD falls in area I, it does not receive a positive evaluation as it is inefficient. Interestingly, IQWiG neither recommends PPDs in area IIa although such drugs are more cost-effective than the existing therapies. The reason cited here is that new drugs should not lower the level of care in an indication. PPDs in area IIb which are more effective than the current best therapy but less costly, are evaluated positively and recommended for full reimbursement. For PPDs which are more effective and more costly – as will most often be the case – IQWiG states that a new drug should "not lead to a deterioration of efficiency in a given therapeutic area measured against the efficiency frontier" (IQWiG 2009). Such a deterioration is avoided if the new therapy lies on or above the extrapolated frontier in Figure 7. In this case, the incremental utility-cost ratio between the hitherto most effective drug B and the new drug would be at least as high as the incremental utility-cost ratio between drugs A

and *B*. Graphically the reimbursement ceiling corresponds to the level of cost which places a new drug on the extrapolated frontier. Consider, for example, a drug *X* which generates utility U_X in Figure 7. The reimbursement ceiling would be R_X.

IQWiG's approach has been received with great skepticism by German and international health economists (Ausschuss für Gesundheitsökonomie im Verein für Socialpolitik 2008; Drummond and Rutten 2008; Kifmann 2010). A practical problem is that the construction of the efficiency frontier requires up-to-date and comparable cost and utility data which is not available for most therapies. The commissioning of additional studies would most likely involve considerable time and financial costs. A more fundamental criticism, however, concerns the refusal to compare the utility increments of innovative drugs across indications. IQWiG states in its methods: "The intention of the health economic evaluation is … neither to establish priorities for resource consumption across the whole health system nor to take account of associated trade-offs" (IQWiG 2009). This statement puts into question the very purpose of economic evaluation – enabling an efficient distribution of limited healthcare resources. In line with IQWiG's rejection of efficiency reviews across indications is its decision to use indication-specific utility measures rather than a generic measure like Quality-Adjusted Life Years (QALYs), as used by IQWiG's English pendant, the National Institute for Health and Clinical Excellence (NICE). Furthermore, IQWiG's method of evaluation is prone to leading to different reimbursement standards across indications. In particular, this standard will be lower in areas with low incremental utility-cost ratio, creating the danger of "adding inefficiencies to inefficiencies" (Drummond and Rutten 2008).

Apart from the validity of IQWiG's method, there are concerns with the setting of a reimbursement ceiling for PPDs itself. The reimbursement ceiling rule allows that a pharmaceutical company can charge a higher price. The difference between the reimbursed amount and the manufacturer price must be paid by the patient. This causes allocational and distributional problems. Given that the reimbursement ceiling reflects the societal willingness to pay for a PPD, a manufacturer price above the ceiling exceeds this willingness to pay. In total, SHI and patients therefore pay more than what is adequate from a social point of view. Furthermore, the reimbursement ceiling for a PPD with higher utility at higher cost lies above the full reimbursement for the second most effective drug

in the indication. Consider drug *X* in Figure 7. The reimbursement ceiling is R_X which is higher than the cost of drug *B*. If the price exceeds R_X, patients who have the means to buy the new drug receive a higher reimbursement than patients who can only afford the fully reimbursed second most effective drug *B*. This is at odds with the principle of solidarity in healthcare advocated in Germany's public healthcare system. A stricter reimbursement rule that provides reimbursement only if the manufacturer price does not exceed the reimbursement ceiling would avoid this problem.

Overall, the limitation to disease-specific utility measures and the avoidance of utility comparisons across indications make it doubtful whether IQWiG's work can inform rational reimbursement decisions. The extrapolation of the efficiency frontier will most likely create different reimbursement standards across indications. Furthermore, the practicability of IQWiG's approach remains an open question.

The new approach: negotiations – arbitration – evaluation

In spring 2010, the new government adopted a draft bill containing a new approach towards the market for PPDs (Bundesministerium für Gesundheit 2010). Price negotiations between the SHIs and manufacturers form the main building block of this new cost containment effort that will be debated in parliament this fall.

Price negotiations are not an entirely new instrument in the German healthcare system. Since 2003, individual SHIs can negotiate rebates with pharmaceutical manufacturers. At first, however, the negotiations only played a minor role. This changed in 2007 when pharmacies were obligated to preferentially sell drugs of manufacturers with which the patient's SHI had negotiated a rebate (unless the prescribing physician had explicitly ruled out the substitution). In response to this new regulation, the market share of pharmaceuticals under negotiated rebate contracts greatly increased. The largest German SHI, AOK, for instance, estimates that negotiated rebates have saved it EUR 1 billion between 2007 and 2010 (Beckmann et al. 2010).

To date price negotiations have only been effective, however, for indications for which several competing drugs are available. By contrast, in the case of PPDs with unique therapeutic value, there is no incentive for manufacturers to give rebates: as a monopolistic sup-

plier they cannot expect sales volumes to increase through a rebate contract that warrants preferential sale of their drug.

The new government's approach makes negotiations the standard method for PPD price setting. The proposed mechanism consists of three stages that are also summarized in Figure 8.

The negotiation stage

The manufacturer continues to set a PPD's price freely at its market launch. Within three months of the launch, a rapid assessment of the new drug's additional therapeutic value is carried out by or under the auspices of the Federal Joint Committee. For the rapid assessment and all further evaluations the new legislation stipulates that manufacturers must make available all clinical studies – irrespective of their outcome. Drugs with no additional therapeutic value are either assigned to a reference group or, if no reference group exists, given a price that is cost-neutral compared to alternative therapies. If a drug is superior to existing medications, the National Association of SHIs and the manufacturer negotiate a rebate on the launching price. An agreement has to be reached within six months after the rapid assessment is concluded. The resulting rebate contract may include agreements on supplied volumes.

The arbitration stage

If no rebate agreement is reached in time, an arbitration committee sets a binding price within three months that becomes effective from the 13th month after market launch. In its pricing decision the committee is encouraged to consider prices in other European countries. The committee is formed by two representatives of the National Association of SHIs, two representatives of the pharmaceutical manufacturer and three independent members agreed upon by the National Association of SHIs and the manufacturer. If the two parties fail to reach an agreement on the independent members, the decision is taken by drawing lots.

The evaluation stage

Following the arbitration committee's decision, both the National Association of SHIs and the manufacturer can request an economic evaluation by IQWiG. Its results form the basis for re-negotiations between the National Association of SHIs and the manufacturer. If no agreement can be reached, the arbitration committee sets the price based on the economic evaluation's findings.

At any stage of the new price setting mechanism, individual SHIs can negotiate exclusive rebate contracts

Figure 8

PPD PRICE SETTING IN THE NEW GOVERNMENT'S REFORM PROPOSAL
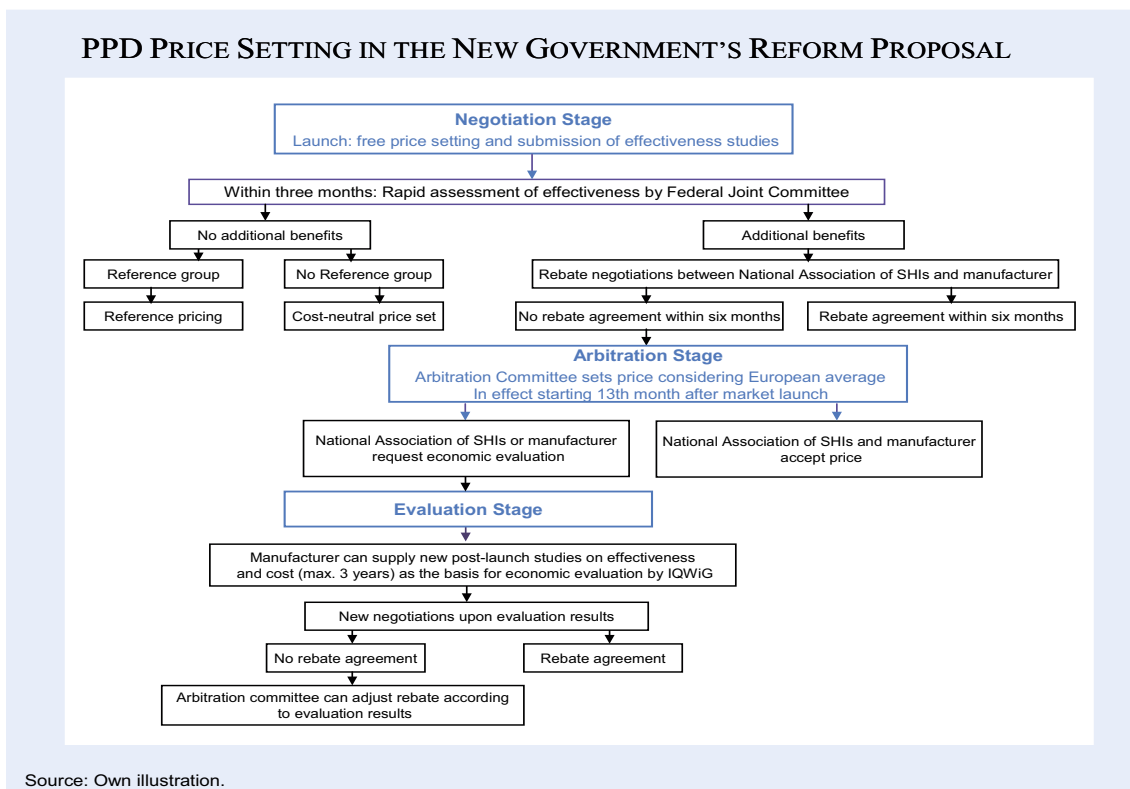
Source: Own illustration.

with manufacturers on the condition that the resulting price does not exceed the level determined through the central negotiations between the National Association of SHIs and the manufacturers. The new negotiation scheme not only applies to newly introduced PPDs but also to PPDs already marketed.

Essentially, the bill eliminates the manufacturers' right to set PPD prices freely and forces them to give SHIs a rebate on their list price. If enacted, it can be expected to have a strong impact on PPD prices. Rapid assessments may result in identifying me-too drugs more quickly. For drugs with additional therapeutic value, the reference to prices in other European countries in the arbitration stage will likely generate downward pressure on prices. If, for example, the arbitration committee sets prices close to a European average, the National Association of SHIs has little reason to agree on a higher price in the negotiation stage.

The outcome of future economic evaluations in the third stage is difficult to predict. In particular, it is unclear to what extent IQWiG's efficiency frontier methodology will be used. The method was originally designed to recommend reimbursement ceilings for PPDs. Such ceilings, however, are no longer required in a price setting system that builds on the negotiation of rebates on manufacturer list prices. Furthermore, under the new law, the Federal Joint Committee can specify what existing therapies are to be used by IQWiG for its comparison. This eliminates the universal assessment needed to construct the efficiency frontier. At the same time, however, the extrapolation method can no longer be used for guidance. This shows that the government's new approach towards PPDs is only a first step. An evaluation method that is both transparent and coherent must still be developed.

Concluding remarks

PPDs have been the main driver of the strong increase in pharmaceutical spending Germany has experienced in recent years. To regain cost control, lawmakers have taken a variety of direct and indirect measures to regulate PPD prices. These regulations attempt to sidestep the principle of free price setting and full reimbursement of PPDs, which unlike most other countries is still upheld in Germany.

The combination of patient co-payments and reference prices has been successful for drugs whose patents have expired. This instrument, however, has had little effect on PPD prices and expenditures because reference group requirements for PPDs remain high. By contrast, physician spending caps have been effective for cost containment but their effects in terms of rationing and cost-shifting to other SHIs are questionable. The promotion of pharmaceutical imports has also placed pressure on German pharmaceutical prices.

Price moratoriums and compulsory rebates have often been used to contain pharmaceutical spending. However, these measures do not affect price setting for newly launched drugs. They do not take into account the varying therapeutic value of PPDs and may thus hamper the incentive for true innovation. Here, economic evaluations could inform efficient PPD reimbursement decisions. However, IQWiG's current methodology does not seem to be suited to meet this objective. It is prone to leading to different reimbursement standards across indications.

The new government's reform proposal represents a radical change in policy. It practically eliminates the right of manufacturers to set PPD prices freely as they will be forced to offer SHIs a rebate on their list price. If the two parties do not reach a timely rebate agreement, an arbitration committee will set a binding price with reference to prices in other European countries. This price can only be changed following an economic evaluation that either party can request.

If enacted, the new law is likely to generate downward pressure on PPD prices, in particular through reference to prices in other European countries in the arbitration stage. A crucial question is to what degree the option to request an economic evaluation will affect negotiated outcomes. Among other things, this will depend on the evaluation method. Here the new law offers a chance to reconsider IQWiG's current methodology. Ultimately, prices for PPDs can only be set in a meaningful way if their therapeutic value is evaluated with a sound method.

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