



**Research paper**

# **Economic effects of Germany's reference pricing policy for drugs**

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**December 2006, Brussels**



## Executive Summary

Public authorities in Germany, like those in most other OECD countries, have instituted compulsory health insurance systems aiming to provide the populace with universal coverage and nearly free health care. Those compulsory systems became an uncontrollable source of spending on health care and drugs, with substantial rises in recent decades.

The reference pricing (RP) policy for drugs is among the means used by public authorities to reduce the costs of public insurance. It seems increasingly to be in fashion. While RP was formally instituted for the first time in 1989 in Germany, other countries across the world also adopted it since then. For example, the Netherlands and New Zealand instituted it in 1991 and 1993 respectively. France, Italy, Spain, Denmark, Australia and the Canadian province of British Columbia, among others, also apply today the RP system to varying degrees.

The principle of reference pricing is simple. Drugs which are judged by an insurer to be interchangeable are classified in therapeutic classes, and a reimbursement ceiling is unilaterally set up for the whole class, generally equivalent to the lowest or the median price in the group.

It is thus possible to create classes with only bioequivalent drugs (i.e. containing the same active substance; so-called type 1 RP). But German-style RP goes beyond that by putting non-bioequivalent drugs in the same class if they are judged to be therapeutically similar. Thus, there are classes with chemically or pharmacologically similar drugs (type 2 RP) and classes with drugs which chemically can be completely different but are used to treat the same symptoms (type 3 RP). Through type 2 and type 3, patented drugs can consequently be submitted to the RP system.

A careful study of the German context shows that there are many effects of RP.

- First, in the insurance field, by emphasizing cost reduction, RP provides savings for funds related to the use of medication. However, such a policy also has its drawbacks. For example, it provides the insured with limited coverage for certain drugs, and it relies on the use of a bureaucratic classification of groups of drugs that are considered substitutable even if patients may not see it in the same light. In this type of situation, only free competition among insurers and the freedom of all insured person to choose - currently absent in Germany - can indicate if and where RP policy can effectively present added value in the eyes of patients.

- Second, German-style RP represents a reimbursement policy which has an indirect effect on pharmaceutical innovation by discriminating against new medicines. Drugs representing incremental innovations - which are bureaucratically classified in the same classes with old and generic drugs - are especially penalised. Such bureaucratic classification tend however to disregard the fact that pharmaceutical innovation - like the process of innovation in other fields - remains by its nature an incremental process and its results have to be evaluated by the beneficiaries of new drugs, i.e. the patient / insured. German-style RP thus ends up also penalising the process of innovation itself without giving any opportunity to these beneficiaries to approve or disapprove such a policy.

In their cost containment efforts, governments using the RP policy are ultimately decreasing indirectly the returns from investment in R&D and are reducing incentives to invest in developing future drugs. In the context of compulsory health insurance, such measures may indeed easily run against the preferences of the patient and the insured who are waiting and willing to pay for more new innovative treatments.

In order to achieve optimal spending on drugs - that patients are willing to pay directly from their pockets or indirectly through their insurers, recognising consequently the potential added value of new drugs - public health insurance monopolies would have to be called into question and the insured given the freedom to subscribe to the insurer of their choice.

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## Introduction

Public authorities in Germany, like those in most other OECD countries, have instituted compulsory health insurance systems aiming to provide the populace with universal coverage and nearly free health care. In doing so, they eliminated a health insurance market in which individual choice curbed undesirable cost increases, with insured persons deciding voluntarily whether or not to finance their health insurance policy if cost escalations were to occur. Compulsory health insurance systems also became an uncontrollable source of spending on health care and drugs, with substantial rises in recent decades in most OECD countries.

Rather than let the insured choose to finance coverage that matches the way they would prefer to handle this spending growth, governments have instead instituted or added a broad range of policies aimed at artificially containing the costs of providing services and health care products. These include controls on doctors' fees and drug prices, new or higher co-payments, items de-listed with people still required to pay into a compulsory scheme, etc.

The reference pricing (RP) policy for drugs is among the means used by public authorities to reduce the costs of public insurance. Without insured persons getting any choice in the matter, this was put forward as a policy to help lower drug prices and ultimately to reduce public spending on drugs. The RP system is thus seen as a way to contain costs while full universal drug coverage is offered presumably with no serious drawbacks for insured persons.

RP policy seems increasingly to be in fashion. It was formally instituted for the first time in 1989 in Germany<sup>1</sup> where, since 2004, it has gone into a new phase. It may now include new or recently patented medicines, whereas for a long time they were not subject to it<sup>2</sup>.

Following Germany, other countries also adopted RP policy. For example, the Netherlands and New Zealand instituted it in 1991 and 1993 respectively, including patented drugs from the start. France, Italy, Spain, Denmark, Australia and the Canadian province of British Columbia,<sup>3</sup> among others, also applied the RP system to varying degrees.

The RP system is often criticised because of the way it penalises pharmaceutical innovation. However, although the RP system in effect has an undeniable impact on the drug market, in particular because of the influence of public monopolies, this is primarily a reimbursement practice used in the health insurance field and is chiefly the concern of the insured and their insurers.

Accordingly, it is more appropriate to analyse first the effects of RP policy in the insurance field where, by emphasizing cost reduction, it provides savings for funds related to the use of medication. However, it also has its drawbacks: for example, it provides limited coverage for certain drugs, and it relies on the use of a bureaucratic classification of groups of drugs that are considered substitutable even if patients may not see it in the same light. In this type of situation, only free competition between insurers and the freedom of insured persons to choose - currently absent in Germany - can indicate if and where RP policy can present added value in the eyes of patients (Section 2).

But when RP policy is practised by a legal monopoly of health funds, akin to the situation in Germany, it is important to recognise that it represents a reimbursement policy which, in this context, ultimately discriminates against new drugs, producing an indirect effect on pharmaceutical innovation (Section 3).

<sup>1</sup> See, among other, M.N. Graham Dukes, Flora M. Haaijer-Ruskamp, Kees de Joncheere and Ad H. Rietveld, "Drugs and Money: Prices, affordability and cost containment", *World Health Organization*, IOS Press, 2003, p. 86, available at <http://www.euro.who.int/document/e79122.pdf#search=%22Schoffski%20O%2C%20Graf%20von%20der%20Schulenburg%20JM%22>. Also see Patricia Danzon and Jonathan Ketcham, "Reference pricing of pharmaceuticals for Medicare: Evidence from Germany, The Netherlands and New Zealand", *National Bureau of Economic Research*, working paper 10007, September 2003, p. 2, available at: [http://hc.wharton.upenn.edu/danzon/PDF%20Files/NBER%20Danzon\\_Ketcham%20Ref%20Pricing%20of%20Pharma%20for%20Medicare.pdf](http://hc.wharton.upenn.edu/danzon/PDF%20Files/NBER%20Danzon_Ketcham%20Ref%20Pricing%20of%20Pharma%20for%20Medicare.pdf).

<sup>2</sup> If new drugs are judged to provide a therapeutic improvement, they are exempted from RP.

<sup>3</sup> For a critical study of the British Columbia system, see John R. Graham, "The Fantasy of Reference Pricing and the Promise of Choice in BC's Pharmacare", *Public Policy Sources* 66, Fraser Institute, 2002, available at <http://www.fraserinstitute.ca/admin/books/files/graham.pdf>.

Before examining the various economic effects of RP policy, however, it is appropriate to start by setting out the principles it is based on and the context in which it was instituted in Germany (Section 1).

## 1. Germany's reference pricing policy<sup>4</sup>

First, although reference pricing is the chosen term, it should be emphasized that this is not in itself a pricing policy as such, even when practised by compulsory health insurance systems. What it involves is the establishment of reimbursement ceilings - created and set by the health insurance - for the drug costs of persons covered by the system.<sup>5</sup> Drug manufacturers remain, at least legally, free to set their prices.

It would actually be more appropriate to speak of a uniform payment policy or fixed amount policy. French economists Annick Le Pape, Valérie Paris and Catherine Sermet refer correctly to a "fixed-reimbursement drug policy".<sup>6</sup>

Other economists who have studied RP policies also pointed to this ambiguity in the concept, noting that "RP implies a reimbursement limit, not a final market price. Reference pricing is not, strictly speaking, a pricing system."<sup>7</sup>

The basic idea that RP policies rely upon - and Germany is no exception - is relatively simple: for an insurer it theoretically involves classifying drugs regarded as interchangeable into therapeutic groups (1.1) and applying a reimbursement ceiling for each group or sub-group formed in this way (1.2). In keeping with these principles, RP policy has been instituted incrementally by German public authorities (1.3).

### 1.1. Forming interchangeable drug groups

With RP policy, the criteria for putting drugs into groups can vary in breadth. Forming therapeutic groups may rely on the bio-equivalence of products or on a therapeutic equivalence judged sufficient by health insurance authorities.

#### - Groups based on bio-equivalence of drugs

Two drugs are considered bio-equivalent if they contain the same active therapeutic substance and if the body absorbs the pharmaceutical product at exactly the same speed and intensity (bio-availability). From a medical stance, it is thus the same molecule and the same drug.

By definition, with this type of reference pricing, also called "generic referencing" or type 1 reference pricing, each group is formed by an original molecule (a brand name drug with an expired patent) and its generic copies that have been proven bio-equivalent to it.

#### - Groups based on similarity of therapeutic effects

By broadening the criteria for forming groups, it is possible to group drugs that, although different and not bio-equivalent, are used to treat the same illnesses or symptoms.

<sup>4</sup> The notion of reference pricing that is the focus of this study must not be confused with the use by public authorities in some countries of international prices as a reference in setting domestic drug prices, also known as cross-national referencing. On this subject, see, among others, Danzon and Ketcham, 2003, op. cit., p. 5.

<sup>5</sup> This involves only drug spending in pharmacies under a compulsory insurance system. Such spending will be the subject of this study. Drug spending by private insurance is not involved with the RP system in Germany, and nor is spending by hospitals that negotiate drug purchases directly with wholesalers or producers. On this last point, see Nina Pavchnik, "Do pharmaceutical prices respond to out-of-pocket expenses?", *working paper*, 2002, p. 5, available at <http://www.rje.org/abstracts/abstracts/1983/rje%20health%20symposium/rje.health.pavchnik.pdf>.

<sup>6</sup> Annick Le Pape, Valérie Paris and Catherine Sermet, "Les politiques de forfaits de remboursement des médicaments en Allemagne et aux Pays-Bas", *Centre de recherche d'étude et de documentation en économie de la santé*, Report No.1300, April 2000, Paris, available at [http://www.irdes.fr/En\\_ligne/Rapport/rap2000/rap1300.pdf](http://www.irdes.fr/En_ligne/Rapport/rap2000/rap1300.pdf).

<sup>7</sup> See Guillem Lopez-Casasnovas and Jaume Puig-Junoy, "Review of the literature on reference pricing", *working paper*, April 2000, p. 9, available at <http://www.econ.upf.edu/docs/papers/downloads/362.pdf>.

In an RP system with such groups, referred to as "therapeutic reference pricing", drugs with similar therapeutic effects are classified together without having the same active molecule.

It is possible to distinguish two cases in applying this type of therapeutic reference pricing.

1) On the one hand, it is possible to put drugs with similar but not identical active substances (pharmacological or chemical similarity) into the same group or sub-group, in contrast to the use of reference pricing set out above. This case involves a type 2 or class 2 reference pricing system. For example, it is possible to put the various statins (atorvastatin, fluvastatin, pravastatin and simvastatin) into the same group. These are drugs that reduce cholesterol levels and are judged effective in preventing cardiovascular incidents.

2) On the other hand, it is possible for an insurer to broaden drug classification criteria even further under an RP policy. It may group drugs that contain very different chemical substances and molecules but that have similar therapeutic effects in handling the same symptoms. A reference pricing system containing this type of drug group is referred to as type 3. For example, all hypertension drugs that fall into different classes, such as calcium channel-blocking agents or beta-blockers, could be grouped together.<sup>8</sup>

Under type 2 and type 3 RP policies, there is a double effect that we will examine in greater detail below. On the one hand, there is a risk to the patient if drugs are not bio-equivalent and can be considered non-substitutable by the patient or the physician. On the other hand, it is possible, in contrast to type 1 RP policy, to include new patented drugs. This may have an indirect impact on pharmaceutical innovation, with new drugs benefiting from the same amount of reimbursement as older or generic drugs. This is the case in particular with "jumbo groups", i.e. type 2 or type 3 groups containing both patented and generic drugs.

## 1.2. Fixed maximum reimbursement limits

Once drugs are placed in groups based on therapeutic similarity, the logic of an RP policy is to establish reimbursement ceilings, generally set at the lowest price, the mean price or the median price in a particular therapeutic group (see Table 1). This becomes the group's reference price. It is then revised on a regular basis - often downwards - by health insurance systems.

Table 1: Examples of setting reference prices in Europe

Country	Year of establishment	Criteria for setting reference prices
Germany	1989	Statistically derived reference price calculated on the basis of drug prices in a therapeutic group
Netherlands	1991	Average price of drugs with similar pharmaco-therapeutic effects
Denmark	1996	Price of the least expensive equivalent generic drug available
Spain	2000	Arithmetic mean of the three least expensive therapies, grouped by formulation and calculated according to their standard daily dosage
Belgium	2001	Equal to a price 26% below the price of the original brand name drug for equivalent generic drugs
Italy	2001	Price of the least expensive equivalent generic drug available
Portugal	2003	Price of the least expensive equivalent generic drug available

**Source:** Monique Mrazek and Elias Mossialos, 2004, p. 125.<sup>9</sup>

Thus, contrary to the traditional insurance practice of using *ad valorem* reimbursements (in other words, based on a percentage of the market value of a drug), a reimbursement ceiling is set at the reference price level established by the insurer according to its own criteria. We shall see below that it is important to give the insured, who are most affected by these criteria, the choice of approving this or punishing the insurer by switching to a competitor.

<sup>8</sup> Alexandra Hauber, Dominic Valder and Sav Neophytou, "European Pharmaceuticals; Germany: Reform cuts 'me-too' lifecycle short", *Bear&Stearns*, European Equity Research Pharmaceuticals, February 2004, p. 14.

<sup>9</sup> See Monique Mrazek and Elias Mossialos, "Regulating pharmaceutical prices in the European Union", in *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, edited by Elias Mossialos, Monique Mrazek and Tom Walley, *European Observatory on Health Care Systems Series*, Open University Press, Chapter 6, available at <http://www.euro.who.int/document/e83015.pdf>.

A reimbursement policy of this type generally indicates that, if a drug is priced at or below the reference price, it is comprehensively covered (minus any deductible or co-payment). On the other hand, if a drug has a price higher than the reference price, the insured have to pay the full difference. They may thus be facing a double co-payment, comparable to the situation in Germany: in addition to the existing co-payment that exists for any drug purchase, the insured must also pay this difference either directly from their pockets or indirectly by subscribing to and paying premiums for supplementary private insurance.

There are difficulties inherent in instituting an RP system. While it is easy to compare two drugs in type 1 groups (the same chemical substance) and to set a reimbursement ceiling for the group, it is much harder to do this for drugs with efficacy levels and side-effects that may vary as in type 2 and type 3 therapeutic groups. In this latter case, it is essential to choose a standard presentation for the group and to establish an "equivalence factor" between the various drugs and the standard presentation so as to be able to calculate reference prices for each product. In reality, these choices all involve compromises. As we shall see, it is important to give the insured freedom of choice, enabling them to punish decisions by an insurer if they find that no added value is provided.

### 1.3. Incremental establishment of the RP system in Germany

Germany's compulsory health insurance system, *Gesetzliche Krankenversicherung*, or GKV, covers drugs. During the 1980's, it had a policy of 100% coverage of all prescription drugs sold in Germany, apart from a list of non-reimbursed drugs introduced in 1983 as a first step to control spending.

It is clear that this coverage, financed by compulsory levies and offering drugs almost free at point of purchase, removed any restraint on drug costs that would have existed naturally had there been free competition in the insurance field. But rather than giving choice and responsibility to insured persons and limiting growth in costs, German public authorities were the first to institute an RP policy, referred to as *Festbetrag*, with the 1989 health care reform (*Gesundheitsreformgesetz*, or GRG, also called the Blüm reform).<sup>10</sup>

The GKV health care funds cannot deviate from RP policy because it in effect forms part of the German social legislation code, or *Sozialgesetzbuch* (§ 35 SGB V). As pointed out by German specialists, this legislation "stipulates that reference prices are defined: for drugs containing the same substance, for drugs with similar substances and for drugs with comparable efficacy."<sup>11</sup> This law sets the legal basis for the *Festbetrag*, imposing the formation of type 1, 2 and 3 therapeutic groups on all GKV funds.

Implementation of the *Festbetrag* occurred in three stages.<sup>12</sup>

- The first stage began with the Blüm reform in 1989 and concerned only drugs containing the same active molecule, i.e. unpatented brand name drugs and their generic forms (type 1 groups). Accordingly, this involved reference pricing based on the bio-equivalence of pharmaceutical products.

- In 1992, the reference pricing system was extended to drugs with active substances that were similar but not identical; this new stage instituted type 2 reference pricing.

- Finally, since 1993, the German reference pricing system has included products with similar therapeutic effects but chemically different active substances (type 3).

The Federal Joint Committee of physicians and health insurance funds (*Gemeinsamer Bundesausschuss*, or G-BA), a bureaucratic public law organisation with extensive regulatory powers in the health care field in Germany, has additional regulatory powers thanks to the RP system. It is in

<sup>10</sup> With the GRG reform drugs not falling under the RP system were submitted to a co-payment, thereby transferring a portion of costs to the insured persons.

<sup>11</sup> Jonas Schreyögg, Klaus-Dirk Henke and Reinhard Busse, "Managing pharmaceutical regulation in Germany: overview and economic assessment", *working paper*, 2004, p. 38, available at <http://www.wz.wz.tu-berlin.de/diskussionspapiere/2004/dp06-2004.pdf>.

<sup>12</sup> See Annick Le Pape, Valérie Paris and Catjerien Sermet, op. cit., and Guillem Lopez-Casasnovas and Jaume Puig-Junoy, op. cit.

charge of the formation of therapeutic groups and the standard presentation of equivalence factors for each group, required to apply the RP system. On the other hand, the reference prices and the reimbursement ceilings for each presentation based on its dosage and packaging size<sup>13</sup> are set unilaterally by the federal association of health insurance funds (*Spitzenverbände der Krankenkassen*, or SK) without the insured having any power at all to oppose such choices if ever these choices went against their preferences.

With the incremental establishment of the system, Germany in 2000 had 197 active chemical molecules subject to type 1 reference pricing, 166 molecules divided into 23 groups and subject to type 2 reference pricing, and 31 chemical combinations subject to type 3 reference pricing.<sup>14</sup> Drugs subject to the RP system represented half the value of the German pharmaceutical market and nearly two-thirds of prescriptions.

### **RP policy and new drugs**

As we have already pointed out, new drugs - which under current regulations are patented drugs - may or may not be subject to reference pricing policy, in particular through their inclusion in type 2 or type 3 groups. From the start, RP policy in Germany was intended to encompass patented drugs. However, following changes in the law, patented drugs were exempted from the *Festbetrag* system after 31 December 1995.

In contrast to RP policies in the Netherlands and New Zealand, where patented drugs have been subject to RP, in Germany, as of 1996, patients had comprehensive coverage of their new drugs (minus a co-payment), which could be prescribed and reimbursed based on their selling price and thus outside the RP system. These drugs have accounted for a growing portion, higher in 2003 than in 1996, of drug sales in Germany.<sup>15</sup>

Since the beginning of 2004 with the health insurance modernisation act (*Gesetz Zur Modernisierung der GKV*, or GMG), RP policy in Germany has entered a new phase. Patented drugs can once again be subject to RP as was the case before 1996.<sup>16</sup> Physicians and patients can thus no longer have new drugs, previously reimbursed based on a percentage of their price, unless they are judged by the Federal Joint Committee of physicians and health insurance funds to be products that represent a sufficient therapeutic contribution for them not to be subject to the RP system. Drugs that are considered not to represent an adequate contribution (judged to be "me-too" drugs) will, in contrast, be subject to RP. A number of groups have already been formed, including patented drugs as well as generic drugs (jumbo groups).

## **2. The main effects of RP in the health insurance field**

The quality of an insurance policy depends on factors including the range of coverage that an insurer offers to those it insures. In general, the more complete the reimbursement and the coverage, the higher the premiums paid by the insured tend to be. Conversely, an insurer in a competitive market may also decide to lower a policy's levels of reimbursement and quality of coverage so as to reduce costs and make the policy more affordable to those who so desire. By varying the quality of coverage and the amount of the premium, insurers are able to offer insurance policies that match their clients' preferences.

The reimbursement conditions applied by health insurers also vary widely. These conditions depend on a number of factors:

- whether the insured have to pay a deductible, corresponding to the amount payable by them

<sup>13</sup> For a detailed description of reference pricing calculation in Germany, see Annick Le Pape, Valérie Paris and Catherine Sermet, op. cit., pp. 27-28.

<sup>14</sup> Patricia Danzon and Jonathan Ketcham, op. cit., p. 6.

<sup>15</sup> See Annick Le Pape, Valérie Paris and Catherine Sermet, op. cit., and The German Association of Research-Based Pharmaceutical Companies (*Verband Forschender Arzneimittelhersteller eV*, or VFA), "The pharmaceutical industry in Germany", 2005, p. 56, available at <http://www.vfa.de/en/statistics/statoverview.html>.

<sup>16</sup> See, among others, Alexandra Hauber, Dominic Valder and Sav Neophytou, 2004, op. cit.

before the insurance begins covering expenses;

- whether there exists a co-payment and the amount of any such co-payment; it may be set at a fixed level or may vary depending on the size of the package or the selling price of the drug;
- whether different conditions can apply to reimbursement, with the latter based on selling prices, set at fixed amounts, based on multiple levels, etc.<sup>17</sup>

RP policy generally is instituted in various countries with the idea of achieving savings for compulsory health insurance funds (2.1.). But it also presents drawbacks for the insured (2.2.); for a reimbursement policy to be truly beneficial to them, it is important for them to have free choice in their insurance (2.3.), unlike the GKV's monopoly in Germany (2.4.).

## 2.1. Savings for health insurance funds

The RP system is thought to have a number of advantages, such as allowing for increased competition on the drug market,<sup>18</sup> avoiding direct control of drug prices when applied by a compulsory health insurance system,<sup>19</sup> or leaving physicians free to prescribe the drugs that they feel suit their patients best.<sup>20</sup>

But there is no doubt that the main advantage of this type of reimbursement is that it provides for drug reimbursement limits and ultimately controls spending in this field more effectively. Whatever the selling price of a drug subject to the RP system, the insurer always reimburses the same amount, based on the therapeutic group that the drug in question belongs to. Any excess amount in the selling price beyond the reference price is simply not covered by the insurer and remains entirely at the expense of the insured.

Theoretically, even a private insurer in a competitive situation could have an interest in relying on this type of reimbursement policy and could offer less expensive insurance policies for some of its clients. By setting a ceiling on reimbursements, it limits the risk it incurs and the cost of covering it by actually transferring part of the risk to the insured. The risk varies on a case-by-case basis for each drug, based on the difference between the selling price and the reference price set by the insurer. The wider this gap, the greater the risk borne by the insured. Despite this, such a policy could theoretically enable a private insurer to gain market share among clients who are prepared to assume greater risk. Thus, voluntary adhesion by the insured is, in the final resort, the guarantee that an RP policy creates added value in their eyes.

This power to contain reimbursements is also the aspect of the RP system that is particularly attractive to governments seeking ways of limiting growth in public spending on drugs. Its establishment in Germany in 1989 was consistent with this desire by public authorities at the time to halt growth in the pharmacy costs of compulsory health insurance funds which came close to 30% in constant euros, i.e. after taking account of inflation, between 1981 and 1988.<sup>21</sup> Unlike the use of the RP system by a private insurer, however, with a public health insurance systems in a monopoly context, as in Germany, the insured are obliged to accept this type of reimbursement policy, whether they like it or not.

It is difficult to estimate the savings that are due solely to establishment of RP policy by the German government. This difficulty arises from the fact that other cost containment policies were also adopted in Germany and affected drug spending by the GKV funds. For instance, as of 1993 physicians were subject to budget allocations and incurred financial penalties in the event of overruns. After this drastic measure was introduced, drug spending by the funds underwent a significant decline of 15.5% (taking account of inflation),<sup>22</sup> and this prohibition continued to have restrictive effects on spending by the compulsory insurance system.

<sup>17</sup> See S. Jacobzone, "Pharmaceutical policies in OECD countries: Reconciling social and industrial goals", *OECD, Labour market and social policy Occasional Papers* 40, 2000, pp. 29 and following, available at [http://www.oecd.org/LongAbstract/0,2546,fr\\_2649\\_33729\\_1886987\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/LongAbstract/0,2546,fr_2649_33729_1886987_1_1_1_1,00.html).

<sup>18</sup> For a criticism of this argument, see Danzon and Ketcham, 2003, op. cit.

<sup>19</sup> We shall see, however, in Section 3 that, due to regulation, pharmaceutical research laboratories are subject to a major *de facto* pressure to lower their prices.

<sup>20</sup> We shall see that, due to regulation in Germany, physicians are encouraged to prescribe the cheapest drugs.

<sup>21</sup> See Annick Le Pape, Valérie Paris and Catherine Sermet, op. cit., p. 20; OECD for the consumer price index; calculations by the author.

<sup>22</sup> See also, Tom Walley and Elias Mossialos, "Financial Incentives and Prescribing", in *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, European Observatory on Health Care Systems Series, 2004, p. 190; OECD, Op. cit.; calculations by the author.

According to estimates, RP policy may nonetheless have saved compulsory health insurance funds in Germany more than 15 billion euros from its establishment in 1989 up to 2002 (see Figure 1).

The successive reforms of the *Festbetrag* system in Germany have always kept an eye on lowering expenses, and spending control remained a priority in the GMG reform of 2004, through a broadening of the RP system to new patented drugs. Savings due to this extension and to the lowering of reference prices in existing groups might come to more than three billion euros a year for the health insurance funds.<sup>23</sup>

Sebastian Schneeweiss, a specialist in this field, provides a good summary of the advantages of the RP system for public health insurance systems, which "tend to appreciate the financial predictability and scalability of RDPs [reference drug programs]: savings within RDPs can easily be predicted because a fixed reimbursement limit is set for a group of drugs, and, by lowering the reimbursement limit or expanding an RDP, drug plans can increase their savings."<sup>24</sup> However, unlike the adoption by an insurer in a context of free competition with incentives to transfer these savings to its clients (who otherwise might leave and go over to a competitor), persons insured by the monopoly GKV funds may not benefit from it.

But if the RP system presents real advantages, it also presents drawbacks that the insured could regard as more significant and, if they had the choice, would lead them to change insurers. These drawbacks could explain why private insurers - in the United States as in Germany - are reluctant to adopt it so as to avoid losing a portion of their clients.

## 2.2. The drawbacks of reference pricing for the insured

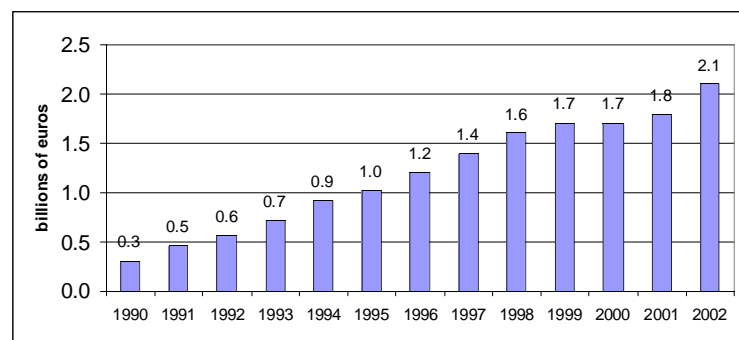
### Limited coverage for some drugs

If the RP system can lead to substantial savings for an insurer, such savings are made possible solely because there are ceilings on reimbursement for each group of drugs and because part of the risk is transferred to the insured as a result.

In theory, the major drawback of an RP policy for the insured is that they have limited coverage of drug expenses, especially for drugs priced above the reference prices. As we have pointed out, in cases where a more expensive drug is prescribed to a patient, the difference between its price and the reference price is not covered by the insurer, unlike an *ad valorem* reimbursement policy that varies as a percentage of the selling price.

For example, if a therapeutic group includes two drugs, A and B, that are not bio-equivalent and that are priced in pharmacies at 50 and 125 euros respectively, the insurer will not provide reimbursement beyond a set amount (the reference price for this group), perhaps 50 euros, equal to the price of the less expensive drug. This amount is the same regardless of which of the two drugs is prescribed. Thus, even if a patient requires the more expensive drug B because he suffers from major side-effects with drug A or because the latter is ineffective for him personally, the insurer will cover the cost only up to the reference price set in this instance at the same level as the less expensive drug. The insured will have to pay the difference of 75 euros either directly from his pocket or by taking

**Figure 1:** Savings due to RP policy in Germany, 1990-2002



**Sources:** Annick Le Pape, Valérie Paris and Catherine Sermet, op. cit., p. 37, and Jonas Schreyögg, Klaus-Dirk Henke and Reinhard Busse, op. cit., p. 39.

<sup>23</sup> See The German Association of Research-Based Pharmaceutical Companies (VFA), "The pharmaceutical industry in Germany", 2005, op. cit., p. 56.

<sup>24</sup> See Sebastian Schneeweiss, "Effectiveness of Reference Drug Programs and Policy Implications", paper presented to the conference on "Health Services Restructuring: New Evidence and New Directions", organised by the John Deutsch Institute, Queens University, Canada, November 17-18, 2005, p. 3, available at [http://jdi.econ.queensu.ca/Files/Conferences/HealthServicesconferencepapers/Schneeweiss\\_paper.pdf#search=%22reference%20pricing%20and%20physicians%20drug%20budgets%22](http://jdi.econ.queensu.ca/Files/Conferences/HealthServicesconferencepapers/Schneeweiss_paper.pdf#search=%22reference%20pricing%20and%20physicians%20drug%20budgets%22).

supplementary insurance. In all cases, the insurance company limits its reimbursement costs for all drugs in the therapeutic group. It is clear that, in this particular case, an *ad valorem* reimbursement policy that covers more than 40% of the selling price would provide the insured with a higher reimbursement (in other words, more than 50 euros) than under RP policy.

With an RP policy, such situations are or may become quite frequent, and insurance policies may no longer provide coverage that matches the preferences of some insured persons who, depending on circumstance, might prefer to change insurers and obtain coverage that comes closer to matching their preferences and their personal situations.

On the other hand, public health insurance systems generally are monopolies and have captive clients. Insured persons, even if they find their coverage less than optimal, have no choice and are obliged to put up with potential drawbacks due to the limited coverage provided under an RP system. And these coverage drawbacks could well be greater with a type 2 or type 3 RP system. As indicated by economists Patricia Danzon and Jonathan Ketcham:

"For therapeutic substitutes that differ in their effects for different patients, RP is unlikely to provide the optimal tradeoff between risk spreading and cost control for patients who do not respond to the cheaper drug. RP is likely to be inferior to a co-insurance rate, which would provide some risk protection for the incremental cost of more expensive drugs for these patients."<sup>25</sup>

Although the coverage provided under RP policy exposes persons insured by public systems to the risk connected to this added cost, this risk may not materialise if drug producers can be pushed into lowering their prices. If this were the case, insured persons would obviously have no price difference to pay. As we shall see in greater detail in Section 3, public health insurance systems can exert indirect influence in lowering drug prices, as is the case in Germany. This impact is due above all to the monopoly position of the GKV funds and to the adoption of other forms of regulation aimed at reducing demand for drugs by bureaucratic means, even though such measures may go against the interests of insured persons who do not have the choice of leaving the GKV's legal monopoly.

This was notably the case in Germany prior to 2004: given that new patented drugs - which could provide added value and for which producers might be more likely to demand higher prices - were excluded from the RP system, they were traditionally reimbursed based on their selling price. In contrast, for other drugs subject to the RP system, producers lowered their prices to the extent that the risk for insured persons of having to pay supplementary costs did not materialise. In a certain sense, this enabled the effects of limits in coverage on persons insured by a compulsory system to be hidden, and reimbursements for new drugs continued to be made as they were prior to establishment of the RP system.

But with the inclusion after 2004 of new patented drugs for which producers are more likely to demand prices that exceed the reference prices, there is a greater risk that insured persons may have to pay this price difference. This is all the more plausible in that prices in Germany influence prices charged elsewhere in Europe. In fact, the governments of other European countries use German prices as a benchmark in calculating the prices set in their own countries (see Table 2). In this case, producers will be more reluctant to lower their German prices because this would cause a domino effect, with lower prices for their products elsewhere in Europe.

As emphasized by specialist Elisabeth Beck, "New medicines are mostly marketed by international companies that set price corridors across Europe. There is a greater probability that such products will be sold at rates above the reference price, with patients having to bear the

**Table 2:** Countries using German prices to set their domestic prices, 2003

Country	Method of calculating domestic prices
Belgium	Manufacturers' prices in <i>Germany</i> , France, Luxembourg and the Netherlands
Denmark	Average of European manufacturers' prices including <i>Germany</i> (excluding Greece, Portugal, Spain and Luxembourg)
Finland	Average EU wholesale price, including <i>Germany</i>
Ireland	Average of wholesale prices in <i>Germany</i> , France, the Netherlands, Denmark and the United Kingdom
Italy	Weighted average of manufacturers' prices in the EU including <i>Germany</i> (excluding Luxembourg and Denmark)
Netherlands	Average of manufacturers' prices in <i>Germany</i> , Belgium, France and the United Kingdom

**Source:** Monique Mrazek and Elias Mossialos, 2004, op. cit., p. 118.

<sup>25</sup> Patricia Danzon and Jonathan Ketcham, op. cit., p. 31.

additional cost."<sup>26</sup>

In Germany, this additional cost that patients have to pay may sometimes be greater than the amount reimbursed and may be as much as 70% of the selling price of a drug.<sup>27</sup> In order to avoid coverage drawbacks it is important to have free competition among insurers and letting clients choose and finance the coverage that suits them best.

### **The risk of inadequate substitutability among drugs**

RP relies fundamentally on the hypothesis that drugs classified in the same therapeutic group are interchangeable and thus can be substituted for one another. However, substitutability is in reality a matter of compromise when it comes to different products and when different drugs do not have the same effects, at least on certain patients.

More important yet is that, from an economic stance, the notion of substitutability between two goods ultimately depends on consumers' assessment and remains a subjective notion. It is consumers who ultimately decide whether or not two goods are substitutable. Some goods with physical and functional similarities may be considered substitutable by some consumers but not by others. For example, someone may consider two wines as perfectly substitutable, whereas this may not be the case with someone who is a connoisseur and who truly regards the two wines as different. A slight difference in colour, taste and so on may result in two goods that seem similar in terms of objective characteristics not being considered by consumers as equivalent or interchangeable.

What is valid for consumers is just as valid for patients who "consume" drugs. What counts in the pharmaceutical field is the value of drugs for patients who are the ultimate beneficiaries of pharmaceutical products.

It matters little that experts hired by a private insurance company or bureaucrats with public health insurance systems consider two drugs to be substitutable. What is important is how patients consider them in their personal case.

### **Substitutability among drugs in a type 1 groups**

As long as the drugs in a group are bio-equivalent (type 1 group), the risk to patients from an RP policy is limited. The drugs represent the same molecule, and there is a strong chance that patients and the physicians prescribing them find them substitutable.

However, it is possible, even in type 1 groups, that drugs may not be perfectly identical. In effect, drugs are combinations of substances. Apart from the active therapeutic substance that remains the same within a type 1 group (meaning the original drug and generic copies), other substances, called excipients, may differ from one drug to another within the group. These excipients may also have economic value for patients (for example, a better taste that makes a drug easier to take). Also, the colour, the presentation or the packaging of the molecule, etc., may vary, affecting attractiveness or convenience for patients.

Accordingly, as pointed out by Maassen, drugs containing the same active molecule may present certain differences for patients.<sup>28</sup> Even if a drug is the same from a medical standpoint and is judged as such by an insurer, it is conceivable that patients may regard it from an economic standpoint as not being perfectly substitutable.

It is quite possible in such a case that some insured persons, given the choice, would prefer to pay for insurance policies that cover both brand name and generic drugs. On the other hand, for those who regard drugs as substitutable, private health insurers - like PBMs in the United States<sup>29</sup> - readily

<sup>26</sup> Elisabeth Beck, "Tough Love: German Healthcare Reform", *IMS Health*, 2003, available at [http://www.imshealth.com/web/content/0,3148,64576068\\_63872702\\_70260998\\_70960201,00.html](http://www.imshealth.com/web/content/0,3148,64576068_63872702_70260998_70960201,00.html).

<sup>27</sup> For examples, see German Institute of Medical Documentation and Information (*Deutsches Institut für Medizinische Dokumentation und Information*, or DIMDI), list of products under Festbetrag, available at <http://www.dimdi.de/static/de/amg/fbag/index.htm>.

<sup>28</sup> Mentioned in Guilem Lopez-Casasnovas and Jaume Puig-Junoy, 2000, op. cit., p. 13.

<sup>29</sup> Pharmacy Benefit Managers. See Danzon and Ketcham, op. cit.

offer policies based on the type 1 RP system, providing for lower spending and giving patients financial incentives to substitute generic drugs for more expensive original drugs. In contrast, persons insured by a monopoly health insurance system situation get scarcely any choice from their insurer and are obliged to contribute financially to coverage that runs against their preference if they regard this substitutability between drugs in type 1 groups as inadequate.

### **Substitutability in type 2 and type 3 groups**

The risk of substitutability being inadequate for patients becomes greater in comparing drugs with active molecules that are not identical and that form type 2 or type 3 groups. Specialists go even further in emphasizing that this concept of interchangeability is a bureaucratic rather than a medical concept.<sup>30</sup>

Spanish economists Guillem Lopez-Casasnovas and Jaume Puig-Junoy sum up the many reasons that result in two drugs - even if regarded as therapeutic substitutes by an insurer - may nonetheless have different effects on patients. Thus, "[h]eterogeneity between medicines with the same level and price reference group may stem from:"<sup>31</sup>

- differences in the quality of a drug (e.g., the presence of impurities);
- a drug's performance (speed of absorption, indications, side-effects);
- differences in the chemical preparation of drugs;
- differences in the way a drug is taken (e.g. oral, topical, rectal);
- differences in power and dosage (weak, medium or strong dosage);
- differences in bio-availability (fast or slow action, with or without delay);
- differences in the number and type of indications treated;
- differences in the type and frequency of undesirable side-effects;
- differences with respect to counter-indications, etc.

Different drugs in a therapeutic group, although classified together, may thus not be perfectly substitutable even from a medical standpoint. Accordingly, they may easily present major differences in the eyes of some patients and of prescribing physicians.

Such differences risk being even greater in the case of jumbo groups containing new patented drugs along with older generic drugs, as has been the case in Germany since 2004. The new drugs often represent improvements - even if only slight - compared to existing drugs. These incremental improvements could nonetheless provide economic value in the eyes of patients if informed about them or in the eyes of physicians who are not penalised for prescribing them. Though bureaucrats can decide, for instance, that a drug offers only easier administration (e.g., orally rather than by injection) but provides no therapeutic progress, it may nonetheless be different from a patient's point of view. With lower drug costs as a priority, the Federal Joint Committee of physicians and health insurance funds, which is in charge of deciding on the substitutability of groups, may adopt broader criteria - especially since the 2004 reform - and include drugs it considers substitutable but that patients are more likely to find different.

The verdict of consumers / insured persons is crucial in bringing added value to the substitutability criteria in their eyes. It is worrying to see - contrary to the possible adoption of an RP policy by a private insurer - that patients have no way of expressing their choice in the context of public health insurance systems. The sanction of profits and losses (i.e. the market test) does not exist in a legal monopoly but does remain the only criterion in determining, on the one hand, if therapeutic categories are well defined and, on the other hand, if insurance policies based on these categories match what patients want.

### **Effect on patients' health and possible use of other medical resources**

In theory, a reference pricing system provides financial incentives to use drugs priced at levels that do not exceed the reimbursement ceiling. But in public health insurance systems, the authorities add other regulatory measures, as in Germany, where physicians have been subject to budget spending

<sup>30</sup> J. Zammit-Lucia and R. Dasgupta, "Reference pricing. The European experience", *Health Policy Review*, Paper N°10, St. Mary's Hospital Medical School, 1995, cited in Guillem Lopez-Casasnovas and Jaume Puig-Junoy, op. cit., p. 12.

<sup>31</sup> Ibid.

caps for prescription drugs (see below). These measures give patients and prescribing physicians strong incentives to change therapies and use less expensive drugs.

Such a change is all the more probable given that patients in public health systems do not have varied sources keeping them informed of the relative efficacy of the drugs in a particular therapeutic group. In countries including Germany, public insurance systems are virtually their only source of information. There may exist a bias because of the monopoly held by public systems and the cost reduction priority imposed by public authorities. Patients cannot, for example, be informed directly by the producers about the greater efficacy or potential benefits of a drug because direct-to-consumer advertising related to prescription drugs remains prohibited. In this context, the creation of therapeutic groups may be interpreted to mean that the drugs in each group are perfectly substitutable without this actually being the case even from a medical standpoint with type 2 and type 3 groups.

Information on the therapeutic effects of drugs is all the more important given that a change in therapy carries risks that an informed patient may prefer not to take. As noted by specialists in New Zealand, "If a drug is working for the patient, make an alteration only with good reason. It often takes a great deal of time and effort to achieve concordance with the patient on what is the right drug for them, at the right dose, and in the right combination with other drugs. Changing from one drug to another in the same class at assumed equivalent doses, should not be undertaken lightly. It is likely to result in therapeutic failure in some patients (through under-dosage), appearance of new side effects in others (through over-dosage, or particular drug idiosyncrasies), and drug interactions with varied effects in others."<sup>32</sup>

This could result in administration of a less effective drug or one with more side-effects, necessitating extra visits to the doctor's office or the hospital. Even if the RP system can lead to savings in spending on certain drugs, it can also produce an increase in other health care costs and in non-monetary - though very real - costs for patients in lost time, suffering, etc.

Casasnovas and Juig conclude that this "may involve increased expenditure on other complementary health care services or even additional drugs."<sup>33</sup> In New Zealand, for example, with the introduction of RP, persons insured by the public system who were receiving simvastatin and pravastatin were required to pay an additional cost. Fluvastatin, less expensive and considered substitutable, was fully reimbursed by the public system. It later emerged that, though the public system achieved savings through a change in therapy to fluvastatin, those who did so experienced substantial increases in their cholesterol levels and therefore faced a higher risk of cardio-vascular incidents.<sup>34</sup>

In Germany, until 2004, this type of problem involving changes in therapy had been marginal because, with new drugs exempted, producers lowered the prices of older drugs to levels close to the reference prices. Patients could thus continue to be reimbursed for new drugs and to use older drugs without price surcharges. This meant they had no incentive to change therapy.

The 2004 reforms could modify this situation by bringing into the RP system new patented drugs that are probably priced above reference thresholds, which are based on the prices of drugs discovered and developed several decades earlier. If so, patients will either have to pay a higher portion of costs (a reminder that RP policy has led to less coverage of these drugs without patients being able to change insurers) or will have to change therapy with the risks this involves, without necessarily being informed of their existence.

<sup>32</sup> Evan Begg, Andrew Sidwell, Sharon Gardiner, Gary Nicholls and Russell Scott, "The sorry saga of the statins in New Zealand - pharmacopolitics versus patient care", *Journal of the New Zealand Medical Association*, 14 March 2003, Vol. 116, No 1170, available at <http://www.nzma.org.nz/journal/116-1170/360/>.

<sup>33</sup> Guillem Lopez-Casasnovas and Jaume Puig-Junoy, op. cit., p. 13.

<sup>34</sup> M.C. Thomas, J. Mann and S. Williams, "The impact of reference pricing on clinical lipid control", *New Zealand Medical Journal*, 1998, No. 111, pp. 292-4, cited in Patricia Danzon and Jonathan Ketcham, op. cit., p. 4. See also Evan Begg, Andrew Sidwell, Sharon Gardiner, Gary Nicholls and Russell Scott, op. cit.

### 2.3. The role of free competition and free choice for insured persons

RP policy provides advantages for insurers (which in a context of monopoly health insurance may not benefit captive clients) and may also present major drawbacks for those they insure.

In the presence of such effects, the role of competition among various insurers (who are free to offer insurance policies based on different reimbursement plans) and freedom of choice for insured persons are of crucial importance. It is important that insured persons have the option of changing insurers if they consider that the RP policy established by their existing insurer does not suit their wishes. It is also important that other insurers have the freedom to offer the reimbursement plan of their choice to respond most effectively to what their clients prefer.

This is especially true when what is involved is therapeutic reference pricing that includes type 2 and type 3 groups. In effect, to the extent that these therapeutic groups contain drugs that are not bio-equivalent, the insured have all the more reason to be reluctant to sign up with insurers that apply such pricing, despite the cost reductions that this type of RP system should eventually provide. If the RP system truly brought added value to insured persons, competing insurers would not hesitate to offer it to them and gain market share.

Even if they adopted an RP system similar to that of the GKV in Germany,<sup>35</sup> they would always be continuously obliged to pass the market test and to keep on showing its added value so as to retain their clients or to win over new ones. Competition from other insurers and the opportunity for the insured to go elsewhere remain the best guarantee for therapeutic groups to be constituted properly and only in situations where clients get added value.

Free competition ends up providing the guarantee that an RP system will be used advisedly, without running counter to patients' interests. It is worrying to see that this freedom of choice and free competition among insurers does not exist in Germany, where the RP system applies to a great majority of the populace.

### 2.4. Danger from the monopoly of compulsory health insurance funds in Germany

Only part of the German populace is permitted to leave the compulsory system completely and cease paying into it. Taking advantage of the opting out provision, these people can insure themselves with a private insurance company. To be eligible they must have incomes exceeding a threshold set at 3,937.50 euros per month in 2006.<sup>36</sup> More than 9% of the German populace gets health insurance from private insurers.<sup>37</sup>

On the other hand, Germans who are below this income threshold are required to be affiliated with a compulsory health insurance fund. Unlike France, where health funds are assigned to insured persons, in Germany since the 1996 reform each fund competes to attract subscribers. But this is not real competition. The only thing likely to make a difference at the margins is the level of the compulsory contribution taken off salaries (split almost evenly by employer and employee); this is nearly the same from one fund to another. The GKV system thus covers more than 90% of the populace (10% voluntarily and 80% by obligation).

To sum up, although it is possible to choose insurance funds geographically, the great majority of people in Germany do not have the option to leave compulsory health insurance.<sup>38</sup> This obligation gives health funds legally protected monopoly power and ends up providing them with a captive customer base that lacks the choice of changing insurance policies.

<sup>35</sup> John Inglehart mentions the plans of private insurers in the U.S. to adopt this type of therapeutic reference pricing. See "Will Reference pricing address the health cost conundrum?", *Health Affairs*, Vol. 22, No. 3, May-June 2003, p. 8, available at <http://content.healthaffairs.org/cgi/reprint/22/3/7.pdf#search=%22will%20reference%20pricing%20address%22>.

<sup>36</sup> See Alain Vasselle and Bernard Cazeau, *Rapport d'information sur les évolutions du financement de la protection sociale et la réforme du système de santé en Allemagne*, Social Security assessment and control mission, Senate (France), June 2006, p. 16, available at <http://www.senat.fr/rap/r05-439/r05-4390.html>.

<sup>37</sup> Ibid. See also "Private Health Insurance in OECD Countries," *OECD Observer*, November 2004, available at <http://www.oecd.org/dataoecd/15/41/33915167.pdf>.

<sup>38</sup> See David Green and Benedict Irvine, "Health care in France and Germany", *Institute for the study of civil society* (Civitas), London, 2001, p. 54, available at <http://www.civitas.org.uk/pdf/cs17.pdf>.

In drug insurance, this means that 9% of the populace benefits from insurance policies offered by private companies that do not use the RP system. In contrast, compulsory health insurance funds are obliged to follow RP policy as stipulated by law. Even if they wanted to apply other reimbursement policies, they would not be free to do so. This means in reality that about four-fifths of Germans have no choice of insurance policy and cannot express a preference or rejection regarding RP policy. Given the potential drawbacks this policy presents, it is important to allow all Germans truly to choose their insurance and to let free competition play out between insurers that could offer reimbursement policies their clients value most highly.

But it is this monopoly - and government support - that ultimately gives the health funds in an RP system the power to affect drug demand and to have an indirect impact on the pharmaceutical market and on drug prices.

### 3. The indirect impact on the drug market and on pharmaceutical innovation

Pharmaceutical markets in various countries are subject to many sets of regulations that often have opposing effects. The existence of patents increases incentives to invest in R&D on the one hand, whereas long and costly procedures elsewhere, for example to obtain drug approvals and marketing authorisations from various national authorities, creates an artificial increase in uncertainty along with the risk of investing in pharmaceutical innovation and the cost of new drugs. Direct price controls on new drugs also have the effect of reducing incentives for producers to pursue R&D and to develop new treatments.

Does the German RP system - as a specific reimbursement policy - add to these effects in the overregulated context of pharmaceutical innovation? If so, what form does this impact take, and how is it exerted?

Unlike the effects exerted by direct price controls on the prices of new drugs, the RP system has an indirect impact that is more difficult to determine. This impact is all the greater in that RP policy has been adopted by a compulsory health insurance system that weighs heavily in this market (3.1.). This results in downward pressure on prices of patented drugs in this market (3.2.). In particular, it penalises new drugs that are judged to represent only incremental innovations and improvements compared to existing drugs<sup>39</sup> (3.3.). Finally, the German RP system artificially reduces the incentives and the means of the pharmaceutical industry to pursue R&D and develop new drugs (3.4.).

#### 3.1. Germany's pharmaceutical market: the compulsory insurance monopoly dominates

The German pharmaceutical market is the biggest in Europe and the third biggest in the world after the United States and Japan.

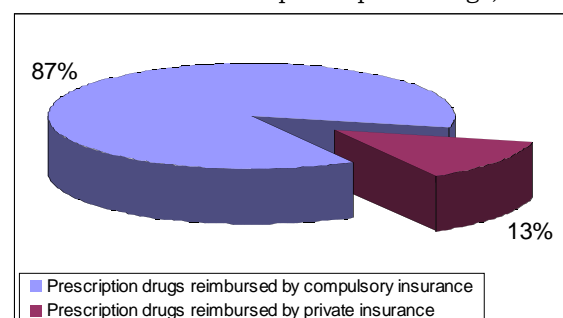
The GKV monopoly - exerted through its financing of drug expenditures - has a major influence in this market. In 2004, for example, prescriptions covered by GKV funds represented 25.2 billion euros, or 74% of the entire retail pharmaceutical market. Drugs covered by private sector insurance accounted for 15% and over-the-counter drugs for the remaining 11%.<sup>40</sup>

If we look only at the market for prescription drugs, the presence of the compulsory health insurance monopoly is even greater, rising to 87% of drug sales compared to only 13% for private insurers (Figure 2).

#### 3.2. Price pressures on patented drugs in Germany

Theoretically, in the absence of direct controls on drug prices by the public authorities, drug producers have no incentive to lower their prices except to the extent that demand for their products risks falling.

**Figure 2:** GKV monopoly power in the German market for reimbursed prescription drugs, 2004



Source: VFA, p. 47.

<sup>39</sup> These are wrongly considered as copies, or "me-too" drugs, as opposed to pioneer drugs embodying major rather than incremental innovation.

<sup>40</sup> The German Association of Research-Based Pharmaceutical Companies (VFA), op. cit., p. 47.

## Discriminatory reimbursement with respect to more expensive drugs

We can note first that a change in relative prices may lead patients to reduce their demand for drugs that become relatively more expensive for them. Going from *ad valorem* reimbursement to an RP policy (as in Germany) modifies these relative prices. Such a policy discriminates against drugs with selling prices above the reference price and favours less expensive drugs that are fully covered by the health insurance funds and for which the cost at the moment of purchase for the patient may be nil, apart from any co-payment that may apply. In Germany a new set of regulations accentuates this discriminatory effect since it allows insured persons to be fully exempted from this co-payment when buying drugs with a selling price 30% below the reference price.<sup>41</sup>

To illustrate this effect resulting from the change in relative prices for insured persons following a switch in reimbursement policy, we can take the example of drug A and drug B, with selling prices that can be expressed respectively as  $P_a = 100$  euros and  $P_b = 50$  euros. In the absence of insurance coverage, the relative price of A compared to B for the patient at the moment of purchase is 2 (in other words,  $P_a / P_b = 100 / 50 = 2$ ).

- An *ad valorem* reimbursement system leaves the relative prices between drugs unchanged. With an insurer covering 70% of the price, for example, the relative share of the price covered by the patient stays at 2 ( $30\% \times P_a / 30\% \times P_b = 30\% \times 100 / 30\% \times 50 = 30 / 15 = 2$ ).

- On the other hand, with the introduction of an RP system, the situation changes. In the presence, for example of a co-payment (C) of 5 euros and a reimbursement ceiling set by the insurer at the level of the cheaper drug, in other words 50 euros, the relative price of drug A compared to drug B soars from 2 to 11 ( $[P_a - P_b + C] / C = [100 - 50 + 5] / 5 = 11$ ). RP policy thus discriminates in favour of cheaper drugs at the expense of drugs with selling prices higher than the reference prices. When the insured choose voluntarily to subscribe to such a reimbursement policy in a free market, this discrimination reflects their preferences and their assessments with respect to new drugs.

In contrast, for drugs priced below the reference prices, introducing an RP system could increase demand. Producers of these drugs would thus get an incentive from RP policy to raise their prices. Increases in the prices of certain generic drugs that bring them close to reference prices have been observed in Germany, as in other countries.<sup>42</sup>

The impact of this discriminatory effect on selling prices is not automatic, however. It will tend to vary with the power of an insurer. If a private insurer applies an RP policy in a competitive context, the discriminatory effect may not be sufficient to cause market demand for innovative drugs (which are among the most expensive in their class) to fall significantly, in which case this policy will have only a minor impact on the selling prices of drugs. An insurer applying such a policy thus lacks the influence to give drug producers an incentive to lower their selling prices. It all depends on the power of the insurer.

The situation of public health insurance systems is crucial in this regard. These systems, in Germany as elsewhere, have monopolies that let them play a significant role in the drug market. Because of their power in financing drug spending, health insurance funds can exert a far greater impact on demand from patients, giving them incentives to turn to cheaper drugs that are fully covered. Producers of patented drugs, generally priced above reference prices, thus have a greater incentive to lower their prices if they wish to sell their drugs to the great majority of the German populace through the intermediary of the monopoly funds.

To the extent that RP policy in Germany - or in other countries - has caused prices to drop, these price reductions must be attributed largely to the protected monopoly position of the public systems in

<sup>41</sup> See Alain Vasselle and Bernard Cazeau, *Rapport d'information sur les évolutions du financement de la protection sociale et la réforme du système de santé en Allemagne*, 2006, op. cit., p. 59.

<sup>42</sup> See Guillem Lopez-Casasnovas and Jaume Puig-Junoy, 2000, op. cit., p. 16.

the health insurance field. It enables them to play a role on the drug market similar to that of a sole buyer in a monopsonistic market.<sup>43</sup>

There exist in Germany a broad range of other regulations that are likely to lower demand for drugs priced above reference prices. As pointed out above, RP policy has been accompanied by measures that result in more expensive drugs being penalised. Unless they lower their prices, producers risk losing market share.

### **- The prohibition on advertising prescription drugs**

Downward pressure on prices also results from the fact that patients who have to pay out of their own pockets when a drug price exceeds the reference price are unwilling to do so unless the drug provides added value in their eyes. Without advertising, though, it is hard for producers to make the advantages of their new drugs directly known to patients. The latter are deprived of a potential means to know whether a drug offers them added value.<sup>44</sup>

If patients were informed of the specific characteristics of new drugs, they would be more likely to pay for a drug that would certainly cost them more but would also potentially be better adapted to their situation.

### **- The information requirement and budget spending caps for physicians**

To have an impact on demand for drugs, it is also important for health fund monopolies to control the behaviour of these who prescribe drugs, i.e. physicians.

In Germany the public authorities have, on the one hand, put physicians under a legal obligation to inform patients if they are prescribing a drug priced above the reference price and to explain the reasons for this. This obligation imposes a time cost on physicians that is not reimbursed by the health insurance funds in Germany, thereby giving them an incentive to prescribe cheaper drugs and avoid this cost.<sup>45</sup>

On the other hand, between 1993 and 2002, budget spending caps were imposed on physicians so that, when spending exceeded a certain threshold set by the health funds, physicians were likely to be subject to financial penalties.<sup>46</sup>

Although the system of spending caps on drugs was eliminated in 2002, another system of "spending by goal" and a "bonus-penalty" system, dating from 2006, have restricted the freedom of physicians to prescribe the drugs they consider best adapted to their patients. A "reference table" of drugs to be used for a given pathology, including an average cost, is provided to physicians. "In case these averages are exceeded, the physician will be sanctioned on an individual basis."<sup>47</sup> In contrast, a bonus is provided if a physician manages to prescribe drugs at below average cost.

With such measures, there are powerful incentives for physicians to prescribe a given drug over another for the sole reason that one of them costs less, whereas the other may actually be better suited to a patient's individual condition. This measure is obviously a further step in the direction of bureaucratised medical practice that leaves little room for a physician's free judgment in the face of a patient's specific situation.

<sup>43</sup> This is a market in which, due to regulations, there is only a single buyer. See on this subject Walter Block and William Barnett II, "An Austrian critique of neo-classical monopsony theory", working paper, p. 2, available at <http://www.mises.org/journals/scholar/block12.pdf#search=%22block%20monopsony%22>.

<sup>44</sup> See on this subject the Economic Note from the Molinari Economic Institute titled "Is the ban on drugs publicity good for health?", January 2006, available at <http://www.institutmolinari.org/pubs/note20061.pdf>.

<sup>45</sup> Danzon and Ketcham, op. cit., p. 15.

<sup>46</sup> Jonasz Schreyögg, Klaus-Dirk Henke and Reinhard Busse, op. cit., p. 31.

<sup>47</sup> See Alain Vasselle and Bernard Cazeau, *Rapport d'information sur les évolutions du financement de la protection sociale et la réforme du système de santé en Allemagne*, op. cit., pp. 58-59.

Even if they have helped lower the prices of drugs that in a great majority of cases cost more than the reference prices, these drastic measures have had their own perverse effects. For example, when budget spending caps were in effect, physicians would refer patients to specialists or would send them to the hospital solely to avoid exceeding their allocation. In the first seven months of 1993, the rate of referral to other doctors rose by 9% and the rate of hospital admissions by 10% compared to the previous year.<sup>48</sup>

Such measures may also contribute artificially to the existence of a deficit in the use of drugs by patients. German specialist Oliver Schöffski found in a study conducted in 2002 that more than 2.5 million German asthmatics, for example, were not receiving suitable therapy, and "the total costs of this disease in all sectors of the health care system are much higher than necessary."<sup>49</sup> In addition, only 50% to 60% of patients suffering from chronic bronchitis were receiving the recommended treatment, and only 74% of persons with high cholesterol levels were getting adequate up-to-date treatment, increasing their risk of cardio-vascular incidents.

In conclusion, these regulations all have the overall result of effectively reducing demand for patented drugs, generally among the most expensive in their respective therapeutic groups.

### 3.3. "Incremental" innovations penalised

In a free market, the added value of each innovation is assessed by its ultimate beneficiaries, consumers, who choose it deliberately in preference to existing products and pay its cost.

The same principles are theoretically valid for drugs if public authorities do not get in the way. Individuals show if they prefer new drugs by paying directly out of their pockets or indirectly through insurance policies that cover them. In this context, their purchasing power and their preferences determine naturally whether an innovation offers added value in their eyes, and this gives producers information as to whether R&D needs to be increased or if the economic resources they use should go toward innovation in other areas of the economy.

However, the establishment of a compulsory health insurance system like the one in Germany has replaced these individual decisions with almost full reimbursement of any drug sold in the country. Faced with the explosion in drug spending that followed, rather than yield to free competition and to the individual decisions of patients and their doctors, the German government preferred to use the RP system through which experts and bureaucrats are able to decide in their place which drug represents an innovation (a therapeutic contribution) and which drug is just a "copy" of existing drugs, even if it actually provides incremental innovations from a therapeutic standpoint in the eyes of patients.

With the German RP system, drugs considered to provide incremental improvements are those most likely to be penalised. Drugs providing major therapeutic innovations will have a greater chance of not being subjected to the RP system. This bureaucratic distinction between innovative products may not be reflected in the assessments of the ultimate beneficiaries, i.e. the patients, who are not given the opportunity to approve or disapprove such judgments.

Moreover, bureaucratic assessments of this sort under the RP system in Germany tend to disregard the fact that pharmaceutical innovation - like the process of innovation in other fields - remains by its nature an incremental process. As we are reminded by specialists Albert Wertheimer, Robert Levy and Thomas O'Connor, "the history of pharmacology is characterized by incremental improvement in the safety, efficacy, selectivity and utility of drugs."<sup>50</sup> Penalising these incremental improvements through RP policy thus ends up also penalising the process of innovation itself.

<sup>48</sup> J.M.G. von der Schulenburg and Oliver Schöffski, "Implications of the structural reform of Healthcare Act on the referral and hospital admission practice of primary care physicians", *Discussion Paper N°34*, November 1993, cited in Guillem Lopez-Casasnovas and Jaume Puig-Junoy, op. cit., p. 19.

<sup>49</sup> See Oliver Schöffski, "Diffusion of Medicines in Europe", University of Erlangen-Nuremberg, 2002, p. 9, available at [www.gm.wiso.uni-erlangen.de/downloads/alle/Diffusion\\_of\\_Medicines\\_in\\_Europe-Text.pdf](http://www.gm.wiso.uni-erlangen.de/downloads/alle/Diffusion_of_Medicines_in_Europe-Text.pdf).

<sup>50</sup> Albert Wertheimer, Robert Levy and Thomas O'Connor (2001), "Too many drugs? The clinical and economic value of incremental innovations", *Investing in Health: The Social and Economic Benefits of Health Care Innovation*, Vol. 14, p. 80, available at <http://www.npcnow.org/resources/PDFs/toomanydrugs.pdf>.

"Incremental" innovations may present therapeutic and economic advantages for patients. The fact that there are many different drugs presents advantages. If a treatment fails, physicians have more choice in finding the most effective drug for their patients. Given that each patient reacts differently to drugs, the existence of different active substances for the same illness enables the efficacy of treatment to be personalised and improved.

### 3.4. The impact on R&D financing

RP regulations have a dual impact.

- First, by putting downward pressure on the prices of patented drugs, they decrease the returns from investment in R&D and reduce incentives to invest in developing future drugs. This effect risks being all the greater in that Germany is one of the world's three biggest pharmaceutical markets. In addition to the risks inherent in pharmaceutical R&D, companies run the added risk of seeing their products subjected to the RP system. As a European Commission report points out, "encouraging generics while holding prices of branded products constant or even forcing them to fall reduces the returns to innovation. In the longer run this lowers the incentive to bring products to the market."<sup>51</sup>

- Second, self-generated revenues from drug sales are one of the main resources used by pharmaceutical companies in pursuing R&D and discovering new drugs. The RP system directly reduces these revenues and the investment capacity of pharmaceutical companies generated by revenues from drug sales in the country.

Its effects have been amplified in Germany by other measures that further reduce revenues used to finance pharmaceutical innovation. The public authorities have thereby imposed compulsory discounts on producers (6% in 2003 and 16% in 2004 on the prices of drugs not subject to the RP system) as well as drug price "freezes" in 1993-1994 and 2006 for all drugs.<sup>52</sup> The discounts in 2004, on their own, reduced the revenues of pharmaceutical companies in Germany by nearly 1.7 billion euros, or about 8.4% of their total sales.<sup>53</sup> These are resources that could have been used to finance R&D, which in that same year declined - in constant euros - by about 1.6%.<sup>54</sup>

For local companies, such declines in revenues have direct effects.<sup>55</sup> For multinational companies - with investment budgets that depend on many other factors - this effect is also present. The logic of R&D projects within these companies is such that various subsidiaries of a given company are generally in competition for mandates from the parent company. The latter manages R&D budgets at the central level.<sup>56</sup> However, one criterion for obtaining a new project is the level of autonomous revenues likely to be generated by the sale of drugs in the given country. Artificially amputating these revenues through regulatory measures in Germany causes a deterioration in the business environment for new R&D investment. These policies have no doubt contributed to R&D increasingly losing ground in Germany - and in Europe more generally - to the benefit of the United States.<sup>57</sup>

At the end of the road, it is not the role of public authorities to assure pharmaceutical companies of revenues to pursue their R&D, but in the cases above it should not be their role either to limit them artificially through additional bureaucratic measures in a drug market that is already overregulated. To avoid penalising innovation in a way that runs counter to the preferences of the populace, it is essential to eliminate the monopoly powers held by the GKV funds over the insured person who gain from the potential benefits of drugs and over the physicians who prescribe them.

<sup>51</sup> See the study "Innovation in the pharmaceutical sector", produced for the European Commission by Charles River Associates, p. 17, available at [http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2004/nov/eu\\_pharma\\_innovation\\_25-11-04.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2004/nov/eu_pharma_innovation_25-11-04.pdf).

<sup>52</sup> See Alain Vasselle and Bernard Cazeau, *Rapport d'information sur les évolutions du financement de la protection sociale et la réforme du système de santé en Allemagne*, 2006, op. cit., p. 59.

<sup>53</sup> The German Association of Research-Based Pharmaceutical Companies (VFA), 2005, op. cit., p. 48.

<sup>54</sup> The German Association of Research-Based Pharmaceutical Companies (VFA), 2005, op. cit., p. 25; calculations by the author.

<sup>55</sup> These harmful effects on revenues from the Germany market can be more or less offset if there are prospects for exports and thus revenues from abroad for German companies. Of course, it doesn't contradict the fact that without RP overall revenue would have been greater.

<sup>56</sup> John Vernon, "Drug research and price controls", *Regulation Magazine*, winter 2002-03, available at <http://www.cato.org/pubs/regulation/regv25n4/v25n4-7.pdf>.

<sup>57</sup> See Alfonso Gambardella, Luigi Orsenigo and Fabio Pammolli, "Global competitiveness in pharmaceuticals, A European perspective", report prepared for the European Commission, November 2000, available at <http://ec.europa.eu/enterprise/library/enterprise-papers/paper1.htm>. See also the report by Charles River Associates, "Innovation in the pharmaceutical sector", op. cit.

## **Conclusion: Toward free competition in health insurance to reward pharmaceutical innovation**

To deal with the higher costs encountered by public health insurance monopolies, the public authorities have established a broad range of cost reduction policies, including the RP system. RP was imposed in Germany with the aim of achieving savings for the compulsory health insurance system.

This type of system also creates drawbacks for the insured, who are required to put up with a reimbursement system that provides limited coverage of drugs priced above the reference price and with a bureaucratic substitutability between drugs that may be inadequate in their personal case. RP policy also has an indirect impact on pharmaceutical innovation and could go against the preferences of consumers and the ultimate beneficiaries of drugs, namely insured persons or patients.

This impact is due to the fact that the insurance and drug markets are closely linked and that the RP system discriminates against the use of drugs priced above reference prices and including innovative drugs. The impact is all the greater in that the great majority of spending, especially in Europe, is financed by monopolistic compulsory insurance systems.

The RP system may not only be acting against the preferences of insured persons but also affecting pharmaceutical innovation indirectly by penalising new drugs and reducing incentives to conduct R&D. In this respect, if various governments, like the German government, truly wish to reduce drug spending, there would be less discrimination against innovation if they simply lowered reimbursements in the same proportion for all drugs, even for all health care, rather than adding further regulations and imposing an RP policy.

To achieve optimal spending on drugs - that patients are willing to pay directly from their pockets or indirectly through their insurers, recognising the potential added value of new drugs - public health insurance monopolies would have to be called into question and the insured given the freedom to subscribe to the insurer of their choice.

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Printed in Belgium

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