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PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN GERMANY

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ABSTRACT

This paper describes pharmaceutical pricing and reimbursement policies in Germany, considering them in the broader environment in which they operate, and assesses their impact on the achievement of a number of policy goals. Pharmaceutical coverage is comprehensive, with a high level of public funding, and ensures access to treatments. However, recent increases in out-of-pocket payments may impair affordability for the poorest part of the population. Germany does not regulate ex-manufacturer prices of pharmaceuticals at market entry (though distribution margins are regulated for reimbursed drugs). On the other hand, maximum reimbursement amounts (known as reference prices) are set for products which can be clustered in groups of equivalent (generic) or comparable products. Maximum reimbursement amounts are in effect for a large part of the pharmaceutical market covered by statutory health insurance funds (representing 44% of value and 70% of volume in 2006), putting pressure on prices of clustered products. In addition, across-the board price reductions or freezes have occurred on several occasions, and rebates have been regularly imposed on manufacturers. These measures, along with incentives influencing physicians' prescriptions, have helped Germany to contain the growth of pharmaceutical expenditures. All the same, German pharmaceutical prices have been found to be among the highest in OECD, both for patented and generic drugs, when considered at either the ex-manufacturer or the retail level. The 2007 reform introduced two important changes with the aim of ensuring value for money in pharmaceutical expenditures. First, statutory health funds are allowed and encouraged to contract with manufacturers to obtain lower prices in exchange for a "preferred status" for their drug on their formulary. Second, the Institute for Quality and Efficiency in Health Care will assess the benefits and costs of new drugs with the aim of capping reimbursement prices of new entrants if necessary to ensure that their use is not less efficient than existing therapies. Though these reforms may encourage price erosion in some market segments, they will not address all issues: health insurance funds will remain price takers for new drugs without therapeutic alternatives and losses in transparency will be significant.

JEL Classification: I18, I11

Keywords: Pharmaceutical policy; pricing and reimbursement; pharmaceutical market; Germany

RESUME

Ce document décrit les politiques de prix et de remboursement des médicaments en Allemagne, en les replaçant dans le contexte plus large dans lequel elles s'insèrent, et évalue leur impact sur l'atteinte de plusieurs objectifs. La couverture des médicaments par l'assurance maladie est bonne, caractérisée par un haut niveau de prise en charge publique, et permet un bon accès aux traitements. Cependant, les augmentations récentes des paiements à la charge des usagers pourraient entraver l'accessibilité financière pour les populations les plus modestes. L'Allemagne ne régule pas les prix fabricant des médicaments à leur entrée sur le marché, mais seulement les marges des distributeurs pour les médicaments pris en charge par l'assurance maladie. D'un autre côté, des montants maximum de remboursement (souvent nommés "prix de référence ") sont fixés pour les produits qui peuvent être rassemblés au sein de groupes de produits équivalents (génériques) ou comparables. Ces montants maximum de remboursement affectent une grande partie du marché pharmaceutique couvert par l'assurance maladie (44% en valeur et 70% en volume en 2006), exerçant ainsi une pression sur les prix des produits concernés. De plus, des baisses et gels des prix ont été décidés à plusieurs reprises, et des rabais régulièrement imposés aux fabricants. Ces mesures, associées aux incitations influençant les prescriptions des médecins, ont permis à l'Allemagne de contenir la croissance des dépenses pharmaceutiques. Cependant, les prix des médicaments allemands sont parmi les plus élevés des pays de l'OCDE, pour les produits brevetés comme pour les génériques, qu'ils s'agissent des prix fabricant ou des prix de détail. La réforme de 2007 a introduit d'importants changements dont l'objectif est d'assurer une meilleure efficience des dépenses de médicament. Premièrement, les caisses d'assurance maladie sont autorisées et encouragées à passer des contrats avec les laboratoires pour obtenir de meilleurs prix en échange d'un statut privilégié pour leur médicament sur le formulaire (liste positive) de la caisse. Deuxièmement, l'Institut pour la qualité et l'efficience des soins de santé (IQWiG) devra évaluer les coûts et bénéfices des nouveaux médicaments, qui pourra conduire, si nécessaire, à la fixation d'un montant maximum de remboursement, afin d'assurer que leur utilisation ne sera pas moins efficiente que le recours à des thérapies existantes. Si ces réformes peuvent conduire à des baisses de prix sur certains segments de marché, elles ne régleront pas tous les problèmes : les caisses d'assurance maladie n'auront guère plus de moyens pour peser sur les prix des médicaments réellement innovants et le recours aux contrats implique une perte de transparence sur les prix réellement payés par les caisses.

Codes JEL : I18, I11

Mots-clés : Politique du médicament ; prix et remboursement ; marché pharmaceutique ; Allemagne

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INTRODUCTION

1. This report is the sixth in a series of case studies aimed at describing and analysing pharmaceutical policies used in selected OECD countries. These case studies are part of a broader OECD project on the impact of pharmaceutical pricing and reimbursement policies.

2. The main objective of this paper is to describe and analyse the German pharmaceutical reimbursement and pricing policy and, as far as possible, to assess their effects at the national level.

3. However, since these policies cannot be considered in isolation from other policies and contextual elements, this paper presents the main policies pertaining to the pharmaceutical sector in Germany and the characteristics of the German pharmaceutical market, and then offers an assessment as to how well policy goals are being achieved and what role pharmaceutical policies have played in this respect.

THE POLICY ENVIRONMENT

Pharmaceutical market approval procedures and outcomes

4. Since the 1978 Pharmaceutical Act, new pharmaceutical products are required to obtain a marketing authorisation in order to enter the German market. Since the creation of the European Medicines Agency in 1995, three routes are available to obtain marketing authorisation in Germany: the centralised procedure, the decentralised procedure and the national procedure (see Box 1).

5. The Federal Institute for Pharmaceuticals and Medical products (*Bundesinstitut für Arzneimittel and Medizinprodukte-BfArM*), an independent administrative body under the supervision of the Ministry of Health, is responsible for market approval. The BfArM assesses pharmaceuticals against efficacy, safety and quality criteria, and grants marketing authorisations – normally for an unlimited period, but this can be limited to a five-year period on the basis of any concern requiring monitoring through pharmaco-vigilance procedures following introduction of the product. BfArM also grants market authorisation for pharmaceuticals used in alternative or traditional medicine, i.e. herbal medicine, homeopathy and anthroposophy. However, the assessment of these drugs, whose effectiveness is presumed (rather than demonstrated), is limited to safety and quality (BfArM, 2003). Another institute (the Paul Ehrlich Institute) is responsible for granting marketing authorisation to sera, vaccines, allergen and antigen tests as well as blood products. BfArM is responsible for post-marketing pharmaco-vigilance.

6. The German pharmaceutical market comprises a very high number of products. In 2007 about 55,700 products have a marketing authorisation (BfArM, 2007), many more than any other European market (ÖBIG, forthcoming). Yet, the number of available products has been decreasing continuously over the last 25 years. When the 1978 reform came into effect, more than 140,000 existing products were supposed to be re-assessed against the new criteria for approval. Due to market withdrawals of old products and to work accomplished by BfArM, 8,500 pharmaceuticals and 4,000 homeopathic products were on the waiting list for assessment in 2003 and the re-assessment of the whole pharmacopeia was supposed to end in 2005 (BfArM, 2003).

7. BfArM has faced criticism for long approval delays. Though the Pharmaceutical Act established a targeted delay of 7 months, the average delay for approvals sought through national procedure by the Institute was estimated at 26 months in 2005 (Schmucker, 2005). These long delays are likely to affect less innovative drugs since European procedures are used for these products. Overall, according to latest available estimates, approval delays for new drugs with worldwide launch are relatively short in Germany by international standards (see Figure 1).

Box 1. Marketing Authorisation in the European Economic Area

To be marketed in the European Economic Area (EEA)1, a medicine must obtain a marketing authorisation. The authorisation may be issued by the competent authority of any EEA country and valid for its own territory, or granted for the entire Community (i.e. EEA). In any case, the marketing authorisation holder must be established within the EEA.

The London based European Medicines Agency (EMEA) was established in 1995 to coordinate the evaluation and European market authorisation for both human and animal medicinal products. The EMEA operates under the aegis of the European Commission's DG Enterprise.

Three main procedures exist for obtaining marketing authorisation in an EEA country: the centralised procedure, the decentralised and mutual recognition procedures, and the national procedure.

(1) The Centralised Procedure ends up with a marketing authorisation valid in all EEA countries. The use of this procedure is mandatory for biotechnology, AIDS, cancer, diabetes, neurodegenerative disorder medicines as well as orphan drugs. However, the procedure can be used for other types of products. Manufacturers submit applications to the EMEA. The Committee for Proprietary Medical Products (CPMP) – comprised of 2 experts nominated by each member state – evaluates applications and subcontracts the assessment to two rapporteurs, from a pool of 3 500 drug evaluation specialists in national regulatory agencies. The CPMP provides a recommendation to the European Commission, which is responsible for final approval. The CPMP has 210 days to assess the dossier but the clock can be stopped when rapporteurs request additional information from the applicant. Total accumulated clock stop time generally should not exceed 6 months.

(2) The Decentralised and Mutual recognition procedures are based upon the principle of recognition by other member states of a first assessment performed by the authorities of one member state. They provide for the extension of marketing authorisation granted by a member state to one or more other member states identified by the applicant.

Through the Mutual Recognition Procedure, manufacturers can obtain marketing authorisations in designated or "concerned" member states by validating the national marketing authorisation previously granted in another member country ("reference member state"). The competent authority of each concerned member state has 90 days in which to agree with the reference member state's decision for granting marketing approval. In case of disagreement, the reference member state sends the concerns to the CPMP; if a consensus is not reached after a further 60 days then the procedure moves into arbitration by the CPMP.

Legislative changes introduced the Decentralised Procedure (DP) in 2005 in order to increase the EMEA's co-ordinating role and facilitate the harmonisation of marketing approvals. Under this procedure, manufacturers designate a "reference member state" (RMS) to undertake the assessment of their drug and submit identical dossiers to "concerned member states" (CMS) where approval is also sought. The RMS steers the approval process, seeking agreement on elements that must be harmonised in CMS and provides a decision. A maximum of 210 days is granted (including a maximum of three months for clock stops to allow for applicants to respond or resolve to objections raised during evaluation) to the RMS and the CMSs to come to an agreement on the full dossier. If agreement is not forthcoming then an additional 90 days are granted for arbitration, with a final decision by the CPMP. The recommendation is then forwarded to the European Commission for final decision on granting or refusing a marketing authorization valid in all concerned member states.

The mutual recognition procedure is used for products that have already obtained market authorisation in at least one member state while the decentralised procedure is used for new products not yet marketed in Europe (and not obliged to use the centralised procedure).

(3) Manufacturers can also seek National Marketing Authorisation – at least for medicines not included in the mandatory scope of the Centralised Procedure – when they intend to market a drug in a single country or as a first step to mutual recognition procedure. Recent legislation to increase transparency requires that national regulatory bodies make marketing authorisations available 'without delay' and publicly release clinical documentation, assessment reports and reasoning for decision.

In reality, manufacturers still often use decentralised and national procedures for products which are not included

1. EEA is composed of European Union member countries plus Norway, Iceland and Liechtenstein.

in the mandatory scope of the centralised procedure. Specifically, generic manufacturers often seek approval through national procedures, for two main reasons: (1) expiring dates of patents and supplementary protection certificates may be different from one country to another, as a remnant (heritage) of former differences in patent legislation and marketing dates; (2) original products may have different forms, strength, and labelling, necessitating different studies to prove bio-equivalence. Since 2005, generic medicinal equivalents of centrally authorised products may be authorised through centralised procedure.

While the centralised procedure was developed to better facilitate market harmonisation and reduce authorisation delays, manufacturers' choice of approval path often depends on issues related to final marketing expectations such as firm experience, familiarity with national agency, expected effects from parallel trade and reference pricing and flexibility in national marketing (e.g. dosing, packaging, labelling requirements and limitations). Given the variety of factors under consideration, manufacturers often opt for approval via mutual recognition or the decentralised mechanism, since they afford a greater degree of flexibility and control over their products, despite the ease the central procedure was intended to provide.

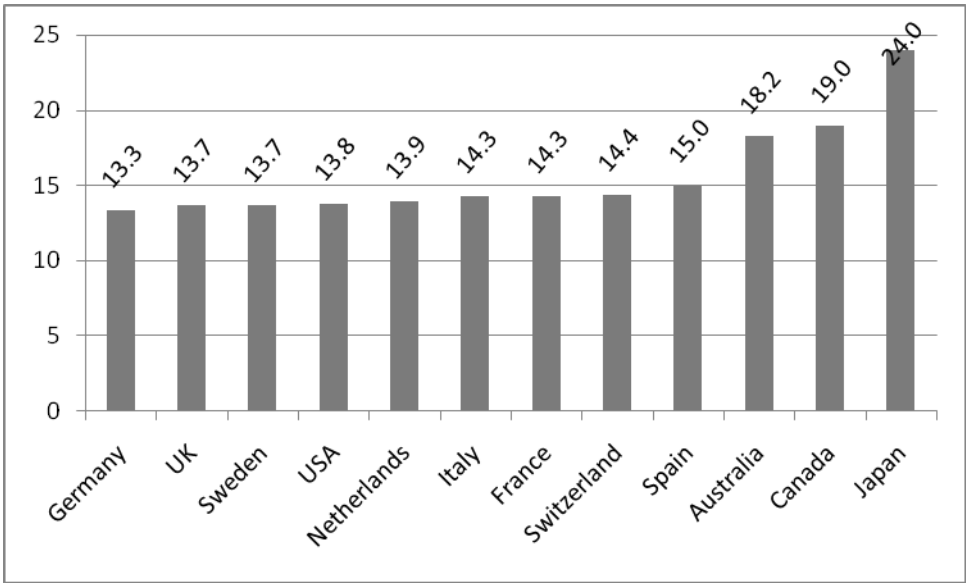
Source: European Commission (2005), Danzon, Wang and Wang (2005), Garattini and Bertele (2004), EMEA 2007).

8. As long delays were considered harmful to the German pharmaceutical industry, a Task Force created in 2003 with members of both government and industry agreed to take steps to accelerate the national marketing authorisation procedure. A bill, examined by the Parliament in March 2007, proposed to change the BfArM's status from an administrative body to an independent agency, with a more efficient management structure. Private funding would be higher, mainly coming from application fees supposed to be related to the applicants' turnover. This bill faced strong opposition from many stakeholders. The BPI (*Bundesverband der Pharmazeutischen Industrie*), representing German pharmaceutical companies, protested against the risk of inequitable treatment of applications due to differential fees and the unnecessary burden such pricing practice would put on an already overwhelmed agency (Ginnow, 2007). Other stakeholders argued that the proposed reform prioritized industry's interests over those of patients by playing down safety standards (BUKO Pharma-Kampagne, 2007).

9. According to EU legislation, manufacturers may request an accelerated assessment procedure in EU marketing approval for products of major therapeutic interest, from the point of view of public health and in particular from the viewpoint of therapeutic innovation (EMEA, 2006). The time frame of accelerated assessment is reduced to 150 days. This provision was only recently implemented and the first accelerated assessment took place in 2007. Moreover, some products may obtain temporary authorisations, subject to annually reviewable conditions.

10. In addition, patients with life-threatening disease or severe disability may obtain access to drugs whose marketing authorisation application through the centralised EU procedure is pending, or to products which are being tested in clinical trials when there is sufficient evidence of their efficacy and safety (compassionate use).

Figure 1. Average delay between application and market approval (months) for drugs with worldwide launch between 1999-2003



Source: Pharmaceutical Industry Competitiveness Task Force, 2005, from Association of the British Pharmaceutical Industry calculations.

Coverage of pharmaceuticals

11. The German population is covered for pharmaceutical consumption, either by statutory or private health insurance. Statutory coverage of prescription medicines is comprehensive, with the exception of a relatively small number of prescription medicines included on a negative list. OTC products are generally not covered, as in many OECD countries. Patients usually share the cost of prescriptions drugs.

Health insurance coverage

12. About 90% of the German population is covered by the statutory health insurance and 10% by private health insurance. The self-employed and people whose earnings are above a certain level can opt out of social insurance and take out private health insurance; the rest of the population is covered by the statutory health insurance (Busse and Riesberg, 2004; Brandt, 2008). In any case, people can choose their health insurance fund.

13. Though health insurance funds compete in the market, the basket of health goods and services covered by the statutory health insurance (SHI) is defined at the national level by law and government regulations (Busse *et al.*, 2004). Private health insurers generally cover the same basket of goods and services but may offer extended or restrained coverage in some areas (Thomson *et al*., 2002). For pharmaceuticals, private coverage is most often equivalent to that offered by statutory health insurance, sometimes extended.

Pharmaceutical coverage

14. Unlike most OECD countries, the basket of reimbursed pharmaceuticals is defined negatively by the exclusion of several categories of products from statutory health insurance coverage (5th *Sozial Gesetzbuch* –hereafter SGB – V §34; Nguyen-Kim *et al*., 2004).

15. The law excludes from reimbursement the following categories (SGB V, §34.1):

1. Pharmaceuticals used in adults for the treatment of minor ailments, i.e. drugs used in the treatment of cold and flu syndrome, including cold medications, cough suppressants and expectorants, and painkillers; mouth and throat medications other than antifungal; laxatives; and drugs for motion sickness.

2. Over-the-counter drugs are not covered unless they are prescribed to children up to 12 years (up to 18 years in certain cases) or they are used in standard treatment of serious diseases according to guidelines established by the Federal Joint Committee (hereafter G-BA; see Box 2).

3. Pharmaceuticals whose main indication aims to improve the of quality of life, particularly treatments of the erectile dysfunction, smoking cessation treatments, slimming drugs, appetite suppressants, anti-obesity drugs, and capillary treatments.

16. While the first category of drugs has been excluded from reimbursement since 1983, OTC and lifestyle drugs were excluded by the Health Insurance Modernisation Act of 2004.

17. In addition, the law states that the Minister of Health, in accordance with the Ministry of Economy and Labour and with Parliamentary approval, may further exclude from reimbursement medications pertaining to one of the following categories:

1. Pharmaceuticals mainly used in the treatment of minor health disorders (SGB V § 34.2)

2. So-called "non economic pharmaceuticals", defined as pharmaceuticals which contains unnecessary active ingredients, pharmaceuticals whose effectiveness cannot be assessed because they contain too many active ingredients, and pharmaceuticals whose therapeutic benefit is not proven (SGB V §34.3).

18. The last category has existed since 1991 and corresponds to a list of identified products, which is referred to in Germany as the "*Negativliste*"[2].

19. The coverage of medicines used in preventive care may appear less extensive than in some other OECD countries. For instance, contraceptives are reimbursed only up to 20 years of age. Until 2007, vaccination for communicable diseases was not part of the drug benefit package but was included in the "optional services" that SHI funds were allowed to offer to their affiliates (Busse *et al.*, 2004). This was changed by the 2007 reform which included vaccines in the benefit basket.

20. The definition of the pharmaceutical benefit basket has generated longstanding debates, reform attempts and litigation. The introduction of a positive list has been envisaged several times and was introduced in the law twice, in 1996 and 2000, but never implemented (*Busse et al.*, 2005). Similarly, in 1999, an attempt of the Federal Committee to issue guidance limiting the scope of reimbursement faced lawsuits by the pharmaceutical industry. A Court stated that the Committee exceeded its competencies, which were at that time limited to issue practice guidelines. The 2004 reform consequently extended the scope of the Federal Committee's competencies.

2. G-BA Arzneimittel Richtlininien, Anlage 3 http://www.g-ba.de/downloads/38-254-9/RL_AMR3-2003-10-18.pdf, accessed on October 26, 2007.

Box 2. The Federal Joint Committee

The Federal Joint Committee (*Gemeinsame Bundesausschuss* – G-BA) is a college composed of physicians', hospitals' and health insurance funds' head associations. Patients' representatives attend the meetings and are consulted by the Committee. The Committee is in charge of issuing recommendations for coverage of health goods and services and practice guidelines. The G-BA plays an important role in the definition of pharmaceutical coverage, through several missions:

- define indications for which OTC products will be reimbursed;
- make an inventory of drugs with insufficiently proven efficacy,
- select products to be included in the *NegativListe*;
- compose *Festbetrag* clusters.

Source : http://www.g-ba.de

Reimbursement and cost-sharing arrangements for drugs

21. Patients are generally required to contribute to meeting the cost of the pharmaceuticals they use. Cost-sharing takes two different forms: statutory copayments applying to all reimbursed medicines and "extra-billing" for products subject to maximum reimbursement amounts (*Festbeträge* in German) whose price exceeds the maximum reimbursement amount. Overall, user charges for medicines reimbursed by statutory health insurance are relatively low since they averaged 7.4% of total SHI expenditures for drugs[3] in 2006 (Coca *et al*., 2007).

Copayments

22. Copayments for drugs were introduced in 1977 and have been continuously increasing, taking various forms (fixed prescription fee, later linked to the price of every item, then to the package size)[4]. Since January 2004, copayments have taken the form of a 10% co-insurance, with a minimum of €5 and a maximum of €10. Copayments have been used as a means to tackle annual health insurance fund deficits and have represented between 3.9% and 15% of annual expenditures for reimbursed medicines (Schröder *et al.*, 2006, Nink and Schröder, 2006).

23. Patients are exempted from copayments in various cases. Categorical exemptions were reduced in 2004 to two categories, including children up to 12 years, or up to 18 years in case of growth problem or serious disease. In addition, patients may be exempted from copayments once they have reached an annual cap, set at 1% of their income for chronically ill patients and 2% for other patients (Busse *et al.*, 2005). In those cases, patients have to apply for exemption and show that they are entitled to it in order to be exempted for the rest of the year. In addition to these exemptions linked to patients' characteristics, products may be exempted from copayments in two cases: when their price is at least 30% under the *Festbetrag* (since 2006) or when the health insurance fund decides to eliminate copayments for products for which a contract was signed with the manufacturer (since 2007).

24. Overall, about half of prescriptions do not require user's participation and the average copayment on non-exempted prescriptions is estimated at 20% (Schwabe, 2006, p. 39). This means that copayments are concentrated, like the whole market, on product whose price does not exceed €50.

3. Before the exclusion of rebates paid by manufacturers.

4. For a complete history, see Schröder *et al.*, 2006, pp. 55-56

Box 3. Reforms affecting the pharmaceutical sector since 1989

1989 *Gesundheitsreformgesetz* (GRG) – Health Care Reform Act

- Implementation of *Festbeträge* (Reimbursement amounts)
- Setting of *Festbeträge* for level 1 clusters
- Increase in users' cost-sharing for products not subject to maximum reimbursement amounts (set at the lowest of DM 3 or the product's price, whichever was less).
- Introduction of the *Negativliste*

1992 Setting of *Festbeträge* for level 2 clusters

1993 *Gesundheitsstrukturgesetz* (GSG) – Health Care Structure Act

- National budget cap for prescription drugs, with financial liability of manufacturers and physicians in case of excess
- Across-the-board price reduction of 5% for reimbursable products not subject to maximum reimbursement amounts, 2% for non reimbursable products and price freeze until the end of 1994
- Extension of users' copayment to all reimbursed drugs (incl. those subject to *Festbetrag*), with a three-tiered copayment, related to the box size (DM 3, 5 or 7), from January 1994
- Setting of *Festbeträge* for level 3 clusters
- Introductio*n of a positi*ve list (never enforced).

1995 Exclusion of drugs patented from the maximum reimbursement amount system after December 31, 1996

1996-97 *KrankenversicherungsbeitragsentlassungsGesetz* –Health Insurance Contribution Rate Exoneration Act

- Increase in users' participation to DM 4, 6 and 8
- Cancellation of pharmaceutical spending caps (from 1998)

1997-98 *Gesetz zur Neuordnung von Selbstverwaltung und Eigenverandwortung in der Krankenversicherung* – Reform for reorganization, self-administration and individual responsibility in health insurance

- Increase in users' participation to DM 9, 11 and 14
- Introduction of individual prescription volume targets for physicians

1998 *Gesetz zur Stärkung der Solidarität in der Gesetzlichen Krankenversicherung* – Act to Strengthen Solidarity in Statutory Health Insurance

- Maintenance of pharmaceutical spending caps in spite of 1996-97 Act
- Decrease in users' copayment to DM 8, 9 and 10

2000 *GKV-Gesundheitsreform* – SHI Reform Act 2000

- Introduction of a positive list for pharmaceuticals (never implemented)
- Introduction of mandatory treatment guidelines

2001 ABAG – *Arzneimittelbudget Ablösung Gesetz – Elimination of collective prescription budgets*

2002 AABG – *Arzneimittelausgabenbegrenzungsgesetz* – Pharmaceutical expenditure limitation act

- *Aut-idem* regulation

- Rebates paid by pharmacies increases from 5 to 6%
- Exceptional "solidarity payment" by the pharmaceutical industry (200 Mo. €).

2003 *Beitragssatzsicherunggesetz* – Contribution Safeguard Act

- Introduction of the possibility for SHI funds to contract with pharmaceutical companies to obtain rebates
- Introduction of a wholesalers' rebate of 3%, of a manufacturers' rebate of 6% for non reference-priced drugs, increase of pharmacists' rebates to 10% for high-priced drugs

2004 GMG *GKV-Modernisierungsgesetz* – Health insurance modernisation Act

- Change in copayment: 10% co-insurance, with a minimum of €5 and a maximum of €10. Introduction of a cap for total patients' copayments (1% or 2% of revenues) instead of the previous system of exemption categories.
- Exclusion of OTC drugs from reimbursement
- Deregulation of the OTC market, liberalization of distribution margins in this market
- Possibility to include patented drugs in *Festbetrag* clusters (first groups created in January 2005)
- Price freeze for products not subject to *Frestbeträge from 2003*
- Pharmaceutical companies' rebate set at 16% for one year (2004) until the Joint Federal Committee had clustered products for maximum reimbursement amounts
- Pharmacy mark-up changed to a combination of a fixed fee (€8.30) and a percentage of the ex-factory price (3%).
- Wholesalers' mark-up halved but cancellation of rebates paid by wholesalers to SHI funds.

2006 AVWG-*Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz* Pharmaceutical care Efficiency Act

- Introduction of a 10% rebate on off-patent drug prices
- Lowering of *Festbeträge* in all clusters; *Festbeträge* in clusters of 2nd and 3rd levels must be set at the lowest third of the price distribution in each cluster.
- Two-year freeze of ex-factory prices from April 2006 to March 2008
- Cancellation of users' cost-sharing for drugs whose price is 30% below the *Festbetrag*
- Prohibition of benefits in-kind supplied by manufacturers to pharmacists
- Introduction of bonus-malus linked to physicians' prescribing in January 2007

2007 *GKV-WSG WettbewerbStärkungGesetz* – Health Insurance Competition Enhancing Act

- Introduction of the possibility to set a maximum reimbursement price for products not subject to maximum reimbursement amounts, based on pharmaco-economic studies, from mid 2008.
- New possibilities for SHI-providers contracting
- Introduction of vaccines (formerly reimbursed by health insurance funds on a voluntary basis) in the mandatory benefit package
- Second opinion will be necessary to prescribe special pharmaceuticals with high costs or high risk potential (the list of which will be prepared by the G-BA)
- Increase of rebates paid by pharmacists to SHI funds to €2.30 per package.

Increase in VAT from 16% to 19% (following a general VAT increase in Germany)

Source: Haússier et al. (2006), Paris et al. (2002), Busse and *Riesberg* (2004), Coca et al. (2006).

Festbeträge or maximum reimbursement amounts

25. In 1989, Germany was the first European country to introduce maximum reimbursement amounts (*Festbeträge* in German) for clusters of products. The general principle of this policy is now well-known: health insurance funds define a reimbursement level for a cluster of products considered to be therapeutically equivalent; the pharmaceutical company is still free to set any price above this reimbursement amount, but patients are required to pay any difference between the price and the reimbursement amount. This policy is often referred to as "reference price policy" though it does not aim to regulate the prices of pharmaceuticals.

26. In Germany, products are clustered by the Federal Joint Committee according to three different levels:

- At the first level, clusters include products with identical active ingredients and comparable administration mode and/or bioavailability;
- At the second level, clusters include products with therapeutically or pharmacologically comparable active ingredients;
- At the third level, clusters include products with comparable therapeutic effects.

Products with different administration modes (oral, parenteral, etc.) are never clustered in the same groups. Table 1 provides examples of *Festbetrag* clusters.

Table 1. Examples of *Festbetrag* clusters

Level	Cluster	Active ingredients
Level 1	Aciclovir, group 1, Oral Tablets, Film-coated tablets, Effervescent tablets, Suspension	Aciclovir
Level 1	Aciclovir, group 4, Perenteral	Aciclovir
Level 2	Angiotensin II receptor antagonist, Oral, Tablets, Film-coated tablets, capsules	Candersation, Eprosartan, Irbesartan, Losartan, Olmesartan, Telmisartan, Valsartan
Level 3	Antidepressants, group 7 Selective Serotonin Ruptake Inhibitors, Oral, normal release, Tablets, Film-coated tablets, Capsules	Fluoxetin, Fluvoxamin maleate, Paroxetin

Source : BKK (2007b)

27. The maximum reimbursement amount is computed for each cluster using an econometric model that takes into account the prices of existing products, in such a way as to ensure that a certain share of the products in the cluster will be available at no additional out of pocket expense to patients[5] (Stargardt *et al.*,

[5]. At least 1/5 of packages and 1/5 of prescriptions should be available without extra-payment from patients.

2005). Reimbursement amounts are checked annually and updated if necessary to adapt to new market conditions. Initially, in clusters of generic groups (level 1), fixed reimbursement amounts had to belong to the first tercile of the cluster's price distribution. The 2006 AVWG Act lowered all maximum reimbursement amounts (see Box 3) and extended the rule of the first tercile to cluster levels 2 and 3 (Schröder *et al.*, 2006). In addition, this act allowed health insurance funds to exempt patients from copayments for every product whose price is at least 30% below the *Festbetrag*.

28. Initially, in 1989, patented products were included in the maximum reimbursement amounts scheme and potentially included in clusters. Following lobbying by the industry, patented products were excluded from the scheme in 1996, before being re-introduced in 2004. Since then, as soon as three products compete in a therapeutic area, they may be clustered and subject to maximum reimbursement amounts.

29. Under the reference price policy, health insurance limits the reimbursement to a maximum level for all products judged to have similar therapeutic effects. Manufacturers are still free to price their products at the desired level. Doing so, they take into account consumers' willingness to pay for any perceived added value of the product. The model ensures financial accessibility since the patient has, in principle, the option to select a product without a price differential in each therapeutic class. In practice, however, patients are not always able to autonomously assess the clinical benefits of drugs and the potential differences across products. Their preferences will rest largely on comfort and quality of life characteristics (symptom relief, side effects, convenience), or on trademarks, which are not always directly related to clinical effectiveness.

30. In fact, physicians are responsible for the choice of the prescription medicine and may prescribe drugs with a price differential with or without any substitution opportunity, and even prevent any substitution whenever possible. However, physicians are required to inform patients about any price supplement they will be exposed to when the price of the prescribed product exceeds the reimbursement amount. This provides the opportunity to inform patients about the added value likely to justify this price supplement. It also may serve as a disincentive to prescribe products whose prices exceed the reference price.

31. Actually, manufacturers most often set prices under the *Fesbetrag* for products included in reference price groups. In 2005, only 1,975 products over the 27,908 included in the maximum reimbursement amounts scheme had prices above the *Festbetrag*, which represents only 4% of all products (Haüssler *et al*., 2005). In some cases, however, manufacturers chose not to lower their price to the reference price level, notably to avoid spill-over effects in countries using Germany as a benchmark country in their price regulation. In the case of a Pfizer drug, well known thanks to a media campaign by the company, the firm chose to keep the price above the reference price but undertook to reimburse the price surcharge to those patients who were exempted from co-payments (SBEG, 2005).

32. The market share covered by the maximum reimbursement amounts scheme changes over time, along with clustering opportunities, relative prices of clustered products and the entry of new drugs not subject to the scheme in the pharmaceutical market. From a maximum of 60% in 1997, the market share of products subject maximum reimbursement amounts fell to 35% in 2003 before rising again and reach a level of 48% in 2005 (Häussler *et al.*, 2005). In 2006, the *Festbetrag* market covered almost 28,000 pharmaceuticals, more than half of which were clustered in generic groups; it represented € 9.9 billion and 409 million prescriptions (see Table 2).

Table 2. The Festbetrag market in July 2006

Type of cluster	Level 1	Level 2	Level 3	Total
Number of groups	313	64	57	434
Number of active substances	192 substances	210 substances	26 combinations	Not available
Number of packages	14,362	9,318	4,032	27,712
Turnover (billion €)	3.9	5.0	1.0	9.9
Prescriptions (million)	223	136.8	49.2	409

Source: BKK, 2007a

Contracts between health insurance funds and manufacturers for rebates on listed prices

33. Since 2003, health insurance funds have been allowed to contract with pharmaceutical companies to obtain rebates on listed prices. However, since health funds had few possibilities to influence volumes of drugs, this contracting opportunity was not really exploited.

34. There was a notable exception for the case of rapid-acting insulin analog in the treatment of type II diabetes. The Institute for Quality and Efficiency in Health Care (hereafter IQWiG, see Box 4) assessed the clinical effectiveness of this product against the effectiveness of existing drugs and concluded that superiority of the insulin analog was not proven. Following this assessment, the G-BA recommended that health funds not reimburse this drug, except at a price 30% lower than that proposed by the manufacturer (to equalize the price with that of its competitors). Health funds contracted with the manufacturer to obtain rebates on the list price and made the drug available to their members. This solution allowed the manufacturer to obtain a subsidy from the German health insurance funds without lowering the list price, which may be referred to by other countries using international benchmarking to regulate their prices.

35. The idea of fostering competition through contracting between SHI funds and manufacturers was formulated first by academics and the scientific institute of the AOK[6] and further developed by academics in a report commissioned by a pharmaceutical industry union and published in 2005 (Klauber and Schleert, 2006). The scheme proposed to modify the current national benefit basket (in which each marketed product eligible for reimbursement must be reimbursed by any health insurance fund) by a list of reimbursable active ingredients and to let SHI funds define their own positive list or formulary. Such a scheme would allow funds to negotiate prices with one or several manufacturers in exchange for guaranteed volumes of sales. SHI funds could increase their negotiation power through group purchasing. Under these scenarios, reference prices were supposed to disappear in the long run.

6. *Allgemeine Ortskrankenkasse*, Local health insurance funds, which cover about one third of the total population.

Box 4. The Institute for Quality and Efficiency in Health Care (IQWiG)

The Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirkschaftlichkeit im Gesundheitswesen* – hereafter IQWiG) is an independent body in charge of evaluating the quality and efficiency of health services and health products. It was created in 2004 and is expected to play a more and more important role in the pharmaceutical policy. The Concerted Action on Health Care recommended in 2001 the creation of an institute to conduct cost-effectiveness analyses of health care strategies. However, there was no political consensus and the mission assigned to IQWiG in 2004 was limited to clinical effectiveness. The 2007 reform extended this mission to cost-effectiveness assessment.

IQWiG generally conducts evaluations on request of the G-BA. Besides the G-BA, the Federal Ministry of Health, patients' representatives in the G-BA and the Commissioner of the Federal Government for patients' issues can request evaluations from IQWiG. The Institute does not produce practice guidelines, nor reimbursement decisions, but rather makes available the results of evidence-based assessment to help stakeholders to make decisions. For pharmaceuticals, cost-benefit assessment can be undertaken for any new patented prescription product, as well as for any other significant product. The Law defines the conditions and criteria to be used in evaluations (SGB V §35). The assessment must consider the added therapeutic value of the assessed product, by comparison with existing pharmaceuticals or other treatments, in relation to costs. According to the Law, benefits for patients shall notably be assessed against the following outcomes: improvement of health status, a reduction in duration of illness, an increase in life expectancy, a reduction in adverse events as well as an improvement in quality of life. Economic assessment shall address whether coverage by health insurance seems appropriate, acceptable and reasonable.

IQWiG is in charge of defining concrete methods and criteria to be used for cost-benefit assessment, on the basis of acknowledged international standards and published a report for consultation in January 2008. Before the 2007 reform, IQWiG used to consider 5 dimensions to assess the benefits of a pharmaceutical: impact on mortality, impact on morbidity and symptoms, impact on quality of life, the disease burden and patients' opinion. These criteria should be enhanced in the future to take account of IQWiG's new missions.

IQWiG employs 60 staff members and works with a network of about 100 experts and thus works with means comparable to those of the English National Institute for Clinical Excellence and of the French High Authority on Health. The board of directors is composed of representatives of the Federal Ministry of Health, of health insurance funds, of hospitals, physicians, and of a representative of the Federal Joint Committee (G-BA) with a consultative voice.

Source : http://www.iqwig.de/index.2.html, accessed on January 16, 2008

Perspectives of the 2007 reform: new levers to activate contracting opportunities and price caps based on pharmaco-economic assessment

36. The Health Insurance Competition Enhancing Act (GKV-WSG for GKV *Wettbewerbsstärkunggesetz)* had two main objectives in the pharmaceutical sector: first, to reinforce contracting opportunities and second to introduce price caps for new products, based on pharmaco-economic assessment.

37. The 2007 Act designed a set of incentives to activate the existing contracting opportunities. The Law now obliges pharmacists to substitute, whenever possible, a contracted product for the prescribed medicine. In addition, SHI funds are allowed to sign contracts with physicians and pharmacists to encourage them to prescribe or dispense products for which they have signed contracts with manufacturers and have the possibility to reduce or eliminate patients' copayments for those "contracted products".

38. These new rules allow health insurance funds to obtain price reductions from manufacturers in exchange for volume commitments. Since April 2007, SHI funds have signed agreements with generic manufacturers. As of July 2007, 239 funds had signed such contracts with 55 companies for about 18,000 products, significantly affecting the generic market. In a few months sales of "contracted products"

increased dramatically while sales of competitors decreased (Beck et al., 2007). Though the law does not explicitly exclude patented products from contracting opportunities, the lack of appropriate incentives has not favoured the development of contracts for them. However, there have been some challenges in implementing contracts. Some have been challenged by manufacturers in front of German social or civil courts, German competition authorities and the European Commission, leading in some cases to contracts being cancelled. One of the contentious issues is compliance with European public procurement directives (e.g., in some cases, health insurance funds are expected to issue EU-wide calls for tender).

39. In addition, the 2007 reform states that pharmaceuticals which are not clustered in maximum reimbursement amount groups must be subject to pharmaco-economic assessment by IQWiG and that a maximum reimbursement price will be either negotiated with the manufacturer or set by the Federal association of health insurance funds (*Spitzenverband Bund der Krankenkassen*) according to the results of the assessment. IQWiG is in charge of producing the methodology for this assessment, according to criteria defined by the SGB and to international standards of cost-effectiveness assessment (SGB V §35b).

40. IQWiG published in January 2008 a report on methods to be used for the assessment of relation of benefits to costs in the German statutory health care system (IQWiG, 2008). The Institute proposes to define efficiency frontiers within therapeutic areas to compare the relative costs and benefits of new therapies to the most efficient existing therapeutic alternatives. Mortality, morbidity, health-related quality of life and validate surrogate will be used to assess benefits. Costs will be considered from the perspective of SHI patients: they should include costs for SHI funds (net of any savings achieved) but may also take into account significant costs faced by users. New drugs should be at least as efficient as older ones to be approved for reimbursement by health insurance funds at the proposed price; if they show no or marginal benefits over existing products, their price will be capped at the price of alternatives. If a new drug is both more effective and more costly, IQWiG will not propose a price cap and policy makers will make a decision depending on budget impact (assessed by IQWiG) and affordability.

41. This method does not allow setting price cap for new drugs for which no therapeutic alternative is available, which means that SHI funds will remain price takers for this kind of innovative drugs –as it is the case in other OECD countries. Afterwards, follow-on products' efficiency will be benchmarked to costs and benefits of the first entrant.

Payment for hospital drugs by health insurance funds

42. In hospitals, pharmaceuticals are mainly financed via the Germany's DRG payment scheme, meaning that the costs of most medicines used in the course of a hospital stay are included in the payment to the hospital, rather than billed separately. Hospitals usually draw up their own formularies and negotiate directly with manufacturers on the basis of volume-price agreements.

43. In an effort to avoid impairing access to very expensive technologies, costly medicines and implants are financed through "specific additional payments" (*Zusatzentgelte*) on top of DRG payments. The list of drugs financed through this channel includes, among others, cancer drugs and immunoglobulins. The National Institute for payment in hospitals (*Institut für das Entgeltsystem im Krankenhaus – InEK*) annually updates both the DRGs and additional payments. In most cases, the InEK defines homogeneous payments for DRG and for high cost drugs at the national level, based on national data costs. In a few cases, however, such payments cannot be defined due to lack of cost data and payments are negotiated at the level of individual hospitals. In 2008, individual payments were negotiated for 43 DRGs (over 1,137) and 51 high-cost medicines or implants (over 115).

44. Moreover, a procedure exists to guarantee access to innovative treatments. The InEK annually reviews hospitals' applications for the funding of new diagnostic and therapeutic methods in the following

year. After a clinical assessment, the InEK decides whether the new treatment should be financed by health insurance or not and whether its cost can be included in DRG payments, necessitates a specific additional payment or –due to lack of data – must be funded by a special budget outside the DRG system Overall, additional funding for high cost drugs represents 2% of total hospital expenditures (Aoustin, 2007).

Adequacy of drug coverage and financial protection against drug expenditures

45. Overall, almost all of the German population is covered by health insurance and has access to a comprehensive drug benefit package. The extent to which copayments may hinder access to medications is not known. In a survey of about 700 German adults with chronic conditions that were asked about their experience in health care, 20% mentioned that they "did not see the doctor, did not get recommended care, skipped doses or did not fill prescriptions because of cost" (Schoen *et al.,*2007). This share is higher than that of the Netherlands (5%), the United Kingdom (9%) and Canada (14%), but is half the share reporting this in the United States (42%). Ten per cent of German patients with chronic conditions said they spent $500 or more out of pocket to buy prescribed medicines over the past year,[7] where only 1% of Dutch patients and 2% of British patients said so. In Australia, Canada and the United States, the percentage reached respectively 30%, 27% and 42%.

Pharmaceutical pricing policy

46. The German market is characterised by the absence of direct regulation of ex-factory prices, even for reimbursed products. On the other hand, distribution margins are regulated and the listed retail price of a reimbursed product must be the same for the whole German territory. Before 2007, retail listed prices corresponded to the prices paid by health insurance, except for products priced above the *Festbetrag*. Since the 2007 reform has been introducing new contracting opportunities between health insurance funds and manufacturers, effective prices can differ substantially from listed prices. .

Manufacturers freely set their price at market entry

47. In Germany, the ex-factory prices of pharmaceuticals are not regulated at market entry. Since 1989, pharmaceuticals covered by statutory health insurance have been subject to regulation limiting the amount to be reimbursed under certain circumstances (maximum reimbursement amounts). Manufacturers are always permitted to price their products above this cap. Patients are required to pay any difference between the retail price and the amount paid by his/her health insurance fund.

48. In the market segment not subject to maximum reimbursement amounts, health insurance funds used to act as price-takers until the 2007 reform, since they were required to cover any pharmaceutical eligible for reimbursement at the price set by the manufacturer.

49. In order to curb health insurance funds deficits, across-the board price freezes and price reductions have been used several times. In 1993, prices of pharmaceuticals not included in the maximum reimbursement amount were lowered (by 5% for prescription drugs and by 2% for OTC drugs). Further price freezes were imposed in 1993-1994, 2003-2004, and most recently from November 2005 to March 2008 (Schröder *et al.*, 2006).

50. In addition, manufacturers are usually required to pay rebates to health insurance funds for all products which are not included in maximum reimbursement amount clusters. Generally limited to 5-6% of

[7] Survey responses appear inconsistent with the existence of a cap for out-of-pocket payment, set at 1% of chronic patients' income. Respondents may have overstated their expenses. Alternatively, it may be that patients are not aware of the cap or do not choose to apply for the exemption.

the ex-manufacturer price, these rebates reached 16% in 2004. A 10% rebate was created in 2006 for off-patent products (both generics and originals) whose price is not at least 30% below the *Festbetrag* (Klauber and Schleert, 2006, SGB V §130a.).

From ex-factory to public price

51. Like many OECD countries, Germany regulates distribution margins for prescription drugs covered by statutory health funds. Wholesale and retail margins are no longer regulated for OTC products since their exclusion from the benefit basket in 2004, except in the few cases where they are covered by SHI.

52. Wholesalers' mark-ups are capped for prescription medicines as well as reimbursable OTC drugs. Maximum mark-ups are defined by law according to a sliding-scale that includes both mark-ups expressed as a percentage of ex-factory prices and fixed amounts (see Table 3). The wholesalers' mark-up was halved by the 2004 reform (ÖBIG, 2006, Schröder *et al.*, 2006).

Table 3. Wholesale mark-up for prescription-only medicines and reimbursable OTC

Prescription-only medicines		Reimbursed OTC medicines	
Ex-factory price	Max mark-up	Ex-factory price	Max mark-up
0.00 - 3.00	15%	0.00 - 0.84	21.00%
3.01 - 3.74	€0.45	0.85 - 0.88	€0.18
3.75 - 5.00	12%	0.89 - 1.70	20.00%
5.01 - 6.66	€0.60	1.71 - 1.74	€0.34
6.67 - 9.00	9%	1.75 - 2.56	19.50%
9.01 - 11.56	€0.81	2.57 - 2.63	€0.50
11.57 - 23.00	7%	2.64 - 3.65	19.00%
23.01 - 26.82	€1.61	3.66 - 3.75	€0.70
26.83 - 1.200	6%	3.76 - 6.03	18.50%
From 1200	€72.00	6.04 - 6.20	€1.12
		6.21 - 9.10	18.00%
		9.11 - 10.92	€1.64
		10.93 - 44.46	15.00%
		44.47 - 55.58	€6.67
		55.59 - 684.76	12.00%
		From 684.77	3.0% € 61.63

Source: Arzneimittelpreisverordnung Act, updated 26.03.2007, ÖBIG, 2006

53. Pharmacists were also paid through a sliding-scale margin until 2004. The 2004 reform amended this payment scheme to disconnect –at least partly– the payment of pharmacists' services from the price of pharmaceuticals. Since then, pharmacists receive a fixed amount of €8.10 per prescription as well as 3% of the wholesale price for prescription medicines (Arzneimittelpreisverordnung Act). Mark-ups for reimbursed OTC medicines are still set according to a sliding scale margin (see Table 4).

Table 4. Pharmacy mark-up for reimbursed OTC drugs

Wholesale price in €	Pharmacy mark-up	
0.0 - 1.22	68%	
1.23 - 1.34		€0.83
1.35 - 3.88	62%	
3.89 - 4.22		€2.41
4.23 - 7.30	57%	
7.31 - 8.67		€4.16
8.68 - 12.14	48%	
12.15 - 13.55		€5.83
13.56 - 19.42	43%	
19.43 - 22.57		€8.35
22.58 - 29.14	37%	
29.15 - 35.94		€10.78
35.95 - 543.91	30%	
From 543.92	8.263%	+ € 118.24

Source: Arzneimittelpreisverordnung Act, updated 26.03.2007, ÖBIG, 2006.

54. Pharmacists are required to pay rebates to health insurance funds, set in 2007 at €2.30 for prescription drugs and 5% of the price for OTC drugs.

55. By contrast with most European countries, pharmaceuticals are subject to the full VAT rate in Germany. The VAT rate increased in 2007 from 16% to 19% (ÖBIG, 2007).

56. In 2006, distribution costs accounted for 21% of the average retail price of reimbursed medicines (3.8% for wholesalers and 17.2% for pharmacists). The share accruing to manufacturers was 57.2%. The government got 13.8% through VAT and health insurance funds received 8.1% through rebates paid by manufacturers and pharmacists (Coca *et al.*, 2007).

57. In the past, German distribution costs used to be higher than those of other European countries. However, the recent reform of pharmacists' margins and changes in the basket of covered medicines lowered the relative share of distribution costs to bring it more in line with other countries (Coca *et al.,* 2007).

58. As seen before, pharmaceutical companies can choose their prices freely at market entry, but they then have to be sold at the same price to all wholesalers. Wholesalers' and pharmacies' mark-up being fixed implies that prices of pharmaceuticals are the same in every pharmacy and that there is no price competition in distribution (OECD, 2008b).

Impact of reimbursement and pricing regulation on German pharmaceutical prices

59. Germany is included in many studies comparing ex-factory prices of pharmaceuticals. Though results are very sensitive to the methodology, Germany generally ranks among the countries where manufacturers receive the highest prices for their products. (For a detailed review of these studies, see Annex 1.) German ex-factory prices of patented pharmaceuticals have been found to be among the highest in Europe, comparable to those of Canada, and exceeded by those of Switzerland and the United States. German ex-manufacturer prices of generic pharmaceutical products have also been found to be high, both in comparison to other European countries and to the United States; however, prices of generics were found to be higher in Canada. Recent reforms are reported to have decreased generic prices, but studies are not available to confirm this fact.

60. The combination of high ex-manufacturer prices, a relatively high VAT on pharmaceuticals, and (until recent reforms) relatively high distribution costs explains the finding that Germany's retail pharmaceutical prices were the highest in the European Union in 2005 (Eurostat, 2007). When all OECD countries are taken into account, Germany's retail prices appeared to be comparable to those of Canada and the United States and exceeded only by Switzerland and Iceland (see Annex 1 and OECD, 2008).

Policies and other initiatives intended to influence drug use

61. The German Code of Social Security (*Sozial Gesetzbuch*) states that benefits financed by statutory health insurance funds must be "sufficient, appropriate and efficient (*wirtschafltlich*) and must not exceed what is necessary" (SGB V, § 12). To achieve this objective, several incentives have been developed to improve the efficiency of drug prescription and drug dispensing.

Policies to influence drug prescription

62. Professional autonomy is emphasised in Germany. Two main tools are used to influence drug prescription: the definition of practice guidelines and the setting of prescription targets at the collective or individual level. Both involve physicians' associations or representatives in the decision or negotiation process. Cost-containment has long been the main objective of German pharmaceutical policies, but quality improvement has become more apparent as a motive in the 2000s.

Prescription budgets and targets

63. Since the early 1990s, several measures have aimed to affect physicians' prescriptions, through collective as well as individual incentives.

64. The first expenditure target with collective liability was implemented in 1992 for the following year. A target budget was set and both regional physicians' associations and the pharmaceutical industry were supposed to refund a portion of any excess above this target. In 1993, pharmaceutical expenditures did not exceed the fixed target and even declined by comparison to the previous year. However, this policy was applied only once and replaced from 1994 by expenditure targets negotiated at the regional level by health insurance funds' and physicians' associations, the latter being liable in case of excess. Abandoned for a time (due to a political transition), regional targets were reintroduced in 1999 in a revised version. Financial sanctions were theoretically applicable, but were never enforced because of uncertainty about the legal implications of sanctioning an individual (a physician) who was not personally responsible for any "breach". Collective financial liability was abolished in 2001 but regional associations of funds and physicians are still mandated to negotiate regional agreements (*Zielvereinbarungen*) which may contain regional expenditure targets as well as other objectives such as targets for the prescription of generics or parallel imports. These agreements may contain provisions for financial penalties when targets are exceeded as well as bonus payments when objectives are achieved (Busse and Schreyögg, 2006, Schröder, 2006, ÖBIG, 2007).

65. Individual volume targets (*Richtgrössen*) were introduced in 1989 but could not immediately be enforced because appropriate data were not available to monitor physicians' prescriptions. However, these targets were progressively enforced. Regional physicians' associations define individual volume targets by attributing to each specialty its share in prescriptions in year n-1 to the expected volume of prescription in year n. Very expensive drugs are not taken into account and volume targets for each specialty are split into two sub-targets corresponding to retired and no-retired patients. Volume targets are expressed as the average expected cost per patient and per year. When a physician exceeds by 15% the volume target, he is

alerted by a letter and invited to revise his prescription habits. If the target is exceeded by 25%[8] or more, the physician is asked to justify this excess. If not justified by specific characteristics of his patients, the physician must reimburse the excess amount comprised between 15 and 25% of the volume target and all sickness funds must be paid back *au prorata* of the number of patients covered. Financial penalties can take the form of reduced fees or physicians' payments to SHI funds. Regional associations of physicians and health insurance funds are responsible for monitoring physicians' prescriptions. To ensure compliance with these rules, SHI funds used to carry out both targeted (for high-prescribing physicians) and random (2% of physicians each quarter) controls. Since 2001, information about SHI physicians' prescriptions has been systematically collected by health insurance funds through the GAmsi system (*GKV-Arzneimittelschnellinformation*), based on review of claims processed. Since 2003, the statutory health insurance funds have made information available to physicians on their recent prescriptions, as compared to those of physicians of the same specialty.

66. According to Busse and Schreyögg (2006), in Berlin in 2002, 16% of physicians had exceeded volume targets by more than 15%, with 12% exceeding them by more than 25%, allowing SHI to recuperate (after several years) about 0.3% of the total of the region's pharmaceutical expenditures. However, sanctions are relatively rare since the existence of multiple SHI funds makes the collection of data and production of evidence quite complex and physicians often invoke exceptional circumstances to justify their outlying prescriptions.

67. In 2006, the AVWG introduced a new scheme for the regulation of physicians' prescriptions, known as the *Bonus-Malus-Regelung*. Each year, physicians' and SHI funds' associations were supposed to identify the most commonly prescribed therapeutic classes with some potential for efficiency improvement[9]. For each of these therapeutic classes, the average cost of the daily prescribed dose was computed and set as a targeted cost for each physician. Any excess of 10% (20%or 30%) over this targeted cost was supposed to lead to financial sanctions, set at 20% (30%or 50%) of the excess amount. On the other hand, when average costs were below the targeted cost, SHI funds were allowed to pay bonuses to physicians' associations under the form of "prescription credit". According to the Law, physicians' and SHI' regional association had the choice between applying the bonus-malus regulation and contracting on the basis of other arrangements with comparable objectives to improve the efficiency of physicians' prescriptions. In 2007, eight regions applied the bonus-malus rules defined at the Federal level, three regions applied them with some variations and six regions concluded other arrangements (BKK, 2007). The Berlin physicians' associations, applying the federal framework, computed that for the first quarter of April 2007, almost 20% of the city's physicians had to refund SHI funds of an average sum of €90, with a maximum penalty of €2,700 (Hyde, 2007).

68. However, in October 2007, federal associations of SHI funds and physicians agreed that objectives set in terms of average cost of prescriptions were not compatible with the existence and development of SHI-manufacturers contracts and that the bonus-malus regulation was no longer

8. Thresholds for control and refund were provisionally lowered by the 2000 reform (to respectively 5% and 15%) but were raised again a few months later.

9. For 2007, the following classes were identified: proton pump inhibitors (antiulcer drugs – excluded from the scheme in the course of 2007), selective beta-blockers (anti-hypertensives), statins (anti-cholesterol), alpha-reductase inhibitors (for the treatment of prostatic hyperplasia), biphosphonates (osteoporosis), triptans (migraines) and selective serotonin reuptake inhibitors (antidepressants).

applicable. They decided to replace these targets by regional prescription targets allowing the exploitation of efficiency potential in twelve therapeutic classes[10].

69. Beyond the withdrawal of the bonus-malus regulation, new contracts may have other consequences on prescription targets and regional agreements. Contracted products cannot really be taken into account in expenditure targets since their "real" price is not known by all stakeholders. This new framework requires (at the least) the redefinition of methods used to set expenditure targets. In addition, the 2007 reform allows SHI funds to create incentives to encourage physicians to prescribe "contracted products". Though such types of incentives do not seem to exist yet, they may be used in the future.

Practice guidelines, quality circles and peer visits

70. The G-BA (see Box 2) prepares and publishes practice guidelines which are legally binding for physicians[11]. These recommendations rely on IQWiG's assessment reports, as appropriate.

71. In addition, the 2007 reform decided that the prescription of very expensive products ought to be subject to second opinion.

72. A few quality circles have appeared on a voluntary basis in ambulatory as well as in hospital sector. The first pharmacotherapy circles were created by the regional physicians' association of North Essen and targeted high prescribers and some therapeutic areas (hypertension, gastro-intestinal therapy, cholesterol treatment, psychotherapy). The assessment of these experiences showed positive effects on both quality and efficiency of prescription: increase in the prescription of established antidiabetics and anti-cholesterol drugs, of standard antibiotics, of generics, as well as decrease in the prescription of drugs of disputed effectiveness (SGEB, 2005). Other pharmacotherapy circles have developed but there has been no generalization of the experience.

73. In parallel, several activities have been developed to counterbalance the information delivered by pharmaceutical companies to doctors. Health insurance funds and physicians' associations have sent peers to medical doctors, targeting high prescribers or practices with high savings potential, with the aim to provide evidence-based information. According to SBEG (2005), in some occasions, these visits were well accepted and viewed as successful.

Health insurance funds' initiatives relating to drugs with disputed effectiveness

74. One of the successes of the pharmaceutical policy is the reduction in the prescription of drugs with disputed effectiveness. In spite of continuous efforts undertaken to re-assess the whole pharmacopeia against criteria in operation for granting marketing authorisations, numerous products are still present in the German market without due assessment by the BfArM or authorised via an alleviated registration procedure not based on evidence-based medicine (Busse *et al.*, 2005). SHI funds hence took the initiative to publish a list of drugs with contested effectiveness (*Umstrittene Arzneimittel*) as assessed by their own experts. The list contains preparations "whose effectiveness is not or not yet evidence-based or whose risk-benefit ratio was negatively assessed" by health insurance funds' experts (Schwabe, 2006). This list of active ingredients has been published in annual reports on SHI prescriptions since 1985 and updated every year. In 2005, it includes 60 therapeutic groups, among which antiemetic medicines, cardiac or antiprostatic phytotherapy products, vitamin combinations, etc. (Schwabe, 2006, p. 20-23).

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10. The 8 therapeutic classes mentioned in the last note + four other classes: ACE inhibitors (anti-hypertensive), non-steroid antirheumatic drugs, low-molecular-weight-heparin (thrombosis), oral antidiabetics, and loop diuretics.

11. *http://www.g-ba.de/downloads/62-492-57/RL-AMR-2007-06-21.pdf*

75. The prescription of drugs with contested effectiveness has continuously decreased since 1991. The number of such prescriptions decreased by 87% over the 1991-2005 period. Those products represented 30% of SHI-covered turnover in 1992 and only 4% in 2005. In the last years, the decrease has concentrated on drugs used in the treatment of dementia, vasodilatators, neuropathics and veinotonics. Schwabe (2006) mentions that many of these drugs are not even available in the United States or in the United Kingdom.

Policies to influence drug dispensing

76. Until August 2002, pharmacists could only substitute a generic product for the prescribed drug if the physician had expressly authorised it on the prescription form. Since 2002, pharmacists have been obliged to substitute whenever possible by a cheaper drug, with a price included in the lower tercile of price distribution for a given substance. The physician is still allowed to oppose such a substitution for medical reasons. However, according to Busse *et al.* (2005), pharmacists had no financial incentives to substitute and no sanction if they do not. As a result, the substitution rate was still quite low (7.6% of cases). In addition, the 2002 Act required pharmacists to dispense parallel imports when their price is 15% or €15 below the price of the prescribed products, with a general savings target set at 5.5% in 2002 and 7% in 2003 (Busse *et al.*, 2005).

77. Since April 2007, pharmacists have been required to substitute whenever possible by a product for which the health insurance fund contracted with the manufacturer, without taking into account listed prices. Where no "contracted" product is available, the older substitution rule applies.

Policies to regulate promotion

78. The Law on advertising in the field of medicine (*Gesetz über die Werbung auf dem Gebiete des Heilwesens*) regulates the promotion of pharmaceuticals. It determines the type of information that promotion messages must contain and not contain, as well as what is considered as inappropriate or misleading. The Law prohibits direct-to-consumer advertising for prescription medicines (SBEG, 2005).

79. In detailing, pharmaceutical firms' representatives may, under certain conditions, deliver samples of products to physicians, who can dispense them free of charge to patients. Representatives are not allowed to offer and physicians are not allowed to accept gifts, although gifts of limited value may be permissible under certain circumstances (SBEG, 2005).

80. In 2000, 15,000 pharmaceutical reps had 20 million contacts with physicians in Germany, which represented 200 contacts per physician (SBEG, 2005).

Innovation policies

81. Intellectual property rights play an important role in shaping pharmaceutical markets and providing incentives to invest in R&D. Other policies, such as development of high skilled human capital, public investments in R&D and tax incentives are important to make a country attractive for R&D investments.

Intellectual property rights

82. In Germany, intellectual property rights are shaped by international treaties and EU regulations.

Patents

82. Germany is one of the 32 contracting states to the European Patent Convention (EPC) treaty. The EPC provides a single, harmonised procedure for granting patents in contracting countries. The European Patent Office (EPO) grants so-called European patents which are valid in all countries designed by the applicant.

83. Applications can be made in one of the official languages of an EPC contracting state to the EPO's offices in Munich, but processing of the patent is done in one of the three official languages of the EPO (English, French and German).The applicant designates which countries of the EPC it wishes to file for patent protection. A favourable decision by the EPO grants a patent in each of the designated states. However, the determination of ownership, validity and infringement are subject to respective national laws. Furthermore, while a national court may invalidate a patent in one country, the European patent remains valid in the other designated countries. A European patent is, in effect, non-unitary across all EU countries and independent in each.

84. The EPC does impose some limits on its signatories. The basis for determination of validity of a patent by national law is limited to a few reasons, but the standard on which the determination is made is that of national law. The convention also requires all jurisdictions to give a European patent a term of 20 years from the filing date, either the date of filing with the EPO for a European patent or for an international application under the Patent Cooperation Treaty. [12]

Supplementary Protection Certificate

85. Since 1992[13], a holder of a pharmaceutical patent still in force in the European Economic Area can apply for a supplementary protection certificate (SPC), an extension of intellectual property rights for said patent. An SPC is a unique, patent-like IPR that comes into force after the patent expires. The term of the SPC equals the time elapsed between patent application and granting of the first marketing authorisation in the European Union[14], less 5 years. In any case, the total term of the SPC cannot exceed 5 years and the total term of "patent + SPC" protection cannot exceed 15 years. SPC applications are made on a country by country basis, and to the extent that patent application dates (for national patents) differ, terms and end of SPCs may vary from one country to another. An SPC is a tool governments use to compensate manufacturers for the lengthy period of time it sometimes takes for granting marketing authorisation, however it does delay the entry of generic drugs onto the market.

Intellectual property rights exhaustion and parallel trade

86. The member states of the European Union have developed a hybrid of the national and international IPR exhaustion regimes – Community-wide exhaustion. Under this doctrine, "once a product has been put on the market in a particular Member State, by or with the consent of the legitimate trademark owner, the owner can no longer rely on this national rights to prevent the importation of the product from that State into another Member Sate."

12. The Patent Cooperation Treaty provides a unified procedure for filing patent applications.

13. Before 1992, some European countries had national instruments to extend patent life or pharmaceuticals, with different lengths of protection.

14. For the purpose of granting an SPC, marketing authorisations granted in Switzerland are also considered since Liechtenstein automatically accepts authorisations granted in Switzerland.

87. Community-wide exhaustion was adopted in the spirit of harmonizing trade within the EU; it is the IPR issue underlying the parallel trade of pharmaceuticals within the European Union. However, European Court of Justice rulings have made it clear that the principle of community-wide exhaustion supersedes national exhaustion regimes (Carboli, 2002), restricting parallel trade to within the member states of the European Union.

The European "Bolar-type" provision

88. The use by generic manufacturers of pharmaceuticals still under patent protection for the purpose of submitting information to regulatory agencies for obtaining marketing authorization has, until recently, been governed in Europe by each member state's national law. The European Commission decided that a provision for generic manufacturers similar to the Hatch-Waxman Act's so-called "Bolar provision" should be permitted for all member states. In 2004, the EC revised Directive 2001/83/EC on the Community code relating to medicinal products for human use, to include the following amendment: "Conducting the necessary studies and trials … and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.[15]

89. Member states had 18 months from April 2004 to implement the Directive into their national laws. The amendment clearly allows the use of on-patent medicines by users other than the holder of the patent for "conducting the necessary studies and trials" for "consequential practical requirements", but left uncertain the legality of other actions, such as supplying or exporting on-patent medicines to generic manufacturers. By using the ambiguous wording "consequential practical requirements", the EC has apparently left the interpretation to national courts (Ashurst, 2005).Data exclusivity

90. Complementary to Bolar type provisions are legislation that protect the clinical trial data that original product manufacturers are required to submit in their applications to regulatory agencies for marketing authorisation.

91. One of the 2004 European Commission's amendments to Directive 2001/83/EC revised EU aspects of data protection. It provided that test data supplied by the manufacturer of an original product, as required by marketing authorisation legislations, are protected for a period of eight years following the first marketing approval in a member state. This period of exclusivity is followed by a two-year period during which generic versions of the original product may not be launched on the market of any member state, although marketing authorisation can be granted during this period. Finally, the original producer can obtain an additional one-year period of market exclusivity beyond the two-year period if, during the eight-year data-exclusivity period, the producer obtains marketing authorisation for additional indications which bring a substantial clinical benefit compared with existing therapies. In effect, this new regulation creates the so-called "8+2+1" formula which guarantees the original producer a period of market exclusivity equivalent to ten years, with the possibility of extending that exclusivity to 11 years (Sanjuan, 2006).

92. Member states had until 30 October 2005 to implement the new Directive. In the face of opposition to the new law from prospective member states who were not able to vote on it, these states can request derogation. The law came into full effect in November 2005, meaning that the first generic drugs to be affected by this law will not come on to the market in the European Union until 2015.

Other policies relating to innovation

93. In Germany, innovative activity has somewhat declined in the first half of the 1990s with a drop of total and business-financed R&D. Apart from the effects of reunification, several factors have been put

15 . Directive 2004/27/EC, Article 10(6), 31 March 2004.

forward to explain this relative decline: the administrative burden to create enterprises, the relative inability for Germany to reap the benefits of ICT for raising the productivity in other industries, the small size of venture capital market, and some deficiencies in the education and availability of high-skilled manpower (OECD, 2004). The pharmaceutical sector did not escape the general trend and Germany lost in the beginning of the 1990s its traditional leadership in pharmaceutical R&D to the benefit of the United States and, to a lesser extent, the United Kingdom (OECD, 2006).

94. A Task force was set up in 2003 with the mission to improve location conditions and innovation opportunities for the pharmaceutical industry in Germany. Chaired by the Ministry of health and social security, the task force included members of the ministries of industry, of education and research as well as representatives of the pharmaceutical industry. It issued a first set of recommendations in 2004, whose status and implementation were assessed in 2005 in the second Report of plan of action (Task Force Pharma, 2005).

95. As a result, several measures were implemented to facilitate the realisation of non-commercial clinical trials (clarification of funding responsibilities, creation and funding of clinical trials centres in universities) and to finance R&D activities in biotechnology (project funding, creation of clusters) (OECD, 2006; Task Force pharma, 2005).

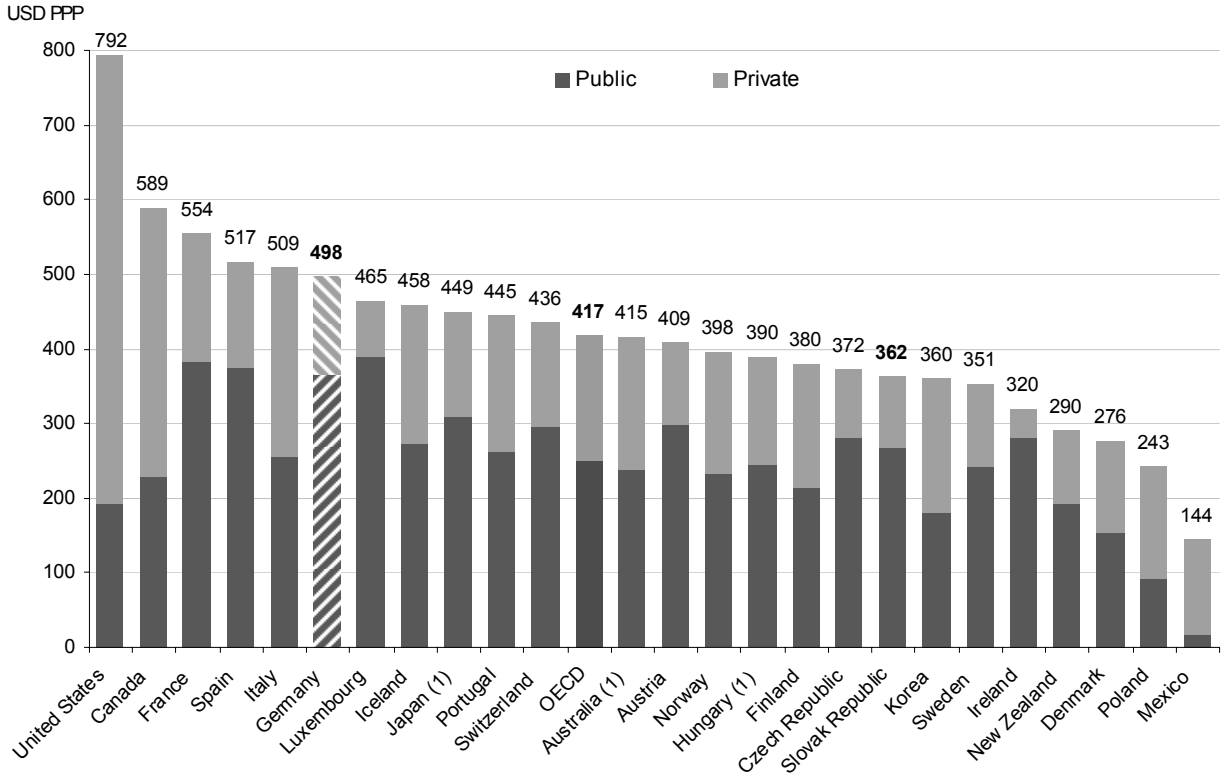
PHARMACEUTICAL MARKET CHARACTERISTICS

96. This section reviews the various components of the pharmaceutical market in Germany, including expenditure trends and components of spending, pharmaceutical production, supply and trade.

Expenditure level

97. Germany spent 41.1 billion USD PPP in 2005 on drugs, third highest among OECD countries. Per capita pharmaceutical expenditure was 498 USD, above the OECD average and not far behind other neighboring European countries of France, Spain and Italy (see Figure 2). In 2005, Germany devoted 15.2% of its total health spending to pharmaceuticals, below the OECD average of 17.2%. Pharmaceutical spending was 1.6% of GDP, above the OECD average (see Figure 3).

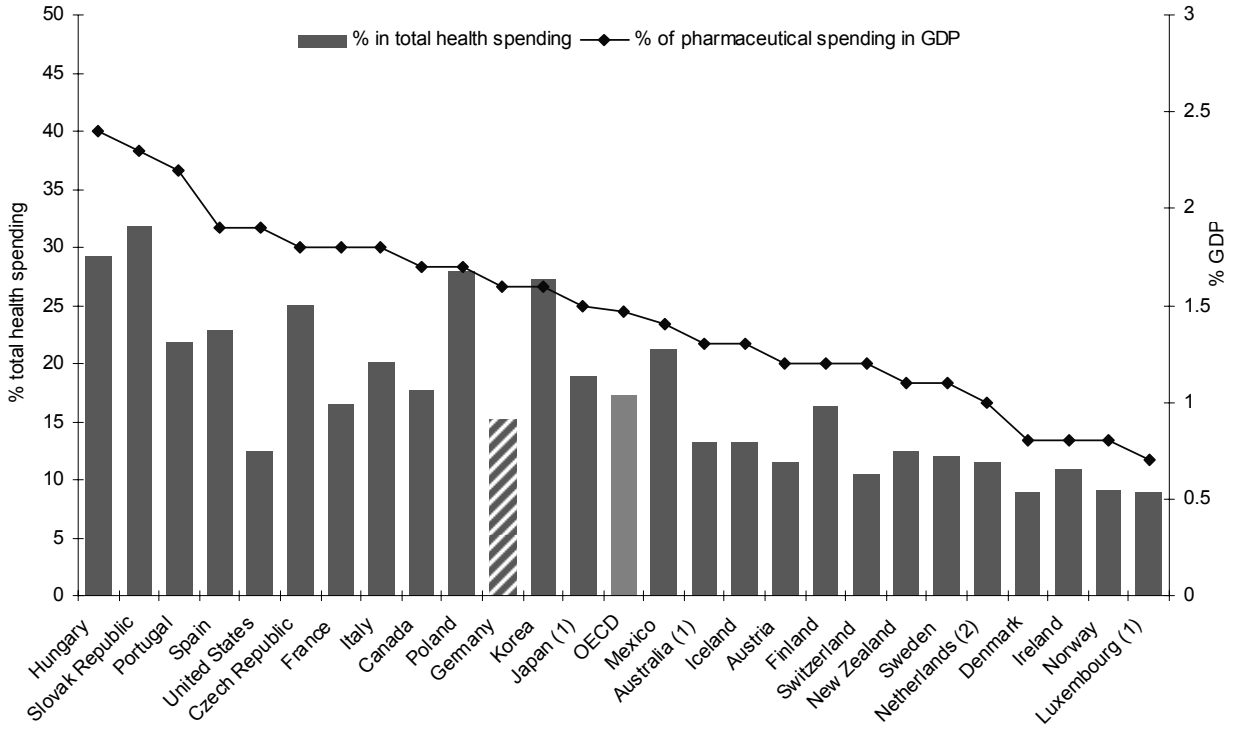
Figure 2. Drug expenditure per capita, public and private spending, 2005



(1) 2004

Source: OECD HEALTH DATA 2007, July 07

Figure 3. Share of pharmaceutical expenditure in total health spending and in GDP, 2005



(1) 2004; (2) 2002

Source: OECD HEALTH DATA 2007, July 07

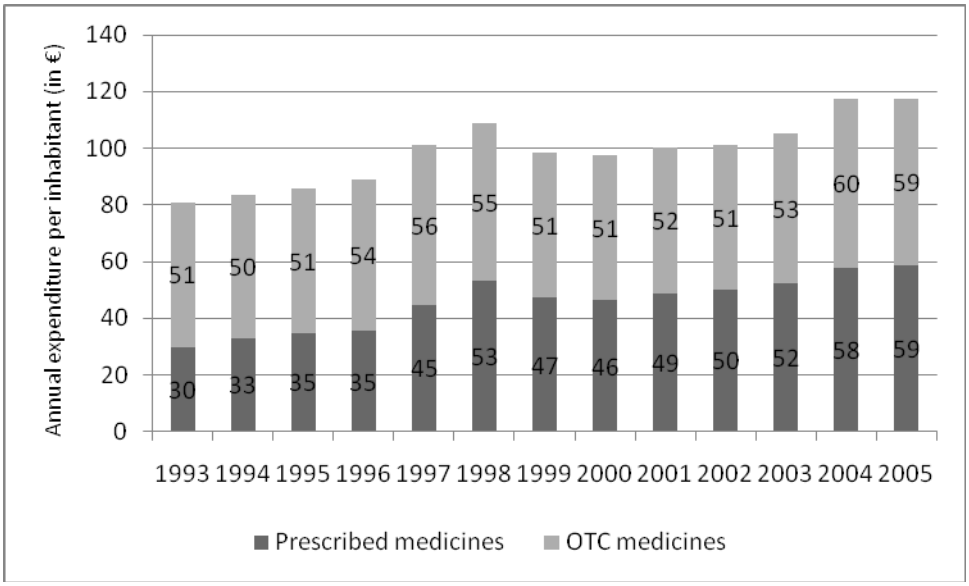
Financing

98. In 2005, the public sector financed almost three quarters of pharmaceutical expenditures (69% via social security funds and 4.2% via direct governmental expenditures). Households financed 20.5% of these expenditures, through out-of-pocket payments for prescribed and reimbursed medicines (35% of households' expenditures) and self-purchase of OTC medicines (the remaining 65%). Private insurance financed 6.2% of total pharmaceutical expenditures.

99. The share of public funding is relatively high, by comparison with other OECD countries. In 2005, only 4 countries (Ireland, Luxembourg, Czech and Slovak Republics) had higher levels of public funding. Since the middle of the 1970's, the share of public funding has fluctuated in a small range between 67.3% (the lowest level, observed in 1998) and 74.6%, (the peak, observed in 2002).

100. Fluctuations in public funding logically impacted households' expenditures. In 2004, households' expenditures increased by 15% (+13% for OTC purchase and +19% for copayments). In 2005, out-of-pocket expenditures averaged 118€ per inhabitant, equally split between self-medication and copayments for reimbursed pharmaceuticals (see Figure 4).

Figure 4. Private expenditures for prescription and OTC medicines

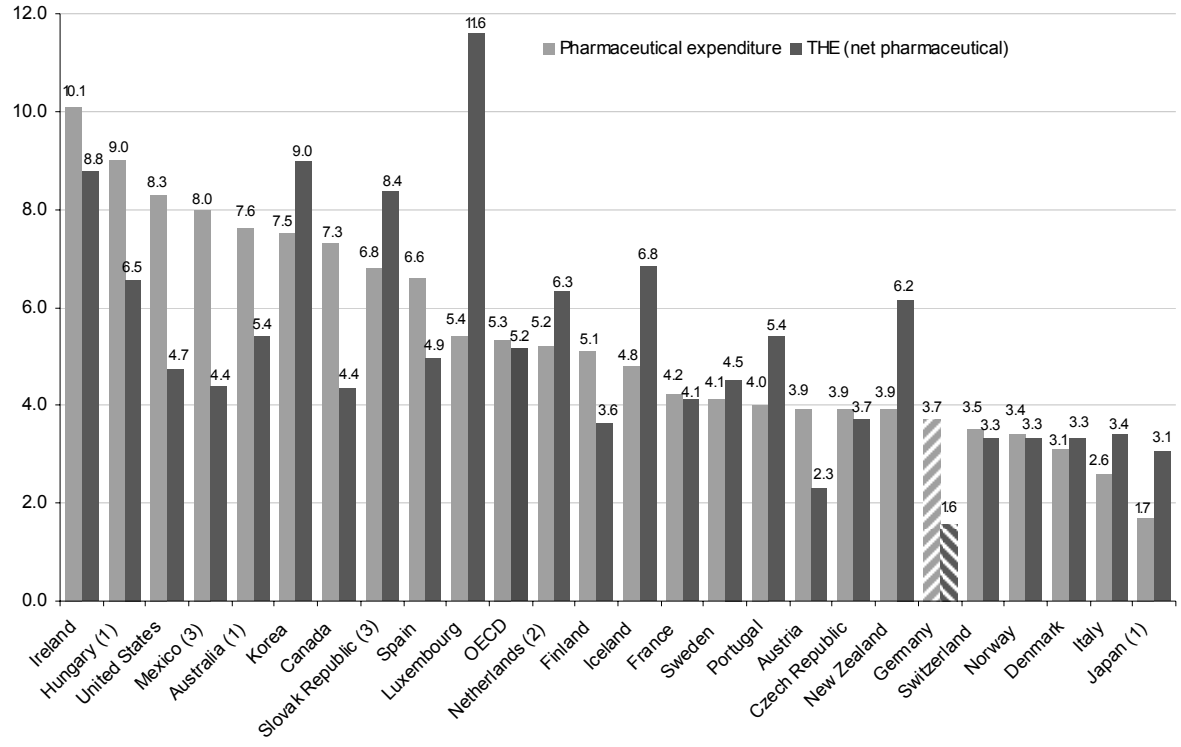


Source: OECD Health Data, October 2007.

Expenditure growth

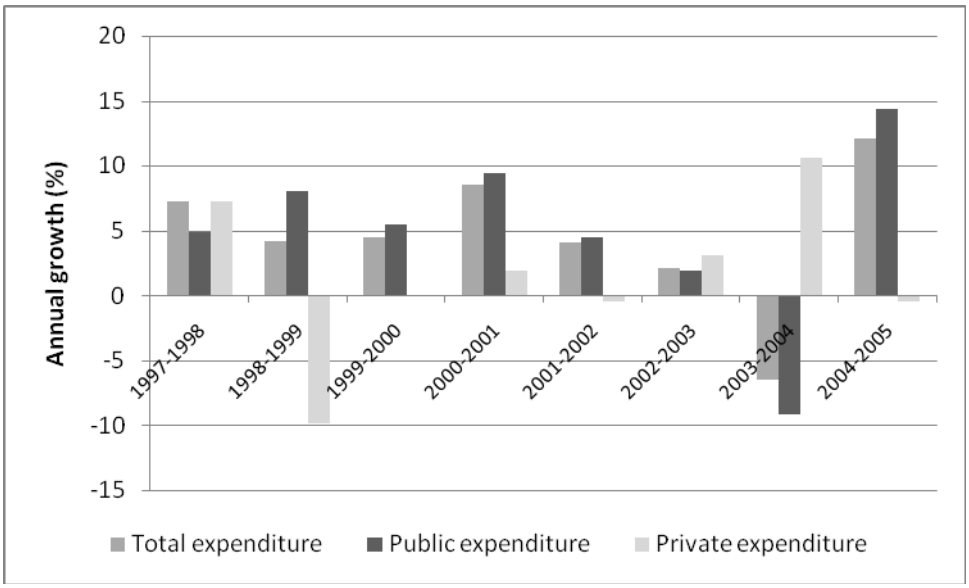
101. Germany has been experiencing greater annual growth in pharmaceutical spending (3.7%) than in other health spending (1.6%) over the last 8 years, although both have been below the OECD averages (see Figure 5). This 8-year trend hides significant variations in annual growth rates between 1997 and 2005 (see Figure 6). The SHI Modernization Act caused a dramatic decrease in public expenditures in 2004. However, this decrease was somehow compensated by a sharp increase in public expenditures in the last quarter of 2003 (Coca *et al.*, 2007, p. 156) and a subsequent increase in 2004/2005. In the meantime, private spending for drugs increased by more than 10% in 2004 (see figure 6). If the shift towards private funding is easily attributable to the narrowing of the benefit basket, the sharp increase of public spending in 2005 is less easy to interpret.

Figure 5. Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1997-2005



(1) 1997-2004; (2) 1992-2002; (3) 1999-2004
Source: OECD HEALTH DATA 2007, July 07

Figure 6. Real annual growth of pharmaceutical expenditure in Germany, 1997-2005



Source: OECD HEALTH DATA 2007, October 07

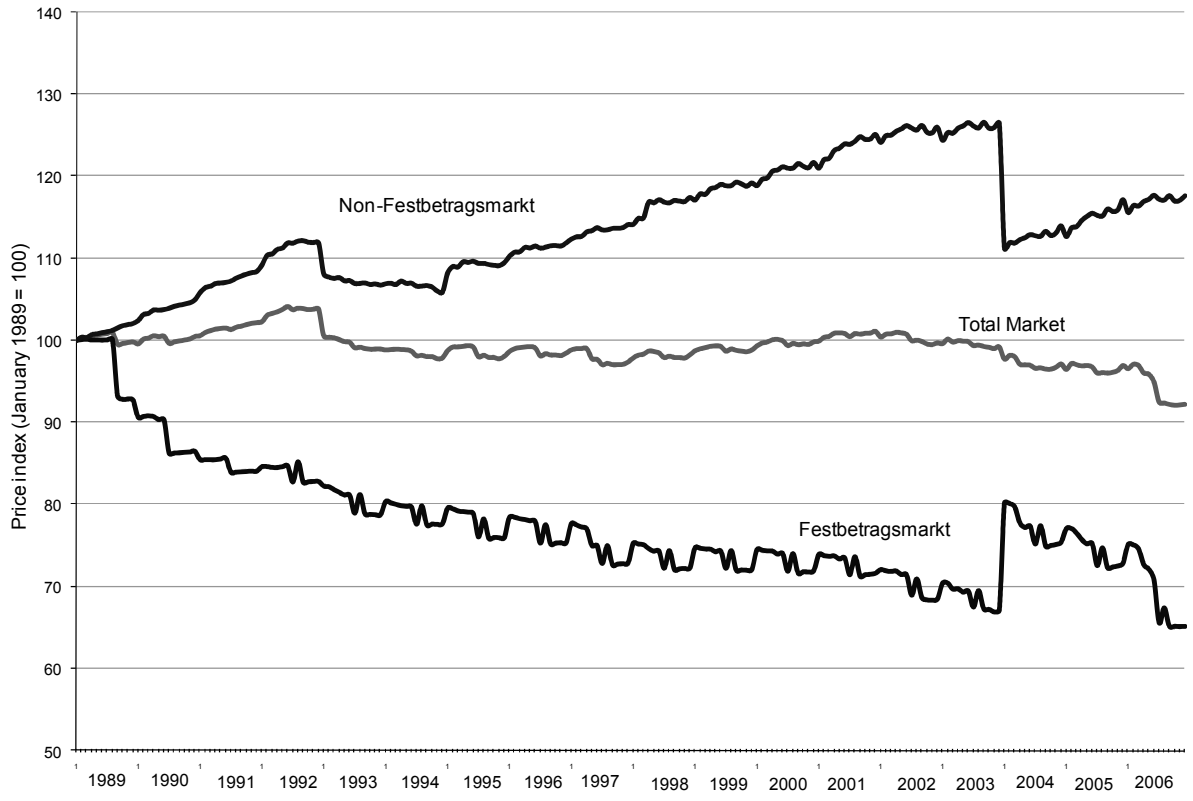
Components of expenditure growth

Prices

102. Pharmaceutical prices have been relatively stable since 1989, but this general trend results from two opposing trends: a price increase of almost 20% in the market segment not affected by reference prices and a 35% decrease in the affected segment (see Figure 6). Hence, analysts generally consider that reference prices have contributed to the relative stability of prices in the German market. However, it is not easy to disentangle the impact of the reference price scheme from what would have happened absent this scheme in this market segment, which contains mainly generic products. The literature review recently undertaken by the Cochrane collaboration on the impact of reference prices, which takes inventory of all studies presenting a high level of evidence, does not mention any conclusive study on the German case (Aaserud *et al.*, 2006).

103. Some analysts (quoted in Schröder *et al.*, 2006) even conclude that the reference price scheme had adverse effects on generic prices by not stimulating price competition below the reference price. In fact, German generic prices are relatively high in international comparisons (see annex 1). In addition, the average price differential between original preparations and generics has regularly decreased since 1993, from 43.4% to 31.2% in 2005 (Nink and Schröder, 2006).

Figure 7. Price trend for SHI-covered pharmaceuticals 1999-2006 (monthly data)

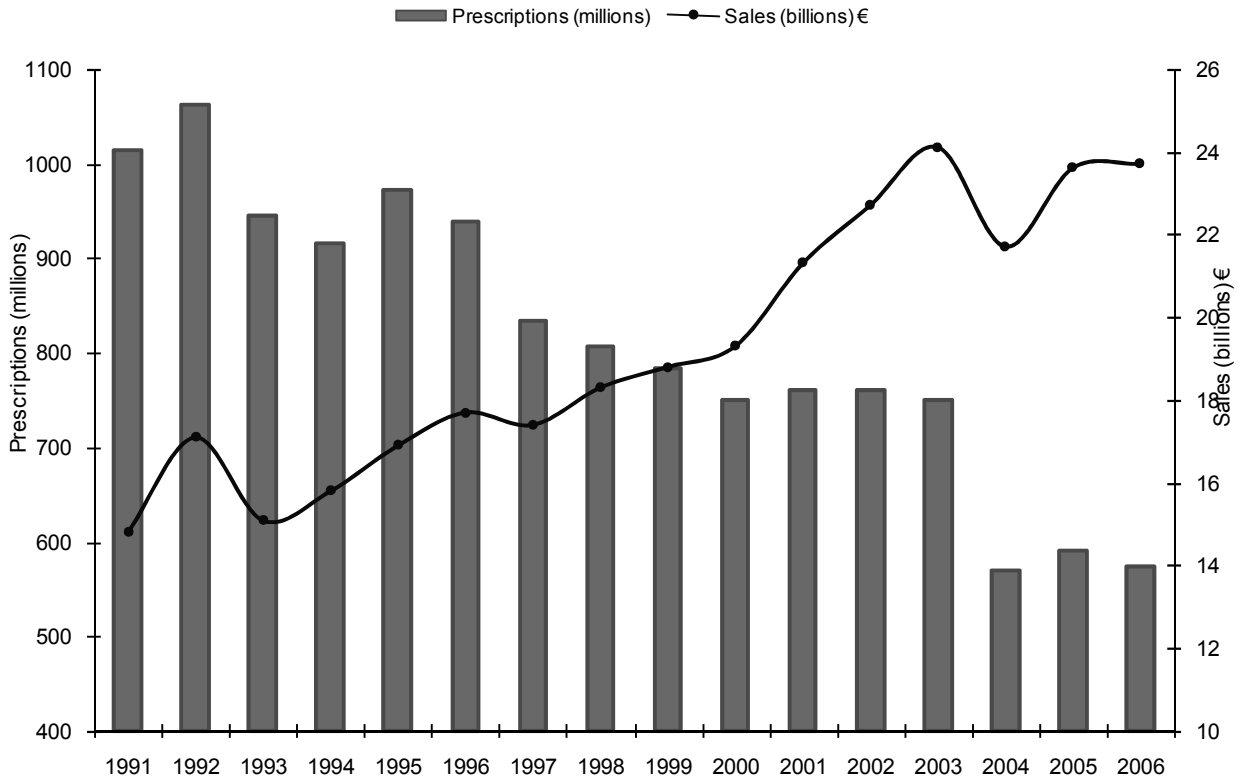


Source : Schröder et al., 2006.

Changes in volume and therapeutic mix

104. The volume of prescriptions financed by SHI has regularly decreased since the beginning of the 1990s: from 1 billion in 1992 to 574 million in 2006 (see Figure 7, Coca *et al.*, 2007). However, the number of prescriptions is not an ideal indicator of consumption since the package size has continuously grown during this period to allow savings in the treatment of chronic disease (Schwabe, 2007, p. 4). Nonetheless, the number of SHI-covered prescriptions decreased dramatically in 1993, when global budgets were first implemented, in 1997, and again in 2004, when OTC and lifestyle products were excluded from the benefit basket.

Figure 8. Prescriptions and sales of SHI-covered pharmaceuticals



Note: Sales of SHI-covered pharmaceuticals include both patients' copayments and manufacturers' and pharmacist's rebates. These components should be subtracted from sales to obtain SHI expenditures.

Source: Arzneiverordnungs Report 2007 (2007)

105. As in many countries, the use of newer and more expensive products explains a large share of German pharmaceutical expenditure growth. Year after year, expenditure growth is highly driven by new and expensive products. In 2006, for instance, the growth of pharmaceutical turnover for SHI-reimbursed products was 0.6%, the result of a 3% decrease in the volume of prescription and a 3.6% increase of the average cost per prescription, the latter being in turn explained by a 2.3% decrease in prices more than offset by a change in the therapeutic mix explaining 6.1% of the growth. Further analysis of this change shows that more than half of it came from real changes in the mix of drugs used (+3.9%), the rest resulting from changes in package size, dosage or form for the same product (+2,1) (Schwabe, 2007). Overall, between 1992 and 2006, the average cost of prescription jumped from €16 to € 41 (Coca *et al.*, 2007).

Volume and Consumption

106. Despite a high level of expenditure, Germany ranks only 11th for the volume of pharmaceuticals consumed per capita (expenditure converted using pharmaceutical-specific purchasing power parities), with a volume level very closed to the OECD average (OECD, 2008). Similarly, volume consumed in some therapeutic classes (antidepressants, antibiotics, lipid-lowering drugs) is below the OECD average when measured in Defined Daily Doses (OECD, 2007b).

Generics and parallel imported products

107. In Germany, physicians are allowed to prescribe either by international non-proprietary name (INN) or by brand name. They chose the first option in 55% of cases, which is quite high compared to international standards. In addition, generic prescribing and substitution have been encouraged by measures adopted to influence physicians' and pharmacists' behaviour.

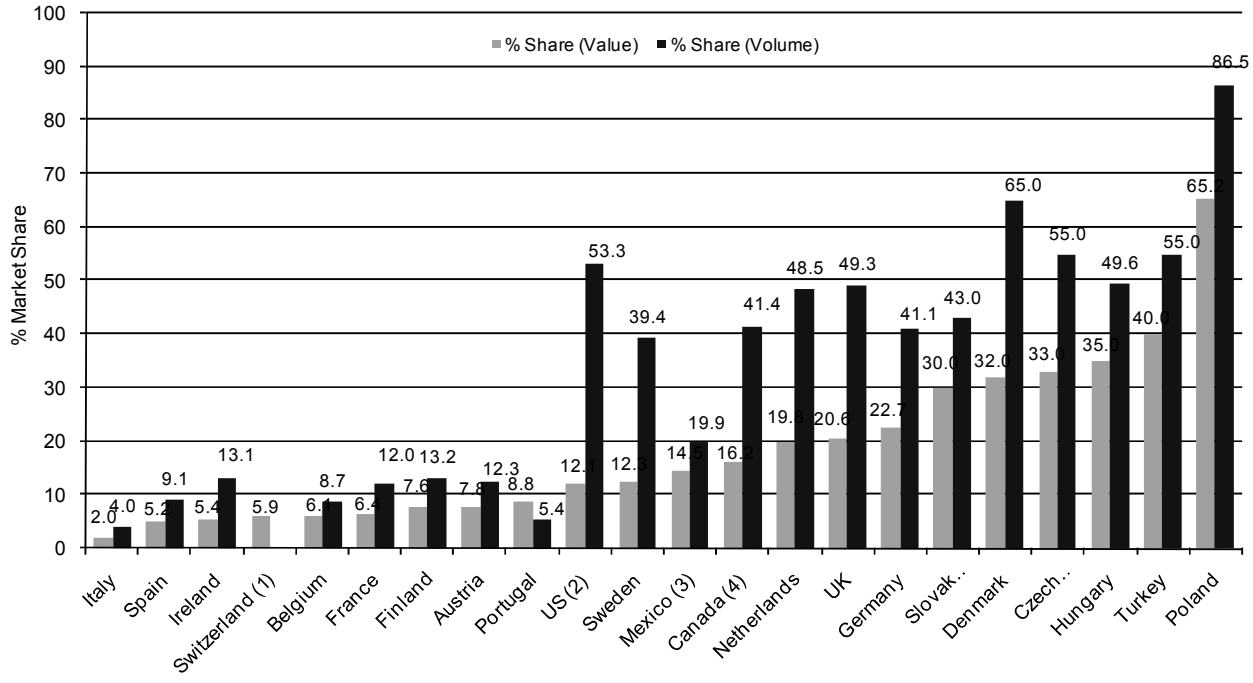
108. Generic prescription has continuously increased since the beginning of the 1980's (Coca *et al.*, 2007). Generics represent 76.7% of prescriptions and 74% of SHI turnover for the off-patent market in 2006, which makes respectively 60% and 35.9% of the total SHI-market (see Table 4). Penetration rates are slightly lower when the whole market is considered, i.e. including OTC and hospital markets. Germany ranked nonetheless among OECD countries with the highest generic penetration in 2004 (Figure 9).

Table 5. Generic penetration in the SHI pharmaceutical market 1989-2006

Year	Share of generic in off-patent market SHI prescriptions	Share of generic in off-patent market - SHI sales	Share of generic in total market - SHI prescriptions	Share of generic in total market - SHI sales
1989	49.8	36.1	28.6	23.4
1990	51.8	37.9	30.3	24.3
1991	60.3	44.3	36.5	28.8
1992	59.5	44.0	37.9	29.2
1993	62.1	47.7	41.6	32.3
1994	60.8	47.8	41.0	32.3
1995	62.1	50.0	42.3	33.0
1996	63.1	51.2	43.4	32.3
1997	65.0	54.2	45.0	32.3
1998	65.7	55.9	44.9	31.2
1999	68.2	59.4	47.1	31.4
2000	71.0	63.7	49.0	31.9
2001	72.2	65.2	50.2	30.0
2002	74.7	68.2	52.3	29.9
2003	75.0	67.3	54.3	30.4
2004	74.1	70.1	55.2	34.3
2005	74.2	68.3	57.3	34.6
2006	76.7	74.0	60.0	35.9

Source : Coca et al., 2007

Figure 9. Generic market shares in OECD countries 2004



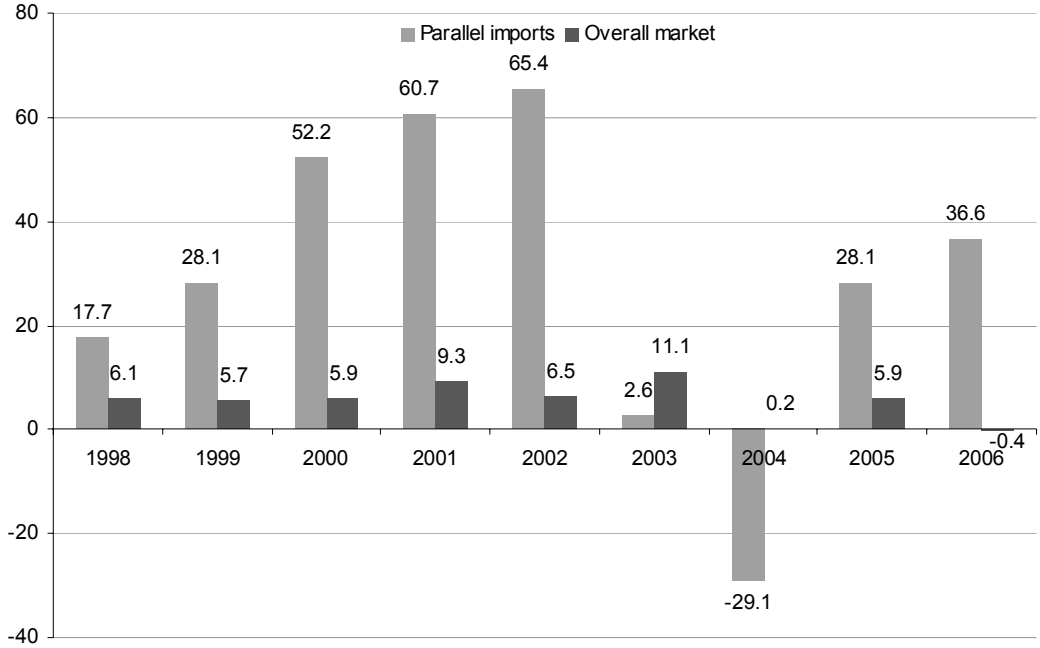
Source: EGA, (1) EFPIA; (2) IMS; (3) 2002, ANAFAM; (4) CGPA

Parallel imports

109. Parallel imports have also sharply increased since the end of the 1990s, creating some savings for health insurance funds. In 2006, parallel imported products represented 7.5% of SHI-covered turnover and 22.5% of the potential market, i.e. market in which parallel imported products are available (WIDO, 2007). Parallel imports deceased by almost 30% in 2004 (see Figure 10) because of across-the-board price reductions imposed by the SHI Modernization Act which rendered them less attractive for traders. However, the growing trend resumed the following year (VFA, 2007).

110. Several studies have estimated savings due to parallel trade, with somewhat contradictory results. The most recent (Enemark *et al.*, 2006) estimated direct savings to €145 for 2004, which was however a trough in parallel trade activity.

Figure 10. Growth rate of parallel imports and the global market1998-2006



Source: IMS Health, InsightHealth, VFA

Pharmacy industry activity

111. Two types of companies co-exist in the German pharmaceutical industry, represented by two distinct associations, with sometimes diverging interests (Blankart and Wolf, 2005). The VFA (*Verband Forschender Arzneimittelhersteller*) represents German companies and affiliates of foreign companies with international scope, which invest significantly in R&D. The VFA's 44 affiliates account for almost two-thirds of the German pharmaceutical market[16]. The BPI (*Bundesverband der Pharmazeutischen Industrie*) represents smaller German companies with smaller investments in R&D; it counts 260 members.[17]

112. Five German companies are among the world's Top 50 pharmaceutical companies and generate 8.6% of total sales among this group. In Europe, only the United Kingdom (3 companies 15.9% of sales), Switzerland (3 companies, 10.7% of sales) and France (one company, 8.6% of sales) have a better or equivalent position. The United States ranks first, with 20 companies representing 39.7% of worldwide sales (Gray, 2006)[18].

113. In terms of production, Germany ranks third in Europe, behind France and the United Kingdom (EFPIA, 2007). Production grew in the 1990s at a rate comparable to that of the United States, in the United Kingdom and in France (5% annually between 1991 and 2001), but lower than those observed in a few European countries such as Sweden, Denmark and Belgium (+12%) or Ireland (+23%) (OECD Health Data, 2007).

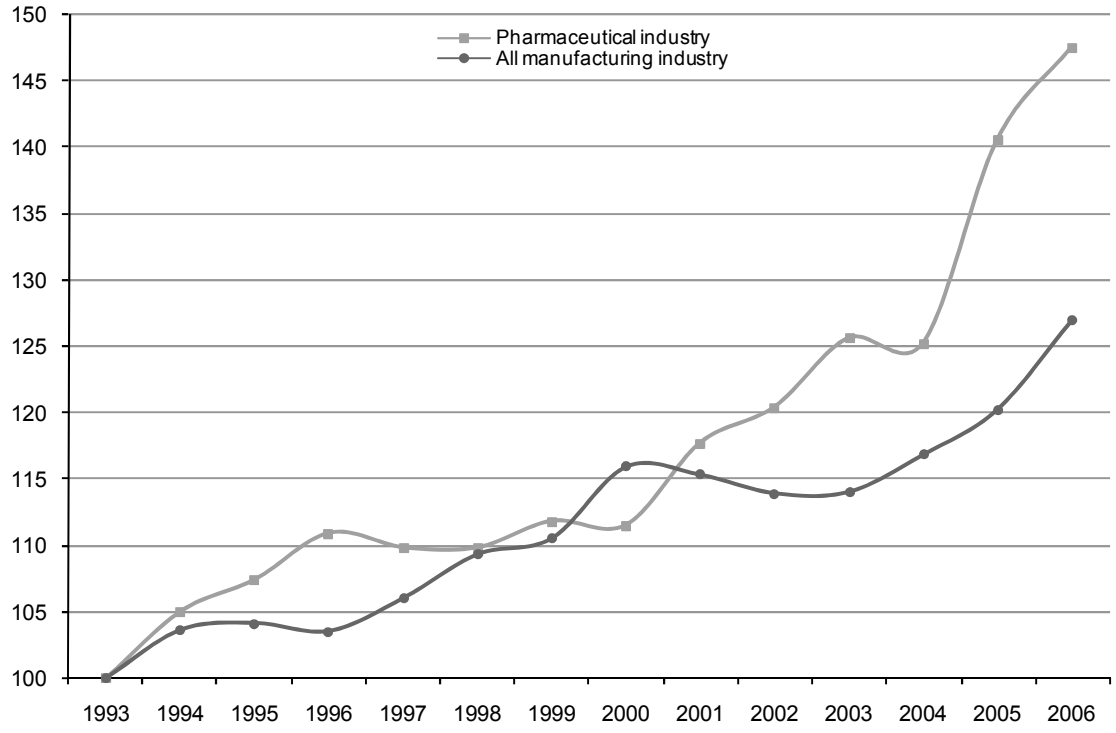
16. *http://www.vfa.de*, accessed on January 15, 2008

17. *http://www.bpi.de*, accessed on January 15, 2008

18. The Top 50 pharmaceutical companies account for about 70% of worldwide sales.

114. Within Germany, the production of pharmaceuticals grew faster than production in other manufacturing sectors between 1993 and 2006. Nonetheless, total employment in the sector has been slightly decreasing since 2004 (-4.8% between 2003 and 2006). In 2006, 113,234 people work in the pharmaceutical industry.

Figure 11. Production in the pharmaceutical industry and in total manufacturing industry 1993-2006

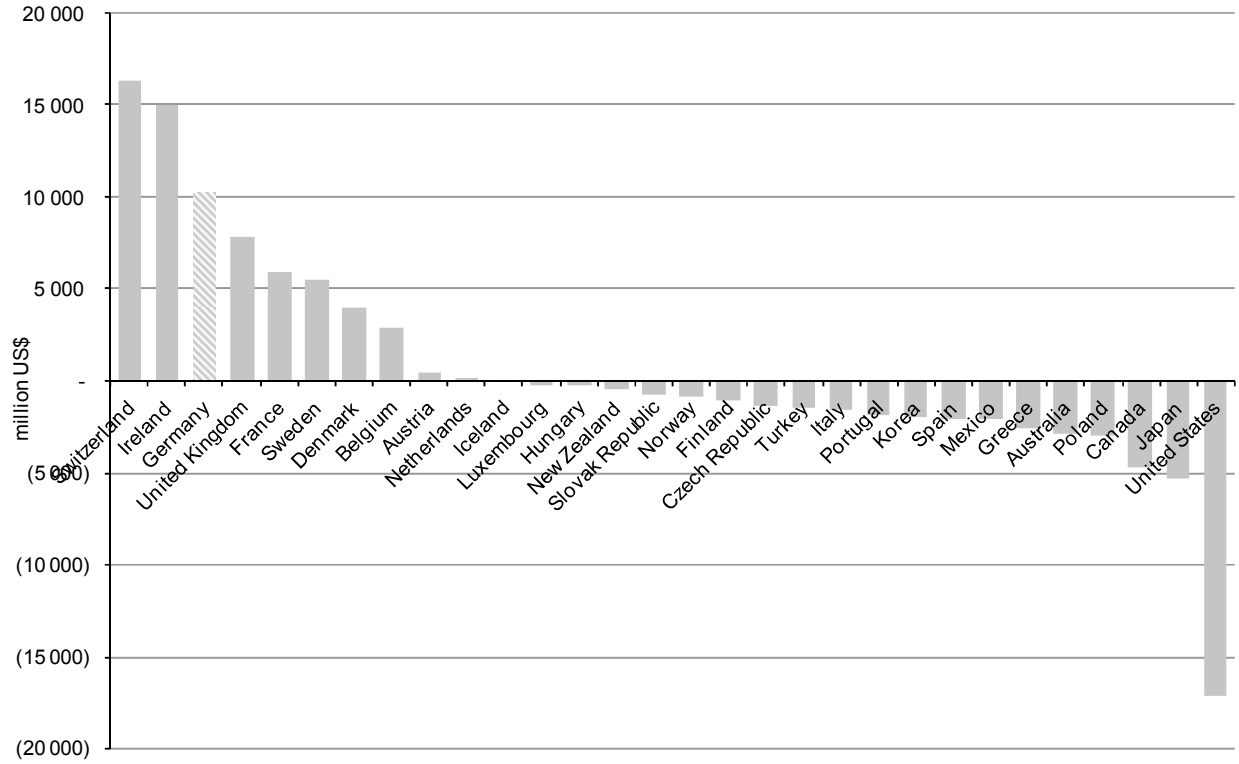


Source: Federal Statistical Office, cited by VFA 2007.

115. Germany has long been a net exporter of pharmaceuticals; ranking third among OECD countries in 2006 (see Figure 12). Both imports and exports have been increasing sharply since 2002 (see Figure 13). Ireland is the main source for pharmaceutical products imported to Germany (30% of imports), followed by the United States (18%), Switzerland (10%) and France (7%). Main destinations for German pharmaceutical exports are Belgium (28% of exports[19]), the United States (12%), the Netherlands (7%) and Switzerland (6%) (Statistisches Bundesamt, cited by BPI, 2007).

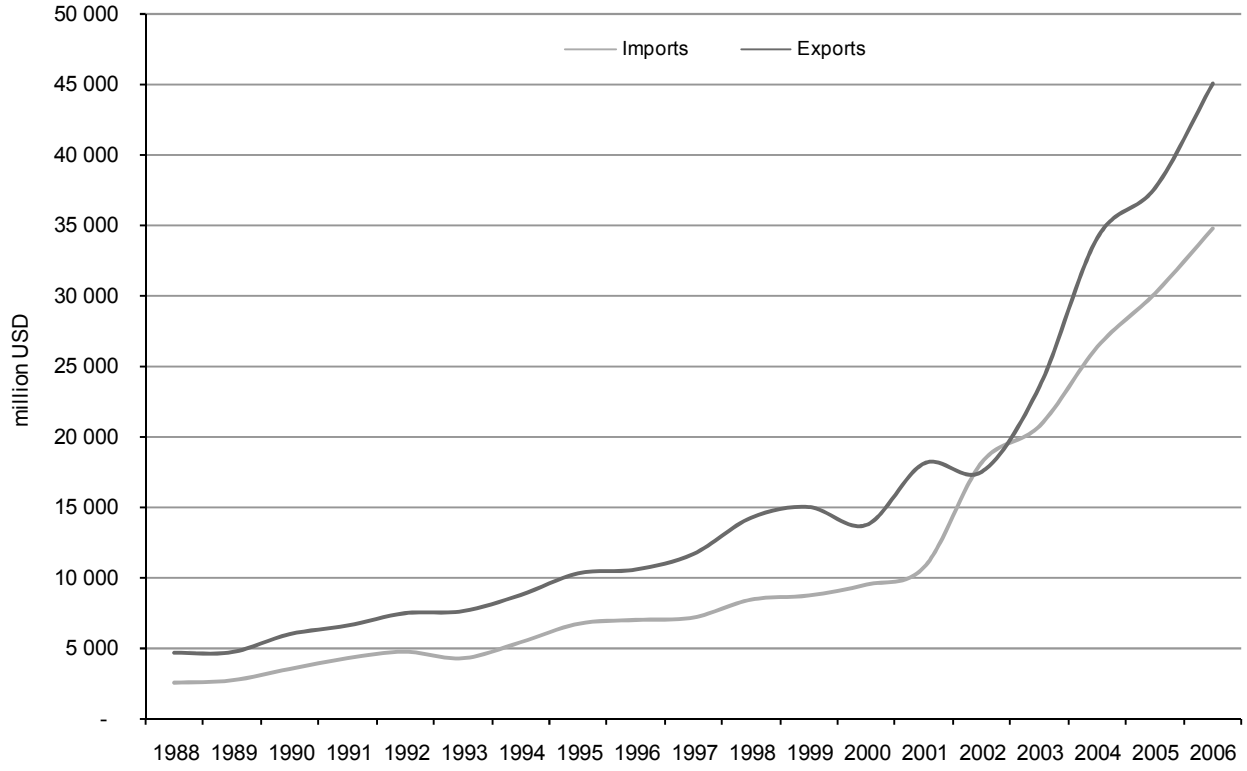
19. A big pharmaceutical company has set up a distribution centre in Belgium, where drugs are imported from production centres to be re-exported to other countries. This probably explains the volume of exports to Belgium.

Figure 12. Pharmaceutical trade balance 2006



Source: OECD International Trade Statistics, 2007.

Figure 13. Trend of Import and exports of pharmaceuticals



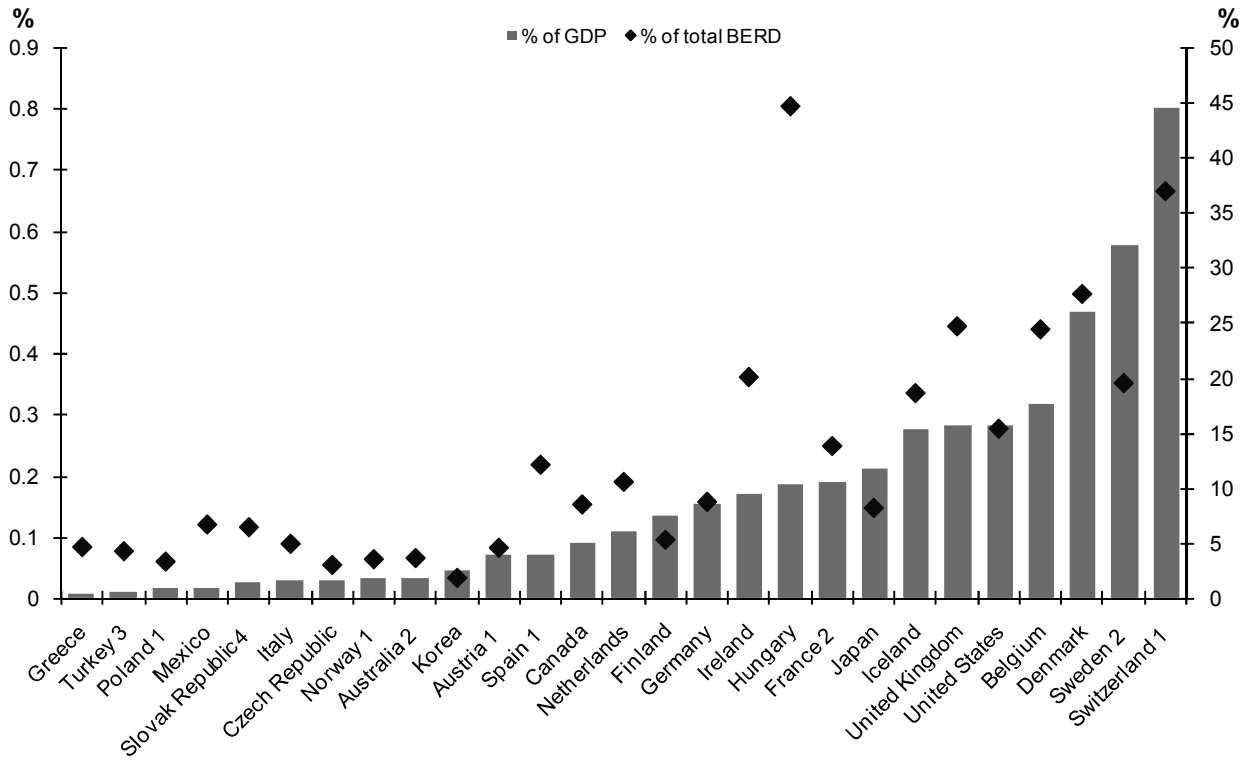
Source: OECD International Trade Statistics, 2007.

116. Germany ranks second in Europe for R&D performed in the pharmaceutical industry, after the United Kingdom (OECD, 2007a; EFPIA, 2007). These investments represented 0.15% of GDP in 2004, which is similar to the average level observed on OECD countries for which data are available, and similar to the United Sates' level. They also represented 8.4% of all Business R&D expenditures, which is much lower than in some European countries (such as Switzerland, Denmark, United Kingdom, Belgium, Sweden or Ireland, see figure 14).

117. The European pharmaceutical industry's competitiveness has deteriorated in the 1990s. During this period, US companies overtook their European counterparts in terms of worldwide market shares and R&D outcomes (Gambardella *et al.*, 2000). The decline was more pronounced for German firms than for British ones, a trend that some analysts attribute to differences in institutional frameworks in which they operate: British firms, led by shareholders and a flexible labour market are deemed to be more adaptable and oriented to the search of short-term financial results, which make them more likely to produce blockbuster drugs (Casper and Matraves, 2003).

118. Nevertheless, outcomes of R&D investments by German firms are comparable to those of their European counterparts. German firms originated 42 of the new chemical entities launched between 1993 and 2003 (see Figure 14), a level comparable to those of Switzerland though the discoveries of Swiss firms are on average more innovative (more often global, first-in-class, biotech). However, the firm nationality does not dictate the location of R&D activities, which are widely internationalized. In other words, the R&D activities of German firms are not restricted to Germany.

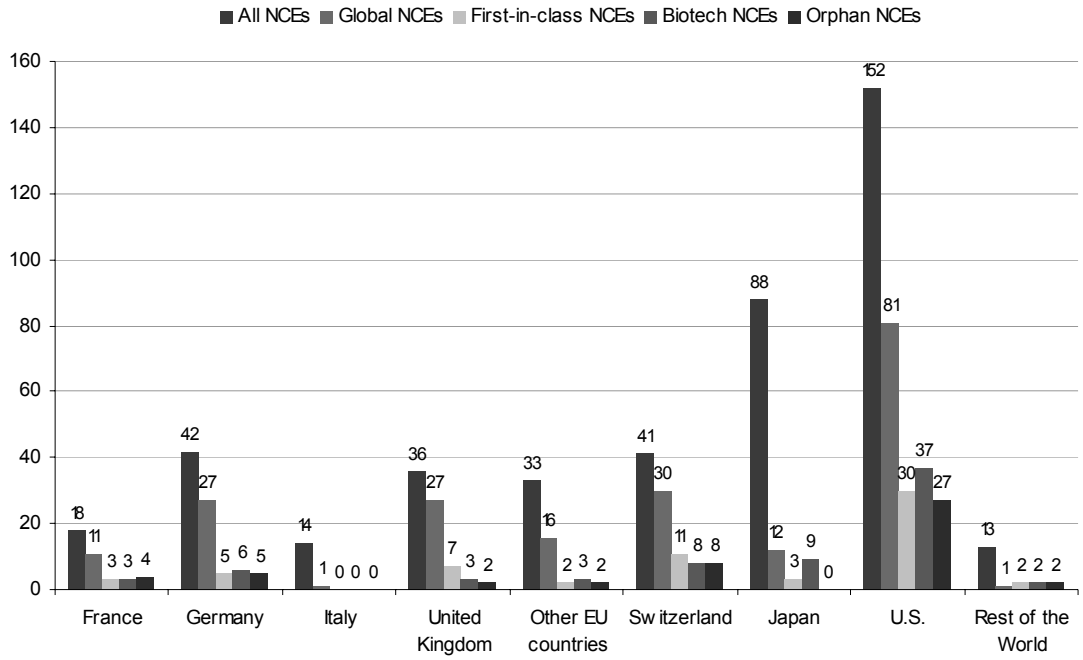
Figure 14. Business expenditures for R&D performed by the pharmaceutical industry 2005



1. 2004; 2. 2003; 3. 2002; 4. 2001; BERD: Business expenditure for R&D

Source: OECD Science and Technology Indicators, 2007

Figure 15. New chemical entities (NCEs) launched between 1993 and 2003, by firm's nationality



Source: Grabowski and Wang, 2003

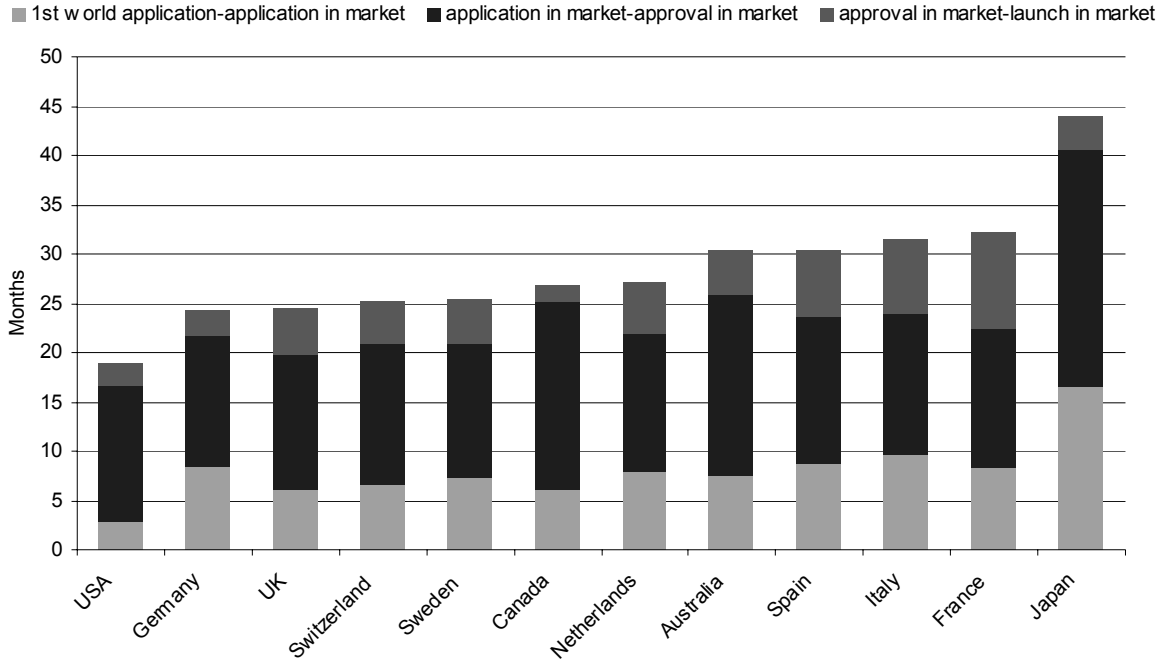
Germany is an attractive market for the global pharmaceutical industry

119. With 80 million inhabitants and a relatively high income, Germany represents 5.3% of worldwide sales, ranking fourth behind the United States (45.1%), Japan (9.3%) and France (5.6%) (IMS Health, 2007).

120. Delays for marketing authorisations are not long, by comparison with other countries, and there is no "reimbursement and pricing" delay since drugs eligible for reimbursement are immediately reimbursed by health insurance funds as soon as they enter the market, at the price set by the manufacturer. As a result, pharmaceutical products are promptly available in Germany, about 24 months after first world application, i.e. quicker than in all other markets but the United States (see Figure 16).

121. However, the diffusion of new molecules (measured by the number of daily doses per capita within the three years following launch in the country) is slower than in many other countries (Japan, France, Australia, United States, Spain, Italy, Canada), though similar to the diffusion rate observed in the United Kingdom (Danzon and Furukowa, 2008). According to VFA statistics, in 2005, the market share of new molecules 5 years after market launch in Germany was the lowest among a set of EU countries : 6.5% against 9.8% in Norway and Denmark, 11.7% in Switzerland, 14.6% in the United Kindgom, 16% in the Netherlands and 20.9% in Sweden (VFA, 2007).

Figure 16. Average delay between first launch in the world and launch in each country for drugs launched between 1999 and 2002



Source: Pharmaceutical Industry Competitiveness Task Force, 2005, from Association of the British Pharmaceutical Industry calculations.

Supply and distribution of pharmaceuticals

122. More than 95% of approved pharmaceutical products are available only in pharmacy (BfArM, 2007); the remaining may be sold in drugstores or supermarkets. Physicians are generally not allowed to dispense drugs. Hospitals usually purchase pharmaceuticals directly from manufacturers, while 90% of pharmacies' purchases transit by wholesalers.

123. Sixteen full-line wholesalers operate in the German market, 4 of which operate nationwide and 12 regionally (ÖBIG, 2006).

124. With about 25 pharmacies per 100,000 inhabitants, the density of pharmacies is just above the EU average (20 pharmacies per 100,000 inhabitants, from ÖBIG, 2006).

125. The 2004 GMG reform liberalised the pharmacy sector in order to foster competition: pharmacy owners are now allowed to own up to 4 outlets, mail order has been authorised and the price of non-reimbursed OTC drugs was completely liberalised (Busse and Riesberg, 2004).

ASSESSMENT OF THE IMPACT OF PHARMACEUTICAL POLICIES ON POLICY GOALS

Goals for health-system performance

126. This section provides an overall assessment of the impact of the German pharmaceutical reimbursement and pricing policies on goals set for health-system performance.

Containment of drug expenditures

127. By comparison with other OECD countries, Germany has succeeded in containing pharmaceutical expenditures growth since the end of the 1990s. This success reflects a number of one-off measures to lower or stabilise ex-factory prices and/ or distribution margins, for example, as well as ongoing policies such as employment of maximum reimbursement amounts and prescription targets.

128. As in other countries, the main component of growth is the shift towards new and more expensive products. Pharmaceutical prices have remained relatively stable since the beginning of the 1990s; price decreases in the market segment subject to maximum reimbursement amounts have compensated price increases in the other market segment.

129. However, retail prices of pharmaceuticals are relatively high by international standards. For the bulk of the on-patent market (as far as they are not subject to maximum reimbursement amounts), high ex-manufacturer prices are explained by two factors. First, SHI funds were, up to 2007, "price takers", and second, manufacturers have the incentive to launch products early in Germany at relatively high prices, aware that they will serve as a benchmark for many other European countries. As to the generic market, explanations are more complex. The reference price scheme has sometimes been suspected of placing a floor, rather than a ceiling, on generic prices, though this is belied by the fact that products often have prices below the *Festbetrag*. It seems that competition in the generic market mainly takes place at the pharmacy level, where manufacturers or wholesalers offer lower prices or benefits in kind to pharmacists which they do not pass on savings to health insurance funds. In this market segment, the recent prohibition of benefits in kind and the proliferation of SHI-manufacturers contracts should intensify competition whose effect will be reflected in retail prices. New contracts are stated to have led to price reductions in generics; however, no study is yet available to confirm this.

Sustainability and equity of financing for pharmaceuticals

130. Out-of-pocket payments have often been used to tackle health insurance funds' deficits. Though out-of-pocket payments remain the less equitable way to finance health care, they are not particularly high in Germany as far as pharmaceuticals are concerned. Moreover, safety nets exist to prevent people from spending more than 2% (1% for chronically ill) of their revenues for health care.

131. The Parliament has regularly levied rebates on manufacturers' and pharmacists' sales to avoid deficits and managed to curb pharmaceutical expenditure growth. However, this kind of measure has important the drawbacks. First, it has only a one-shot impact and second, it creates a relatively unstable environment.

Efficiency of expenditures in the pharmaceutical sector

132. Measures adopted to improve the efficiency of pharmaceutical expenditures have achieved some success: prescriptions of drugs with contested effectiveness have decreased while generic prescribing and dispensing has continuously increased, as has the use of parallel imported drugs.

133. The reduction in the prescription of drugs with contested effectiveness is probably the result of both pharmaceutical policy and market trends. However, the fact that declines in the prescription of such drugs were particularly pronounced in years with stringent cost-containment measures (mainly budgets) suggests that physicians have responded to those incentives by eliminating the less effective medicines from their prescriptions.

134. Germany shows a high generic penetration in the pharmaceutical market. Until 2007, this positive outcome, in terms of efficiency, was somewhat counter-balanced by the fact that generic prices were relatively high by international standards. According to the German Ministry, the new contracting opportunities have enhanced price competition between generic manufacturers and generated price erosion, but the actual outcome of the reform will be difficult to assess given that contracts and rebate agreements are confidential. Similarly, parallel imports are encouraged by incentives and have been increasing since the beginning of the 1990s, allowing some savings for health insurance funds.

135. Each year, the annual report on pharmaceutical prescription prepared by the scientific institute of health insurance WiDO estimates the potential savings which could be achieved through the prescription of cheaper so-called "analogue pharmaceuticals". These "analogue products" are defined as new products with no or marginal therapeutic advantage over existing products. They more or less correspond to what is usually referred to as "me-too" products. These studies claim that further savings could be achieved by a more efficient prescription (Schwabe, 2007).

136. Though prescription budgets have succeeded in slowing pharmaceutical expenditure growth, several studies mentioned that they may have had spill-over effects on other sectors. One study showed that macro-budgets for pharmaceuticals in 1993 led to an increase to specialist referrals and in hospital expenditures (SBEG, 2005). This is a well-known adverse effect of incentives based on silo-budget approaches.

137. Other studies have shown that patients with private health insurance were more likely to receive newer and more expensive drugs for some diagnoses (Ziegenhagen *et al.*, 2004; Wild, 2008). The authors of these studies do not explain these differences by differences in copayments (which are not mentioned at all) but rather by the fact that physicians' prescriptions for privately insured patients are not subject to prescription targets. These studies confirm the effect of prescription targets on doctors' behaviour without drawing conclusions about differences in quality or efficiency in pharmaceutical spending for PHI and SHI patients. Ziegenhagen *et al.* (2004) observed that there were no significant difference in the prescription of drugs with disputed effectiveness between private health insurance and social health insurance.

138. Finally, prescription targets, collective and individual, are based on past expenditures, which are not necessarily at efficient levels.

Availability of pharmaceuticals in Germany

139. By international standards, pharmaceuticals are promptly available in the German market. Pharmaceuticals approved through the national procedure may incur longer approval delays. However, given the fact that the most important drugs are approved through European centralised or decentralised procedures, this does not imply poor availability of treatments for patients –though it may affect manufacturers' revenues. In any case, medicines not authorised for marketing in Germany can be made available to patients when medically appropriate.

Accessibility of pharmaceuticals in Germany

140. The lack of health insurance coverage has never been an important issue in Germany, as the few uncovered people were deemed to be rather wealthy and healthy. Nonetheless, the 2007 reform made

health insurance coverage mandatory and introduced measures to improve its affordability (OECD, 2008b, Brandt, 2008). The list of reimbursable medicines is quite comprehensive though OTC drugs are no longer reimbursed since 2004 (as is the case in many other OECD countries). Vaccines, previously reimbursed on a voluntary basis by health insurers, have been included in the mandatory benefit basket since 2007.

141. Though copayments exist for pharmaceuticals, total copayments for health care are capped at 1% (for chronically ill persons) or 2% of income, which guarantees that no insured German patients can be exposed to exceptionally high levels of copayment.

142. The fact that diffusion of new medicines is relatively slow in comparison with other countries may reflect incentives established by physician prescription targets or other factors. On the other hand, access to expensive drugs seems more than satisfactory by international standards. Germany ranks in the top 5 for the uptake of new cancer drugs in share of total oncology market (European Society for Medical Oncology, 2007). Similarly, orphan drugs are readily available and almost always reimbursed by health insurance (Alcimed, 2005).

Quality of care, health outcomes

143. Several reports mentioned inadequacies of pharmaceutical therapy in some areas. For instance, results of an epidemiological study on hypertensive patients showed several shortfalls in treatments by general practitioners (SBEG, 2005):

- The majority of hypertensive patients are not correctly regulated: more than 70% of them have a blood pressure ≥ 140/90 mmHg though more than 80% of them were prescribed at least one hypertensive drug;

- Antihypertensive treatments are often installed or augmented when it is already too late for preventive care, especially for older people and/or when complications or other diseases have begun.

144. The publication of guidelines led to improvement in some therapeutic areas but some failures persist. For instance, the prescription of drug hormonal therapy to relieve menopause symptoms has been decreasing since the 2003 guideline recommending against this therapy for most women, but 2.5 million women are still treated (SBEG, 2005).

145. However, the gap between evidence-based guidelines and doctors' prescriptions is not a problem unique to Germany. It is explained by numerous factors relating to the practice of medicine traditionally being considered an "art" subject to factors relating to the physicians' decision-making process, patients' expectations, and last but not least, by promotional activities of the pharmaceutical industry.

146. Adverse effects of medicines are reported to BfArM by health professionals and other stakeholders through a system of spontaneous reporting, which is well known to lead to under-reporting. A few studies have estimated the incidence of adverse drug reactions (ADRs) in Germany. They show that 5% of patients with drug treatment experienced ADRs, that 3 to 6% of hospital admissions are due to ADRs, and that 0.15% of hospitalised patients died because of ADRs, about half of which are due to inadequate use (SBEG, 2007). According to death certificates, the standardised mortality rate for ADRs is of 0.1 per 100,000 inhabitants in Germany, similar to the OECD average (*OECD Health Data*, 2007).

Patient and consumer satisfaction

147. We did not find national studies about patients' satisfaction with pharmaceutical care in Germany. In the survey realised in 2007 by the Commonwealth Fund in seven countries among adults, 26% of German citizens declared that they are "not very or not confident at all that they receive the most effective drugs". This percentage is higher than in the Netherlands (9%), Australia (15%), Canada (16%) and the United States (21%) but equivalent to percentages observed in New Zealand and the United Kindgom (Schoen *et al.*, 2007). Such beliefs may well relate to the existence of constraints on physicians' prescriptions.

Industrial policy goals

148. Like other OECD countries, Germany has implemented innovation policies to make the country attractive to value-added generating activities. These policies are not directly linked to pricing and reimbursement policies, which surely influence decisions to launch or not in the German market, but are not the main determinants for the location of the industry's activities.

KEY FINDINGS

149. Below are some conclusions and observations drawn based on the overview and assessment of pharmaceutical reimbursement and pricing policies in Germany presented in this paper:

- The German population benefits from comprehensive coverage and good access to pharmaceuticals, with a high level of public funding. However, the impact of increasing out-of-pocket payments (due to increased co-payments and de-listing of OTC drugs) on the affordability and effective access for the poorest part of the population should be monitored.

- By comparison with other OECD countries, Germany has succeeded in containing pharmaceutical expenditure growth, thanks to structural reforms (e.g. maximum reimbursement amounts, constraints on physicians' prescriptions) but also to one-shot measures (e.g. increases in rebates and in cost-sharing, delisting).

- Ex-manufacturer as well as retail prices of pharmaceutical were found to be relatively high, by comparison with other European countries. This situation is explained by free pricing at market entry, 'price-taking' by health insurance funds obliged to cover any new drug not explicitly excluded from the benefit basket, and by the fact that Germany is often referred to by countries using international benchmarking for the purpose of price regulation, which incites manufacturers to set high prices. Prices of generic products were also found to be relatively high, which could be partly explained by the fact that there has been, until recently, no price competition at the distribution level. New contracting opportunities are reported to have lowered generic prices but no assessment is publicly available yet.

- Changes introduced by 2007 reforms are expected to tackle some of these issues. New contracting opportunities should lead to price erosion in the generic market as well as in therapeutic classes in which patented competitors are available. Similarly, price caps should help limit the prices of new drugs to those of existing drugs with similar benefits. However, these changes will not address all of the weak spots of the German system.

  - For technical and other reasons, IQWiG proposes to assess relative costs and benefits of new drugs within therapeutic areas rather than to define a cost-benefit threshold for reimbursement, comparing costs and benefits of treatments at the system level. This means that price caps cannot be set as long as there is no therapeutic alternative –as is the case in many other OECD countries. Subsequently, follow-on drugs will be benchmarked to this first entrant for potential price cap setting. While the approach should result in more cost-effective expenditures within therapeutic classes, there is no mechanism for considering relative value across classes.

  - New contracting opportunities overlap and sometimes conflict with existing instruments (maximum reimbursement amount, prescription targets) which are supposed to disappear but are still in effect, increasing the complexity of the system. Benefits and costs of this reform

should be monitored to check that the benefits of price erosion exceed transaction costs and compensate for the loss of transparency in the system. Indeed, Germany's remarkable tradition of monitoring prescriptions and prices of pharmaceuticals, with public reports widely available to stakeholders and the general public, is compromised by the new reform.

– This lack of transparency is likely to affect the cost-benefit assessment, since price caps will be set by reference to list prices of existing comparators rather than to confidential prices effectively paid by health insurance funds.

LIST OF ACRONYMS

BfArM *Bundesinstitut für Arzneimittel and Medizinprodukte*
BPI (*Bundesverband der Pharmazeutischen Industrie*) Association of the pharmaceutical industry

CPMP Committee for Proprietary Medical Products

DRG Diagnostic-related groups

EEA European Economic Area
EMEA European Medicines Agency
EPC European Patent Convention
EPO European Patent Office

G-BA (*Gemeinsame Bundesausschuss)* Federal Joint Committee –
GKV Gesetzliche Krankenversicherung – Statutory health insurance
GKV-WSG *Wettbewerbsstärkunggesetz* Health Insurance Competition Enhancing Act
GMG *GKV-Modernisierungsgesetz* – Health insurance modernisation Act

InEK (*Institut für das Entgeltsystem im Krankenhaus*) National Institute for payment in hospitals
IQWiG (*Institut für Qualität und Wirkschaftlichkeit im Gesundheitswesen)* Institute for Quality and Efficiency in Health Care

OTC Over-the-counter

SHI Statutory Health Insurance
SGB (*Sozial Gesetzbuch*) German Code of Social Security
SPC Supplementary protection certificate

VAT Value-added tax
VFA (*Verband Forschender Arzneimittelhersteller*) Association of R&D based pharmaceutical industry

WIdO (*Wissenschaftlisches Institut der Allgemeine Ortskrankenkasse*) AOK's Scientific institute

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ANNEX 1: INTERNATIONAL PRICE COMPARISONS

150. This annex presents the results of a literature review of ex-factory prices, as well as original analysis using OECD data on retail prices of pharmaceuticals.

Comparison of ex-factory prices

151. Although a number of studies of ex-manufacturer prices have been published since 2000, none of them took Germany as the reference country. We nevertheless tried to assess the relative level of German pharmaceutical prices using the available comparisons.

152. In a report published by INFRAS/BASYS (2002), Swiss prices are compared to prices in Germany, the United Kingdom, France, the Netherlands and the United States. The study covers the June 2000-June 2001 period and is based on the top 100 selling drugs in Switzerland (products with one active ingredient only). The unit price per Defined Daily Dose and then Laspeyres indexes were computed, prices were converted using exchange rates. German prices were found to be lower than Swiss prices, for the entire sample of products as well as for the sub-group of generic drugs.

153. Another study by IMS (2003) compares prices of the top 100 reimbursed drugs in Switzerland, representing 47% of the Swiss market value, with prices in a set of OECD countries, in the second quarter of 2003. Price indexes are computed as the un-weighted average of elementary indexes taking the Swiss price as the reference, considering only identical form-strengths in all countries, and using exchange rates for monetary conversion. According to this study, Germany ranks fourth in Europe, just after Switzerland, Sweden and United Kingdom for ex-manufacturer prices (see table 6).

154. Santésuisse published in 2006 a study comparing prices of the top 100 reimbursed products in Switzerland with prices in the seven countries used as comparators by the Swiss Office of Public Health (UK, Germany, Netherlands, Denmark, and Austria, France, Italy). The sample represents 56% of Swiss turnover for reimbursable outpatient drugs. The authors computed price indexes by weighting foreign-to-Swiss unit price ratios (e.g. per tablet) in 2005, converted using exchange rates, by 2004 Swiss sales. In this study, Germany ranked second for ex-factory prices[20] (Santésuisse, 2006).

155. A study published by the US Department of Commerce (2004) compares the prices of patented products in the United States with prices in ten OECD countries (bilateral comparisons) in 2003. The sample is composed of the US top 54 patented prescription products containing a single molecule, further extended to all products containing this molecule (on- or off-patent). It represents 26% of drug sales across the ten OECD countries, but the share of the market covered in Germany is not known. Fisher Indexes have been calculated based on ex-manufacturer price per standard unit (SU) or per kg of active ingredient. German prices appear to be 48% (per SU) to 41% (per kg) below US prices and comparable to Canadian, Swiss and UK prices, as well as (more surprisingly) French prices. However, as US discounts were not considered, the price differential between Germany and the United States is overestimated.

20. This study considered primarily ex-factory prices, except in Denmark and the Netherlands where only pharmacy purchasing price was available. The OFSP estimates that ex-factory prices in these countries may be respectively 2-10% and 6-12% lower than the pharmacy purchasing price. Similarly, UK ex-factory prices have been estimated by reducing NHS prices by 16%.

156. By contrast, the report shows that German generic prices are just above US generic prices, lower than generic prices observed in Japan, Canada, Switzerland, the United Kingdom and France.

157. Annual reports from the Canadian Patented Medicines Prices Review Board present bilateral comparisons of Canadian ex-factory prices of patented drugs with prices in the seven countries considered in the Canadian price regulation (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). Bilateral comparisons are based on patented products available in Canada and in each comparator country. The average foreign-to-Canadian price ratio for each product is computed, weighted by sales in Canada. Prices are converted by current exchange rates.[21,22] Here again, the extent to which the sample is representative of the German market is not known. In 2005, German prices were close to Canadian prices and higher than all European countries but Switzerland, and lower than US prices (PMPRB, 2006a; 2006b). Using the same methodology, PMPRB shows that German prices of generic drugs are higher than prices in all comparator countries but Canada and Switzerland (PMPRB, 2006b, p. 2).

158. Simoens (2007) compared ex-factory prices of 15 high-selling generic molecule-strengths in selected European countries in 2005. For each molecule-strength, the average price was computed as the average of prices of all existing presentations, weighted by sales in each country. Prices were converted in Euros using exchange rates. On average, Germany had the highest price per standard unit, although it was not the case for each product.

159. The British Department of Health publishes annually bilateral comparisons of ex-manufacturer prices in the United Kingdom, a set of European countries and the United States (OFT, 2007). Comparisons are based on the match of the top 150 branded medicines in the United Kingdom with available medicines in each comparator country. In 2005, German prices were slightly higher than UK prices (108 against 100).

160. Danzon and Furukawa (2008) compared ex-factory prices of originator and generic drugs in the United States with 11 countries, of which 9 are OECD member countries. Prices were converted using exchange rates and indexes of prices per unit are weighted by US sales. When products are matched by molecule-indication-form-strength and formulation, US-Germany matching products represent 18.7% of German products but 49.7% of sales and 32.8% of units sold. When US prices are indexed at 100, the German price index is 74 for single-source originator products, 65 for multiple-source originator products, 151 for generics (branded or not), 77 for prescription products and 192 for OTC products. In this study, US prices of generics and OTC drugs were found to be lower than in all comparator countries.

21 PMPRB uses a fully-lagged 36-month moving average of spot exchange rates for this purpose. This means that long-term exchange-rate movements will be fully reflected in PMPRB's average price ratios only 36 months after they occur, while a short-term fluctuation will influence the ratios up to 36 months after it has been reversed.

22. These price comparisons are based on "publicly available ex-factory prices" obtained by manufacturers in foreign countries and provided to PMPRB for the review of excessive price (PMPRB, 2002). This means that further confidential discounts or rebates consented by the manufacturers are not taken into account, which could lead to under- or over-estimates of differentials between Canadian and foreign prices.

Table 1. Comparisons of ex-manufacturer prices – review of recent studies

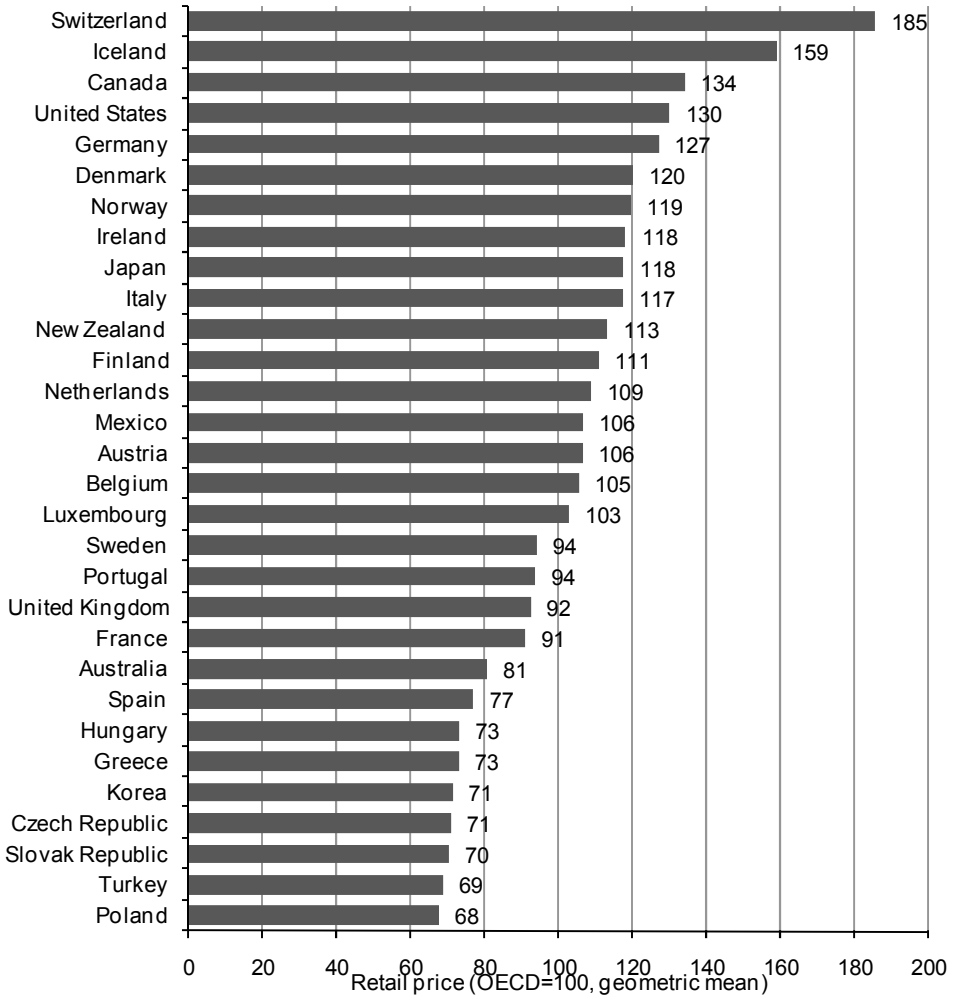
Study	Price comparison	Methodology	Findings
INFRAS/BASYS (2002)	Second half 2001 Ex-factory prices for the top 100 selling drugs in Switzerland	Bilateral comparison, Laspeyres index, prices per DDD, converted using exchange-rates	All products: Switzerland = 100 Germany = 84 Generics: Switzerland = 100 Germany = 56
IMS (2003)	Second quarter of 2003. Ex-factory prices of the top 100 reimbursed drugs in Switzerland	Price indexes computed as the un-weighted average of elementary indexes taking the Swiss price as the reference, considering only identical form-strengths in all countries, and using exchange rates (X-rate) and Purchasing Power Parities (PPPs) for monetary conversion.	X-rate: Switzerland = 100 Germany = 86 PPPs: Switzerland = 100 Germany =120
US Department of Commerce (2004)	2003 ex-factory prices of US top 54 patented prescription products containing a single molecule, further extended to all products containing this molecule (on- or off-patent)	Bilateral comparisons to the US, Fisher Indexes calculated based on ex-manufacturer price per standard unit (SU) or per kg of active ingredient.	(extended) Patented drugs: United States = 100 Germany = 52 Generics: United States = 100 Germany = 110
Santésuisse (2006)	2005 Ex-factory prices of the top 100 reimbursed products in Switzerland	Bilateral comparison, price indexes of foreign-to-Swiss unit price ratios (per tablet…) weighted by 2004 Swiss sales. X-rate.	Switzerland = 100 Germany = 86
PMPRB (2006a)	2005 ex-factory prices of patented drugs available in Canada and in each comparator country	Bilateral comparisons, The average foreign-to-Canadian price ratio for each product is computed, weighted by sales in Canada. Prices are converted by current exchange rates.	Canada = 100 Germany = 96

Study	Price comparison	Methodology	Findings
PMPRB, 2006b	2005 ex-factory prices of patented, generics and non-patented branded prescription drugs available in Canada and in each comparator country	Bilateral comparisons, The average foreign-to-Canadian price ratio for each product is computed, weighted by sales in Canada. Prices are converted by current exchange rates.	Patented Canada = 100 Germany = 106.4 Non-patented branded Canada = 100 Germany = 91 Generics Canada = 100 Germany = 84
Office of Fair Trading (2007).	2005 ex-factory prices, bilateral comparison with UK, based on the top 150 branded medicines in the UK.		United Kingdom = 100 Germany = 108
Simoens (2007)	2005 ex-factory prices of 15 high-selling selected generic molecule-strengths in selected European countries.	For each molecule-strength, the average price was computed as the average of prices of all existing presentations, weighted by sales in each country. Prices were converted in Euros using exchange rates.	Average (15 molecules): Germany = 0.269 Netherlands = 0.260 France = 0.254 UK = 0.222 Finland = 0.220 Belgium = 0.206 Norway = 0.171 Sweden = 0.123 Denmark = 0.104
Danzon and Furukawa (2008)	2005 ex-factory prices, all out-patient drugs available in the United States and each comparator country	Prices per standard unit, converted using exchange rates. Price indexes weighted by US sales. Products matched by molecule-indication-form-strength and formulation.	Single-source originator products: United States = 100 Germany = 74 Multiple-source originator products United States = 100 Germany = 65 Generics: United States = 100 Germany = 151 OTC products: United States = 100 Germany = OTC

Comparison of retail prices

161. The OECD (2008) published relative retail price levels of pharmaceuticals. These are drawn from pharmaceutical purchasing power parities developed by the OECD and Eurostat for input into economy-wide purchasing power parities (PPPs) for OECD countries. Countries were invited to report retail prices of products representing the country's sales from a list of 181 products drawn from top-selling drugs in the OECD, and reported data for 86 products, on average. Comparative price levels (CPLs) provide a measure of the differences in pharmaceutical price levels between countries by indicating the number of units of a common currency needed to buy the same volume of pharmaceuticals in each country. Indices have been computed to show 2005 price levels relative to the OECD average price. While the index serves to provide a general sense of relative price levels, rather than a precise ranking, it suggests that German retail prices are almost 30% higher than the OECD average, similar to prices observed in the United States and Canada, but lower than Swiss and Icelandic prices (Figure 17).

Figure 17. Relative retail pharmaceutical prices in OECD countries, 2005



Source : Eurostat-OECD Purchasing Power Parity Programme, 2007

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