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Valérie Paris and Elizabeth Docteur

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ABSTRACT

This paper examines aspects of the policy environment and market characteristics of the Swiss pharmaceutical sector, and assesses the degree to which Switzerland has achieved certain policy goals.

In Switzerland, pharmaceutical spending has not been growing faster than health expenditure as a whole, as has been the case in many other OECD countries. Swiss pharmaceutical spending per capita and as a share of GDP is modest by OECD standards. This in part reflects relatively low levels of pharmaceutical consumption, given that public prices are among the highest in Europe and the Swiss tend to be early adopters of new pharmaceutical products.

Switzerland's regulation of prices for reimbursed drugs, based on referencing across countries and within the therapeutic class for products with comparators, appears to result in prices lower than what would be obtained absent regulation. Although ex-manufacturer prices are somewhat high relative to other European countries, recent reforms have reduced the differential.

While costs are under control, Switzerland has scope to improve the cost-effectiveness of its expenditures in the pharmaceutical area. Generic penetration of the market is increasing but falls short of what has been achieved elsewhere and the prices of generic products are higher than what is found in other countries. Relatively high mark-ups over ex-factory prices suggest that the distribution chain is a source of further potential efficiencies, although high costs could also reflect characteristics of the Swiss economy.

Although the Swiss health system is characterised by a high share of out-of-pocket spending, the contrary is true in pharmaceuticals, as Switzerland ranks among OECD countries with the highest share of public financing. While there are limits on patients' annual cost-sharing expenditures, low-income persons are not exempted, raising the potential for problems with accessibility and affordability, although no evidence was uncovered in the course of this study.

Although Switzerland is a small market, new medicines are generally available on the market promptly. Manufacturers may choose Switzerland as a country for first or early world launch in part because of the leeway they are granted in establishing an initial market entry price when comparators are lacking.

JEL Classification: I18, I11

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

RÉSUMÉ

Ce document passe en revue différents aspects des politiques et des caractéristiques de marché du secteur pharmaceutique en Suisse et évalue l'atteinte des objectifs relatifs à la politique pharmaceutique suisse.

En Suisse, les dépenses pharmaceutiques n'ont pas augmenté plus vite que l'ensemble des dépenses de santé, contrairement ce qui s'est passé dans de nombreux autres pays de l'OCDE. Les dépenses de médicaments par habitant, et en proportion du PIB, restent modérées par rapport à la moyenne des pays de l'OCDE. Cela tient en partie au niveau relativement faible de la consommation pharmaceutique, puisque les prix publics sont parmi les plus élevés en Europe et les Suisses enclins à adopter rapidement les nouveaux produits.

La régulation des prix des prix des médicaments remboursés, basée sur des comparaisons internationales et, le cas échéant, sur les prix des comparateurs au sein d'une même classe thérapeutique, semble conduire à des niveaux de prix moins élevés que ce qu'ils seraient sans régulation. Même si les prix fabricants sont relativement élevés par rapport à ce qu'ils sont dans d'autres pays européens, les récentes réformes ont réduit l'écart.

Les coûts sont certes maîtrisés mais la Suisse pourrait aller encore plus loin pour améliorer l'efficience de ses dépenses pharmaceutiques. Le taux de pénétration des génériques sur le marché s'améliore mais reste inférieur à ce qu'il est ailleurs et les prix des génériques sont plus élevés que dans d'autres pays. Les marges relativement élevées appliquées sur les prix fabricants donnent à penser que les circuits de distribution pourraient être rationalisés, même si les coûts élevés peuvent aussi refléter certaines caractéristiques de l'économie suisse.

Bien que le système de santé suisse se caractérise par la forte proportion des dépenses à la charge des patients, ce n'est pas le cas pour les produits pharmaceutiques : la Suisse a un niveau de financement public des médicaments relativement élevé au sein de l'OCDE. Si la participation des patients aux coûts des médicaments est limitée par un plafond annuel, les personnes à faible revenu ne sont pas exonérées, ce qui peut potentiellement générer des problèmes d'accès. Cependant, l'étude n'a pas apporté d'éléments à ce sujet.

Alors que le marché suisse est de taille réduite, les nouveaux médicaments sont généralement commercialisés rapidement. Les fabricants pourraient choisir de lancer leurs produits promptement en Suisse notamment pour profiter de la marge de manœuvre dont ils disposent pour fixer le prix initial lorsqu'aucun comparateur n'est disponible.

Classification JEL : 118, 111

Mots-clés : politique pharmaceutique ; tarification et remboursement ; marché pharmaceutique ; Suisse

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INTRODUCTION

1. This report is the third 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. This report describes and assesses policies in Switzerland, a country of 7.4 million inhabitants, speaking with three main native languages: German (65% of the population), French (20%) and Italian (6.5%). The country is rather rich, ranking 6th in OECD with a GDP per capita of almost PPP$ 36,000.

3. As a confederation of 26 cantons, Switzerland is characterised by a high level of political decentralisation. Cantons have their own constitution, parliament, government and courts, and hold all powers not delegated to the confederation. Responsibilities within the health system are shared by the different levels of governments (OECD, 2006a). The federal government is entitled to legislate in areas such as public health, social insurance, professional qualifications, environmental protection, and product safety. Cantons are responsible for disease prevention and health education and for the provision of health care; they partially finance hospital costs and regulate pharmacy and medical practice installations. Municipal levels implement responsibilities delegated by the cantons, such as the provision of nursing and home care.

4. Since the 1996 implementation of the Swiss Law on Health Insurance (LAMal), Swiss residents must purchase basic insurance that covers all goods and services included in the benefit basket defined at the federal level. As a general rule, Swiss patients contribute to the cost of care through the payment of an annual deductible (CHF 300 in 2006[1]) and, once this has been met, a co-insurance set at 10% of the cost of services. Private health insurance held by about 80% of the population provides additional services to supplement the basic benefit package, but complementary insurance to cover cost sharing for services covered by the social insurance is not allowed.

5. The main objective of this paper is to describe and analyse Swiss pharmaceutical reimbursement and pricing policies and, as far as possible, to assess their effects at the national level. 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 Switzerland and the characteristics of the Swiss 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.

[1] In June 2007, 1 CHF = 0.80 US$ = 0.60 €

1 THE POLICY ENVIRONMENT

6. The first part of this document describes the Swiss pharmaceutical reimbursement and pricing policies (section 2 and 4), as well as the policy environment in which they operate: market approval procedures (section 1), coverage of pharmaceuticals (section 3), policies intended to influence drug use (section 5) and innovation policies (section 6).

1.1 Pharmaceutical market approval procedures and outcomes

7. To be launched on the Swiss market, pharmaceutical products have to be approved by Swissmedic. Swissmedic was created by a Federal Act on therapeutic products in 2002[2] (*LPTh: Loi fédérale sur les produits thérapeutiques*) which strengthened the regulation for the manufacturing, export and import, and distribution of pharmaceuticals. Swissmedic is a public institute, placed under the authority of the Federal Council but autonomous for its organization and management. Its main sources of funding are users' fees for market authorisation and other procedures (21%), levies on manufacturers based on volume of sales (51%) and federal contributions (28%). Swissmedic is also responsible for medical devices and veterinary products.

8. Companies filing an application for market authorisation by Swissmedic must be located in Switzerland; those firms that have their headquarters elsewhere must have a Swiss subsidiary. The institute grants a marketing authorisation if the product meets the requirements of quality, safety and effectiveness. The clinical assessment is based on data provided by the pharmaceutical company. This authorisation is valid for 5 years. A simplified procedure exists for the approval of drugs containing known ingredients; complementary medicines[3]; in-house preparations by authorised hospitals and pharmacies for their own clients; drugs manufactured and used in the army; and important drugs for rare diseases. This simplified procedure is also used for parallel imports, which are authorised after patent expiration.

9. Decision time targets for approval procedures are consistent with international standards: 200 days for ordinary procedures and 130 days for fast-track procedures. However, targets for ordinary procedures have not always been met (Swissmedic, 2006a). In order to compensate for extended delays, the LPTh introduced in 2002 "temporary licences" to distribute and dispense non-authorised drugs used in the treatment of fatal diseases, when no equivalent is available, when there is a great expectation about the effectiveness of the treatment and if the use of the drug is compatible with health protection.

10. In 2005, Swissmedic delivered 28 authorizations for drugs containing new active ingredients, of which 5 benefited from fast-track procedures. In addition, Swissmedic granted 23 temporary licences, including influenza vaccines.

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2 Before 2002, marketing authorisations were delivered by an Intercantonal Office.

3 From 2006 on, high-diluted homeopathic products without any specific indications can be marketed with a simple declaration from the manufacturer, provided that the active substance is listed by Swissmedic (Swissmedic, 2006b).

11. Doctors and pharmacists may obtain authorisation to treat a specific patient by importing pharmaceuticals which are not, not yet or no longer approved in Switzerland. In 2005, a change in the legislation simplified the administrative procedures to be used by health-care professionals for that purpose. As a result, Swissmedic considered 1,700 applications in 2005, against 6,225 in the previous year.

12. Drugs are classified by Swissmedic in five categories according to prescription and dispensing requirements as dictated by safety criteria (see Table 1). Pharmacies have a monopoly for the selling of drugs of categories A, B and C while drugs from other categories (D, E) can be sold in drugstores. In addition, drugs of categories A and B must be prescribed in order to be delivered. In the Swiss pharmacopoeia, more than half of marketed products must be prescribed by a physician.

13. The number of medicines available in the Swiss market has been declining, from 9,700 in 1985 to about 6,500 products in 2005. This trend has been observed in other European countries in the past 20 years and is partially explained by more stringent requirements for marketing authorisation. However, the trend is sometimes partially compensated by the development of generics.

Table 1. Number of products available in the Swiss market by category, 2005

Drug categories	Number of products	%
A: Prescription-only, no refill	764	11.8%
B: Prescription-only	2,837	43.9%
C: Dispensed with health professional counselling	747	11.6%
D: Dispensed with specialised counselling	1,950	30.2%
E: General sales	166	2.6%
Total	6, 464	100.0%

Source: Hunkeler (2006), p. 85

1.2 Pharmaceutical pricing policy

14. Switzerland does not regulate pharmaceutical prices across-the-board. Prices of non-reimbursed OTC and prescription drugs are freely set by the manufacturers while the maximum prices of drugs included in the benefit basket reimbursed by basic health insurance are negotiated with manufacturers. Though manufacturers can generally decide to not seek reimbursement and to market their drugs at any price the market can bear, expected benefits of reimbursement status generally lead them to opt for reimbursement and what they perceive as *de facto* price regulation.

1.2.1 Price regulation is limited to health products and services reimbursed by basic health insurance

15. As for prices in traffic and telecommunication sectors, the federal government regulates the prices of health products and services reimbursed by basic health insurance (Surveillance des prix, 2005c). The Department of Interior has the overarching responsibility for the health system regulation and is responsible for the definition of benefit baskets and subsequent price regulation.

16. The Federal Office of Public Health (OFSP) regulates both inclusion in the positive list and pricing of reimbursed pharmaceuticals. The OFSP sets maximum prices for all listed drugs, original preparations --- on- or off-patent--- as well as generic drugs. The OFSP regulates manufacturers' prices as well as distribution margins and payments for pharmacists' services.[4] Manufacturers freely set the prices of OTC and prescription drugs for which they do not seek (or do not obtain) reimbursed status.

17. On top of OFSP price regulation, pharmaceutical prices are subject to monitoring by the Price Council. The Price Council is an independent authority, in charge of protecting consumers against excessive prices resulting from abuses of monopolies or from inappropriate regulation (see Box 1).

Box 1. The Price Council

The Price Council in its current form was created by a law on price surveillance adopted on December 20, 1985, with the mandate to protect consumers against excessive prices resulting from dominant market position. The Price Council is in charge of price surveillance for all goods and services produced by cartels or firms in monopolistic position (private or public), as well as goods and services subject to government regulation. The Council is entitled to take action to hinder excessive prices or excessive price increases and to issue policy recommendations on regulated sectors. It has the duty to inform consumers about price levels, notably through annual reports.

There is no official definition of "abusive price", but the law on price surveillance gives a list of elements to be taken into account in the consideration of price levels by the Price Council: "price trend in comparable markets; the necessity of equitable profits; cost trends; specific services provided by firms; and peculiar situations inherent to the market".

Prices of health products and services are regularly scrutinised by the Price Council. The Price Council periodically publishes comparisons of Swiss drug prices with German ones. It regularly issues recommendations about policy tools likely to lower drugs prices in Switzerland, which it has judged excessive. In addition, the Price Council monitors the implementation and impact of the reform of payment for pharmacists' services. The Price Council can also react to abusive prices of drugs by seeking conciliation with the manufacturer

Source : Surveillance des prix, 2006b

1.2.2 Pharmaceutical market segments not subject to direct government price regulation

18. The government does not regulate prices of drugs which are not included in the positive list. Nonetheless, prices of non-listed drugs may be subject to surveillance by the Price Council, *a fortiori* if they are patented, in order to prevent abuses from a dominant market position. Indeed, the Price Council annually publishes comparisons with German prices of non-listed original products. However, it does not provide much detail about drugs included in this sample and there is no possibility to disentangle prices of non-listed drugs used by hospitals from those of OTC drugs.

1.3 Coverage of pharmaceuticals

19. The Swiss population is covered by universal basic health insurance, which provides drug coverage. Patients generally contribute to the cost of medicines through deductibles and co-insurance.

1.3.1 Health insurance coverage

20. Since the introduction of the law on health insurance in 1996, all Swiss residents must purchase basic insurance, which covers all goods and services included in the benefit basket. As a general rule,

[4] The latter are negotiated with pharmacists and will be described in part 1.4.3 of this document.

Swiss patients contribute to the cost of care through the payment of an annual deductible (CHF 300 in 2006) and a co-insurance of 10% above this deductible.

21. When contracting for basic health insurance, people can choose their insurer (within their canton of residence). Insurers can propose several types of guarantees with different levels of deductibles and corresponding *premia*, the range of possible deductibles being defined by the Federal Council. In 2006, deductibles could vary between CHF 300 and CHF 2,500. In practice, nearly half (48%) of the Swiss population is covered by "ordinary contracts," policies that offer the standard deductible and premium (OFSP, 2007).

22. Patients are protected against high out-of-pocket expenditures by several means. First, children under 18 years are exempted from deductibles. Second, co-insurance payments are capped at an annual ceiling of CHF 700 per adult and CHF 350 per child. Moreover, people are exempted from all or part of cost sharing in certain circumstances: health care related to normal pregnancy is totally free from co-payments; health services dispensed in the framework of cantonal of federal public health programs ---such as mammograms for breast cancer screening and flu vaccines in the case of pandemic crises --- are free from deductible. In addition, insurers may exempt people from all or a part of co-payments in exchange for accepting a limited network of providers and benefit basket. The LAMal (art. 64, al. 6) states that the Federal Council is entitled to exempt people from cost sharing for serious or long illness. However, such a list of serious illnesses does not exist yet. There is no exemption from co-payments for "social" reasons, but low-income people pay lower insurance *premia* through federal or cantonal subsidies.

23. According to an amendment to the law on health insurance, applicable since January 2001, patients' contribution to the cost of reimbursed medicines cannot be borne by social insurance, nor by any private insurance company, association, foundation or institution (LAMal, Art 64-8). However, private insurers may offer coverage options for drugs or indications which are not included in the positive list.

1.3.2 Reimbursement and cost-sharing arrangements for drugs

24. Basic health insurance pays for drugs included in the positive list when dispensed by community pharmacies, hospital pharmacies or dispensing doctors. In ambulatory care, the patient generally contributes by paying 10% of the cost of medicines, after deductible. In 2006, the co-insurance rate increased to 20% for brand-name drugs for which less expensive interchangeable generics are available[5], with a specific annual cap of CHF 933 for the purchase of these drugs.

25. Private health insurance companies sell supplementary insurance packages, some of which furnish coverage for non-listed drugs when prescribed by a physician. However, supplementary coverage does not play a major role in the Swiss pharmaceutical market. According to National Health Accounts, the share of private health insurance in the financing of drugs is only 3%, suggesting that non-listed drugs purchased in ambulatory care are mainly financed by patients.

26. In hospitals, basic health insurance finances medicines used in in-patient care through hospital payment schemes defined in each canton (OECD, 2006a, p. 56). Insured patients may have to contribute to the cost of hospitalisation but bills are not itemised and drugs not isolated in total expenses. In principle, when a stay is not covered by basic health insurance – either because the patient is privately insured or because the hospital stay is not covered by basic health insurance, the hospital produces an itemised bill, on which medicines may be priced at any level. In this specific case, the listed drugs may be priced higher than the maximum reimbursement price, since the final purchaser is not basic insurance. However,

5 A manufacturer can avoid the higher co-insurance by dropping the price of the originator to the price of the generic alternative (or below).

insurance companies providing supplementary coverage tend to sign agreements with hospitals including price arrangements.

1.3.3 Adequacy of drug coverage and financial protection against drug expenditures

27. Thanks to universal coverage by basic health insurance, Swiss residents are entitled to drug coverage for an extensive list of medicines. Cost-sharing is capped annually but there is no exemption for low-income people. Deductibles may encourage people to buy drugs without a prescription, where none is required, and to not seek reimbursement, at least for low-priced drugs.

28. In spite of having out-of-pocket payments for total health expenditures that are high by international standards --- OOP expenditures account for 6.3% of households' final consumption compared to an OECD average of 2.8% --- Swiss residents do not bear high cost-sharing for drugs. Out-of-pocket expenditures for pharmaceuticals, which include self-purchase of OTC products, represent less than 10% of total out-of-pocket health expenditures (against 19 to 65% in 12 countries for which data are available[6]) and 0.6% of households' consumption (against 0.4 to 1.9% in the same 12 countries).

1.4 Reimbursement pricing policy

29. In Switzerland, pharmaceuticals have to go through an assessment process and be included in a positive list in order to be reimbursed by basic health insurance. The following sections describe the process of inclusion of pharmaceuticals in the positive list and the eligibility criteria for inclusion, as well as criteria used for pricing and an assessment of the impact of the Swiss pricing policy.

1.4.1 The process for inclusion in the positive list

30. To be reimbursed by basic health insurance coverage, drugs have to be listed in the *"Liste des spécialités"*, established by the Federal Office of Public Health.[7,8] Reimbursement decisions are informed by the advice of the Federal Drug Commission (See Box 1).

31. The principles and process for inclusion in the positive list of medicines are established by ordinances issued by the Federal Council[9] (OAMaL) and the Department of Interior[10] (OPAS). According to the OAMaL, a medicine must fulfil the following conditions to be included in the positive list (article 65): it must be approved by Swissmedic; be "effective, appropriate[11] and value-for-money ("*économique*").

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6 Available countries are Australia, Canada, Czech Republic, France, Germany, Japan, Korea, Luxembourg, Norway, Poland, Portugal and Spain (OECD System of Health Accounts, 2007).

7 See http://www.bag.admin.ch/themen/krankenversicherung/00263/00264/00265/index.html?lang=fr (accessed September 22, 2006)

8 A specific list is drawn up for magistral preparations, "*Liste des médicaments avec tarifs*". Relevant rules applicable to the Speciality list are also applicable to this list.

9 Ordonnance sur l'Assurance maladie (OAMaL), June 1995 and further revisions (Chancellerie Fédérale, 2006a).

10 Ordonnance sur les prestations de l'assurance des soins (OPAS), September 1995 and further revisions, (Chancellerie Fédérale, 2006b).

11 Ordinances do not provide any definition of "appropriate" as they do for "effective" and "value-for-money". However, article 30 of the OPAS proposes a slightly different set of criteria for inclusion in the positive list, according to which evidence of "effectiveness, therapeutic value and value-for-money" must be provided.

32. The assessment of effectiveness must be based on controlled clinical trials for allopathic drugs[12] (OAMaL art. 65). The Drug Commission relies on Swissmedic's work to assess effectiveness but may require other data (OPAS, art. 32).

33. A drug is considered to be value-for-money when it produces a given therapeutic effect at the lowest possible cost (OPAS, art. 34-1). To evaluate if a drug is "value-for-money", the OFSP considers the manufacturer's proposed price against "its manufacturer's price abroad; its therapeutic effectiveness compared to other medications with identical indications or similar effects; its daily cost or cost per cure, compared with those of medications with identical indications or similar effects" (OPAS, art. 34.2). As the evaluation of a drug's value-for-money plays an important role in the pricing process, the rules used for this assessment will be described in the following section.

34. In principle, drugs are considered for inclusion in the positive list at the manufacturer's request. However, the OFSP has the right to include or maintain a drug in the positive list against the manufacturer's will, when the drug is particularly important. In this case, the OFSP sets the reimbursement price unilaterally (OAMal, art. 70). Delays for reimbursement and pricing procedures were found to rank among the lowest in Europe, with an average of about 175 days between application for listing and publication of the decision in 2002. At that time, delays were shorter only in Sweden, Denmark and Ireland and non-existent in the United Kingdom and Germany, where drugs can be sold virtually as soon as they are approved for marketing[13].

35. The process of systematic assessment and inclusion of pharmaceuticals in a positive list contrasts somewhat with the situation of other medical goods and services. Most curative services or procedures are covered unless they are excluded from the benefit basket (negative list) and medical devices are usually reimbursed as soon as they are prescribed by doctors and dispensed by licensed professionals. Though all goods and services covered by LAMaL are supposed to meet criteria of effectiveness, appropriateness and value-for-money, most medical devices have not been formally assessed. Assessment of medical devices is sometimes undertaken, when requested by health providers, health insurers, health authorities or patients associations (Commission pour les questions conjoncturelles, 2006). Unlike other medical services, whose non-inclusion in the benefit package can only be challenged in court, decisions of the OFSP pertaining to drug inclusion in the benefit basket can be contested via an internal appeal procedure (Gress *et al*., 2005).

36. The Swiss positive list is considered to be quite comprehensive by stakeholders. In practice, a decision not to list a drug that is a candidate for reimbursement is rare, with the main issue being "at what price" to list rather than "whether to list". In 2005, the list contained 2,558 drugs (6,815 presentations), which represent 57% of available drugs. About 87% of listed drugs are prescription only medicines of A and B categories (Interpharma, 2006; Hunkeler, 2006). Coverage of listed drugs may be limited to some indications or limited in treatment duration.

12 This statement suggests that effectiveness for non-allopathic drugs is assessed with less stringent methods.

13 EFPIA data available at http://mednet3.who.int/prioritymeds/report/append/DossierStatistics2004_apx82.ppt.

Box 2. Composition and functioning of the Federal Drug Commission

The ordinance on health insurance of June 27, 1995, created four federal commissions, composed of scientific experts and stakeholders, and charged with the mission of advising the Federal Office of Public Health on the definition of the benefit basket of medical services, drugs, analyses and medical devices.

The Federal Drug Commission is chaired by an official of the OFSP and is composed of 24 members appointed by the Federal Council, among which are: 4 scientific experts coming from medical and pharmacy universities; 3 physicians, among which is at least 1 representative from complementary medicine; 3 pharmacists, among which is at least 1 representative from complementary medicine; 1 representative from hospitals; 5 representatives of health insurers and accident insurers; 2 representatives of insured; 2 representatives of the pharmaceutical industry; 1 representative from the Federal Office of social insurance; 1 representative from cantons; 1 representative of Swissmedic; 1 representative of the Army pharmacy (Ordonnance sur l'Assurance maladie du 27 juin 1995, updated on May 9, 2006).

Like the other federal commissions, the Drug Commission established its own rules pertaining to the organization of work, the number of meetings per year, etc. The Drug Commission members meet 4 to 5 times per year and issue about 250 recommendations annually. There is no public information about drugs considered in each session, about debates or conclusions of the drug commission. Public information is limited to positive decisions issued by the OFSP which indicate: the scope of coverage (sometimes limited to some indications) and the maximum reimbursement price.

Source: Ordonnance sur l'assurance maladie (Chancellerie fédérale, 2006a)

1.4.2 Criteria used for establishing maximum ex-factory prices of listed drugs

37. The negotiation of maximum ex-factory prices is in fact closely guided by the assessment of a drug's value for money. The ordinance on insured health services describes criteria used for this assessment and sets forth the framework for price regulation. The main elements to be considered are: prices of the new applicant drug in foreign countries, the relative effectiveness of the new drug (compared to existing ones), and R&D costs (OPAS, art 34).

38. For comparisons with prices abroad, the general rule is that the ex-factory price of a listed drug must not exceed the average ex-factory price[14] observed in selected countries "in which the pharmaceutical sector has a comparable economic structure" and "in which the ex-factory price is defined with precision by competent authorities or by an association" (OPAS, art. 35). Prices in Germany, Denmark, the United Kingdom[15] and the Netherlands are first considered. France, Austria and Italy can be considered as subsidiary countries, and other countries may be included in the comparison. Prices abroad are reported by the pharmaceutical company but must be attested by the competent authority or association in the relevant country. The pharmaceutical company is also required to provide Swiss authorities with the "EU targeted price[16]" (OPAS, art 30). According to both officials at OFSP and stakeholders[17], this general rule is used

14 Before 2001, international benchmarking was based on retail prices. As a consequence of the reform of the pharmacists' margins introduced in 2001 (described later), comparison with foreign countries is now based on ex-factory prices.

15 The United Kingdom was added to the initial set of reference countries in July 2002 (OFAS Press release of July 3, 2002). The set of subsidiary countries was added at the same time.

16 In French "le prix-cible pour la Communauté Européenne". Within European Unions, manufacturers have been encouraged to adopt a new strategy to set or negotiate prices (See for instance Kucher, 2000). The new strategy, known as the "price corridor" strategy consist in setting a reference price for several countries and a "margin" within which the prices of each country will be allowed to float. Companies are encouraged to set both a "soft upper limit" (price beyond which there is a risk of parallel trade) and a "hard lower limit" (the price that no subsidiary in no country is allowed to undercut, because of expected adverse effects on both parallel trade and external referencing).

with flexibility. For instance, if the price in one of the comparator countries happens to be either exceptionally high or low, it will not be taken into account in the average considered. Similarly, if the drug is not yet available in comparator countries, other countries may be considered. Given that Switzerland tends to be an early launch country [18]and is the country of first launch more often than all but six other countries in the world, it will very often be the case that no or few points of comparison will be available for price benchmarking.

39. The relative effectiveness of the drug is considered when therapeutic competitors exist. In these cases, new drugs which are not more effective than existing ones must be priced at a lower level to be included in the list. According to OPAS (art. 31-2), the Drug Commission should classify new drugs in 5 categories according to their level of innovation: (a) therapeutic breakthrough; (b) therapeutic progress; (c) savings compared to other drugs; (d) no therapeutic progress and no savings; (e) inappropriate for social health insurance (OPAS, art. 31-2). In practice, this classification is only informally used by the Commission.

40. R&D costs must be taken into account "in an equitable manner" in the economic assessment, via the "innovation premium" granted to innovative products (OAMal, art. 65-3bis, OPAS art. 34.2). Theoretically, only categories (a) and (b) among categories defined above are eligible for such a premium. However, in practice, price *premia* are reportedly granted to new products which are the first or the second entrant in a therapeutic class. The innovation premium is generally amounts to 10 to 20% of existing therapeutic comparators' prices when there are any, but premiums granted to breakthrough drugs are not limited in this respect. In addition, higher price *premia* may be consented for drugs with limited market perspectives such as orphan drugs (Hunkeler, 2006). Though the OAMal explicitly refers to "R&D costs", manufacturers are not required to provide data on R&D expenditures. According to Hunkeler (2006), this provision mainly serves the purpose of justifying the discount required from generic manufacturers.

41. Drugs included in the positive list are subject to periodic assessments to confirm that they still offer "value-for-money"; the first one occurs 24 months after their inclusion to check if the entry price was appropriate. If this assessment reveals that the price is "too high" to guarantee value-for-money, the OFSP lowers the price of the drug. Moreover, if the difference between the former price and the new price is greater than 3% and revenues perceived from this difference greater than CHF 20,000, the manufacturer may be required to pay back excess revenues to health insurance (OAMal, art 67). A second assessment takes place at patent expiry[19] or at the latest 15 years after inclusion in the list, and a third one 2 years later (OAMal, art 65). In addition, if new uses have been approved by Swissmedic, drugs must be subject to a complete assessment 7 years after their inclusion in the list, including assessment of effectiveness, appropriateness of indications and value-for money, notably in comparison with other countries (OAMal, art. 66). These periodic assessments were progressively introduced in recent years following recommendations of the Price Council, to provide opportunities for price revisions (Surveillance des prix, 2005b, see Box 3 for a chronology of reforms). The Council had noticed that prices at inclusion time were very stable while market conditions were changing, due to the entry of generic and/or of more effective competitors and recommended periodic price revisions to ensure that listed products remain "value-for-money".

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17 Interpharma and VIPS.

18 For those drugs launched between 1995 and 2001, only Japan, the United States, Germany, the United Kingdom, Italy and France exceeded Switzerland in the number of first world launches.

19 In order to allow price revisions at patent expiry, the OAMaL states that manufacturers have to join identification numbers and dates of expiry of patents and supplementary protection certificates in their application for inclusion in the *Liste des spécialités* (OAMaL, art. 65). However, the OFSP is not in charge of checking the validity of information provided by manufacturers and any contestation of patent validity should be addressed to the competent authority (court).

42. At the time of an original product's reassessment at patent expiry or 15 years after listing, a so-called "reference price" is set for use as a benchmark for pricing of generic alternatives. At market entry, generics included in the positive list must be priced at least 30% below this "reference price." If the reference price of the originator is lowered at the time of the systematic re-assessment occurring 2 years later, the price of generic alternatives is supposed to remain at least 15% lower (OAMal, Art. 65). Switzerland intends to reform this system so that, in the future, regulation of generic prices will occur only at market entry. In any case, if the price of the originator is lowered by its manufacturer, generic manufacturers are not obliged by the law to further reduce their price.

43. Maximum prices are set at the inclusion of the product in the positive list and can not be increased without OFSP's authorisation, which can not be given in the first two years after inclusion. The positive list contains the maximum reimbursement price, which is calculated as the manufacturer's price and the percentage mark-up for distribution (wholesale and pharmacy). This latest component compensates for the logistic services, capital costs linked to transport, storage, and dispensation, and does not include the payment for pharmacists' services (OAMal, art.67).

Box 3. Historical insights on reimbursement pricing in Switzerland

Pharmaceutical price regulation was already in force when LAMal was implemented in 1996; it was based on production costs. This system was replaced in 1996 by a new regulation simulating market conditions and using international benchmarking. In addition, LAMal introduced the practice of periodic price revisions. Before this reform, prices of listed drugs were indexed on the cost of living but never lowered. These changes were notably influenced by public pressure, motivated by high drug prices in international comparisons, accentuated by exchange rates variations.

In addition to changes in the process for inclusion of new drugs in the positive list and periodic revisions, LAMal introduced one-shot measures to obtain lower prices: all drugs included in the positive list before 1985 were revised between 1996 and 1999 in three steps. In a first step, the OFAS re-examined the prices of 280 products launched between 1955 and 1965 against prices observed in Denmark, Germany and the Netherlands. This revision led the OFAS to decide price decreases in most cases but also price increases for 90 products, found to more expensive in comparator countries. However, the Federal Council asked the OFAS to re-consider these decisions and to avoid automatic price increase in following steps. The Federal Council recommended not granting any price increase without a manufacturer's request. He also recommended to consider other parameters than foreign prices for price decisions and to seek advice from the Price Council for any price increase. In a second step, in 1997, the OFAS examined the prices of drugs listed between 1966 and 1973, which happened to be higher than in the three reference countries (Germany, the Netherlands and Denmark) in about half of cases. OFAS' decisions to mandate price decreases were officially contested by appeals in more than 100 cases.

In 1998, the OFAS negotiated with representatives of the pharmaceutical industry and proposed an agreement aimed at reducing drug costs, notably by lowering by 20% the average price of off-patent drugs. As some foreign companies refused to sign this agreement, the reform was not implemented. However, the third and last step of the revision of prices of "old products", focused on drugs launched between 1974 and 1980, achieved some price reductions. At least one company chose to withdraw its product from the positive list rather than consent to a price reduction.

A round table was organized in July 2001 to invite stakeholders to consider measures likely to contain costs in the pharmaceutical sector. Stakeholders agreed to include the United Kingdom to the initial set of reference countries chosen as comparators and to consider prices in European neighbouring countries (France, Italy and Austria). These measures took effect in 2002, as well as the principle of assessment after 2 years of listing, coupled with financial penalties in case of excessive entry price.

An agreement between the OFSP and representatives of the pharmaceutical industry (Interpharma, VIPS and Intergenerika[20]) was signed in September 2005 for a set of measures to be implemented mid-2006:

- Re-assessment for drugs included in the positive list between 1991 and 1996 and price reduction when necessary, with adaptation of corresponding interchangeable generics, whose price must be any case 30% lower than the originator's price;
- Re-assessment for drugs included in the positive list before 1990 and price reduction when necessary, with adaptation of corresponding interchangeable generics, whose price must be any case 15% lower than the originator's price;
- Introduction of new requirements for drugs listed in the positive list:
  - ○ Drug prices must be re-assessed two years after the assessment occurring at patent expiry or at the latest 17 years after inclusion in the list, in order to draw further benefits from increased competition (such as prices decreases in comparator countries, or price decrease of the original preparation). At this time (15+2), generic prices must be at least 15% than originator's price.
  - ○ Drug prices must be re-assessed after 7 years of listing if Swissmedic has approved a new indication for the drug.

Source: Hunkeler, 2006, Rapport écrit du Conseil Fédéral du 2 décembre 1996, Compte rendu de la Session parlementaire de l'été 2002, dixième séance ; Rapports annuels de la Surveillance des prix 1996, 1997, 2001, OFSP, Communiqué de presse du 13 septembre 2005.

1.4.3 From ex-factory to public price of listed medicines

44. The OSFP not only regulates ex-factory prices of reimbursable medicines but also defines distribution margins to be shared between wholesalers and pharmacists in payment for logistic and capital costs of distribution. In addition, agreements between representatives of health insurers and representatives of pharmacists at the federal level regulate payment for pharmacists' services. What is defined at the end of the process is a "maximum public price" for drugs dispensed to patients and paid for by basic health insurance. Any agent of the chain (manufacturer, wholesaler and pharmacist) is free to offer discounts to buyers.

45. Before 2000, the retail margin was set by a cartel[21] for all drugs sold in pharmacies, in dispensing doctors' offices and for indirect sales to hospitals. The margin was a digressive percentage of the ex-factory price. The Swiss competition authority abolished the cartel in 2000 and a new payment scheme was introduced in 2001. The reform split the retail margin in two components: a first component to compensate wholesalers and pharmacists for logistic and capital costs, and a second component to pay for pharmacists' services. However, this new payment scheme only applies to drugs included in the *Liste des spécialités* (LS) reimbursed by social health insurance (see Table 2).

20 Interpharma represents the interest of research-based Swiss companies, VIPS those of foreign research-based companies operating in Switzerland and Intergenerika those of generic manufacturers.

21 The term is used here in its restrictive meaning to qualify a "combination of independent commercial or industrial enterprises designed to limit competition or fix prices" (Merriam-Webster, 2007). This cartel was named Sanphar. It was abolished by the Swiss competition authority in 2000.

Table 2.Components of pharmaceutical public prices (excluding VAT)

Type of pharmaceutical	Reimbursed pharmaceuticals	Non-reimbursed pharmaceuticals
Prescription-only (A & B)	Maximum reimbursement price = ex-factory price set in the LS + distribution margin set in the LS (fixed rate + mark-up) + Payment for pharmacists' services	Market price
Non prescription (C& D)	Maximum reimbursement price = ex-factory price set in the LS + Distribution margin set in the LS (mark-up of circa 80%)	Market price

Source: OECD analysis

1.4.3.1 The payment for logistic and capital costs of drug distribution

46. The OPAS defines general rules for the compensation of logistic and capital costs associated with drug distribution and gives the OFSP the mandate to set applicable margins (art. 35). The OFSP defined two different rules for listed drugs, according to their prescription status. For prescription-only medications, the retail margin is composed of a fixed amount, which varies with the ex-factory price and ranges from CHF 4 to CHF 240, and a proportional margin, set at 8 to 15% of the ex-factory price (see Table 3). For reimbursable drugs of other categories (C and D), the distribution margin is a proportional rate, set at c. 80% of the ex-factory price (Interpharma, 2006).

47. The new system does not distinguish wholesale and retail margins and distributors are supposed to share the logistic margin defined by the OFSP and published in the *Liste des Spécialités*. However, wholesalers are not considered to be "service providers" in the sense of LAMal and thus are not required to pass on discounts consented to them by manufacturers to health insurance funds whereas pharmacists are supposed to do so.

Table 3. Distribution margins for prescription drugs of the positive list, to be shared between wholesalers and pharmacists

Range of ex-factory price	Proportional margin (% of ex-factory price)	Fixed margin (in CHF)
CHF 0.05 – 4.99	12 - 15 %	4
CHF 5.00 – 10.99	12 - 15 %	8
CHF 11.00 – 14.99	12 - 15 %	12
CHF 15.00 – 879.99	12 - 15 %	16
CHF 880.00 – 1800.00	8 - 10 %	60
CHF 1,800 and over		240

Source: Interpharma, 2006, p. 75

1.4.3.2 The payment for pharmacist's services in dispensing listed medicines

48. The 2001 reform modified the status of pharmacists to acknowledge them as "service providers" in the sense of the LAMal. The reform also changed pharmacists' payment by disconnecting it from pharmaceuticals' ex-factory prices. National agreements signed by the Swiss society of pharmacists (SSPh) and the Swiss union of health insurers (Santésuisse) now define the fee-schedule for the payment of pharmacists dispensing drugs reimbursed by basic health insurance.

49. The new payment scheme -- known as RBP for "*rémunération basée sur les prestations* – remunerates pharmacists' services through several fixed rates (see Table 4). The "pharmacist rate" is paid for each prescribed item and covers dispensing and counselling services, as defined in the agreement. The 'patient rate', initially paid every three months for a given drug purchaser, changed in 2007 to a lower rate per-prescription form; it mainly covers the maintenance of the electronic patient's medical record and the check for interaction with other ongoing treatments. Other fixed rates exist to compensate for emergency dispensing, for surveillance, for compliance assistance; and for generic substitution when the difference between the price of the originator and the price of the generic is below a certain threshold. All these rates are defined in the fee-schedule in 'number of points'; the value of the point being subject to negotiation and to adjustments for inflation.

50. The RBP system applies only to prescription products (lists A and B) and to vaccines and immune products listed in the positive list. Reimbursable OTC products were excluded from the scheme for "system consistency". Indeed, the payment of pharmacists' services for OTC products when prescribed and reimbursed would have led to significant differences in prices for a same product, making self-purchase products cheaper than prescribed and reimbursed equivalent products (Hunkeler, 2006).

51. Agreements signed between health insurers and pharmacists include measures of "cost-stabilisation" according to which any gap – positive or negative -- between targeted and actual expenditures must be compensated to the losing party by the other one. In general, pharmacists have to pay rebates in year n+1 because expenditure targets have been exceeded in year n. For 2007-2008, this contribution to cost stabilisation consists in a systematic rebate of 2.5% paid by pharmacists to health insurance for each prescription drug dispensed whose price is below CHF 880.

52. On top of distribution mark-ups, a value-added tax of 2.4% --- relatively low by comparison with most other European countries[22] --- is included in the public price. In 2004, the average price structure in Switzerland was the following: 67% of the public price accrued to the manufacturer, 6% to the wholesaler, 25% to pharmacists and 2% for VAT. The manufacturer's share of the total is higher in Switzerland than in most European countries, except Sweden and Portugal (VFA, 2006, p. 19); however, the Swiss public price does not include the payment for pharmacists' services, which adds significantly to the total payment made by the final purchaser.

[22] For instance, VAT on pharmaceuticals amounted to 10% or more in Denmark, Italy Norway and Slovakia, and 5% or more in Belgium, Finland, the Netherlands, Poland and Turkey in 2006, according to information compiled as part of the Pharmaceutical Pricing and Reimbursement Information project (PPRI, 2007). France (2.1%) and the United Kingdom (0%) have comparably low VAT levels for reimbursed products.

Table 4. Fee schedule for pharmacists' services

Services	RBP I 2001-	RBP II 18/05/2005-31/12/2006	RBP III 01/01/2007 -
Drug validation: check of the prescription, dosage, potential interactions within the prescription form, risk-factors, contra-indications, control of abusive prescription, contact with the physician if necessary.	*Forfait pharmacien*: 4 points per prescription item		
Treatment validation: creation and update of a patient record, check of potential interaction with other treatments, check of potential prescription limitations, control of abusive prescription	*Forfait patient* 8.5 points charged for the first prescription every 3 months		*Forfait patient* 3 points per prescription form Can not be charged twice to the same patient within the same day
Emergency care, for any contact out of usual opening hours	16 points per prescription form		
Surveillance: when pharmaceutical surveillance is required by the medical prescription	10 points		
Compliance assistance: on medical prescription only, the pharmacist prepares multi-dose or customized packaging for patients taking more than 3 medications	20 points per week (limited to an annual turnover of 3 million)		
Generic substitution: applies only to the first substitution (in case of renewal) and depends on the difference between prices of brand and generic drug (D); does not apply in case of NPN prescription	20 points if D > 50 points, otherwise 40% of D (the remaining 60% benefit to the insurer)		
Specific payments (for methadone): Depend on treatment duration	Monthly payment, from CHF 195 to 310		Bi-monthly or monthly payment from CHF 100 to CHF 310

Note: The point value is negotiated when the Consumer Price Index has increased by 5 points, but no more than once a year. On 01/01/2007, the point value was CHF 1.08.
Source: Conventions tarifaires signées entre la Société Suisse des Pharmaciens et Santé Suisse (2001, 2005, 2006)

1.4.4 Impact of reimbursement price regulation on Swiss pharmaceutical prices

53. According to available studies[23], the regulation of reimbursement prices has reduced the gap between Swiss drug prices and prices in other European countries and increased the gap with US prices, though Swiss prices still among the highest in the world.

54. In the nineties, Swiss prices of pharmaceuticals were significantly higher than prices in other European countries (see Annex A and ÖBIG, 2004). Several reports show that the difference between

[23] For a detailed report on Swiss price comparisons with other countries, see Appendix A.

Swiss and foreign prices has been reduced since then and some of them attribute this reduction in price differentials to the reform introduced in 1996. For instance, a study by IMS Consulting (2003) shows that Swiss prices of drugs launched after 1996 are closer to European prices than are those of drugs launched before this date. However, this trend could derive as well from a price convergence towards higher prices in European countries. The Price Council provided further evidence of an impact of the 1996 reform by comparing ratios of Swiss-to-German ex-factory prices of listed and non-listed original drugs launched at different periods in 2005. At that time, the gap between Swiss and German prices was higher for listed drugs whose price had not been revised yet (drugs launched between 1991 and 1995) than for drugs launched before or after this period (47% against respectively 26% and 9%). Similarly, the gap for non-listed drugs is higher than the gap for listed drugs (42% against 21%), which clearly shows an impact of the Swiss reimbursement price regulation.

55. Nonetheless, Santésuisse showed that prices in direct comparator countries were 8 to 15% lower than Swiss prices in 2005. As would be expected, they were even lower in "subsidiary" countries, where drug prices stood from 28 to 32% below Swiss prices[24] (Santésuisse, 2006). These figures, computed on the top 100 of reimbursed medicines in Switzerland, suggest that either entry prices are set systematically higher in Switzerland or that prices in comparator countries are more likely to decrease after launch than in Switzerland. More recent data would be useful to analyse the impact of 2005 and 2006 reforms of pricing and co-payments on drug prices. According to IMS (2007), the average ex-factory price of out-patient prescription medicines (listed or not) decreased between 2005 and 2006 (from 40.39 to 38.92 CHF), and a similar trend is observed for drugs sold to hospitals (from 22.17 to 21.75 CHF). This trend may be partly due to the increase of generic market share as well as the reduction observed in the gap between brand-name and generic prices between January 2005 and December 2006 (from 51% to 28%[25], IMS, 2007).

56. According to the latest available evidence (from 2003 and 2004), prices of generic and other off-patent drugs were relatively high in Switzerland, in comparison with other OECD countries, including the United States.

57. International comparisons of public prices give a less clear picture. The 2001 reform of pharmacist's services payment added complications to the usual methodological issues faced in making price comparisons. The only study which really takes into account pharmacists' payments in Switzerland, as in other countries, places Swiss public prices among the highest in Europe (See Table 7 in Annex 1 and Basys/Infras, 2002), though adjustments for differences in purchasing power across countries slightly lowers the relative level of Swiss prices.

58. Nevertheless, the 2001 reform of the retail margin moderated public price growth by disconnecting the payment of pharmacists' services from ex-factory prices. The Basys/Infras report analysed the impact of the reform between second-half year 2000 and second-half year 2001. Whereas the average ex-factory price did not change for listed products, the average mark-up (wholesale and retail mark-up plus VAT) decreased from 74.5% of the ex-factory price to 71.6%. Within the same period, the average mark-up for non-listed products only showed a slight decrease (74.8 to 74.3%) while there was an increase in the ex-factory price (+2%) (Basys/Infras, 2002). Between 1999 and 2004, the public price structure dramatically changed, with the share accruing to distributors falling from 41% to 31% while the share accruing to manufacturers increasing by 10 points (from 57% to 67%) (VFA, 2001; VFA, 2006).

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[24] Economy-wide comparative price levels compiled by the OECD for GDP-Purchasing power parity calculations show that prices of goods in comparator countries are 15 to 19% lower than Swiss prices, with the exception of Denmark, where prices are 5% higher than the Swiss level. Prices are 16 to 20% lower in subsidiary countries (OECD, 2007, pp. 276-277).

[25] The difference between average brand and generic prices was computed for 80% of sales of products with generic substitutes by IMS (2007).

1.5 Policies and other initiatives intended to influence drug use

59. In Switzerland, professional autonomy is emphasised and government-led policies to encourage appropriate use of pharmaceuticals are limited. Government intervention at the federal level is legitimated by both safety and efficiency concerns, and is limited to drug approval (described in §1.1), to the definition of authorised distribution channels according to drug safety profiles, to the setting of rules for generic substitution, and to the regulation of promotion and marketing activities. Initiatives to influences drug prescriptions are led by health professionals and sometimes supported by health insurers.

1.5.1 Policies to influence drug dispensing

60. According to safety criteria, pharmaceuticals may be sold either in community pharmacies and dispensing doctors' settings, or in drugstores (see § 1.1). Pharmacists and dispensing doctors have a monopoly for the sale of prescription drugs from categories A, B and for most of the drugs from category C. In addition, pharmacists are allowed to prepare drugs on medical prescription for their patients. Drugstore are allowed to dispense drugs from categories C and D. Mail and internet distribution of pharmaceuticals are prohibited[26] (LPTh, art 27).

61. Cantonal governments define the rules for the settlement of pharmacies and authorise (or not) medical doctors to dispense pharmaceuticals. They set standards for the provision of drugs by retail pharmacies, such as the range of available products and opening hours. Pharmacists' services are further defined in agreements signed by the College of pharmacy and Santésuisse, whose main objective is to define services to be provided and corresponding remuneration (see § 1.4.3.2).

62. Switzerland is one of the few OECD countries in which doctors are authorised to dispense drugs, at least in some cantons. This kind of arrangement is well-known to produce perverse incentives to over-prescribe since doctors earn money on drugs they prescribe and dispense. Dispensing doctors have generated a lot of debates in Switzerland, as well as a few studies giving contrasting results about their benefits and costs for the system (see Santésuisse 2004 for a synthesis of studies and debates). Health insurers advocate maintaining dispensing doctors but also introducing agreements with these professionals on standards to improve quality and efficiency of their practice.

63. Since 2001, pharmacists have been allowed to substitute generic drugs for originator products, with the patients' agreement and when the doctor does not expressly oppose to it. According to the Law, pharmacists must inform the doctor in case of substitution (LAMal, art. 52a). In practice, pharmacists inform the doctor if they do not know him but do not phone if they know that the physician usually agrees with the idea of substitution. In addition, generic substitution is encouraged by financial incentives for patients (higher co-payment for the delivery of originator) and for pharmacists (paid by a "substitution rate"). Moreover, the 2001 reform of pharmacists' services payment cancelled the pre-existing negative incentive: from this date, pharmacists do not earn less if they dispense a generic instead of the more expensive original drug.

1.5.2 Policies on promotion

64. The Federal Act on Therapeutic Products defines a first set of limitations on promotional activities by the industry or by distributors. Like in most countries, direct-to-consumer advertising is authorised for OTC products only and promotion for prescription products is limited to professionals entitled to prescribe or dispense pharmaceuticals (LPTh, art. 31 & 32). The Ordinance on Drug

[26] Cantons may grant exceptional authorizations for mail distribution to respond to special needs.

Promotion[27] further regulates promotional activities. Moreover, the OAMaL states that medicines must be excluded from the positive list if the manufacturer makes direct-to-consumer advertising (art. 68d).

65. In addition, the pharmaceutical industry's representatives adopted a code of good practice in 2003[28] to set up standards of quality in promotional activities. Following recommendations of international and European associations and in accordance with Swiss Law, they commit themselves to not promote products or indications not approved by Swissmedic, to clearly separate information from promotion messages, and to deliver complete and evidence-based information to health professionals. Swissmedic is responsible for the control of promotional activities and must check any DTC advertisement before its diffusion.

66. Furthermore, Swiss Law (LPTh and LAMal) defines limitations to benefits of all kinds to be offered by pharmaceutical companies or accepted by health professionals. These limitations and good practice standards are further detailed in the pharmaceutical industry's code of conduct as well as in professional guidelines[29]. According to the LPTh, companies are not allowed to offer benefits in kinds or cash to prescribing dispensing professionals, with the exception of benefits in kind of modest value useful for medical or pharmaceutical practice and usual trade discounts (LPTh, art. 33). Moreover, the LAMal requires health providers to pass on any benefit consented by its supplier to final purchasers (art. 56.3).

1.5.3 Policies to influence drug prescription

67. Public authorities do not regulate physicians' prescriptions: there are no mandatory guidelines, no prescribing budgets or expenditure targets, and no prescription control. Colleges of medical specialties occasionally develop clinical guidelines[30] to help physicians in decision making, but quality circles seem to be the most effective way to influence drug prescriptions.

68. Since 1997, health professionals have initiated quality circles to improve the quality and efficiency of physicians' prescriptions. Quality circles gather 5 or 8 physicians and 1 pharmacist on a voluntary basis. These professionals meet about 5 times a year to establish collectively evidence-based guidelines for a set of therapeutic classes, with the scientific support of the College of pharmacy, and to put these recommendations in practice. Health insurers are involved in quality circles and provide feedback on physicians' prescriptions. Quality circles have proven to have achieved their initial objectives of improving quality and efficiency of prescription. Quality improvements were not systematically associated with cost reduction. For instance, quality circles promoted the use of statins in the treatment of cholesterol and the use of SSRIs in the treatment of depression, over the use of older and cheaper treatments. In other circumstances, however, quality improvements led to savings in prescriptions costs.. "For instance, members of quality circles were more likely than other doctors to use sartans and cox-II inhibitors as "second line treatments" in the treatment of hypertension and inflammatory conditions, respectively, as recommended by evidence-based medicine litterature." Finally, members of these circles more often prescribe generic drugs[31]. In 2006, such quality circles exist in 8 cantons and involve about 300 doctors

27 Ordonnance sur la publicité pour les médicaments (OPMed)

28 Les associations de l'industrie pharmaceutique en Suisse, Code de bonnes pratiques de l'industrie pharmaceutique en Suisse du 4 décembre 2003.

29 Directives de l'Académie Suisse des sciences médicales et de la Fédération des médecins suisses (FMH) ; Directive sur la collaboration du personnel des hôpitaux, cliniques et homes suisses avec leurs fournisseurs.

30 For instance, recommendations for the treatment of cholesterol and for the diagnosis and treatment of heart failure have been published in 1999 and 2002 (Société suisse de Cardiologie, 2000 and 2003).

31 In Switzerland, physicians are allowed to prescribe in International Non-proprietary Names but this does not seem to be the standard behaviour.

and 50 pharmacists. Participation of doctors to these quality circles is validated as part of doctors' continuing medical education obligations. Big insurers finance quality circles up to 50% of savings achieved (Nyffeler, 2002; Bugnon *et al.*, 2006). In addition, quality circles may be partly financed by funds paid by pharmacists' contributions to cost stabilisation

69. Health insurers are more and more active in promoting the appropriate use of drugs. For instance, they have initiated experimental programs of pharmaceutical assistance for long-term care hospitals and they propose risk-sharing arrangements to doctors involved in HMO-type contracts for the prescription of medicines.

70. Like in many countries, the pharmaceutical industry plays a prominent role in the financing of continuing medical education, through the funding of educational events and through academic detailing. Pharmaceutical companies' activities and health professionals' behaviours are regulated through codes of conducts and guidelines produced by their representatives in addition to government regulation, in order to avoid corruption and undue influence on drug prescription. Nevertheless, the pharmaceutical industry remains the main source of information for practising physicians who clearly lack independent information about relative benefits of pharmaceuticals. [32]

1.5.4 Policies to inform consumers

71. Public authorities do not publish much information on pharmaceuticals, with the exception of a compendium containing information on marketed drugs directed at health professionals, although available for consumer use. The Medikamenten-Informationstelle (SMI) was created 12 years ago to provide people with information on consumer rights, opinions and to give the opportunity of public discussion. The SMI receives funds from consumers' and patients' organizations, as well as users' fees for phone counselling and information. SMI also receives funds from health magazines for which it provides a kind of hotline following the publication of news on new drugs for instance. SMI receives a lot of questions about side-effects and a lot of inquiries for a second opinion.

1.6 Innovation policies

72. 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.

1.6.1 Intellectual property rights

73. Patent rights are defined by the Patent Law[33] (hereafter LBI). Like in all countries members of the General Agreement on Tariffs and Trade, patent duration is of 20 years. Compulsory licence (art. 40) as well as partial or total expropriation of patent (art. 32), with relevant royalties for patent holders, are possible when "public interest" is at stake.

74. Like in European Union countries and in the United States, pharmaceuticals benefit from patent extensions to compensate for delays due to specific requirements of marketing authorisation: the Supplementary Protection Certificate (SPC) takes effect at patent expiry for a period equivalent to the delay between patent grant and the first marketing authorisation in Switzerland less 5 years, and limited to

[32] The sole journal independent from pharmaceutical companies is available in German only and therefore covers 65% of the swiss native languages.

[33] Loi fédérale sur les brevets d'invention, June 25, State of June 13, 2006.

5 years. For the purpose of granting SPC, the Federal Council may consider a marketing authorisation delivered in the European Economic Area (EEE) as the first marketing authorisation if it is delivered before the Swiss marketing authorisation (LBI, Titre VII).

75. In addition, data provided by the manufacturer to Swissmedic in the process of marketing authorisation are protected from unfair competition for a period of 10 years (LPTh, art 12). This means that generic manufacturers and Swissmedic are not allowed to refer to these data during this period. The Law further states that the Federal Council may grant "an appropriate protection for results of clinical trials linked to new use, new mode of administration, new forms or new strengths" of an original product, which suggests that longer data protection period may be granted in case of new clinical data. Data protection in Switzerland is thus stronger than in many OECD countries since its duration is of 5 years in the United States and generally 8 years in the European Union.[34]

76. Moreover, patent rights in Switzerland are under the regime of national exhaustion: patent rights are exhausted after the first sale in Switzerland (the buyer can do whatever he wants, including re-sell the product to someone else) but not by the first sale in any other countries (the buyer can not re-sell the product without the authorisation of the patent holder). Consequently, parallel imports of patented drugs are not allowed in Switzerland.

77. This legislation was the subject of public debates and policy recommendations, notably by the Economic Department of the OECD, to allow parallel trade in order to foster competition and lower prices (OECD, 2006b). Several reports were commissioned by the government to assess the expected impact of a liberalisation of parallel trade on the Swiss economy (see Box 4). The Swiss government has thus far maintained its prohibition on parallel trade of patented products.

Box 4. The debates on IPRs exhaustion regime and parallel trade

Several observers have been advocated for a change in IPRs exhaustion regime to allow parallel trade in the last decade (Surveillance des prix, OECD, 2006b).

In 1999, the federal court filled a gap in the federal patent law by favouring the principle of national exhaustion regime for patent in a judgement opposing Kodak SA to Jumbo Markt AG. This ruling confirmed the prohibition of parallel trade in Switzerland. Following this court decision, the federal council ordered several studies to provide legal opinion on different scenarios and economic estimates of the expected costs and benefits of a change in exhaustion regime, with three different hypotheses: switch to a regime of international exhaustion; switch to differentiated exhaustion regimes according to categories of goods (for instance international exhaustion for medicines and national exhaustion for other goods, or the reverse); and switch to a regional exhaustion regime[1] (Conseil fédéral, 2002). A change to international exhaustion regime would generate general price reductions (from 6 to 11%) and increased demand for medicines and other consumer goods, an increase in disposable income of households and a positive impact on GDP comprised between 0 and 0.1%. However, the report notes that such a change in patent regime could be interpreted as a negative signal by the research-based industry with a risk of delocalisation of R&D activities. Similarly, a change to a differentiated regime could produce little economic benefits. A regime of regional exhaustion would be possible only in case of the conclusion of bilateral agreement with the European Union or with member states of the European Economic Area. In conclusion, the Federal Council settles the argument in favour of a *status quo* in IPRs exhaustion regime with a change in the Cartel law to prevent abuses of patent rights.

In 2004, the Federal council published a new report examining the possibility and consequences of a change to a regime of regional exhaustion and ending with a second negative opinion about such a change (Conseil fédéral, 2002).

1. Regional exhaustion would imply exhaustion of patent rights after the first sale in the region (any member country of the European Union for instance if EU is the "region" considered).

78. By contrast, imports from off-patent products have been authorised since 2002. According to the LPTh, off-patent drugs may be imported from countries with an equivalent approval procedure (EU, EEE and EFTA countries, United-States, Australia, Canada, Japan) without further assessment by Swissmedic.

34 Data protection in the EU is of 8 years, possibly extended to 10 or 11 years in certain conditions, but generics can not be marketed before 10 years after the first EU approval.

However, importers must obtain authorisations to import from Swissmedic, provided they fulfil necessary requirements (guarantee of good quality, translation of information in the three official languages for instance). The first 4 authorisations of this type were granted in 2005 suggesting that requirements are acting as barriers to parallel imports.

79. Overall, Switzerland has high standards for protection of patent rights, ranking among the highest in the word.

1.6.2 Other policies relating to innovation

80. Switzerland ranks among top performers by most indicators of innovation, such as R&D investments relative to GDP, number of European, US or triadic patents[35] per capita, and scientific publications (Jaumotte , 2006; Foray and Lhuillery, 2005). However, innovation capacities have weakened in the 1990's and some weaknesses have been identified: relative to other European countries or United States, Switzerland is characterised by low public investments in R&D, low tax incentives, scarcity of domestic scientists and engineers, and low level of education of the Swiss working population (Jaumotte, 2006).

81. Switzerland ranks among the highest investors in R&D, in spite of relatively low public funding. In 2004, Switzerland spent 2.9% of its GDP on R&D, ranking fourth behind Sweden, Finland and Japan and exceeding the OECD average by 30%. Nevertheless, public sector plays a minor role and funds only 22.7% of gross domestic R&D expenditures, when the OECD average stands at 30.2% (OECD, 2006c). In the health sector, like in others, Swiss government's investments in R&D are very low: only 0.01% of GDP for an OECD average (very influenced by the United States) of more than 0.1% (OECD, 2005, p. 29).

82. Compared to other countries, tax incentives for private investments in R&D are also relatively low (OECD, 2006b, p. 119). However, the extent to which low public funding of business R&D activities is damageable to innovation capacities in the pharmaceutical sector is not easy to assess. Given the high level of business investments, greater public subsidies may substitute to private investments rather than create positive spill-overs. However, analysts call for higher public funding of public research institutions, with the overall objective to achieve a better position in applied R&D and bridge the gap between basic R&D, where Switzerland excels, and market (OECD, 2006b).

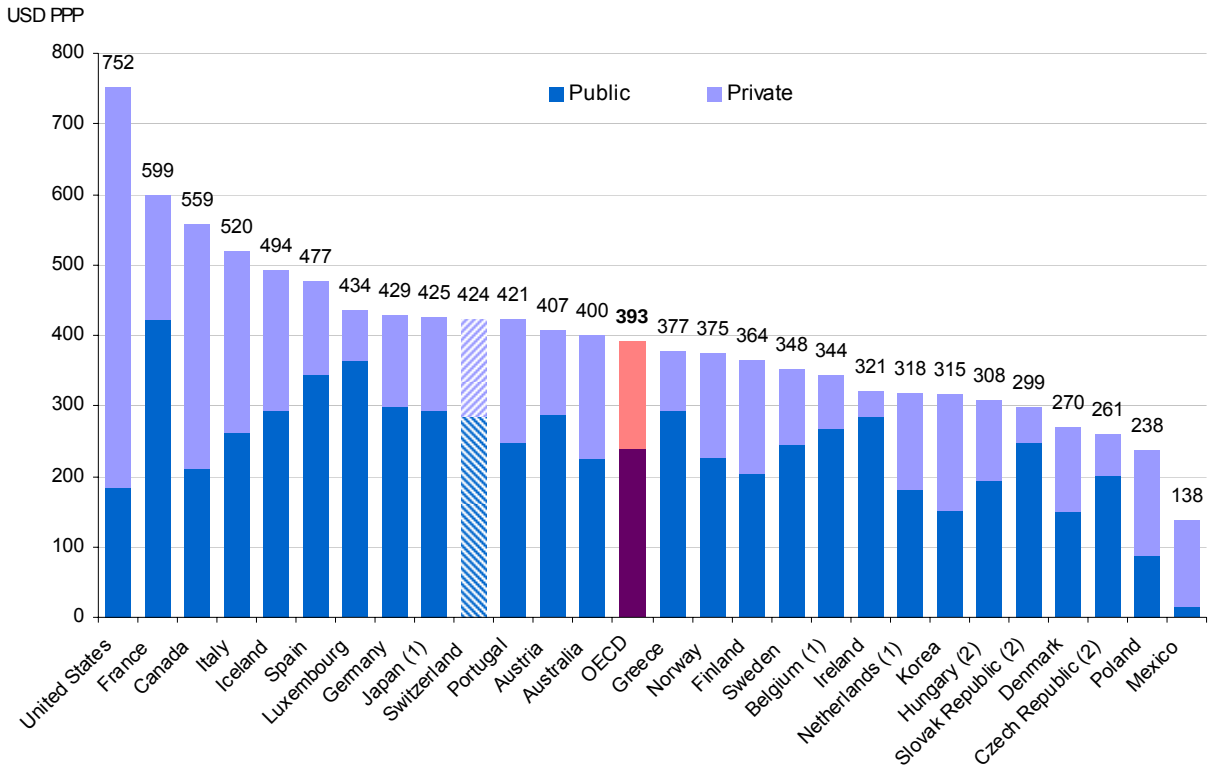
[35] Triadic patents are patents filed in the following patent offices: European Patent Office (EPO), the Japanese Patent Office (JPO), and the US Patent and Trademark Office (USPTO).

2 PHARMACEUTICAL MARKET CHARACTERISTICS

2.1 Expenditures

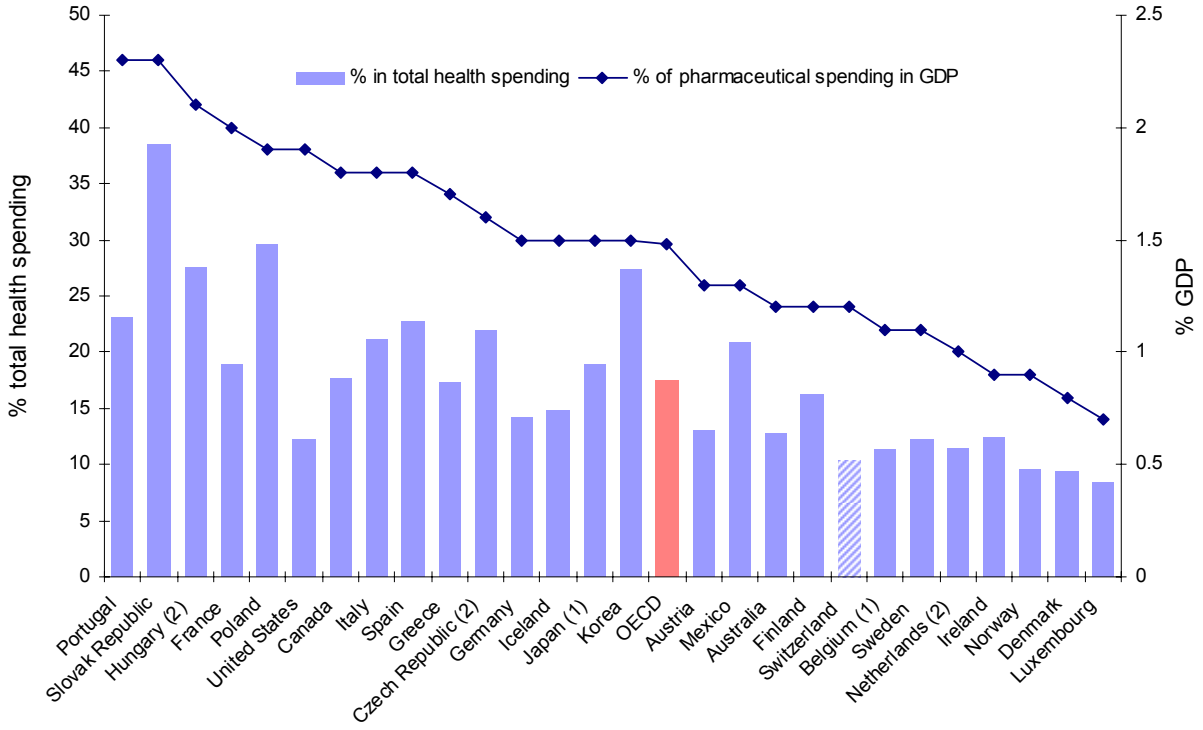
83. In Switzerland, pharmaceutical expenditures per capita amount to 424 US$PPP, which is just above the OECD average (see Figure 1). Given the fact that Swiss prices are among the highest in Europe, this suggests that volume of consumption is rather low compared to France or Italy ---countries with lower public or final drug prices--- for instance. The share of pharmaceutical expenditures in total health spending (10.4%) is below OECD average (17.6%), as is the share in GDP (1.2% versus 1.5%, see Figure 2).

Figure 1. Drug expenditure per capita, public and private spending, 2004



(1) 2003; (2) 2002
Source: OECD Health Data October 2006

Figure 2. Share of pharmaceutical expenditure in total health spending and in GDP, 2004

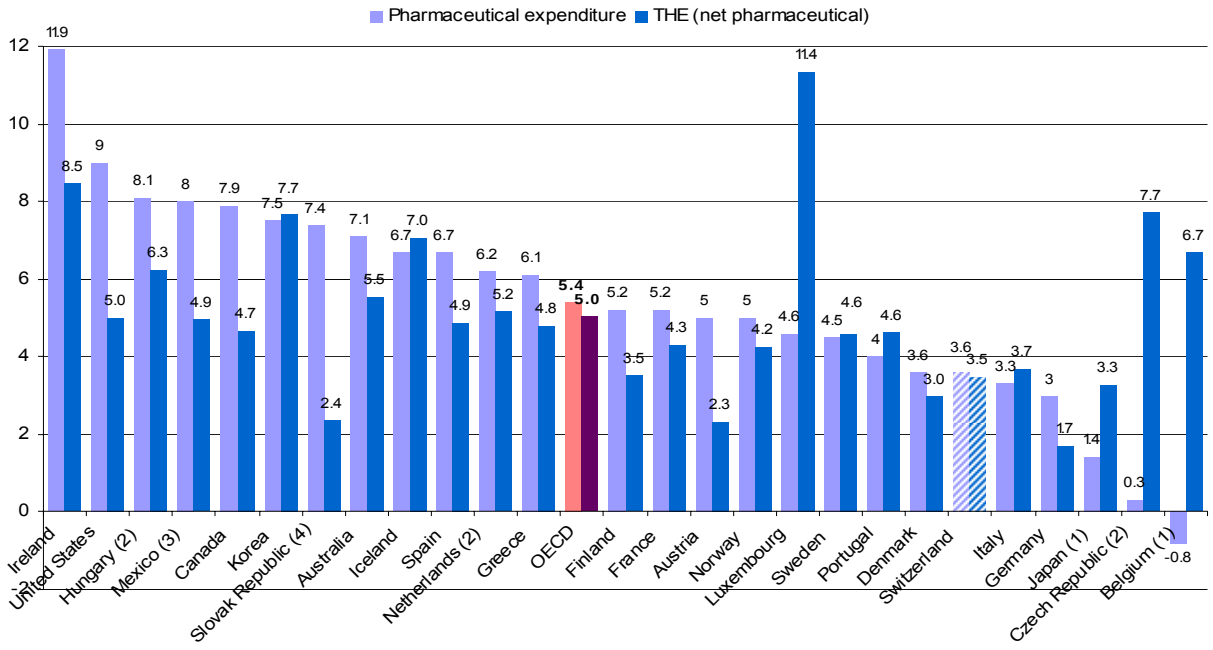


(1) 2003; (2) 2002
Source: OECD Health Data October 2006

84. Unlike many OECD countries, Swiss expenditures on pharmaceuticals have not been increasing more rapidly than other health care components in the last five years (see Figure 3). The average growth of real expenditure[36] was of 3.6% between 1997 and 2004, which is below the OECD average of 5.4%. In fact, the growth of pharmaceutical expenditure was somewhat erratic within this period: it was around 5% each year, except for 2001-2002 (-0.9%) and 2003-2004 (+2.3%) (see Figure 4). The 2002 drop in expenditure growth may be partly due to the 2001 reform of pharmacists' payment. As it was conceived, the 2001 reform was supposed to be "neutral" for total revenues of pharmacists the first year of implementation. Nevertheless, the reform may have influenced drug expenditures and consumption though unexpected channels. In fact, the drop of total expenditures masks two opposite trends: a 6.0% increase in public expenditures and a 12.6% decrease in private expenditures, immediately compensated by a 7.8% increase the year after, breaking with the general trend of weak variations in private expenditures.

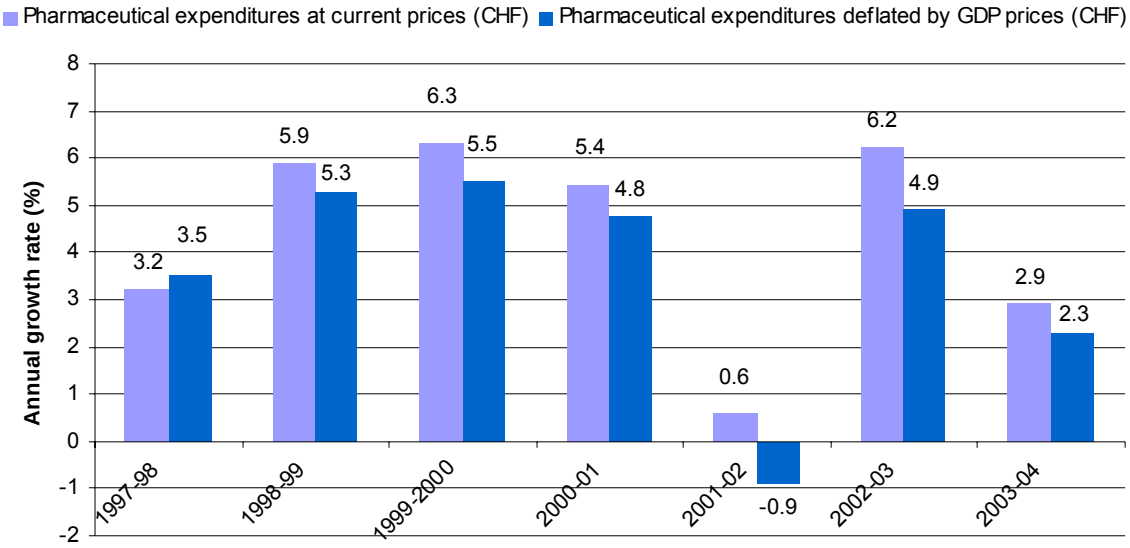
36 Deflated by GDP price index.

Figure 3. Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1997-2004



(1) 1997-2003; (2) 1997-2002; (3) 1999-2004; (4) 1999-2003
Source: OECD Health Data October 2006

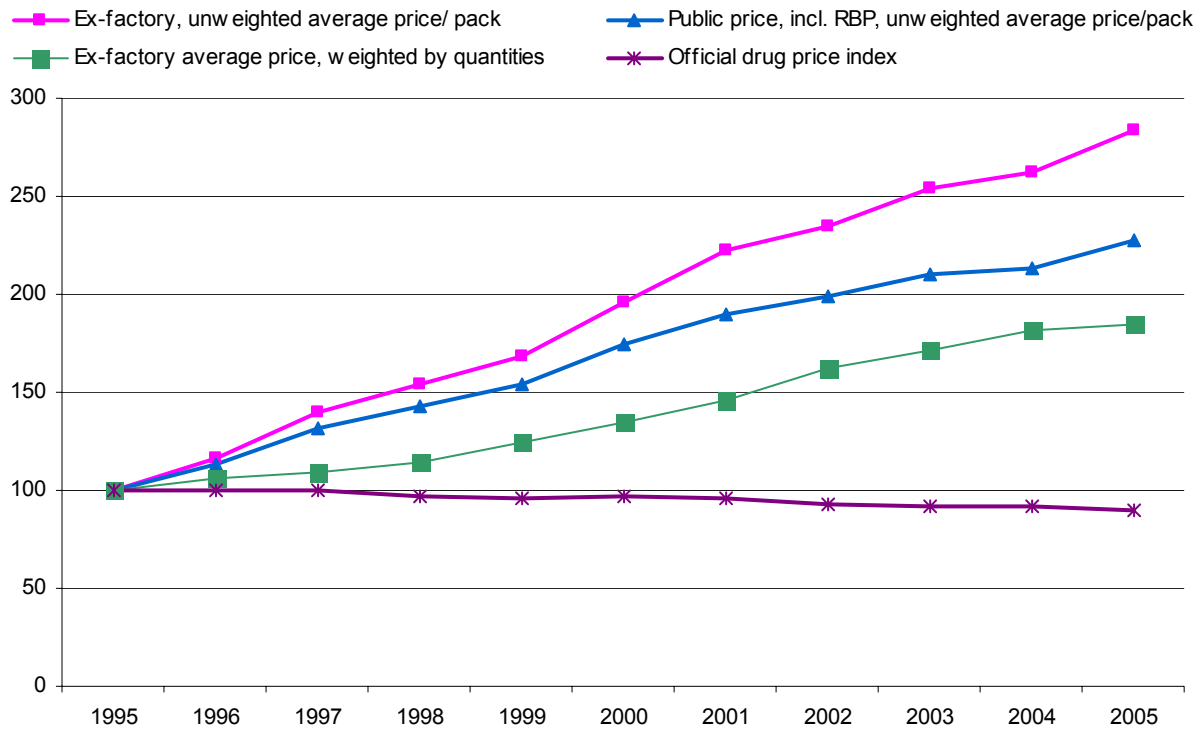
Figure 4. Growth of pharmaceutical expenditures in Switzerland 1997-2004



Source: OECD Health Data October 2006

85. The price-volume components of growth are not easy to disentangle. Like in most countries, the official consumer price index for drugs clearly fails to represent pharmaceutical price trends. Figure 5 shows the contrasting trends of this index, of average ex-manufacturer prices (weighted or not by quantities) and of the average public price (including the payment of pharmacists). While the official consumer price index suggests a slight decline of pharmaceutical drug prices within the 1995-2005 period, the average public price has more than doubled. The federal statistical office acknowledged the weaknesses of the price index in representing new and high-priced drug introductions, as well as generic substitution and proposed a new methodology for the future (Müller *et al.*, 2006). The general idea is to compute average unit prices at the substance level for a large share of the market (around 55% of the whole market) and to aggregate them to produce the price index. The use of monthly and quarterly data on pharmacies' orders and sales will allow more frequent updates of the basket used for the calculations.

Figure 5. Pharmaceutical price trends in Switzerland, 1995-2005



Note: Average prices are computed for products included in the positive list (LS) only.
Source: Hunkeler, 2006, p. 135

86. Hunkeler (2006) analysed the determinants of pharmaceutical spending growth between 1995 and 2004. He identified several factors of growth: first the total number of packages purchased by consumers has increased over the period from 167.1 million to 168.3. This makes a global increase of 0.7% essentially due to demographic trends since the number of packages per capita decreased over the same period (from 23.6 to 22.8). Second, the number of drugs covered by social health insurance has increased over the period: 42% of pharmaceuticals were included in the positive list in 1995, versus 57% in 2005. However, according to the author, the shift towards more expensive drugs is the main explanatory factor of expenditure growth.

2.2 Financing

87. Social health insurance finances 67% of drug expenditures, private supplementary insurance 3% and households 30%. The share of social health insurance in drug expenditures has increased by more than 10 points since the introduction of LAMal: it stood at 54.4% in 1996 (OECDa, 2006). With such a level of public financing[37], Switzerland ranks among countries with the highest levels of public coverage for pharmaceuticals among OECD countries (67.2% against 61.2% for the OECD average), by contrast with the low share of public funding in total health expenditures (58.4% against 72.7% for the OECD average). Drugs represent 21% of the total expenditures of social health insurance.

88. Households' payments include both the cost-sharing paid on reimbursable medicines and the self-purchase of medicines. According to various sources[38], the self-consumption of OTC medicines represents about 18% of total drug expenditures in 2004. It has decreased significantly in the past 10 years, having represented 36% of pharmaceutical expenditures in 1995 (OECD Health Data, 2006).

2.3 Market components

89. The Swiss market represents 0.7% of the world pharmaceutical market (EFPIA, 2006). Prescription drugs dispended in community pharmacies or by dispensing doctors make up 65.6% of total sales at ex-factory prices, drugs dispensed in hospitals account for 19.1% and OTC drugs the remaining 15.3%. The hospital segment is the most dynamic part of the market. According to IMS (2007), Swiss hospital market increased by 7.3% between 2005 and 2006 (at ex-manufacturer prices), while out-patient markets for prescription drugs and OTC drugs grew respectively by 0.6% and 1.4%.

90. Before the 2005 reform introducing two-tiered co-payments when generic alternatives are available, Switzerland had the second-lowest rate for generic penetration in the European Union, just after Spain (EFPIA, 2006, p. 18). Since the implementation of the reform, the generic market has dramatically increased: +41% in 2005 and +46% in 2006 (market value at ex-manufacturer price, from IMS, 2007). With a value of CHF 381.2 million, generics represent now 11.6% of the total market (including hospitals) and generic penetration has reached 54% in the "substitutable" market.[39] This means that the reform allowed the Swiss generic market to reach the level observed in some other EU countries in just one year, showing high demand elasticity. Nevertheless, the Swiss generic market share remains far lower than Dutch, British or German ones (see Figure 6). This can be partly explained by Swiss doctors' preference for new drugs, contrasting with conservative prescription behaviour of UK doctors for instance (Decolligny, 2006).

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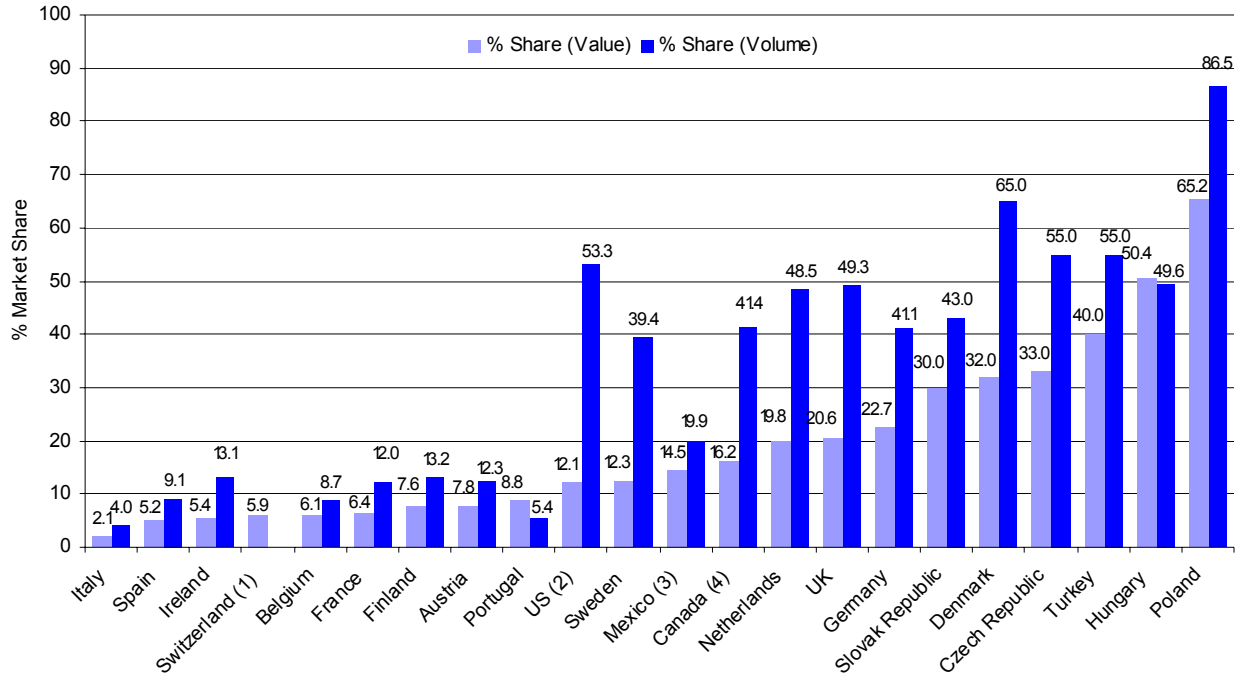
37 Expenditures of private social insurances in Switzerland are classified as "public expenditures" in OECD Health Data in order to take into account the fact that social insurance is compulsory.

38 According to OECD Health Data (2006), "households' expenditures for non-prescription medicines" stands at 18.7% of total expenditures for pharmaceuticals in 2004 in Switzerland. The European Self-medication industry (AESGP) estimates at 17.7% the value of "all medicinal products bought spontaneously by consumers without a medical prescription in Siwtzerland, at public price level, including Value Added Tax (VAT)". (http://www.aesgp.be/publications/Facts-Figures.asp, consulted on January 22, 2007).

39 Market of non-patented products for which at least one generic is available. According to IMS (2007), the non-patented market represent 35.4% of the total market, of which 9.8% are original drugs with generic substitutes, 11.6% are generics and another 14% are original off-patented products without generic equivalents.

Figure 6. Generic market shares in 2004



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

2.4 Drug consumption

91. Since public prices of medicines are relatively high and drug expenditures (per capita) are in line with the OECD average, Switzerland appears to have a low level of drug consumption. Due to the lack of consolidated and published data on the subject, actual drug consumption is not known.

92. Comparing the consumption of drugs used in the prevention or maintenance treatment of cardiovascular disease and stroke in OECD countries between 1989 and 1999, Dickson and Jacobzone (2003) found Swiss consumption to be among the lowest in the OECD, in spite of a quite high share of older people (p.65). Studying further national utilisation patterns, authors showed that Swiss consumption was relatively low for traditional anti-hypertensives (ATC C02) and anti-cholesterol drugs (C10), but relatively high for diuretics (C03) and intermediate for vaso-dilatators, beta-blockers and ACE inhibitors (C04, C07, C09). This consumption profile is not easy to interpret since no marked tendency emerges (such as conservative prescribing, or conversely a trend to quick adoption of new products).

93. Switzerland has the lowest level of antibiotic consumption among European countries (Philippini et al, 2006). However, antibiotic consumption patterns vary widely across Switzerland according to cantons. Antibiotic consumption averaged 9.3 DDD per 1000 people and per day in 2004 for the whole country, with a minimum of 5.3 in Appenzell Ausserrhoden canton and a maximum of 15.4 in the Geneva canton (Philippini *et al.*, 2006). Moreover, there are significant variations in the type of prescribed antibiotics. Analysing the determinants of antibiotic use, the authors found that the level of cantons' income and the level of education were negatively related to antibiotic use (suggesting that richer and more educated people are better informed on the benefits and risks associated with antibiotic consumption).

There was also a negative link with the share of seniors in the population. Conversely, antibiotic consumption was positively related to the number of physicians. Finally, authors found an influence of what they embodied in cultural differences between "latin" cantons (French or Italian speaking ones) and other cantons (German speaking ones).

94. This "cultural" hypothesis is somewhat validated by results of the annual health survey about the consumption of psychotropic drugs in cantons. For instance, according to the survey conducted in 2002, 4.9% of the people living in the French-speaking part of Switzerland had taken anxiolytics in the seven days preceding the survey, against 3% of people living in the Italian-speaking part and 1.6% of people living in the German-speaking part.[40]

2.5 Pharmaceutical industry presence and activity

95. The pharmaceutical industry plays a major role in the Swiss economy, in terms of trade balance, added value and employment. Switzerland shows a high degree of specialisation in pharmaceutical R&D.

2.5.1 Industry activity

96. The pharmaceutical industry has been a traditional pillar of the Swiss economy. Specialised in the production of products with high added value, the sector has contributed significantly to Swiss economic growth during the nineties. The presence of big national research-based companies is one of the singular features of the Swiss pharmaceutical sector since two Swiss companies rank 4th and 8th in the world top ranking of pharmaceutical companies, making respectively 5% and 3.5% of world market shares (Interpharma, 2006).

97. In 2005, 416 manufacturing firms were operating in Switzerland, producing 3.1% of the world's pharmaceutical production and placing Switzerland at the 6th position among European countries (Swissmedic, 2006a, EFPIA, 2006).

98. This high level of production contributes to placing Switzerland in excellent position for the international trade in pharmaceuticals. In 2004, Switzerland ranked second in terms of trade balance just after Ireland (see Figure 6) and fourth for total exports, after Germany, Belgium and the United States. Moreover, pharmaceutical exports make up one fifth of total Swiss exports. Pharmaceutical exports are mainly directed towards OECD European members (66%) and the United States (10%) while imports come mainly from OECD European countries (84%) (OECD International trade statistics database, consulted in March 2007).

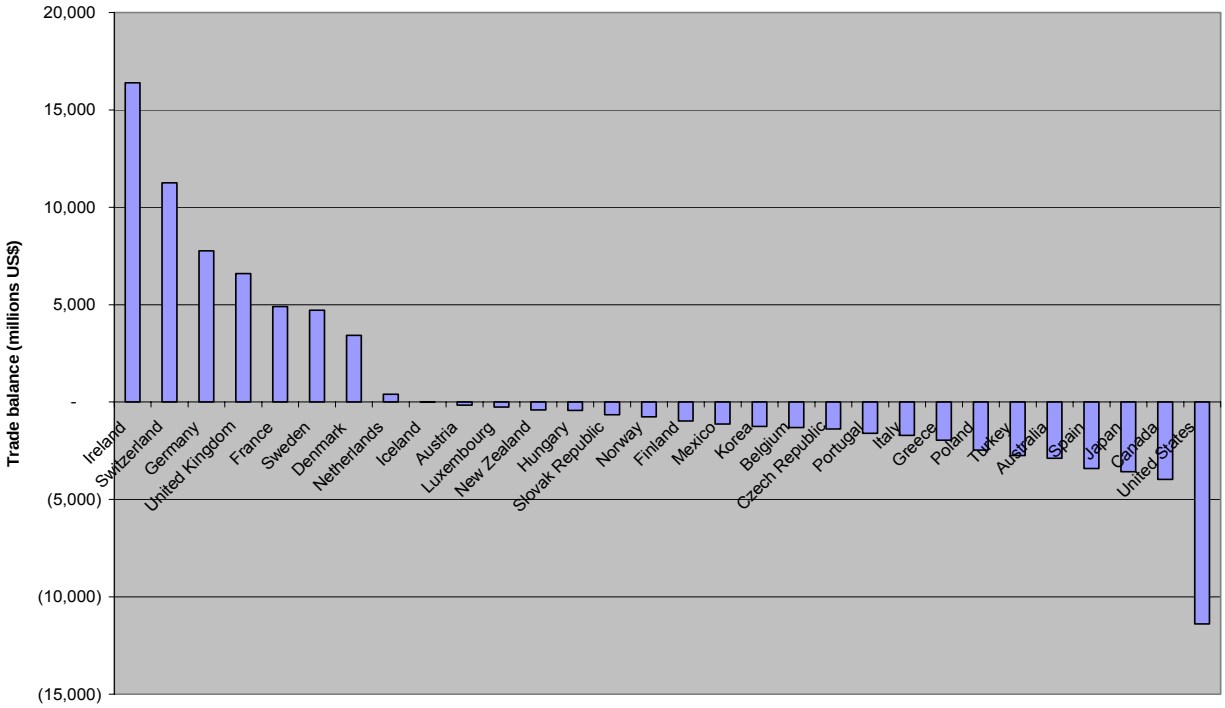
Table 5. Activities of the pharmaceutical industry in Switzerland, 2004 (in CHF million)

Production	21,568
Exports*	28,144
Imports*	14,190
Trade balance*	13,954
Domestic sales at ex-factory price	4,067
Intramural R&D expenditures	3,852

Sources: EFPIA, 2006. Data have been converted by authors from Euros to CHF using annual exchange rates, and *OECD International trade statistics database.

40 Enquête Suisse sur la santé, Office fédéral de la Statistique: http://www.bfs.admin.ch/bfs/portal/fr/index/themen/gesundheit/gesundheitszustand/determinanten/kennzahlen0/verhalten0/medikamentenkonsum.print.html, consulted on March 14, 2007

Figure 7. Trade balance for pharmaceuticals in 2004



Source: OECD International trade statistics database, consulted in March 2007

99. In 2004, the pharmaceutical industry employed 31,000 people in Switzerland, representing 0.7% of total employment, and generated another 70,000 jobs by its activities (Plaut Economics, 2005). National research-based industry accounts for 64% of jobs in the pharmaceutical industry (authors' calculations based on Interpharma, 2006 and Plaut Economics, 2005).

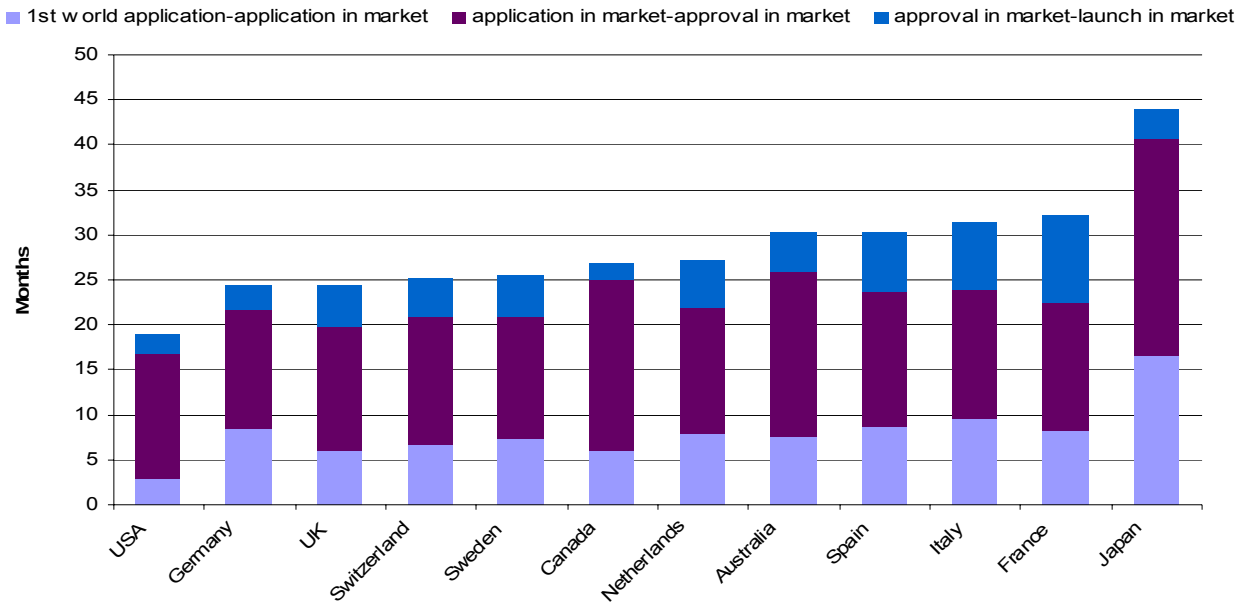
100. Foreign pharmaceutical companies have some activities in Switzerland, but information about their activities is scare. According to a survey conducted by Ernst & Young on a panel of foreign managers, Switzerland is an attractive country for business and the preferred location to establish international or European headquarters. The main characteristics perceived as factors of attractiveness are the stability of the political, legislative and administrative environment, the stability of social environment, the labour law flexibility and the level of corporate taxation (Enrst & Young, 2006). The marginal corporation tax rate is relatively low in Switzerland (21.3%) and highly variable from one canton to another (13.0 to 29.1%) making some cantons particularly attractive for companies (KPMG, 2006). However, foreign direct investments inflows are not as important in Switzerland as in other OECD countries (1.3% of GDP) and the pharmaceutical sector is not the most attractive for FDI.

101. By contrast, FDI outflows are relatively high (11.9% of GDP) and foreign investments of Swiss chemical and pharmaceutical companies are important: in 2002, they accounted for 32 billions CHF, representing 45.8% of total direct investments by the Swiss industry. (OECD, 2006d; Ernst & Young, 2006; SGCI, 2006).

102. In any case, Switzerland seems to be an attractive country for launching new products in spite of its small share in global market sales: it ranks 4th for the average delay between application for marketing authorisation in the first country and application in Switzerland (just after the US, Canada and the UK, see

Figure 8). Moreover, Switzerland was the first-launch country for about 4% of drugs launched over the period 1982-2002 (Lanjouw, 2005).

Figure 8. Average delay between first launch in the world and launch in each country for drugs launched between 1999 and 2002

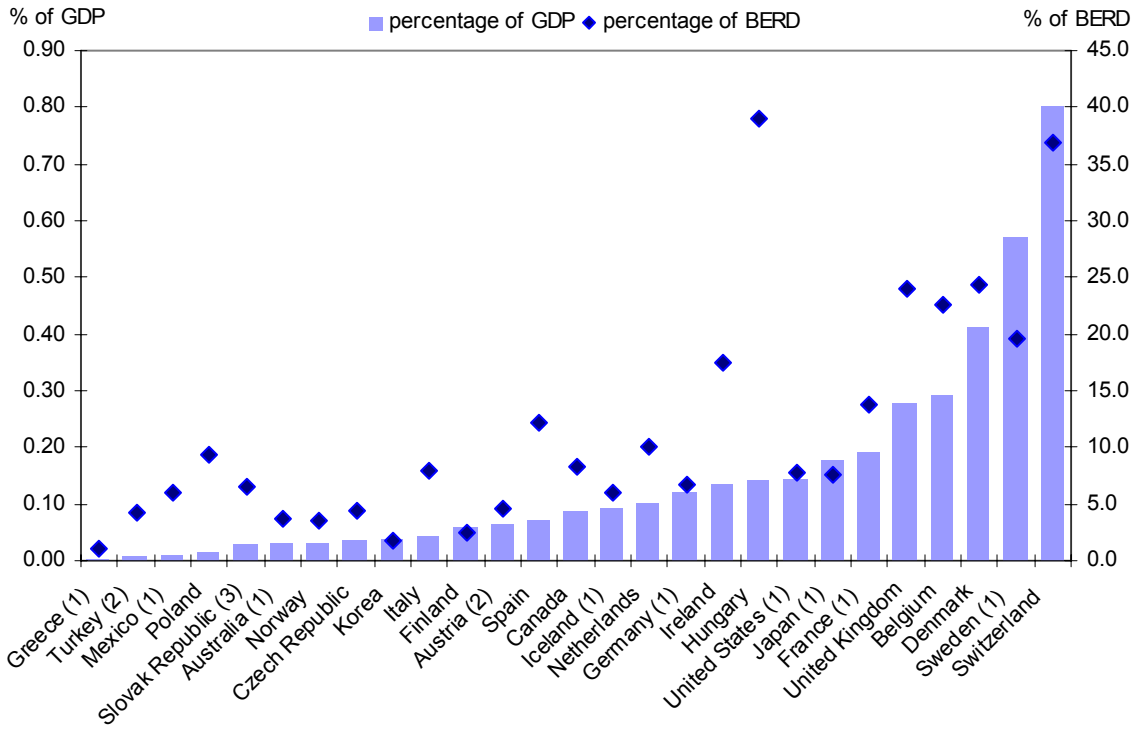


Source: Pharmaceutical Industry Competitiveness Task Force, 2005, from Association of the British Pharmaceutical Industry calculations.

2.5.2 Business investments in R&D and related outcomes

103. Pharmaceutical companies invest a lot in R&D activities undertaken in Switzerland. Business enterprise expenditures on pharmaceutical R&D represent 0.8% of the Swiss GDP, the highest level among OECD countries. With 40% of total business R&D expenditures dedicated to pharmaceuticals, Switzerland shows a high degree of specialisation in the sector. R&D performed in Switzerland represents 4.8% of global pharmaceutical R&D of leading countries in spite of its relative small market share in global sales (0.7%) (authors' calculation based on Interpharma, 2006 and OECD, 2005; EFPIA, 2006). In 2004, Switzerland was among world leaders for R&D in the fast-growing biotech sector (Whyte, 2004).

Figure 9. Business expenditures for R&D (BERD) performed in the pharmaceutical industry (Share in GDP and in total BERD)

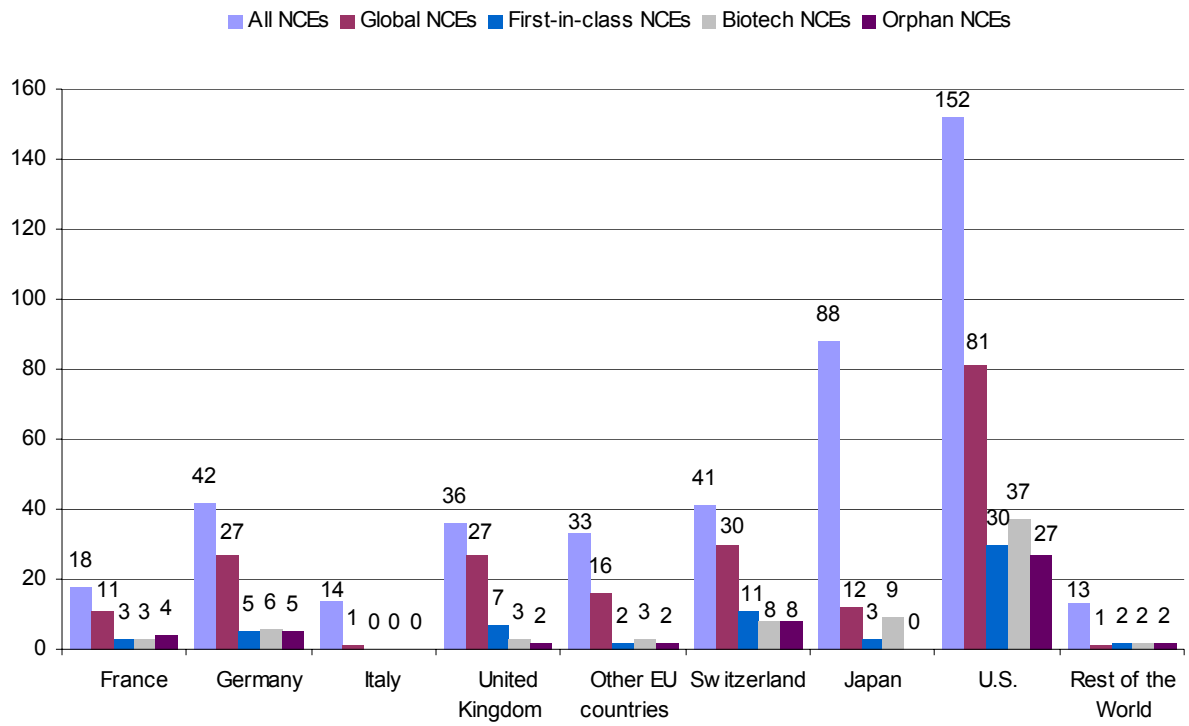


(1) 2003; (2) 2002; (3) 2001
Source: OECD Science Technology and Industry Scoreboard 2005

104. Swiss companies' investments in R&D produce valuable outcomes: Swiss companies originated 8.5% of all new chemical entities (NCEs) launched between 1993 and 2003, but 15% of all global NCEs[41], 16% of all first-in-class NCEs, 11% of biotech NCEs and 16% of orphan NCEs. With such results, Switzerland ranks first in Europe for drug discovery and shows a good ability to produce innovative drugs (Grabowski and Wang, 2006; see Figure 9). Another study shows that 3 Swiss companies invented 7 out of the 41 most innovative drugs marketed in France between 1997 and 2002 and assessed by the French Transparency Commission (Foray and Lhuillery, 2005).

41 i.e. NCEs launched in at least 4 of the G7 countries.

Figure 10. New chemical entities launched between 1993 and 2003, by firm nationality



Source: Grabowski and Wang, 2006

2.6 Supply and distribution of pharmaceuticals

105. In the Swiss market, more than half (54.2%[42]) of pharmaceuticals are dispensed in pharmacies, one quarter (24%) by dispensing doctors, 19.5% by hospitals and 2.3% in drugstores (Interpharma, 2006).

2.6.1 Wholesalers

106. Wholesalers are not “LAMal providers" and are not, as is the case in many other countries, obliged to supply all available drugs. Since 2001, wholesalers’ margins are no longer directly regulated; rather, the share of the distribution margin set by OPFSP that goes to wholesalers is negotiated with retailers. Thus, wholesalers compete on the drug prices they can offer to pharmacists, as well as on quality and prices of related services (such as logistic services or marketing counseling services provided to pharmacists).

107. The Swiss wholesale market is highly concentrated. Five full-line wholesalers make up about 85% of market share, one of them being owned by dispensing doctors and exclusively turned towards the supply to dispensing doctors. Twelve to 13 smaller wholesalers also targeting dispensing doctors make up another 10% of the market and a few short-liners make up 4% of the market (personal communication).

42 Market share, at ex-manufacturer prices.

2.6.2 Pharmacies

108. Community pharmacies are the main distributor of pharmaceuticals in Switzerland and evolve in a competitive environment. Swiss pharmacists and insurers put a great emphasis on the quality of professional services.

109. Swiss cantons deliver authorisations to open pharmacies but generally, there is no restriction to opening a new pharmacy, except that the presence of a registered pharmacist is required during opening hours (Guignard and Bugnon, 2006). Between 1995 and 2002, the number of pharmacies remained stable at 1,650. With 4,445 inhabitants per pharmacy, Switzerland has an intermediate position relative to European Union members (Jordan, Enderle, 2006; ÖBIG, 2007). However, this intermediate level is somewhat compensated by other distribution channels (namely dispensing doctors and drugstores) which are generally not available in all EU countries. Similarly, the co-existence of dispensing doctors in many cantons explains at least partially the huge differences between cantons' densities of pharmacies: the maximum density is observed in Tessin (1,820 inhabitants per pharmacy in 2002) where no doctors dispense medicines and the minimum density in Nidwald (19,550) where the dispensing doctor density is relatively high.

110. Chain pharmacies are allowed and about 20% of pharmacies are part of chains. Due to the need for vertical integration to increase profitability, the pharmacy sector has experienced consolidation in recent years, as well as a development of group purchasing (Guignard and Bugnon, 2006; Jordan and Enderle, 2006). Some stakeholders say that the 2001 reform of pharmacists' services payment has increased competition between drug distributors at the benefit of chains which were able to offer the "patient rate" to their clients, which other pharmacies could not afford. Similarly, the practice of discounts is reportedly more common; many chains and mail-order pharmacies offer discounts of up to 17% on listed medicines.

111. The 2001 reform of pharmacists' payment officially recognized the added-value of professional services in the sector of drug distribution, independently from logistic and distribution functions. The Swiss society of pharmacists has always promoted the quality of pharmacist services, for instance by creating postgraduate of continuing education programs for its members. Since 1999, the SSPh has been developing a program promoting quality standards in community pharmacies. In 2004, 20% of community pharmacies participated in the program on a voluntary basis, of which 250 obtained the "QMS-Pharmacy" quality label valid for 3 years. The 2005 agreement signed by the SSPh and SantéSuisse requires all community pharmacies to obtain the QMS quality label and plans a development and funding of quality circles in case of positive assessment of existing circles in 2005 (Guignard and Bugnon, 2006).

2.6.3 Dispensing doctors

112. Swiss cantons are responsible for setting the rules to authorize doctors to dispense medicines (LAMal, art. 37). Half of Swiss cantons authorise doctors to sell medicines to their patients, 9 cantons prohibit this practice while 4 other cantons have a mixed situation (Santé Suisse, 2004). In addition to cantonal authorisation, doctors have to sign a contract with health insurance for their patients to be reimbursed. In 2002, 3,868 doctors were authorised to dispense medicines and their number increased by 37% between 1995 and 2002 (Jordan and Enderle, 2006).

113. The scheme of dispensing doctors fostered debates in Switzerland. Opponents criticize the perverse incentives and the loss of the double checking of prescription by pharmacists. In 2003, the Federal Council observed that costs were rising faster for drugs dispensed by doctors than for drugs dispensed by pharmacies and concluded that distribution by pharmacists should be favoured to contain costs and

improve quality (Conseil national, 2003). In spite of lively debates on the subject, a ban on dispensing doctors does not seem to be on the political agenda.

2.6.4 Drugstores

114. Drugstores sell health products as well as cosmetics and products for home and gardens. They employ professionals who must have validated 4 years of training in biology, physics, chemistry, knowledge of therapeutic agents and products in order to be able to provide adequate counselling to their clients. They sell OTC products as well as natural medicines. Their services may be compensated by supplementary private health insurers. Due to increased competition by supermarkets, the number of drugstores fell by 13% to 797 between 1993 and 2002 (Jordan & Enderle, 2006).

2.6.5 Hospitals

115. Hospitals have to purchase drugs on their budgets[43] and there is no specific funding for very expensive drugs. However, stakeholders agree that Swiss hospitals are not constrained in access to innovative and costly treatments. Drugs used in inpatient care are generally not charged separately to health insurance (as their cost is included in the case or *per diem* fee).On the other hand, hospitals charge basic health insurers for drugs used in outpatient care at the maximum price.

116. For drugs included in the positive list, with maximum reimbursement prices set by the OFSP, hospitals generally negotiate prices under this level. The fact that each hospital establishes its own formulary (the list of drugs to be purchased) provides opportunities for price negotiations, at least when there is some competition in a therapeutic category. Moreover, according to stakeholders, manufacturers are inclined to consent discounts to hospitals even for new products without competitors when initial prescriptions by hospital doctors are expected to generate subsequent prescription in ambulatory care. Although drug purchase through wholesalers is possible, hospitals mainly purchase their drugs directly from the manufacturer.

[43] Cantons have the responsibility to determine how hospital services will be paid by health insurers. As a consequence, payment schemes vary widely across Switzerland (For more details see OECD, 2006, p. 56).

3 ASSESSMENT OF THE IMPACT OF PHARMACEUTICAL POLICIES ON POLICY GOALS

3.1 Goals for health-system performance

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

3.1.1 Containment of drug expenditures

118. By comparison with other OECD countries, out-patient drug expenditure growth in Switzerland is relatively slow. Moreover, public expenditure growth on pharmaceuticals has continuously slowed down between 1999 and 2004, which is not the case in many countries. This can be --- at least partially --- attributed to successive measures of cost-containment introduced since the adoption of LAMaL, among which are tighter control of ex-factory prices and the disconnecting of payment for pharmacists' services from ex-factory prices.

119. By contrast, the Swiss hospital drugs market is growing very fast (+7 % for 2006), as in many OECD countries. This growth is driven by the introduction of very costly new drugs. In 2006, cancer treatments represented 21.3% of hospital drug expenditures and showed a 31% growth (IMS, 2006). For now, no specific policy has aimed to contain hospital drug costs, though drug purchases could be somewhat constrained by cost-containment measures affecting hospital funding. However, according to data collected from 30 Swiss hospitals in 2005, medication represented, on average, 5% of total hospital costs for inpatient acute somatic care, though they accounted up to 16% of costs in some hospitals (SwissDRG, 2006). This means that drug expenditures are probably not the primary focus of cost-containment policies in most hospitals.

3.1.2 Sustainability and equity of financing for pharmaceuticals

120. In Switzerland, equity in financing health insurance is mainly addressed through canton' subsidies to the poorest part of the population. Although the system has been assessed as broadly adequate, its decentralised character does not ensure horizontal equity between cantons (OECD, 2006a). The financing of pharmaceuticals does not raise any additional specific equity problem, although out-of-pocket payments are likely to weigh heavier in poor households' revenues.

3.1.3 Efficiency of expenditures in the pharmaceutical sector

121. Efforts have been made in recent years to increase efficiency of drug expenditures. Periodic price revisions of listed drugs certainly contribute to these efforts. However, assessment of the impact of these revisions is not available. In addition, the reliance on external and internal price benchmarking, rather than pharmacoeconomic assessment, as a basis for establishing prices, suggests that Switzerland may have scope to improve the cost-effectiveness of its pharmaceutical expenditure. Beyond this, relatively high mark-ups over ex-factory prices suggest that the distribution chain is a source of further potential

efficiencies, although high costs could also reflect broader characteristics of the Swiss economy (e.g. relative high labour costs).

122. The 2005 introduction of two-tiered co-payments for brand-names and interchangeable generics has led to sizeable savings. The generic market is growing fast but has not yet reached the high penetration rates observed in the UK, Germany or the US. Indeed, even if brand-name prices make the Swiss market very attractive for generics, its relative small size, as well as administrative constraints (such as labelling translation in three official languages) may dampen generic manufacturers' enthusiasm to enter the market. Moreover, the need to be established in Switzerland to file applications for market approval may act as a barrier to generic entry. According to Santésuisse (2006) savings potential from generic competition have not been fully exploited yet and could be by further reductions of generic prices (to be more in line with generic prices in other countries) or by systematic substitution by the cheapest generic.

123. Quality circles provide opportunities to improve efficiency of expenditures. Their generalisation and systematic funding is under consideration.

124. The dispensation of medicines by prescribing doctors is well known to produce perverse incentives for over-prescription. The extent to which Swiss dispensing doctors prescribe more medications than non-dispensing ones is the subject of debates, which are not always based on clear evidence. Studies of the impact would be useful in informing this debate.

3.1.4 Availability of pharmaceuticals in Switzerland

125. Pharmaceuticals are available in Switzerland on a timely basis. Companies file applications for the Swiss market quite early, and at least until 2003 approval delays were in line with those observed in the US, UK and Germany, though recent bottlenecks in Swissmedic may have damaged this good position. Recently introduced fast track procedure and temporary licences have further increased the availability of new products in the Swiss market. Swissmedic faces significant pressure: though Switzerland is a small country, the pharmacopoeia is not smaller than in other countries and the public is believed by at least some stakeholders to have high expectations for the availability of new drugs. A relatively simple procedure allows patient access to medicines not (yet) available on the Swiss market.

126. Members of the European Union are now sharing the work-load of drug assessment between national agencies though European procedures. In fact, the possibility that Switzerland could market drugs approved by selected European drug agencies with high standards for assessment without further assessment by a Swiss authority has been considered. However, the option was not adopted since World Trade Organisation's agreements would entail that Switzerland accept drugs assessed by any other signatory country if they accept drugs approved by a given country.

127. Similarly, delays for reimbursement and pricing decisions are quite short when compared to other countries with such procedures, although the most recent data available are from 2002, and some countries have probably improved during that period to conform with EU directives.

3.1.5 Accessibility of pharmaceuticals in Switzerland

128. Thanks to universal coverage and annual caps on co-payments, the Swiss population is well protected against exposure to high drug expenditures. Stakeholders agree that the Swiss positive list is comprehensive. This means that pharmaceuticals are not only available in Switzerland but also generally subsidised through reimbursement.

129. The only identified "gap" is the case of off-label use of new and very expensive drugs which are not --- or not yet --- covered by basic health insurance. However, in most cases, private insurers or

manufacturers themselves pay for "off-label" use, for instance when the new indication is waiting for approval (Bolder & Arsever, 2007).

130. Nevertheless, deductibles and co-payments may act as hurdles to access medicines for the most deprived part of the population, since there is no exemption from co-payment[44] until people have reached the annual cap. However, no evidence is available to support this hypothesis. Moreover, drugs represent only a relatively small share of total households' out-of-pocket payments and are therefore probably not the most critical issue in access to health care in Switzerland. Similarly, by comparison with other countries, out-of-pocket payments do not represent a large share of households' general consumption expenditures.

3.1.6 Quality of care, health outcomes

131. Very few data are available to assess the quality of care. A study estimated the incidence of adverse drug events caused by medication errors in inpatient care at 0.4%. This adverse outcome is in line with incidence in other countries for which data are available (Hardmeier et al., 2004). Another study focused on drug interactions in 2002 and showed that an average of 127 harmful drug interactions are managed each day in a pharmacy, among which 4 are potentially lethal (study unreferenced, quoted in Jordan and Enderle, 2005).

132. Features of the pharmacy payment scheme show the importance given in Switzerland to professional services supplied by pharmacists. Since 2001, pharmacists are specifically paid for checking drug interactions and counter-indications on medical prescription forms. Some stakeholders note that this "double" quality control is not in operation when drugs are dispensed by the prescribing physician.

133. Quality circles seem effective in promoting appropriate prescriptions. Assessment studies have shown that they are not focused on cost-containment and that they sometimes increased the utilisation of drugs –such as statins- based on evidence-based recommendations. In other cases, the promotion of quality led to a better compliance with "second line treatments" for some products (Cox2 inhibitors for instance). As said before, a global assessment of these circles is ongoing to test to opportunity of a generalisation.

3.1.7 Patient and consumer satisfaction

134. Health systems stakeholders and, more specifically, insured people, are well represented in the Drug Commission charged with providing recommendations for drug inclusion in the positive list (Gress et al., 2005). The most obvious failing of the system is the lack of transparency: no public information is available about manufacturers' applications, nor about recommendations of the Drug Commission, nor about negative decisions of the OFSP. Yet, such information could be useful for physicians and for patients. For instance, upon introduction of physicians' budgets in Germany, prescriptions of drugs with disputed effectiveness decreased, while prescriptions of other drugs continued to increase (Schreyögg and Busse, 2005). This example shows how "public information" may modify prescribing doctors' decisions even when drugs are not excluded from the benefit package. Quality circles may be seen as an alternative to this type of public information for health professionals, but information produced by involved professionals is not accessible to the general public.

135. The approval procedure is not really more transparent. Swissmedic does not publish any public detailed reports about approved medicines, unlike the American Food and Drug Administration and the European Medicines Agency.

44 Social assistance may cover the copayment for those in receipt of benefits (OECD, 1999, p 92).

3.2 Industrial policy goals

136. The attractiveness of Switzerland for pharmaceutical business and R&D activities is still high, thanks to a range of factors related to taxation and R&D capacities. If the reimbursement pricing procedure does not seem to play any role in firms' decisions to locate activities in Switzerland, the reverse may be possible. Switzerland maintains good cooperative relationships with the pharmaceutical industry, and particularly with Swiss firms. In assessments of the reimbursement and pricing procedure made by the two associations representing pharmaceutical industry in Switzerland, representatives of Interpharma, which represents the interests of Swiss companies, described the procedure as "flexible," without indicating that this flexibility proved unduly problematic from an industry perspective, whereas VIPS, representing foreign companies operating in Switzerland, indicated that the unpredictability of the system was problematic in some respects.

KEY FINDINGS AND CONCLUSIONS

137. This paper has undertaken a comprehensive review and assessment of Switzerland's pharmaceutical pricing and reimbursement policies and the market and policy environment in which those policies operate. Key findings are the following:

- Reimbursement price regulation has very likely been responsible for reducing the differential between prices of pharmaceuticals in Switzerland and other European countries since 1996, although Swiss prices are still among the highest in the world. Switzerland's prices are less high when prices are adjusted for economy-wide price differences.

- The Swiss pharmaceutical price differential is particularly high with respect to public prices, despite Switzerland's having a low VAT relative to many other European countries and having instituted reforms in 2001 that de-linked the retail margins from the ex-manufacturer prices. This suggests that further efficiencies in the supply chain may be achievable, although high distribution costs may also reflect characteristics of the Swiss economy (e.g. relative high labour costs).

- International price benchmarking does not provide a strong basis for regulating prices of reimbursed products at market entry, given that Switzerland is most often a first-launch or early-launch country. While therapeutic referencing serves to furnish consistent relative price levels within classes, it does not offer assurance that prices across therapeutic classes are differentiated according to relative benefit.

- Switzerland has scope to get better value from its pharmaceutical expenditures by making explicit assessments of costs relative to benefits when considering the reimbursement and pricing of pharmaceutical products covered by social insurance. This could provide an opportunity for making the whole process more transparent than it is now.

- Reforms that change the financial incentives faced by patients and pharmacists have increased generic penetration of the Swiss market. While certain characteristics of the Swiss market suggest it will be very difficult for the country to obtain the best world performance in generic competition, there is scope to further improve in this area (for example, by encouraging generic prescribing, increasing patient incentives to choose lower-cost products, or by reforming generic pricing rules), thereby increasing the cost-effectiveness of pharmaceutical expenditure.

- Pharmaceutical cost containment is facilitated in Switzerland by the relatively low level of drug consumption. This appears to reflect physician practice patterns or patient preferences, as little is done by government or insurers to influence pharmaceutical use.

- New products are available on the Swiss market promptly and accessibility is enhanced by processes to make available products not (yet) on the Swiss market. Thanks to an extensive positive list and reasonable cost-sharing requirements, pharmaceuticals are also affordable for patients. In principle, failure to exclude low-income persons from cost-sharing requirements could result in problems with affordability or accessibility, although no evidence of this has been found. Neither hospitals nor patient associations report problems with access to new and costly medicines.

138. These findings regarding Swiss pricing and reimbursement policies have been drawn on the basis of an assessment of the direct impact of the policies in Switzerland. However, an important consideration of ongoing work in the area of pharmaceutical pricing policy is the so-called global and cross-national impact of policies. Impacts of interest include the hypothetical effect of pricing and reimbursement policies in one country on prices and availability of medicines elsewhere, and the impact of pricing and reimbursement policies on investment in pharmaceutical R&D and the resulting impact on pharmaceutical innovation. These issues have been alluded to in this report without being directly assessed. This case study of Switzerland will provide input into OECD work to assess the hypothetical global and cross-national impact of different pricing and reimbursement schemes and policies.

LIST OF ACRONYMS

AESGP	Association Européenne des Producteurs de Spécialités Pharmaceutiques Grand Public (European Self-medication industry)
EEE	European Economic Area
EFTA	European Free Trade Association
EPO	European Patent Office
FMH	Fédération des médecins suisses (Swiss medical association)
JPO	Japanese Patent Office
LAMal	Loi fédérale sur l'Assurance-maladie (Swiss Law on Health Insurance)
LBI	Loi fédérale sur les brevets d'intervention (Patent law)
LPTh	Loi fédérale sur les produits thérapeutiques (Law on therapeutic health products)
NCE	New Chemical Entity
OAMaL	Ordonnance sur l'Assurance-maladie (Ordinance on Health insurance)
OFSP	Office Fédéral de la Santé Publique (Federal Office of Public Health)
OPAS	Ordonnance sur les prestations de l'assurance des soins (Ordinance on health services)
OPMed	Ordonnance sur la publicité pour les médicaments (Ordinance on drug promotion)
RBP	Rémunération basée sur les prestations (Payment of pharmacists' services)
Santésuisse	Association des assureurs de la branche maladie (Swiss Union of Health Insurers)
SMI	Medikamenten-Informationstelle
SPC	Supplementary Protection Certificate
SSPh	Société Suisse des pharmaciens (Swiss Society of Pharmacists)
SU	Standard Unit
USPTO	US Patent and Trademark Office

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APPENDIX: PRICE COMPARISONS

Price comparisons with foreign countries

139. A literature review was undertaken to assess the level of Swiss prices of pharmaceuticals in international comparisons. A previous literature review undertaken by ÖBIG (2004) presented the results of 7 comparisons studies including Switzerland. These studies covered different years within the 1992-1998 period and presented comparisons based either on ex-manufacturer or on public prices. As these studies were Austrian, German, Swedish and Danish, none took Switzerland as the reference country, limiting the utility of the studies for the purpose of considering whether Swiss pay more or less for the particular mix of drugs consumed in Switzerland. The share of the Swiss market covered in these studies is not indicated in the ÖBIG report. According to these studies, Swiss prices always ranked among the highest in Europe, although they were in some studies exceeded by Danish and Dutch prices.

140. In a report published by BASYS INFRAS (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). These products represent 61% of the Swiss pharmacy market and 57% of the reimbursed market. The unit price per Defined Daily Dose and then Laspeyres indexes were computed. For ex-manufacturer prices converted to a common currency using exchange rates, Swiss prices were half the level of US prices and slightly lower than UK prices but higher than German, French and Dutch prices (see Table 7). Similarly, public prices were lower than US prices but higher than German, British, French and Dutch prices.

141. The BASYS INFRAS study provides interesting price comparisons with foreign countries for different market segments (on-patent versus off-patent; generic versus original products; prescription-only versus OTC products). When compared to the Netherlands, France, Germany and the United Kingdom, Swiss prices appear to be systematically higher than prices in other countries, except for OTC products and for generics (see Figure 1). When purchasing power parities were used to compare public prices, prices in Germany and the United Kingdom were higher than in Switzerland (respectively 112 and 105 for Switzerland = 100). However, these comparisons date from 2001 and the situation has probably changed in recent years for some categories, notably generic drugs.

142. 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, ex-manufacturer prices in Switzerland are higher than prices in any European comparator (see Table 7). They are also higher than Canadian prices but lower than American prices. By contrast, Switzerland ranks third for public prices, just after Austria and Germany. However, when public prices are converted using purchasing power parities, only Swedish prices appear to be lower than Swiss prices. This suggests that all countries except Sweden pay higher end prices for this set of products than Swiss consumers, relative to their purchasing power.

143. However, the IMS study must be interpreted with care. First, rebates consented to health insurance funds are not taken into account, though they may be relatively high --- as they are, for instance, in Austria. Second, US prices are those of the Federal Fee Schedule and can not be considered to be representative of US prices. Last but not least, Swiss public prices are net of the pharmacists' services payments which are included in all other public prices. This, by the way, explains the contradictory results between IMS' and BASYS INFRAS studies for public price levels. The BASYS INFRAS study is the only one which takes into account payments for pharmacists in Switzerland as well as in other countries. Although its results are quite old, they are probably the most reliable for the purpose of comparing the public prices in effect at that time.

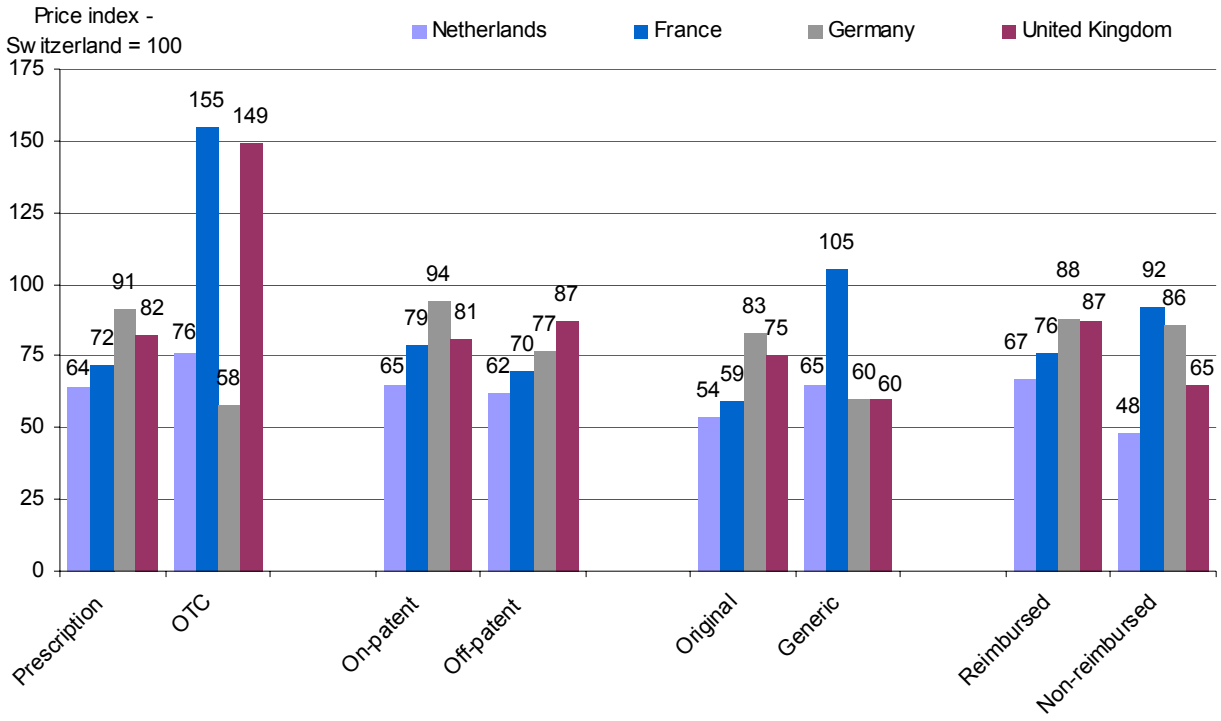
Table 6. Swiss prices in international comparisons taking Switzerland as the reference country

	BASYS INFRA Second half of 2001			IMS 2d Quarter 2003				Santésuisse 2005	
Countries	Ex-factory price (X-Rate)	Public price* (X-rate)	Public prices* (PPP)	Ex-factory price (X-rate)	Public price** (X Rate)	Ex-factory price (PPP)	Public price** (PPP)	Ex-factory price (X-rate)	Public price*** (X Rate)
Direct comparator countries									
Denmark				86	100	94	110	92	81
Germany	84	88	112	86	133	120	185	86	84
Netherlands	78	62	86	82	97	107	127	85	70
United Kingdom	102	87	105	87	94	112	122	85	67
Switzerland	**100**	**100**	**100**	**100**	**100[a]**	**100**	**100[a]**	**100**	**100[a]**
Subsidiary comparator countries									
Austria				75	138	106	194	68	64
France	79	76	96	76	91	103	123	72	65
Italy				76	96	115	145	68	70
Other countries									
Canada				88	95	140	151		
Sweden				90	78	105	90		
United States	209	161	181	135	93	187	129		

Note: * excluding VAT and rebates consented by manufacturers; ** including VAT; rebates to health insurance funds are taken into account *** excluding rebates, VAT and other taxes. [a] Swiss public prices used in these studies do not include pharmacists' services payments and are thus underestimated.
Sources: BASYS INFRAS, 2002: IMS consulting, 2003; Santésuisse, 2006

144. 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 OFSP (UK, Germany, Netherlands, Denmark, and Austria, France, Italy). The sample represents 56% of Swiss turnover for reimbursable outpatient drugs. Authors computed price indexes by weighting foreign-to-Swiss unit price ratios (per tablet or other unit) in 2005, converted using exchange-rates, by 2004 Swiss sales. They considered ex-factory prices[45] as well as public prices, but without corresponding prescription-fee, discounts, VAT and other taxes. In this study, ex-factory prices in direct comparator countries appear 8 to 15% lower than Swiss prices, while prices in "subsidiary" countries appear to be 28% to 32% lower (Santésuisse, 2006). The differential for the "public" prices was even greater, despite the fact that the estimate excluded payments for pharmacists' services.

Figure 11. Price comparisons with four European countries, according to market segments
Manufacturers' prices 2001, converted using exchange rates



Source: BASYS INFRAS, 2003

145. 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 54 US top-selling 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 Switzerland is not known. Fisher Indexes were calculated based on ex-manufacturer price per standard unit (SU) or per kg of active ingredient. Swiss prices appear to be 41% (per SU) to 50% (per kg) below US prices and comparable to

[45] 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%.

Canadian, German and UK prices, as well as (more surprisingly) French prices. However, as US discounts were not considered, the price differential between Switzerland and the United States is overestimated.

146. Hypothesising that, in absence of price regulation, prices in the ten OECD countries would be fully determined by the income level of each country, the US Department of Commerce estimated that Swiss prices of patented drugs would be higher if they were not regulated. Indeed, Switzerland is the country showing the highest difference between actual prices and "hypothetical prices in absence of price regulation" (US Department of Commerce, 2004).

147. By contrast, the report found that Swiss generic prices rank among the highest in the ten OECD countries: they were higher than US generic prices and higher than prices in most European countries (p. 22).

148. 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.[46,47] Here again, the extent to which the sample is representative of the Swiss market is not known. The 2005 report publishes foreign-to-Canadian price ratios for years 1987, 1997 and 2004. The trend shows a convergence of Swiss patented drugs' prices with European and Canadian prices, as well as an increase in the gap with US prices (PMPRB, 2006a). Another PMPRB report, using the same methodology, shows that Swiss prices of generic drugs are higher than prices in all comparator countries other than Canada, while Swiss prices of off-patent original drugs are higher than all comparator countries except the United States (PMPRB, 2006b).

Assessment of the 1996 reform

149. The IMS study assessed the impact of the regulation introduced in Switzerland in 1996, by comparing Swiss prices to foreign prices for two groups of products: those launched before 1996 and those launched after this date. The study concludes that Swiss prices of products launched after 1996 are closer to prices in other European countries (IMS, 2003).

150. The Swiss Price Surveillance Authority regularly publishes price comparisons with Germany. The 2005 annual report shows comparisons of ex-factory prices of original products according to their reimbursement status and launch date in Switzerland (Surveillance des prix, 2006a). As shown in Table 8, the Swiss-to-German price ratio is significantly higher for drugs whose price has not been revised yet according to LAMal principles (i.e. drugs launched between 1990 and 1995) than for other categories (1.47 versus 1.26 and 1.09 respectively for drugs launched before 1990 or since 1996). In addition, the Swiss-to-German price ratio is higher for non-listed drugs (1.42) than for listed drugs (1.21). In conclusion, the Price Council finds that the LAMal reform had some effectiveness in reducing the gap between Swiss and German prices.

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46 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.

47 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 7. Comparison of Swiss and German prices in December 2005

Products (original products only)	Number of products considered	Swiss-to-German price ratio
Products on the positive list	2,377	1.21
Of which		
- Products launched before 1990	*770*	*1.26*
- Products launched between 1990 and 1995	*374*	*1.47*
- Products launched from 1996	*1,233*	*1.09*
Products not included in the positive list	807	1.42

Notes: Exchange rate used: 1€ = 1.55 CHF
Source: Surveillance des prix, 2006a

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