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PHARMACEUTICAL POLICIES IN OECD COUNTRIES: RECONCILING SOCIAL AND INDUSTRIAL GOALS

S. Jacobzone

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**DIRECTORATE FOR EDUCATION,
EMPLOYMENT, LABOUR AND SOCIAL AFFAIRS**

OCCASIONAL PAPERS

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SUMMARY

Regulation of the pharmaceutical sector needs to reconcile private and social objectives. Public intervention pursues multiple goals which relate to both health and industry policy. Many OECD Governments are also heavily involved as buyers of pharmaceuticals in publicly-financed health care systems. This paper describes recent trends in pharmaceutical expenditure and financing in a first chapter. A second chapter discusses the economics of pharmaceutical markets. A third chapter provides a review of national policies and their attempts to balance public and private objectives.

Pharmaceutical expenditure has been rising steadily as a share of GDP since 1970. However, total health expenditure has also risen. As a result, pharmaceutical expenditure has, on average, maintained its share of total health expenditure in the OECD, close to 15 %. Across countries, pharmaceutical expenditure per capita depends on relative incomes but is also influenced by institutional features. The pharmaceutical share of health expenditure tends to be higher in low-income countries than in high-income countries.

A brief economic survey suggests that consumers' demand for drugs tends to be sensitive to price, but the sensitivity varies across different groups of patients. However, physicians' prescribing behaviour seems to show little sensitivity to economic factors.

The structure of the industry is driven by Research and Development (R&D), leading to patented products, marketing and competition. Research and Development, linked with the patent system, is a key economic factor, which determines the competitive strength of companies. Rising costs of R&D and market pressures have encouraged a series of international mergers among companies to secure economies of scale. Also, the increased competition from generic drugs has recently had an impact on several large markets. As a result, distribution systems have changed, particularly in the United States. European Union regulation has also been an important factor in Europe.

Pharmaceuticals are usually covered by public health insurance, except in North America. Most countries define formularies and impose co-payments for drugs, usually with exemptions for groups such as the poor and chronically sick. In a majority of OECD countries, more than three-quarters of pharmaceutical expenditure is reimbursed in some way. Coverage has decreased in some countries facing fiscal consolidation.

Many countries negotiate prices product-by-product but a few regulate the profits of pharmaceutical companies. Product-by-product price fixing has been chosen when prescription pharmaceuticals are provided by a universal health-care system, or to avoid deterring patient access for financial reasons, and when public funds are limited. Product-by-product price fixing may involve distortions and it is difficult to assess since it can bias statistical instruments such as price indices. In addition, the need to control health expenditure has led governments to control volumes of consumption through global budgets. When countries have faced fiscal constraints, particularly in Europe, attempts to stabilise expenditure have involved price cuts, de-listing, or lower reimbursements. This may result in short-term savings but has generally left the underlying rate of growth of expenditure on pharmaceuticals unchanged.

Reforms of pharmaceutical policies need to foster efficiency and preserve equity. This can be realised through increased market pressure to obtain competitive prices for non-patented drugs while allowing higher prices for those still on patent. Recent experience from OECD countries points to some success in this direction. The reference pricing system is now used in several countries for non-patented products and the use of generics has been increased in many countries. A few countries have introduced a test of cost-effectiveness before new drugs will be accepted for reimbursement under the public scheme. Innovative

management methods derived from managed care settings and tools to improve the cost-effectiveness of prescribing are also important measures to obtain the best value for money.

Using the power that governments have to regulate drug prices, or pharmaceutical expenditure, presents something of a dilemma. If prices for patented and branded products are set too low, the incentives for further innovation will be diminished. This dilemma is complicated by the fact that the market for important pharmaceuticals is a global market. Successful innovation has some of the characteristics of a public good. Therefore, the costs of R&D also need to be shared at the international level. As pharmaceuticals represent a significant cost driver in the health care systems of OECD countries, further work will be needed to identify for an increasingly global economy the appropriate mix of public policy in this field.

RÉSUMÉ

La régulation du secteur pharmaceutique doit réconcilier des objectifs sociaux et privés. L'intervention publique poursuit des objectifs multiples, relatifs tant à la politique de santé qu'à la politique industrielle. De nombreux gouvernements de l'OCDE sont également profondément engagés en tant qu'acheteurs de médicaments dans des systèmes de santé financés sur fonds publics. Dans un premier chapitre, cette étude décrit des tendances récentes des dépenses pharmaceutiques et du financement. Un second chapitre discute l'économie des marchés du médicament. Un troisième chapitre offre une revue des politiques nationales et de leurs efforts pour équilibrer les objectifs publics et privés.

Les dépenses pharmaceutiques ont vu leur part du PIB s'accroître constamment depuis 1970. Cependant, la part des dépenses de santé s'est aussi accrue. Il en résulte que les dépenses de médicament ont dans l'ensemble maintenu leur part au sein des dépenses de santé, proche de 15 %. Les dépenses de médicament par tête dépendent des revenus relatifs mais sont aussi influencées par des caractéristiques institutionnelles à travers les pays. La part médicament des dépenses de santé tend à être plus élevée dans les pays à bas revenu que dans les pays à haut revenu.

Un bref examen de la littérature économique suggère que la demande des consommateurs pour les médicaments tend à être sensible aux prix, mais que la sensibilité varie à travers les différents groupes de patients. Cependant, le comportement de prescription des médecins semble être peu sensible aux facteurs économiques.

La structure de l'industrie est dominée par la recherche et développement (R&D), conduisant à l'établissement de produits brevetés, le marché et la compétition. La Recherche et Développement, liée au système de brevets, est un facteur économique clé, qui détermine la compétitivité des entreprises. Les coûts croissants de la R&D et les pressions du marché ont encouragé une série de fusions internationales au sein des entreprises pour obtenir des économies d'échelle. La croissance accrue des médicaments génériques a eu aussi récemment un impact sur plusieurs marchés de grande taille. Par conséquent les systèmes de distribution ont changé, particulièrement aux États-Unis. Les régulations de l'Union Européenne ont également été un facteur important en Europe.

Les médicaments sont habituellement couverts par l'assurance maladie publique, sauf en Amérique du Nord. La plupart des pays définissent des formulaires et imposent des tickets modérateurs pour les médicaments, d'ordinaire avec des exemptions pour des groupes tels que les personnes démunies ou les malades chroniques. Dans une majorité de pays de l'OCDE, plus des trois quarts de la dépense pharmaceutique est remboursée d'une façon ou d'une autre. La couverture a diminué dans certains pays faisant face à des contraintes de consolidation fiscale.

De nombreux pays négocient des prix produit par produit, mais quelques-uns régulent les profits des entreprises pharmaceutiques. La fixation des prix produit par produit a été choisie quand les médicaments de prescription sont fournis par un système de santé universel, ou pour éviter de dissuader l'accès des patients pour des raisons financières, et quand les fonds publics sont limités. La fixation des prix produit par produit peut induire des distorsions et est difficile à évaluer car elle peut biaiser les instruments statistiques tels que les indices de prix. De plus, le besoin de maîtriser les dépenses de santé a conduit les gouvernements à contrôler les volumes de consommation à travers des budgets globaux. Quand les pays ont fait face à des contraintes fiscales, particulièrement en Europe, les tentatives pour stabiliser la dépense ont inclus des réductions de prix, des déremboursements ou des niveaux de remboursement moindres. Ceci peut générer des économies à court terme mais a généralement laissé inchangé le taux de croissance sous-jacent des dépenses de médicament.

Les réformes des politiques du médicament doivent stimuler l'efficacité et préserver l'équité. Ceci peut être réalisé à travers des pressions de marché accrues pour obtenir des prix compétitifs pour des médicaments non brevetés, tout en permettant des prix plus élevés pour les médicaments brevetés. L'expérience récente des pays de l'OCDE montre un certain succès dans cette direction. Le système de prix de référence est désormais utilisé dans divers pays pour des médicaments non brevetés, et l'utilisation des génériques a été accrue dans de nombreux pays. Quelques pays ont introduit un test de coût-efficacité avant que de nouveaux médicaments soient acceptés pour le remboursement dans le cadre du système public. Des méthodes de gestions innovantes dérivées des systèmes de soins coordonnés, et des mécanismes pour améliorer l'efficacité-coût de la prescription sont également des mesures importantes pour obtenir la meilleure valeur pour l'argent.

L'utilisation par les gouvernements de leur pouvoir de réguler les prix des médicaments ou la dépense de médicament, représente cependant un certain dilemme. Si les prix pour les produits brevetés et les produits de marques sont établis à un niveau trop bas, les incitations pour l'innovation future seront diminuées. Ce dilemme est compliqué par le fait que le marché pour les médicaments importants est un marché global. Une innovation réussie présente certaines des caractéristiques d'un bien public. Dès lors, il existe également un besoin de partager les coûts de la R&D au niveau international. Comme les médicaments représentent un facteur de coûts important dans les systèmes de santé des pays de l'OCDE, des travaux ultérieurs seront nécessaires pour identifier le mix de politiques appropriées dans une économie de plus en plus globale.

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INTRODUCTION PRIVATE SUPPLY AND THE MULTIPLE GOALS OF PUBLIC INTERVENTION

1. Over the past decades, pharmaceuticals have made a significant contribution to the reduction of mortality and morbidity in OECD countries. For example, neuroleptics have played an important role in helping many patients out of psychiatric wards. The most recent example is the treatment of AIDS using multiple therapy. The most important factor differentiating the practice of medicine in 1999 from that in 1899 or 1949 may well be the availability of increasingly powerful and effective drugs, such as antibiotics, cancer controlling drugs and thrombolytics, to mention just a few. As these drugs are the result of continued technological progress in drug discovery, there is a high collective interest in fostering further innovations in the pharmaceutical sector, both through well designed patent policies and publicly-funded medical and biological research. Pharmaceuticals represent also a distinctive part of health care systems, as they are the products of a market-based international manufacturing industry, in which Research and Development (RD) play a key role.

2. The pharmaceutical market is very complex, are subject to conflicting policy goals and numerous public interventions. Pharmaceutical products are often complex products, including several therapeutic elements, packaged in many different ways. This product heterogeneity makes it difficult to perform ordinary price comparisons. In addition, the intervention of insurance modifies prices as perceived by patient/consumers, since for them real prices are only the out-of-pocket payments to be borne privately, which introduces a potential for moral hazard, with an increase of consumption when perceived prices are lower. Rapid market transformation in recent years often led to rapid changes in markets, due to the exhaustion of patents for drugs introduced in the 1960s and 1970s, together with the entry of generics. These market changes were sometimes only partly reflected in traditional economic indicators, such as price indices.

3. Pharmaceutical markets themselves differ from country to country, as the very definition of a pharmaceutical market often depends on the definition of drugs and the extent of regulation for prescription and non-prescription drugs. The role of public regulation is multi-faceted in the pharmaceutical sector. It is important to distinguish between two major public policy goals:

- Health policy and social interventions to enhance the welfare of patients, which may imply cost-containment strategies.
- Industrial policy to strengthen economic efficiency, competitiveness and innovation.

4. Ideally, instruments of policy should be specific to each goal, while not distorting the achievement of other goals. Health policy's main concern is to optimise the level and distribution of pharmaceuticals at an affordable level while industrial policy ought to foster innovation in the light of public expenditure constraints. In regulating medical expenditure, public authorities are therefore playing a double role, often through different bodies:

- as the main implicit *buyers* of drugs in most countries, they may exert monopsony power to maximise the patients' surplus. They have to obtain the best price for old non-patented products, while putting some limits on the monopoly rents for the producers of very innovative drugs. This inevitably leads to some forms of cost-containment policy. However at the same time, they wish to foster cost-effective innovation.
- as *insurers*, to arrange for a widespread sharing of the burden of drugs for very ill patients, they have to facilitate access to the most vulnerable groups in the population. This may

require sharing the financial risk with other partners in the field (doctors, manufacturers) through prospective budget arrangements.

5. Turning to industrial policy, world trade issues and the protection of patent property rights have to be considered at the international level. There is in fact a general agreement on Trade-Related Aspects of Individual Property Rights annexed to the World Trade Organisation Convention, which was created following the end of the Uruguay round, in 1994 (WHO 1998). Patents are not in fact issued world wide, even if they can now be issued at the European level. Therefore the discussions of property rights at the international level have to be embodied in trade-related negotiations. This question will not be developed at length here as this paper will concentrate on the social and health policy aspects of the regulation of pharmaceuticals, while bearing in mind the economic and industrial aspects. This should by no means hide the fact that patent protection is a key aspect shaping the whole output of the pharmaceutical sector. Therefore, RD-related aspects will be examined closely in relation to their health policy dimension. The following issues will be investigated:

- How can these different objectives best be pursued, bearing in mind that public intervention often relies on a limited set of instruments?

- How can the supply and consumption of existing drugs be optimised while providing dynamic incentives for the innovation, approval and financing of new drugs?

- Which strategies have been implemented in developed countries to address the challenge of appropriate pharmaceutical pricing while facing rising expenditure?

6. The paper addresses these issues by utilising existing OECD health data, and a special survey of pharmaceutical policy carried out in 1997 across OECD countries[1] and updated since then. The paper is organised in three chapters. Firstly, it discusses briefly expenditure patterns and relates them to income levels, institutional settings and the general health policy and public finance context. Secondly, it analyses the main features of pharmaceutical consumption and production including: demand elasticity; prescription behaviour; Research and Development (RD); competitiveness and international trade. It discusses recent developments, including: recent trends in generic consumption; and changes in the distribution system and restructuring of the industry, including the specific role of European integration. Thirdly, it discusses recent developments in public policy, both with regard to demand side and supply side aspects. This third chapter analyses the policy implications of the empirical economic features discussed in chapter 2, and describes recent policy developments. Therefore, it revisits some of the topics of the previous chapter, but from a different perspective. This chapter also discusses common trends in the search for social and economic efficiency.

1. Responses to the survey were received from all countries, except Iceland, Ireland, Italy, Poland and Portugal. Additional updates and complementary information were obtained from the literature and from several national correspondents.

1. EXPENDITURE PATTERNS: THE COMBINED EFFECTS OF INCOME LEVELS AND INSTITUTIONAL SETTINGS

7. The expenditure patterns analysed in this chapter do not include pharmaceuticals in hospitals (see note on the data). These are included under inpatient care, and are often included in hospital budgets. Drugs in hospitals are estimated to roughly represent 10 to 15 % of the total pharmaceutical market. For example, their share has increased from 10 to 13 % in France between 1984 and 1994 (Delomenie Yahiel 1996). Trends for hospital drugs are similar to those observed for drugs used in ambulatory care settings, except that innovative patented drugs play a more important role in inpatient settings. However, the boundaries between the two sectors are changing over time, since some of the drugs initially reserved for hospital use may be later shifted to the ambulatory care sector, as was the case with drugs for AIDS.

1.1 A small but significant share of GDP

8. Total expenditure on pharmaceutical goods represents between 0.7 and 2.2% of GDP across OECD countries, with a mean at around 1.2% (Table1). Expenditure on pharmaceuticals represents between 8 and 29 % of total health expenditure with a mean around 15.4 %. (Table 2). Although relatively small this order of magnitude is still significant, since in most countries more than half of pharmaceutical expenditure is reimbursed by public funds. Public spending on pharmaceuticals represents 0.7% of GDP. The average share of GDP has increased in most OECD countries by around 50% since 1970, which means that pharmaceutical expenditure in real terms has increased on average 1.5% more per year than GDP growth. However, this increase remains parallel to the total increase in health expenditure, as the share of pharmaceuticals within total health expenditure has only increased moderately among OECD countries as a whole, even if increases were more pronounced in several countries (Table 2). In spite of cost cutting and fiscal-consolidation measures in many countries during the 1980s, public spending has increased significantly since 1970.

Table 1. Total and public expenditure on pharmaceutical goodsas a percentage of gross domestic product

Table 2. Total expenditure on pharmaceutical goods as a percentage of total health expenditure

9. Pharmaceuticals are manufactured goods, often originating from countries with high living standards and high labour costs. In spite of price differentials, pharmaceutical expenditure tends to be a relative heavier burden for health care systems in less developed countries. Hence, the share of GDP is highest in countries such as Portugal, Greece, Hungary and the Czech Republic. On the other hand, the share is relatively lower in countries such as Denmark, Norway, Luxembourg, Switzerland and the Netherlands (Chart 1). Ireland is a special case, as in this country, rapid economic development and relatively low increases in pharmaceutical expenditure resulted in a relative decline of the pharmaceutical share in GDP. Italy is the only major country where strong fiscal consolidation during the 1990s had an impact on the share of pharmaceuticals in GDP. Total expenditure declined slightly between 1990 and 1996, after a very rapid increase from 1970 until 1990. Public expenditure fell from 1 to 0.6% of GDP between 1990 and 1996. There has been a significant decrease in public coverage in this country, due to serious constraints in public finances. France, Japan, Spain and Belgium tend to spend relatively more. The increase in consumption has also been extremely rapid in Portugal. Even in countries with relatively moderate health expenditure growth, such as the UK or the Netherlands, the growth of the share of pharmaceuticals in GDP has been significant.

Chart 1. Total expenditure on pharmaceutical goods as a share of GDP.

10. Expenditure levels per capita in nominal terms (Chart 2) tend to be lower in Northern European countries, particularly in Ireland, Denmark and Norway, which pay doctors mainly by salary and capitation. They are highest in Japan, the United States, France, Iceland, Belgium and Germany. Portugal and Greece stand out among medium income countries with a very high level of expenditure. Public expenditure tends to be highest in countries combining high levels of consumption and large public coverage, such as Japan, Germany, France, Iceland and Luxembourg (Chart 3). On the other hand, public expenditure is very low in the United States[2] and to a lesser extent in Denmark.

Chart 2. Total expenditure on pharmaceutical goods per capita

Chart 3. Public expenditure on pharmaceutical goods per capita

1.2 Consumption levels depend on income but also on institutional characteristics

11. Apart from income effects, institutional features play an important role in pharmaceutical consumption. Generally, there is a good correlation between expenditure on pharmaceutical goods and income levels, as is shown in Chart 4. The correlation coefficient was around 66% in 1990 and increased to 74% in 1996. Consumption was below what could be expected in Turkey in 1996. Once adjusted for income levels, it was generally low in Finland, Sweden Denmark and Norway in 1996. On the other hand, it was generally higher in Japan, France, Germany, Belgium and Ireland in 1996. Between 1990 and 1996, there was a very steep increase in expenditure levels in Japan, although part of this was due to currency variations (which also pushed up the level of GDP itself). Apart from these countries, the United States experienced only slightly higher levels of consumption than average, once adjusted for GDP per capita. This contrasts with the fact that health-care spending as a whole is generally much higher in the United States than in other countries, even when differences in GDP are taken into account. Italy experienced a sharp drop between 1990 and 1996 and is now closer to the average line.

Chart 4. Link between total expenditure on pharmaceutical goods per capita and GDP per capita at current exchange rates

12. Differences become less regular when Purchasing Power Parities (PPPs) rather than exchange rates are used to compare levels of expenditure (Chart 5)[3]. Differences in GDP are narrowed, while divergence from the regression line becomes more pronounced. The correlation coefficient is lower than when computed with current exchange rates and has decreased between 1990 and 1996.

Chart 5. Link between total expenditure on pharmaceutical goods per capita and GDP per capita at purchasing power parities

13. The explanation for these differences lies in a complex interaction between public policy and the strategies of pharmaceutical companies. Most important pharmaceuticals are marketed by large international firms, while price differences do exist, they are apparently not as high on average as the differences between aggregate national price levels reflected in PPPs. The fact that the differences

2. This figure does not include the cost of tax deduction to subsidise the purchase of health insurance. In any case, private and employer-sponsored health insurance play an important role in the US and are not reflected in these figures. According to Kane (1997), of the employed population with health insurance, over 90 % are offered some coverage for prescription drugs. However, there is huge variation in this coverage, from the most comprehensive to those that cover virtually nothing. Most private plans have exclusions that are at least 25 % of total cost of prescription drugs.

3. This refers to purchasing power parity using general GDP price level corrections and not pharmaceutical price levels. In fact, comparisons of pharmaceutical price levels across countries tend to produce highly biased results, which should be considered very cautiously. (see Box on prices measurement).

between the two types of valuation has increased over time suggests that the selling power of large firms may have increased as well, as they have been able to limit price variations from country to country[4].

14. The level of pharmaceutical consumption grows linearly with income, as does general health expenditure. As is the case for overall health expenditure (OECD 1995), levels of pharmaceutical expenditure are influenced by the incentives embedded in reimbursement systems both for users and providers. They are also influenced by the overall prescribing habits of the medical profession: doctors in northern European Beveridgian health care systems are usually cautious prescribers, writing fewer prescriptions. It seems that the imbalances witnessed in some of the markets have increased over time, and that cost control strategies developed in the early 1990s have had limited effects in some countries above the line. Overall growth of GDP has been relatively modest over this period, and the strong growth in pharmaceutical expenditure compared to GDP may reflect the discrepancy between a general sluggish overall economic growth, and relatively strong growth in pharmaceutical markets.

15. A proper econometric adjustment shows that once other factors are controlled for, the income elasticity of pharmaceutical spending is close or inferior to 1. (A 0.8 coefficient is reported in the Annex A, OECD 1995, for the GDP elasticity of pharmaceutical spending). These results also show that a higher share of public spending in pharmaceutical spending increases pharmaceutical expenditure. The capitated systems also have lower spending. However, most of the results used data from the period 1981-1991, which does not integrate all the recent policy developments, and they need to be updated before further implications for current policy can be drawn.

1.3 A significant share of total health expenditure

16. Pharmaceuticals represent roughly 15% of general health expenditure in OECD countries (Chart 6). This percentage declined slightly between 1970 and 1980, but it has risen significantly between 1990 and 1996. As for GDP, this share is higher in countries with relatively smaller levels of GDP per capita. The share of pharmaceuticals is lowest in Switzerland and the United States and is highest in Turkey, Greece, Hungary, Portugal and the Czech Republic. Norway, Denmark and Ireland also are noticeable for relatively low levels. This share has decreased significantly in a number of countries since 1970 (Belgium, France, Greece, Ireland, Luxembourg). It has also declined in the United States and Germany, although most of the decline occurred for these countries between 1970 and 1980. In terms of the share of public health expenditure, pharmaceutical spending only represents a tenth of the total (Chart 7). Compared with the share of pharmaceuticals in general health expenditure, the lower share of public expenditure in total public expenditure on health reflects the fact that co-payment levels are usually higher for pharmaceuticals than for hospitals[5]. Public expenditure represents a smaller share of total expenditure in the United States and Canada than in Switzerland and Denmark.

Chart 6. Total expenditure on pharmaceutical goods, as a percentage of total expenditure on health

Chart 7. Public expenditure on pharmaceutical goods as a percentage of public expenditure on health

17. In terms of public/private mix, most OECD countries constitute a core group, including most of the European Union countries, plus Switzerland and Australia (Chart 8). The United States have very low levels of public expenditure for drugs, as a proportion of total health expenditure. This is due to the institutional features of the health insurance system in the United States. Due to the absence of universal

4. R&D expenditure is incurred in "hard currencies" and is spread accordingly over each market. There is a convergence process in pharmaceutical prices across European countries documented by a Swedish based study (Ljungkvist et al. 1997), with increases of prices in countries with lower prices and decreases of prices for countries with higher prices. See the discussion on price evolutions in the section 3.2.1.3.

5. This is justified by a higher price elasticity of demand for pharmaceuticals than for inpatient care.

health coverage, health insurance is usually provided through employment related benefits, which are not considered as being public as they are not mandatory. Kane (1997) estimated that soe form of third party payment reimbursed 38% of total drug expenditure and up to 60% of prescriptionexpenditure in the United tates in 1994 (see note 2). In European countries with Bismarckian systems, health insurance provided on the labour market reimburses a large share of prescription expenditure and its expenditure is considered as public, which is not the case for the United States.

18. Japan and Spain both have a high share of public expenditure on pharmaceuticals as of total public expenditure on health. This is also true, on a larger scale for the Czech Republic, Greece, Hungary, Portugal, and Turkey where public and total expenditure on pharmaceuticals represent more than 25 % of public and total expenditure on health, due to the high relative prices of pharmaceuticals in these countries, compared with local prices, and the significant share of public reimbursement.

Chart 8. Public expenditure on pharmaceutical goods versus total expenditure on pharmaceutical goods as of public and total health expenditure, 1996

1.4 A rapid increase of expenditure in recent years, with an impact on public finances which led to fiscal consolidation

19. The real growth of total pharmaceutical expenditure was around 40% in constant terms in the 1980s, that is a yearly average of 3.5 per cent, and 30% from 1990 to 1996 in OECD countries, that is a yearly average of 4.6 per cent (Table 3). The most rapid growth rates in the 1980s were observed in Canada, Italy and Portugal in the 1980s. The lowest growth rate was in Switzerland, where there was a decline. Italy and Luxembourg are a special case as there was no increase in pharmaceutical consumption in constant price terms in the 1990s. This is due to a significant decline in public reimbursement for drugs: consumption financed out of public funds fell by 40% in the 1990s in Italy. In the 1990s, the fastest increase in public expenditure was in Greece, followed by Portugal, Sweden, Norway, Denmark, Australia and Finland. On the other hand, the rate of growth declined considerably in Canada. In terms of public expenditure in the 1990s, the increase was fastest in Denmark, and was also very significant in Australia, the United States, Portugal, Ireland and Sweden. Overall, public expenditure increased at a yearly rate of 4.5 per cent in the 1980s and 4.9 per cent from 1990 to 1996.

Table 3. Total and public expenditure on pharmaceutical goods per capita

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A note on the data

Some methodological issues arise in the measurement of pharmaceutical expenditure. There is no agreed systematic framework to define pharmaceuticals at international levels, even if pharmaceuticals could be grouped in the following concentric circles:

- Prescription drugs
  - *Drugs with an international chemical definition (WHO International Non-proprietary name), resulting from international patents, and for which Daily Defined Doses (DDDs) of prescription for the main therapeutic indications have been defined by the Nordic Council.*
  - *Drugs on prescription in specific national markets. (Some of these drugs may be obtained without a prescription in some countries, but are delivered only through the control of a pharmacist).*
- Non-prescription drugs
  - *Over the counter drugs (OTCs), and drugs not subject to any prescription control. This aggregate is looser than the former one, but it needs to be included, as some countries have a stricter definition of prescriptions and sell OTCs drugs which are, in fact, prescription drugs in other countries. (Table 4). This may also depend on the dosage of drugs.*

Table 4 Non-Prescription Drugs and Over The Counter Drugs (OTC) 1996

The information currently presented from the OECD Health database includes prescriptions and self-medication, often referred to as over-the-counter (OTC) products. Vitamins are excluded as they are nutrients. The data include the retail distribution margin when the latter is separate from the price of medicines. The expenditure data includes VAT and sales taxes where applicable. Pharmaceutical consumption in hospitals is included under inpatient care and is therefore excluded from the data. .

2. THE MAIN FEATURES OF PHARMACEUTICAL ACTIVITY

20. The design of public intervention is often constrained by the specific economic characteristics of this sector. In order to perform their role, both as *de facto* insurers and often main buyers of drugs, public authorities have to take into account the main features of *demand* and *supply*. These are structural elements common to all OECD countries pharmaceutical markets, even if some institutional arrangements may vary.

2.1 The role of co-payments and physician prescription behaviour on the demand side

21. This section discusses factors, which influence the demand for pharmaceuticals from an applied economics perspective. Before formulating policy, decision-makers need information regarding the determinants of the purchase decision, recognising that the demand for pharmaceuticals is often indirect, as physicians act as agents on behalf of patients.

2.1.1 Co-payments and drug demand price elasticity

22. This section discusses the price-elasticity of demand. (Policies on co-payments are discussed in section 3.1.2). Financial regulation of demand may be socially efficient if patients are price sensitive but not if it impacts their health status. This requires an estimation of the drug demand price elasticity. The difficulty which arises in many countries is to estimate this elasticity before the intervention of insurance: as drugs are already largely or partly reimbursed, the only actual observed elasticity is often that left after insurance. Hurley and Johnson (1991) overview the studies realised in the 1980s. Most of them agree on the existence of price sensitivity, but they may disagree over its level, and also its potential short-term and long-term effects. Soumerai (1987) showed that a general cap on the number of prescription reimbursements per month had a very significant effect, stabilising consumption over a short period of time, while fixed prescription charges had only moderate effects. Harris (1990) found that a fixed prescription charge of around $1.5 decreased the number of prescription by around 10%, and that an increase to $3 per prescription reduced it again by another 10%. Studies performed using data from the United Kingdom (Birch 1986, O Brien 1989) find elasticities in the range of -0.1 to -0.3, with higher (but questionable) results for O Brien in the period 1978-1986 where co-payments were significantly increased. These imply that a 10% increase in the prescription charge will lead to a fall of 1 to 3% in the number of prescriptions.

23. The most important and relevant study remains the Rand Health Insurance Experiment (HIE) (Newhouse 1993). This controlled randomised study shows that demand is slightly more sensitive to price than the number of prescriptions itself. Co-payments of 25 % reduce demand by a quarter (against 20% for prescriptions). Demand would fall by 43% if its cost were borne at 95% by the patient. These results represent the entire population and they must be complemented by specific observations for poor patients. While higher co-payments are a tool to reduce excess consumption by persons with moderate or high incomes, they may deter deprived persons from access to necessary drugs.

24. Specific studies have concentrated on the most vulnerable groups to be affected by such policies. In a study of the effect on persons aged 55-75 of the availability of Ontario Drug Benefit program, (which occurs at the age of 65), Grootendorst (1995) found that the sicker patients were the most likely to benefit from the public drug insurance program. In a more long-term perspective, Coulson and Stuart (1992) showed that prescription expenditure among the elderly population tended to be persistent, and that this can be observed over a four year period. Hence policies aimed at influencing optional purchases can unduly affect those suffering from chronic disease. Such results call into question the insurability of such expenses by a traditional private-insurance market. Given these features, one of the main attractions of United States Health Maintenance Organisations (HMOs) for the elderly, is to offer them the management of their Medicare coverage, and adding coverage for drugs at no extra cost -- on condition that drug consumption is controlled within the framework of managed care.

25. Whether co-payments help to increase the appropriateness of drug consumption has also been questioned. Over-consumption of particular types of drugs is a matter of important policy concern, especially among the elderly. A report of the General Accounting Office (1995) demonstrated that many elderly still receive potentially harmful drugs. But co-payments are a blunt instrument for reducing this. An overview of the studies (Hurley and Johnson 1992) shows that all types of drugs may be affected by co-payments, both essentials and non-essentials, often through patient non-compliance with the doctor's prescription. Some studies have shown that they decreased the use of such vital drugs as antihypertensive drugs while continuing to use symptomatic drugs such as analgesics or sedatives -- patients chose to have direct primary relief rather than preserving their long-term health capital. In addition, extra-co-payments may lead to lower pharmaceutical expenditure, but also higher hospital expenditure, in the case where health interventions are delayed until the acute phase.

26. Co-payments certainly have an effect on drug consumption. However maximum efficacy in terms of consumption reduction is reached at rates of about 25% according to the results of the HIE study (Newhouse 1993). It appears that co-payments related to the price of the drug are more efficient than fixed charges per prescription. However, lower income groups and those with serious illness that may be disproportionally affected by such a co-payment policy.

2.1.2 Physician prescription behaviour

27. This section discusses the economic influences on physician prescription behaviour (Policies on influencing prescribing behaviours are discussed in section 3.1.3). Unfortunately, the available evidence on the determinants of physicians' prescribing behaviour remains inadequate. Some studies in France have shown that doctors remain rather insensitive to economic considerations as long as they do not bear the cost (Lancry and Paris 1995). The main factors contributing to physician prescribing behaviour are the age of the physician (and implicitly the age of his patients). Other studies have also shown that the physician's risk aversion may also influence the prescribing behaviour (Haajier Ruskamp and Denig 1996). The most complete study to date, using American data from the 1989 National Ambulatory Care Survey (Hellerstein 1998) shows that physician prescribing behaviour displays inertia. Concentrating on the factors which encourage prescribing in generic form, this study shows that the only significant factor leading to a change in prescription habits is to have a large share of the patients enrolled in an HMO. A patient who switches to a physician with a large fraction of HMO patients is 10% more likely to receive a prescription for medication in generic form. Due to persistent prescription habits, all the patients of doctors with a large HMO practice, are more likely to receive generic prescriptions, be they HMO enrolees or not. On the other hand, simple public-information campaigns did not appear to have much effect on final prescription decisions.

28. In the United Kingdom, considerable efforts have been made to influence doctor-prescribing behaviour (Rochaix 1993, GAOb 1994). Information benchmarking their comparative prescription behaviour with respect to colleagues has been given to doctors for a long time. In addition, both under GP Fundholding schemes and the Indicative Prescribing Scheme, financial targets have been given to physicians, based on historical expenditure, demographics of their patients and drug price inflation. Whynes, Heron and Avery (1997) argue that the savings have been one-off and short-term rather than long- term. These savings seem to have been acquired through more willingness to expand rates of generic prescription and more receptiveness to the use of computerised prescribing management systems and audit information such as the Prescribing Analysis and Cost (PACT) data collected by the Prescription Pricing Authority. Although direct studies of the impact of these regulations are scarce, UK prescription patterns in general appear to be rather more cost-saving than those in other countries, with lower rates of use of more expensive drugs, and lower rates of use for symptomatic and potentially unnecessary drugs.

29. Regulatory Medical References introduced to France in 1993 are negative ambulatory-care reference guidelines, penalising physicians who do not comply with them (although penalties have been rather theoretical and very seldom applied). The overall economic effect has been rather limited (Cour des Comptes 1997), as two-thirds of doctors did not change their prescribing behaviour. These negative targeted guidelines had a significant impact only for a limited number drugs under the target, such as certain types of antibiotics or anti-ulcer drugs (Cavalié 1998). These results would tend to reinforce the view that physicians may display inertia in their prescribing behaviour.

2.2 RD and marketing strategies driving supply forces

30. Although the pharmaceutical sector is a competitive market, one of its key features, R&D, deserves attention in terms of public regulation. (The policy implications of R&D are discussed in section 3.4.4). R&D is costly and this should be considered when designing pharmaceutical policies. The whole pharmaceutical industry may be viewed as a product of the patent system, and in the past, countries without such a patent system have been unable to develop a significant innovative pharmaceutical industry. To preserve the incentives to further innovation, it is necessary to allow innovators to recover their costs but also to make supernormal profits, at least on a temporary basis. The patent system works by conferring temporary monopoly power on successful innovation for new drugs passing the regulatory tests of safety and efficacy. However, the diffusion of innovation through information, advertising and marketing is also an important feature of the pharmaceutical industry.

2.2.1 The contribution and the costs of R&D

31. The use of scientific methods to develop new drugs is fairly recent and has been largely influenced by the regulatory process (Scherer 1997). The drug approval process in the United States, initiated with the setting up the Food and Drug Administration in 1938 was strengthened in 1962, by the Kefauver Harris Act, requiring the FDA to certify that new drugs were not only safe but efficacious. The regulatory process itself has been progressively implemented and reinforced due to the perception that consumer choice and awareness of risk were not sufficient to prevent potential adverse effects (Temin 1980). The requirements of the FDA have now been reinforced. Under the new regulations, organisations seeking to test a new chemical entity have to obtain an "Investigation of New Drug" authorisation, based on obtaining data on innocuousness from animal testing before human testing. The period for clinical trials includes three phases, with blind tests and long-term toxicity tests, lasting for a period of 6 years[6]. In some

6. In addition, in some countries a request for cost-effectiveness has been introduced, which has been described by analysts as a fourth hurdle (Australia, Ontario in Canada). (Kanavos and Mossialos 1999).

cases, a fourth phase can be required by the FDA. The total amount of time required for successful drugs to reach the market went from 6.7 years in the 1970s, to 8.5 years in the 1980s and 9.1 years in the mid 1990s. Real costs tripled between 1962 and 1969, and doubled again in the 1970s (Comanor 1986). At the beginning of the 1980s, the cost of one single medical entity was around 140 million dollars (1990 dollars) (Di Masi 1991). However, Dranove and Meltzer (1994) have shown that the more important drugs reached the market sooner and had lower development costs. Some discussion remains over the respective shares of pure RD and marketing costs in developing products for market entry. The impact of public funding for research also has to be taken into account. Cockburn and Henderson (1996) suggest that public sector research plays an important role in the discovery of new drugs, through its interactions with research performed in the private sector in the process of drug discovery. In theory, the role of public sector spending ought to be taken into account when computing the total costs of RD. However, such costing proves to be impossible, as the effects are usually indirect ones.

32. This process has had a dominant effect on general markets for new drugs in OECD countries. The United States currently represented roughly 50% of all major innovations in this period, while Germany, France, Sweden and the United Kingdom represented roughly 25% (GAO 1994a). As a result, the RD expenditure increased constantly in the 1960s and 1970s, while actual patent life decreased[7] (Chart 9). While, in theory, nominal patent life was 20 years in the European Union, 17 years in the United States and 15 years in Japan, the effective patent life was only 6.4 years in Germany, 8.7 years in the United Kingdom and 13 years in France, compared with 9.7 years in the United States and 7-8 years in Japan. (Taggart 1993). (This was also the case in Sweden, with effective patent life being reduced from 12.3 years in 1965 to 8.3 years in 1988 (Andersson and Hertzman 1993).

Chart 9. RD expenditures and effective patent life of NMEs in the United States 1963-89

33. Regulation developments in Europe and Japan have been strongly influenced by the American example. Thomas (1995) shows that the United Kingdom and Germany were the first major nations to follow the US lead. By setting high standards for market entry for new drugs, these countries forced their domestic drug firms to target their RD on drugs of superior efficacy. This means that a strong filtering for market entry and strong regulation for product efficacy and safety had an impact not only on the costs of RD and future prices, but also on quality, and the future competitiveness of the industry. On the other hand, for a long time the French regulatory system was less constrained, with shorter admission times, and formal market authorisation was only strengthened at the end of the 1970s. This contributed to lowering the French industry RD potential. Hence the French pharmaceutical industry, which was very successful in the early 1960s, subsequently lost part of its comparative advantage (Thomas 1995, Barral 1995).

34. A specific distinction has to be made in the pharmaceutical field between "breakthrough" and "me too" innovation. When there are only weak incentives to research and when market entry is relatively easy, there is a risk that the industry may concentrate on relatively less innovative products, known as "me too" products, where innovation at the margin, or galenical innovation, play a key role. It has been found in countries with strictly regulated prices, that "me too" innovation had been used as a tool to bypass price controls, while only contributing marginally to therapeutic improvements (Jacobzone 1997). In all countries, there is a certain balance between "breakthrough" and "me too" innovation. Public incentives should concentrate on the former. It is the role of health technology assessment and clinical evaluative agencies, such as the National Institute for Clinical Excellence (NICE) in the UK, or the Transparency Committee in France to quantify the therapeutic value of health care products, including pharmaceuticals. They provide advice to governments on cost-effectiveness of all new products.

7. The patent life includes some of the initial time required for clinical testing and approval.

35. An important, and still partly unexplained, evolution happened in the 1980s, with a clear acceleration in the costs of RD, without significant regulatory changes. This has been documented by several analysts (Cockburn, Henderson 1995, Scherer 1997). Some have attributed it to a fall in the potential stock of discoveries, after the easy successes of the 1960s and 1970s. Others have claimed that there had been a structural change in the research methods themselves, initiated by the discovery of the first ACE inhibitor in 1978, and the introduction of molecular genetic techniques. This undoubtedly had an important impact on pharmaceutical strategies and on the intensification of pressure for mergers in the pharmaceutical markets. Comparative data on R&D intensity and performance in OECD countries can be found in Tarabusi and Vickery, OECD (1996).

36. In the long run, several other factors play a major role in RD development. Publicly-funded research in related areas has been acknowledged as being an important contributor to quality R&D (Cockburn, Henderson 1996). This is complemented at the level of firms by their ability to pick and catch up with fundamental research. The type of organisation within companies and the implicit recognition awarded to research staff are also of importance. Firms may choose different ways of internal organisation to provide incentives to their researchers and allow them to participate efficiently in the wider scientific community (Cockburn, Henderson 1998). In addition, the role of publicly-funded research has important implications for the rewards attached to pharmaceutical research., as patents usually reward only "private" innovation. Even when the effects of private research are only indirect, pharmaceuticals are also the direct result of public research, as a "public good". This reinforces the special public policy interest in pharmaceuticals, and also justifies some public action to facilitate rapid access to important life-saving drugs. This should be taken into account in the dilemma facing public policy in financing the costs of R&D (See section 3.4.4).

37. The role of R&D, with the market rights it grants to some producers, has important implications for buyers. The competition induced by innovation is oriented towards quality, and is not likely to generate direct savings for public funds, even if it does increase the welfare of patients. Were competition to be oriented towards price, it could be seen as a useful tool for saving public funds. This is valid only for markets where there exist some remaining demand side price elasticity, such as in countries with free prices or reference pricing systems involving substitutable competitive products. As competition is usually not spontaneously oriented towards lower prices in pharmaceutical markets in other countries, specific institutional features have to be added to recreate consistent demand side incentives.

2.2.2 Changing production costs

38. Apart from RD, marketing and distribution play an important role. Distribution costs may account for half of the expenditure on some products, when retail and wholesale margins are included, and may vary up to 10% from country to country (Huttin 1989). Marketing costs are often as high as RD costs. Hence, it is useful to note that the increase in RD costs during the 1980s, although very significant (4 points of total costs) was estimated to be less than the increase in marketing costs (7 points of total costs) (Chart 10). These have been made possible by a fall in production costs (12.5 points of total costs). Along with this general movement, operating profit rates have constantly increased over the 1970s and 1980s. However, part of this profit increase might be due to higher remuneration for greater risks and RD costs, which may not always be reflected in company accounts. It is clear that in spite of intense regulatory pressure, until the end of the 1980s, pharmaceutical companies have been able to maintain robust financial integrity and preserve their operating margins. However, it is essential to update the data in order to observe the impact of the growth in managed care in the United States and of the prolonged cost-containment efforts in European countries. Pharmaceutical RD to domestic or total sales had slightly increased between 1988 and 1995 in most countries (14.1% in the United Kingdom, 16.3% in the United

States, 15.4 % in Switzerland, 28.4% in Sweden, 13.4 % in France, 12.2 % in Germany, 10.6 % in Canada and 7.8% in Italy in 1995) (Patented Medicine Prices Review Board (1997)b.

Chart 10. The changing structure of company costs in the pharmaceutical industry

2.3 An overview of the sector's main characteristics in OECD countries

39. Unlike other parts of health-care systems, the supply of pharmaceutical products is operating at the international level. Hence, it is necessary for national authorities to take into account the position of their country within a global perspective for the design of their national policies. It has been argued by many American analysts (GAO 1994)a, that cost-cutting efforts in some European countries, such as the United Kingdom, do not have as negative an effect on global RD, because of the ability of firms to earn profits in the global market. However, if such measures were to be implemented on a larger scale -- particularly in the United States -- they could impair the whole global RD process and hence the future flow of beneficial new drugs.

2.3.1 Distribution of production and its evolution

40. The distribution of production is disproportionately concentrated in a handful of five to ten countries (see Chart 11)[8]. The United States is the main producer, although its market share declined between 1970 and 1980, it has increased slightly or remained stable since then (Table 5)[9]. This reflects the still very strong position held by the United States in this sector, which has been partly sustained both by the very strict regulation imposed on market entry, and the high levels of domestic consumption. The share of the United Kingdom increased between 1970 and 1980, but it has slightly decreased since then.

41. The evolution of Korea is particularly significant, as it has the fastest growing production of all OECD countries. Its production is now higher than in Spain and as high as Canada and Belgium combined. Growth has remained modest in Australia, Finland, Spain and Portugal. Canada, Finland, Germany Greece, Portugal and Spain experienced some decline in constant US dollars in the 1980s, partly due to fiscal consolidation efforts at home. The same is true for Italy. In the 1990s, growth remained important in Belgium, Sweden, Denmark, France and the United States compared to other countries.

Chart 11. Pharmaceutical production in 1995

Table 5. Trends in pharmaceutical production, 1970-1995

2.3.2 International competitiveness may also be linked to regulatory policies

42. At a first glance, a ranking of standard trade balances underlines the strong position of countries with a research based pharmaceutical industry, such as Switzerland, Germany and the United Kingdom (Chart 12)[10]. One other important message from this presentation is the fact that the United States is not a big exporter of pharmaceutical goods. In order to measure the position of the United States, it is important

8. Switzerland, a major producer had no data for this chart.

9. As for many other industries, their relative share has declined due to stronger growth in other countries.

10. These results might be stronger if one could integrate the trade in active pharmaceutical ingredients, often classified within general chemical trade: for example, in this case the French position would be significantly weaker.

to examine total industry revenues generated by pharmaceutical activity of US based companies. (Some revenues may be transferred through other parts of the balance of payments -- revenues from licences, transfer prices and dividends and do not show on this data). Belgium, Sweden, Denmark and Ireland also have a significant surplus, while the French surplus is relatively small in comparison to the overall domestic French production. At the other extreme, Japan is the main importer of drugs, due to limitations in the Japanese industry (Balance *et al.* 1992, Thomas 1995). The former eastern European countries, Korea, Australia, Italy, and Finland and Norway among the Scandinavian countries also appear as net importers. Among Nordic countries, the pharmaceutical industry is more centralised in Sweden and to a lesser extent, in Denmark.

Chart 12. Net pharmaceutical trade balance, OECD countries

43. An adjustment to compare the trade performance with the size of the domestic market underlines the high performance of the Scandinavian exporting countries, Denmark and Sweden, and also that of the United Kingdom and Germany (Chart 13 and Table 6). Although data were not available for Switzerland for this chart, all evidence points to the fact that this country would come first when comparing exports over the domestic market. On the other hand, as a percentage of its domestic consumption, the Japanese deficit remains modest compared to the results of countries such as Greece, Finland, Portugal or Norway which may have a deficit equivalent up to 40 to 60% of their domestic market. Australia, Canada and Austria also import a significant share of their pharmaceutical consumption.

Chart 13. Exports, Imports and trade over domestic market

(see also Table 6. Exports, imports and trade on pharmaceutical goods)

44. It is also important to take account of the situation at the corporate level, as most of the world trade is realised by large multinational companies (Chart 14). Not surprisingly, the countries enjoying a strong international position are also the home countries of large multinational exporting companies. This is particularly true for Switzerland, the United Kingdom, Sweden and Germany. The United States seems to be fairly international due to the large US market (around a third of the total OECD markets: this means also that US based firms would control roughly half of the OECD area production). Japanese pharmaceutical firms are not internationalised at all while the internationalisation of French and Italian companies remained comparatively modest.

Chart 14. Share of Multinational Drug Company Sales Outside Home Market

2.4 Some key features of recent developments in OECD pharmaceutical markets

45. Three main important structural changes have happened in the pharmaceutical markets of OECD countries in the recent decade, partly fostered by regulatory change and partly by the spontaneous adaptation of players to new market conditions.

2.4.1 The introduction of generic drugs

46. Generic drugs are drugs with the same chemical compound, including the same International Common Denomination. Once products are off-patent, they can be sold as generic drugs at a much lower price. In recent years, with the time limit on patents expiring for an increasing number of products, and the need to generate savings, the interest in generic drugs has grown. Specific policies designed to foster the use of generic drugs will be discussed in section 3.4.3.

47. The rising number of patent expirations and the declining number of effective years of patent protection prompted a reaction from national authorities in the United States. The main goal of this major policy change was to restore appropriate protection for future drugs, allowing for high initial returns on innovation, while cutting long-standing revenue by decreasing the return on old existing products through the promotion of generics. This was initiated mainly in the United States, through the Drug Price Competition and Patent Term Restoration Act of 1984, Waxman-Hatch Act (CBO 1998, Grabowski, Vernon 1992) This law repealed existing laws that prohibited substitution, and also tried to ensure that savings were passed along to consumers. Other countries followed suit at the end of the 1980s, mainly the European countries with advanced regulation systems and high prices such as Germany, Netherlands and the United Kingdom. NERA (1998) examines policy related to generic medicines with specific emphasis on the EU level. This process has now spread to other countries such as Australia, which amended the Patents Act 1990 in 1997, in a manner analogous to the 1984 Act in the United States or France, where measures were introduced in 1997-1999 to speed up diffusion of generic drugs.

48. As a result of the 1984 Act, real patent life was significantly extended in the United States. (Chart 9), back to the levels observed in the mid 1970s, but below the initial levels of the 1960s. Analysis for the United States shows that it would be more effective to speed up the FDA approval process in the future than to grant any further patent extensions, which could be socially costly (CBO 1998). Review time decreased between 1984 and 1992, by around 14 months, so that now US approval time is quite similar to the United Kingdom (GAOa 1995).

49. The new regulations make it possible for generic drugs to enter the market with a special rapid approval process. Additional laws, or some deregulation of antisubstitution laws, have been necessary to effectively promote the consumption of generics. In the United States, by 1989, all states had passed drug product substitution laws that allowed pharmacists to dispense a generic drug, instead of the prescription brand original. Finally in the United States, the pressure of buyers has often been the most efficient way to speed up the diffusion of generics. In other countries, regulatory developments have been more modest, being confined to some extensions of the substitution right. In 1994 for example, brand substitution by pharmacists became effective in Australia. In addition, countries have had to change the way of paying for the distribution system, through some sort of a fixed margin for the pharmacist in order to counter incentives against the diffusion of generics. These flat distribution fees will need to be expanded further to accompany the diffusion of generics.

50. It is now possible to assess most of the likely economic effects of expansion in generic provision, but not to obtain reliable comparative information to describe the extent of generic consumption in OECD countries. Data given below remains indicative, as there is neither an internationally agreed definition for a generic drug nor price differentials required for comparisons. However, available qualitative data[11] enables countries to be categorised in three main groups:

- Countries with significant generic market share
  - United States (an estimate of 18% of prescription sales in 1990, around 28% of number of prescriptions in a study using 1989 NAMCS data (Hellerstein 1998), around 43% of the market in volume (prescriptions) in 1996 (CBO 1998)
  - Canada: While generics represented 12% of total drug sales in 1996-97, they represented 40 % of all prescriptions written in Canada (Health Canada 1997).
  - Denmark around half of the retail market (Balance 1992). (Generic penetration is also high in Finland).

11. Balance 1992, and other sources.

- Germany 40% of all prescriptions in 1997.
- Netherlands: market share should reach 40% in 1993.
- United Kingdom, market share in terms of filled prescription estimated at 51% in 1994 (Burstall 1997). Estimated at 14% in value. More recent data are a high 69 % for the share of generic prescribing, which is also an indicator for assessing performance in primary care (Walley, Burril 2000).
- Generics may also be significant in Australia

– Countries with few generic sales

- Generics exist in these countries and are used in some parts of the market (e.g. hospitals) but remain of limited economic relevance. In France laws were developed in 1996-1997 to develop generic market share, estimated at 3.3% in 1996. The share was estimated at 8.4 % in volume at the end of 1999. The market share was 3% in Belgium and Switzerland in 1997. A possibility for expansion of the market for generics may also exist in Japan but its extent is unknown.

– Countries with almost .no generic sales recorded

- Mediterranean countries. Italy (0.4% mentioned in Fattore and Jommi 1998), Portugal, Spain and Ireland.

51. In terms of economic effects, generics have entered the market as early as three months after patent expiration. A study by former US Office of Technology Assessment at the end of the 1990s showed that brand names had lost around 43% of their market share. It seems that the introduction of a lower-priced version does not affect the price of the initial branded product, as initial branded product prices continue to rise faster than inflation in the United States after generic entry (CBO 1998). This is also consistent with the results of Grabowski and Vernon (1992). Hence, the fall in the *average* price is obtained through a mix of high, possibly higher prices, and low ones. Caves *et. al.* (1991) found some very slight decline for initial prices of branded products when two or three generics are present, at around 2 to 5%. Even after generic entry, financial resources devoted to marketing continue to play a key role in explaining the market share of the original branded product (Berndt, *et. al.* 1995). An empirical assessment of the impact of generic entry on the traditional retail US market is also offered in CBO (1998). The results show that the size of discounts on a brand-name drug tend to increase by 10 to 14 percent when a generic version is available from four or more manufacturers. On the whole, this generated substantial savings. In this traditional distribution system, prices are usually high for innovative drugs, and the share of generic drugs is lower than for other segments of the distribution market (see Table 7). The CBO (1998) study concluded that lengthening patent term extension was not necessarily the only option to balance the increased diffusion of generics. The main option to be explored was to speed the FDA approval process, without sacrificing the safety and efficacy of drugs, are much more beneficial to both the pharmaceutical industry and consumers than is lengthening the patent-protection period. In the UK, where the diffusion of generics has been highest, an increase in generic prices has been observed recently, together with shortages, which has had an impact on primary care groups coping to meet their budget target.

Table 7. Market Share and Average Retail Prescription Price, by type of drug, 1994

2.4.2 The changing structure of the distribution system

52. This section discusses recent changes in the distribution systems, which have occurred in some OECD countries. These changes have some policy implications, which will be discussed in section 3.4.1. A first change observed in pharmaceutical distribution refers to the development of Pharmaceutical Benefit Management companies (PBMs) in the United States, and structural shifts in the way drugs are being

delivered (see Kane 1997 for an overview). This was initially due to the high prices prevalent in the US market, combined with relatively high distribution costs in the traditional retail/wholesale system in this country. Pharmaceutical Benefit Management companies were able to enter this market, by first establishing formularies, and then negotiating rebates on these formularies from manufacturers. Then, they would share part of these economic gains with main purchasers such as health plans and HMOs, by offering an integrated delivery service and payment system (Figure 1). This market pressure created dispersion in pharmaceutical prices to the overall benefit of consumers (Berndt 1994).

Figure 1. How PBMs fit into the payment system for prescription drugs

53. PBMs use fomularies, which are either positive lists of drugs that will be covered, or negative lists that will not be covered. These formularies are relatively opened, when they have either long positive lists and small negative lists. The opposite holds when they are closed. In addition, PBMs have also used methods which were previously developed by public authorities in other countries to monitor pharmaceutical consumption, with the development of Drug Utilisation Reviews (which were in use in the Pharmaceutical Benefits Scheme in Australia (Mitchell 1996). They may pertain either to the PBMs or to the HMOs, operating upstream. PBMs also favour incremental therapy, using the more expensive drugs at a later stage. Finally, one of their main goals is also to promote and facilitate the use of generics, sometimes contacting the physician when required in some US states. Overall, there seems to be a general satisfaction of buyers with PBMs. For example in 1995, 58% of US federal employees were covered by PBMs, and the plans covering federal employees were rather satisfied with the service (GAO 1997b). However, in the more recent period, consumers have felt that PBMs may have imposed restrictive rules regarding refills and have resented failure to notify them about which products require prior authorisation[12].

54. In addition to PBMs, and partly linked to them, new forms of delivery have developed through mail-order pharmacies, which cover around 10% of the US market. These are particularly important for those with chronic illness and older patients. Mail orders are also important in Australia and New Zealand, but they remain rather uncommon in most European countries, due to regulatory barriers and resistance from various actors. For example, an attempt to introduce mail orders in the Netherlands in 1993 failed because wholesalers boycotted the system. However, they may be further fostered by the development of electronic commerce techniques.

55. In addition to these developments and due to cost-containment efforts, restrictive listing by public authorities and a rising demand for health care products, Over the Counter (OTC) drug markets have witnessed the appearance of chainstores specialised in health related products. Although the borders may sometimes be hard to define, this has a significant impact on the traditional method of market distribution through the retail/wholesale circuits. In other countries, distribution systems remain a full part of the public system, as in Sweden, where all pharmacies were nationalised in 1970 to form the Apoteksbolaget, a public agency. While it may be premature to dwell on the details in these early developments, they may constitute an important step in the modernisation of health-care systems.

2.4.3 Corporate reaction: strategies towards more concentration and vertical integration

56. Finally, pharmaceutical markets have also been affected by drug companies' reactions to the above mentioned changes which are eroding their market position. These strategies have developed in two main directions:

12. As reported by M. Dickson.

– Horizontal concentration.

  This means merging with other companies or acquiring other companies in order to gain a larger share of the market, but also to build on a wider RD portfolio, including the biotechnological research.

– Vertical integration

  This means buying some of the agents operating the market downstream, in order to obtain better conditions of access to the distribution system. It may also be achieved through formal long-term contracts (GAO 1995).

57. In short, pharmaceutical companies have either acquired rivals, or companies marketing generics to gain new market shares, or specific organisations such as PBMs to control their distribution. Developments pertaining more to the industry policy side will not be developed at length here. An account of major acquisitions between 1988 and 1995 can be found in Vickery *et. al.*, OECD (1996). Since then, further developments have taken place, with the creation of Novartis in Switzerland, merging two major Swiss companies, and also the merger of Hoechst with Rhone Poulenc Rorer. Additional mergers may come.

58. Several factors explain the pressure towards horizontal integration. Some may be purely linked to the evolving production function of pharmaceuticals and the rising cost of RD. Since RD costs are fixed costs, multinational enterprises that dominate the field provide a structure that organises an industry with important fixed costs. A pharmaceutical company has to be considered in the context of its main assets, which are a portfolio of past and future valuable products ensuring market rights and profits. Mergers lead to a concentration and a rationalisation of research portfolios and also a sharing of both the discovery risk and of the market trends in OECD countries.

59. Concentration is also motivated by the desire to obtain a better ability to resist pressure from the buyer. A company which is largely internationalised is in a better position to plead in favour of international standards *vis a vis* local governments. The primary method of resisting pressure from buyers has been increased vertical integration whenever this was possible. Several interventions by the US Federal Trade Commission in such mergers have resulted in consent agreements aimed at establishing safeguards against non-competitive behaviour. The empirical evidence remains mixed (GAO 1996) and points to the need for continued pressure for the preservation of market competitiveness. However, there seems to have been a few steps back in the United States from vertical integration, as it may not always have yielded the expected results. PBMs have developed mainly in the US market. PBMs use formularies and other tools to monitor prescription as do public authorities in other countries. In spite of the general high costs of the US context, some of the innovative techniques developed in this country which reconcile combining economic constraints and the search for better outcomes and patient quality of life, could be applied to other countries. For the better access to market information available to PBMs can also be used to develop disease management strategies.

60. In addition, companies have had to develop strategies to adapt to a growing demand for generics. Some of these strategies may involve for the manufacturer of a brand to choose to produce its own generic alternative too. It has been shown that when firms choose to produce their own generics, this may correspond to a strategy of market segmentation, with higher prices for the branded good and lower prices for the generic good. Such a situation leads to higher prices than pure price competitions with firms producing only generic drugs (Ferrandiz 1999). This raises important competition policy issues.

2.4.4 The European Dimension and the role of European Integration

61. The European Union has had a significant impact on pharmaceutical activity, as Europe represents a very large share of the world market. An important step towards a European market for pharmaceuticals was the Council Directive 89/105/EEC in 1989 related to the transparency of measures regulating the pricing of medicinal products and their inclusion within national health insurance systems. The extension of patent protection through the Supplementary Protection Certificate (SPC) has also been implemented at the European level (Regulation 1768/92).

62. In the past, national drug licensing systems had been developed independently in European countries. The European Medicines Evaluation Agency (EMEA) has been established (Regulation 2309/93) and has been in operation for five years, with a centralised procedure for marketing approval, which is now in place[13]. From January 1998, a company can either obtain one Member state's drug licence, covering only that Member state and wait five years to apply to another Member state, or it can apply for a pan-European license. However, it is the European Commission that regulates entry to the European market. (Mossialos 1997, Earl Slater 1997). The legislation has also concerned product classification, advertising, good manufacturing practice, provisions relating to labelling and wholesale distribution (Kanavos, Mossialos 1999). The pan-European license saves time and resources in bringing a drug to the market and harmonises the conditions for which the drug is licensed. However, the organisation and financing of health care are the responsibility of national authorities. The Amsterdam treaty gives an expanded role to the EU.

63. Discussions between national authorities and providers in some countries over pricing and reimbursement policies have increasingly involved arguments related to European rules (Earl Slater 1997, Kanavos, Mossialos 1999). The action of the European Court of Justice has ruled that patients can import cheaper Over-the-counter (OTC) drugs for their own use in another Member State, provided that the product is authorised in their home country. It has also ruled in favour of parallel imports. Recent decisions have concerned the right to receive and be reimbursed for care or health services in a different country[14], but with no direct impact on pharmaceuticals.

64. More recently the European commission, under its Industry Directorate, has convened roundtables with working groups on the single market for pharmaceuticals to advocate for a common market for pharmaceuticals (Frankfurt Roundtable 1996, follow up in December 1997, third roundtable in Paris December 1998). The Commission issued a communication in November 1998, on the single market for pharmaceuticals, (COM(1998)588). This communication reviews the principal policy options for pharmaceutical markets, discusses price controls, profit controls and contractual policies. It supports the increase in the provision of generic drugs. It also advocates encouraging least-cost purchasing of pharmaceutical products both by providing prescribers with more comparative information on drug costs for a given treatment and, where necessary requiring prescribers to share the cost of expensive practice[15].

65. Beyond developments pertaining specifically to the drug market, the single European currency, the Euro, and the monetary union have had implicit effects on pharmaceuticals. The single monetary union will increase the push towards price transparency and may have an effect in increasing the role of price

13. A short explanation of the centralised and decentralised procedure can be found at http://www.eudra.org (EMEA Website).

14. These were the Kohl and Decker cases, concerning dental care and spectacles.

15. This may mean that prescribing physicians might have to bear the costs of decisions to prescribe a more expensive similar drug, or of not prescribing the generic drug. Several tools can be used for this purpose, such as for example, global budgets, fundholding with a budget for prescription, or linking the reward for performance to a certain share of generic prescribing.

comparisons across countries. Already, many European countries use cross-European references for regulating the prices of their drugs. On the other hand, the need for rebalancing the public finances in several Member States has had an impact on cost-containment strategies. In several countries spending cuts have been implemented to help public finances meet macroeconomic sustainability criteria. These spending cuts have been achieved by reducing the aggregate rate of public coverage, but also through delisting and price cuts. (See section 1.4, and section 3.3).

3. THE EVOLVING ROLE OF PUBLIC POLICY

66. This chapter discusses alternative policies used in the regulation of pharmaceuticals, addressing both demand and supply objectives. These policies have to take into account the features of pharmaceutical activity, which have been discussed in the previous chapter. It also discusses strategies for short-term fiscal consolidation as well as the need for an information-based and outcome-oriented strategy. It uses the results of the OECD questionnaire on pharmaceutical management and regulation, circulated in 1997. These results have been updated and completed by the Secretariat.

3.1 The regulation of demand

3.1.1 Defining the market: listing systems and formularies

67. The pharmaceutical market is very peculiar in that it is both regulated for public health reasons and often publicly-subsidised, so that one of the key roles of public policy is just to define the market itself. This involves defining rules for admitting drugs to the market, and also defining the basket of goods, which will be listed for reimbursement. Admission refers to whether a drug is safe enough to put on sale and is usually determined by whether it has passed certain tests on grounds of health and efficacy[16], Reimbursement listing applies to any pharmaceutical reimbursement system, public or private. This paper will concentrate essentially on the reimbursement decision process, bearing in mind that sometimes it is difficult to disentangle the two in practice for many countries. All countries have safety tests for drugs. However, not all countries do offer universal coverage for drugs: the United States, Canada and Mexico do not have a universal system for drug coverage, and hence each of the insurance bodies in these countries has to define its own list or its own formulary. This is for example the case for the HMOs in the US, working jointly with Pharmaceutical Benefit Management systems (see below).

68. In most countries, the list defining the drugs eligible for reimbursement is the first economic tool used by public insurance policy in the field in order to influence demand. Therefore, the way in which the list is defined and updated constitutes a crucial aspect of pharmaceutical policy. Lists in most OECD countries are revised several times a year, by either the Department of Health or specific bodies in charge of pharmaceuticals such as PHARMAC in New Zealand. (Table 8). In some cases, lists can be subject to more extensive revaluation, as was the case in the Netherlands where the medicines in the publicly funded package were screened on the basis of needs and effectiveness. The French government has also conducted

16. These tests are administered by the FDA in the United States, and its equivalent in other countries.

an extensive revaluation in 1999. In some ways, most countries base their list on some effectiveness criteria. The list may also be influenced by the drugs which are currently under trial and may reach the market in the coming years. Drug substitutions and updates to the list have to be anticipated, as resources are limited.

Table 8. Listing of drugs eligible for public insurance reimbursement

69. The vast majority of OECD countries has special rules for drugs in hospitals (Table 9). This was apparently not the case for Austria, Germany, Japan, Korea, Norway Sweden and the United States, according to the responses to the OECD questionnaire. In most other countries, specific rules exist for drugs in hospitals, as these drugs are not reimbursed within the rules for prescription drugs, but are covered by the specific rules for hospital care. For example, in Canada, drugs in hospitals are covered as part of hospital treatment. There are also highly specialised drugs, which can be offered only through hospitals, as was the case for AIDS drugs when they first appeared[17]. Drugs in hospitals are not subject to general price fixing mechanisms but are often included in hospital budgets and may be freely bought through negotiations between hospitals and manufacturers.

Table 9. Drugs in hospitals

3.1.2 Influencing the demand of patients

70. Most of the empirical results surveyed in section 2.1.1 point to some price elasticiy in pharmaceutical consumption, with a specific mention for some groups which may be disproportionnally affected by co-payment policy. Therefore, all countries use some sort of financial incentives on patients to regulate demand. Three main points should be noted:

- Some level of financial incentive is generally involved whatever insurance is available for reimbursement, be it private or public.

- Public schemes need to design co-payment policies in ways which protect the chronically ill, the elderly, or poor patients.

- Countries differ in the extent to which they provide public insurance for drugs, the type of regulation they use for the private insurance market and the types and levels of co-payments or deductibles which apply to the various parts of the population.

71. Some sort of financial incentive on patients appears to be inevitable in the design of drug policies, as demand is price elastic for many drugs. Therefore co-payments are imposed for drugs due to price sensitivity in order to limit over-consumption, the risk of which is greater for pharmaceuticals than for other health care goods, such as inpatient care. For example, the NHS in the United Kingdom, originally had very few or very low co-payments for drugs. However, co-payments were gradually introduced and significantly increased between 1978 and 1986. Although they are relatively high now in this country, they only finally "bite" on a rather small number of customers (See paragraph 79).

72. The global implications of high co-payments for the health-care system as a whole need to be considered. Ambulatory-care prices and higher co-payments when associated with an over-subsidisation of hospitals, can lead patients to turn their demand towards the inpatient sector, thus substituting very expensive and intensive care, even though early medical and medicinal management could yield greater savings as a whole (Lichtenberg 1996).

17. In some countries, drugs for AIDS have been shifted to ambulatory care settings since then.

73. Consideration should also be given to patients' perception of co-payments. Even low co-payments for very expensive drugs, in the absence of third-party payments, can deter some patients from buying necessary drugs. On the other hand some countries may have co-payment policies which appear more illusory than real. For example in France, in spite of the co-payments for drugs, prescription drugs are virtually free for 80% of the population who enjoy supplemental insurance coverage (as all the supplemental private insurance companies and cooperative "mutuelles" reimburse most or all of the co-payments instituted by the public scheme). In addition, a recent reform has been established to provide means-tested coverage for supplemental insurance). Among OECD countries, only Austria, Germany, Japan, Spain and Switzerland have officially banned such a cost shifting by reinsurance to a second-tier payment system, on the grounds that it diminishes the incentives put in place in the public schemes (See Table 10).

74. Reimbursement usually applies to prescription drugs as non-prescription drugs are seldom reimbursed. It may also depend on the indication for which the drug is prescribed. The extent of the prescription market is highly variable from country to country: for example France or Germany have a much less constrained definition of prescription drugs than the United Kingdom or Denmark. Delisting has also been used in many countries as a tool for cost containment, and leads to some de facto increase of patient cost sharing for those drugs which are no longer eligible for coverage. Hence, the intensity of co-payments may differ greatly from country to country as they apply to different markets of goods.

75. Although the majority of countries enjoys a public insurance scheme for pharmaceuticals, this is not true for the United States, Mexico, Turkey, and also Canada. (In this country the universal health scheme, implemented for all other medical goods, does not include pharmaceuticals. However, all provincial and territorial governments subsidise the cost of prescription drugs for at least some sectors of the population, most notably seniors, social assistance recipients, individuals with specific disease conditions, and in some cases, home and community care recipients. In addition, the federal government provides universal coverage of drugs to specific groups[18]). In the United States, the issue of out-of-pocket payments for Medicare beneficiaries has been an important topic for public policy in the recent period.

76. The co-payment levels can be defined in specific ways[19]:

- proportionality to the final price.
- with a fixed charge per prescription.
- with an annual deductible or a stop loss.

77. Proportionality to the final price is the standard method used to counter moral hazard in an insurance context. It is used in Belgium, Canada, Denmark, France, Greece, Hungary, Ireland, Korea, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey and by the private health insurance schemes in the United States. (For a general overview of patient cost sharing policies see Table 10.) On the other hand, Australia, Austria, Germany, Japan, New Zealand, the Netherlands and the United Kingdom have largely opted for a fixed charge. Finland and Italy have mixed systems, combining both forms of cost-sharing. Recently in the US there has been a move towards a mixed system with flat co-payments differentiated by type of drugs, generic or brand. In some countries, mostly with private

18. For more detail on the Canadian situation, and the shared responsibilities of the federal and provincial governments, see Vandergrift, Kanavos (1997).

19. The information below draws on several sources: Balance 1992, WHO 1997, official GAO reports for the United States, Commonwealth Department of Health and Family Services (1998) for Australia, and also Ministry of Health and Welfare (1996) for Japan and many other sources (see references).

insurance, an annual deductible is imposed below which no reimbursement is granted. In the United Kingdom, Sweden, the Netherlands and Switzerland stop-loss policies have been integrated.

78. Reimbursement in most countries is differentiated by type of drug, type of beneficiary or both. Korea and Greece operate little differentiation. The differentiation is by type of medical facility in Korea and applies to pregnant women and to patients suffering from chronic disease in Greece. Switzerland and the Netherlands have no major differentiation but have a stop-loss provision. In countries like Australia for example, other mechanisms have been created through concessional cards to exempt the most needy patients from the financial incentives. In France there is the 100% reimbursement clause for the chronically ill. Specific rules exist in the United Kingdom, Spain or Portugal for specific groups of the population, in Canadian provinces for the elderly or social assistance recipients, in Italy or Germany in specifically-defined cases. Australia, Austria, Japan, New Zealand, Norway and the United Kingdom differentiate only by type of beneficiary, while the Czech Republic differentiates only by type of drugs. Most other countries combine both types of differentiation. Co-payment levels are relatively low in Japan and depend on the number of drugs used.

79. It should also be added that a "new" way to implement a method of cost-sharing has been to base reimbursement levels on the price for the lowest-priced available comparable drug, often a generic, through reference pricing policies. The co-payments in this system correspond to the difference between the branded drug and the public reimbursement. As this policy has a greater link with the regulation of supply, it will be discussed in the reference pricing section.

Table 10. Co-payments and Patient Cost-Sharing Policies in OECD Countries

80. Given the variety of schemes and exemptions, it is very difficult to give a homogeneous overview of the various global cost-sharing profiles. As direct co-payments by patients are regressive, and fall more heavily onto the less privileged groups of the population, many OECD countries have implemented specific safety nets to counter the potential negative effects of co-payments. As a result, in the United Kingdom, almost 50% of the population is virtually exempt from co-payments on prescription drugs (on a list which is however more limited than in Germany or in France, but conceived with a view to keeping the essential drugs).

81. Consideration should be given to the share of public pharmaceutical expenditures within total pharmaceutical expenditure which provides an approximation of the global impact of publicly-designed schemes. For countries like the United States, Canada or France, the global third party reimbursement rate for patients is significantly understated, as the impact of employment related or private insurance should also be added. (Chart 15). On average, in the middle of the 1990s, public expenditure represented more than 60% of total pharmaceutical expenditure in the majority of OECD countries. The lowest levels were found, under the above mentioned restrictions, in the United States, Canada, Italy and Belgium. Highest levels were found in the Czech Republic, Luxembourg, Norway, Ireland, Spain and Germany (France should probably be included in this list if supplemental insurance is taken into account).

82. Two groups of countries emerge from Chart 15:

- Countries which decreased public coverage

  This is particularly true for Italy (1970-1996) which witnessed the sharpest decrease, particularly between 1990 and 1996 and Belgium (1990-1996). The impact of the European fiscal convergence criteria, together with the high level of public debt in Belgium and Italy, have brought about strict cost-containment policies, which have had a very significant impact on pharmaceuticals. As a result, Italy experienced a significant relative decline in its total

pharmaceutical consumption in the 1990s. There was some decline in Australia during the 1970s, in New Zealand and Austria during the 1980s. Declines in Luxembourg, the United Kingdom or Germany observed in the late 1980s or 1990s have been modest when compared to other countries.

– Countries which increased public coverage

This is particularly the case in Norway and Ireland. Ireland, which has enjoyed strong economic growth in the last decades, initially had low levels of consumption. Norway, due to its oil resources, has enjoyed very strong public finances. The public share has also increased in Iceland, Canada, the United States, Switzerland, Greece and to a lesser extent in Sweden. In France, total third party reimbursement was increased in reality, due to the increasing coverage with supplemental insurance, which reached 60% in 1980 and 80% in 1990. The recent law on "Universal Health Insurance Coverage" will extend supplemental coverage to 100% of the population.

Chart 15. Public pharmaceutical expenditure within total pharmaceutical expenditure

83. Generally, a higher share of public coverage has not been correlated with higher total expenditure (Chart 16). Significant public intervention in the field of pharmaceuticals, associated with a high level of public coverage has not led to a higher share of GDP for pharmaceuticals. However, this does not control for additional coverage through private health insurance. The econometric results in OECD (1995) tend to support the view that increased public coverage would increase expenditure. However, more developed countries, for which pharmaceuticals generally represent a smaller share of GDP, are also those which generally provide more public coverage. The results of this study may also mean that the cost-containment methods used in public schemes, particularly in Scandinavia, and to a lesser extent in the UK, the Netherlands, Australia and New Zealand, have been quite successful in discouraging unnecessary consumption while safeguarding those in need. Monopsony power of government agencies is also a key determinant of the level of pharmaceutical consumption and has been efficient in the United Kingdom, Australia and Scandinavia for example.

Chart 16. Share of GDP and public coverage for pharmaceutical consumption

3.1.3 Policies and guidelines to influence the prescribing behaviour

84. In addition, OECD countries have at some point integrated the role of physician prescription in the regulation of demand discussed in section 2.1.2. Often, the first phase of health care reforms in the case of pharmaceuticals involves increasing the financial responsibility of patients. Targeting the responsibility of providers in potential over-consumption and misplaced prescription come about, in general, as part of a second phase of health care reforms. The first attempts were originally made in the UK but now most western European countries and managed-care systems in the United States have implemented some sort of monitoring of physician prescription. However, apart from binding financial objectives, these policies have had limited economic effects, as physician behaviour reveals strong habit components and is not amenable to economic incentives. Various tools have been used to influence physician-prescribing behaviour: auditing, developing guidelines and fixing budgets:

– Auditing and benchmarking prescription behaviour

This was first implemented through the Prescribing Analysis and CosT (PACT) system in the UK. For a long time, France has also had a periodic review of physicians individual prescribing activity[20]. It is currently used in Germany and many other OECD countries.

– Guidelines

Prescription guidelines exist now in most OECD countries (see Table 11) and will not be developed at length here. These can be either positive guidelines with indicative general prescribing policies or in some cases like France, they can be negative guidelines, of what should not be done, with possible sanctions. These guidelines have also been linked to formularies.

Table 11. Guidelines for prescription

– Budgets

Individual

In the United Kingdom, individual budgets have been indicative for non-fundholding GPs but they were firm for GP fundholders. As of April 1999, all GPs in England have drugs budgets within Primary Care Groups. (The budgets include also hospital spending). In Ireland, physicians have been offered part of any savings.

Global

Global regional budgets were introduced in Germany for each physician association (regional level) after the Statutory Health Insurance Reform Act (Gesundheitsstrukturgesetz-GSP) in 1993. They were introduced in a similar fashion in France following the Juppé Plan in 1996 (in both cases, pharmaceutical companies can also be financially penalised). However, the main issue remains to know how these global targets may finally apply to each individual physician. These budgets also exist in Belgium, with indicative targets, in Greece for the main social insurance fund, in Italy and in Mexico.

Table 12. Fixed budgets, direct limitations of volume and expenditure

85. In addition to these fixed budgets, controls per episode, per day or per physician are sometimes imposed (table 12). These limitations do not seem to follow a consistent framework across countries. These additional controls and limitations of various sorts exist in around half of OECD countries. Specific restrictions were not reported for countries as Australia, the Czech Republic, Denmark, Finland, Japan, Korea, Norway, Spain Sweden and the United States. However, in these countries, guidelines and peer review of prescriptions may provide an opportunity for monitoring prescriptions.

86. This overview shows that most countries use some sorts of guidelines and prescription reviews. However, arbitrary limits per physician, per episode of care or per day, seem more difficult to justify as improving the cost-effectiveness of prescriptions. As information systems offer further developments, closer links could be created between guidelines, auditing practices and prescription limits. Approaching the issue in terms of "Evidence-Based Medicine" may offer less arbitrary limits, but may also be perceived by physicians as a constraint in their medical decision making, as this offers the possibility of close surveillance of medical activity.

87. Finally, as far as prescription policy is concerned, it should be also noted that the Japanese system is very difficult to compare with other countries, as prescribing and dispensing are by no means separate (Bungyo system, Seo 1994). Drugs were distributed by medical doctors paid for this service, thus

20. Tableaux Synthétiques d'Activité des Praticiens (TSAP).

providing clear incentives towards over-prescription. The Japanese authorities have developed a strategy to separate dispensing from prescribing, and there has been a gradual development along those lines. However, in 1994, only 18% of drugs were dispensed through a pharmacist, as the rest were still distributed directly by medical doctors. (Ministry of Health and Welfare 1996). A similar situation is also to be found in the Netherlands, where the government is also trying to separate these two functions.

3.2 The regulation of supply: price fixing and profit control

88. If there is a certain convergence of policies on cost-sharing and regulating patient demand, this is far from being the case in the sensitive field of pharmaceutical supply regulation. Some analysts have claimed that public regulation has been imposed on what should be considered as private competitive markets. About three-quarters of the final pharmaceutical expenditures however are publicly reimbursed in the vast majority of OECD countries. This so distorts the price mechanism that regulation is inevitable. Recent analytical approaches to public regulation in this field distinguishes between "cost plus" regulation, (reimbursing and controlling costs while allowing a certain cost margin), and "fixed price" systems (fixing prices and allowing for free supply behaviour). Cost plus leads to profit control, and has been extensively used for various public utilities under private ownership such as electricity or water supply. The use of price fixing has been used less in the past than "cost plus" for regulating public utilities. However, its role was developed in the 1980s, mainly for the telecommunications and electricity markets. Specific forms of these systems can be found in the case of pharmaceuticals (Abbott 1995a and 1995b). Price fixing has been used in many countries for several decades but it may not always have worked the way it was intended to: as product heterogeneity has sometimes been improperly understood, serious flaws have affected this method of regulation.

89. Another important dimension to be taken into account when designing public policy for pharmaceuticals, is to meet long-term structural objectives while addressing short-term issues. This has led government schemes to address the challenges of competitive international markets from the perspective of local and constrained resources.

3.2.1 Product price fixing

3.2.1.1 The rationale and limits of price fixing in the case of pharmaceuticals

90. As price fixing risks causing distortions in private markets, it is not applied to many goods. Pharmaceuticals, however have been subject to extensive and wide ranging price-fixing policies in OECD countries, for several decades. Today, pharmaceutical prices are free in only a minority of OECD countries, even if these include some major players such as the United States, Germany and Denmark. The Netherlands also allow for some flexibility in a mixed system. The situation in the United Kingdom is very complex with a semi-free system (Bloom and Van Reenen 1998). Price fixing has been chosen as a public policy when:

- Prescription pharmaceuticals are considered as belonging to the goods provided by a universal health care system

- Patient access is not to be deterred for financial reasons, but public funds are limited.

91. This means that the price sensitivity in the final demand curve is going to be lower than it would have been otherwise the case. This raises the risk of excessive moral hazard phenomena as prices could be artificially raised. Hence, governments act as monopsonies in pharmaceutical markets and use this

monopsony power to counteract the monopoly power of firms enjoying market protection through patented rights.

92. Price fixing has been used in Australia, Austria, Belgium, Finland, France, Greece, Hungary, Japan, Italy, Korea, Mexico, Norway, Spain, Sweden and Switzerland. At times, some control over prices has been exerted in Canada, Germany and the United Kingdom and most OECD countries, except the United States. (see Table 13 for more details). In many cases, these policies have been implemented since long ago. A couple of countries have transformed their system over time, particularly to move to reference pricing in the recent couple of years. Their system has been described as mixed. (This will be discussed in the last section on reference pricing).

Table 13. Price controls

3.2.1.2 Fixing which prices: boxes or quality-adjusted therapeutic properties?

93. The difficulty with price fixing in the case of pharmaceuticals is that prices are fixed for what is apparently traded on the market, namely boxes, while in fact, what is actually bought is a certain set of chemical substances with therapeutic properties. Everything depends on the strategy which will be used in price fixing, as some sort of comparison has to be made to decide the price of a product as there is no market equilibrium. OECD countries use a combination of criteria to fix the prices for drugs supplied to insured consumers. These include:

- the therapeutic value of the drug

  This approach is used in Australia, Belgium, the Czech Republic, Finland, France, Hungary, Japan, Korea, Norway, Spain, Sweden, Switzerland and Turkey, according to the responses to the OECD questionnaire. Methods used vary from country to country. Some of these countries require cost-effectiveness studies in their New Drug Application (Belgium, France, Italy and Sweden for example).

- reference to existing products

  The questionnaire responses for Australia, Belgium, Canada, the Czech Republic, Finland, France, Hungary, Japan, Korea, Norway, Spain, Sweden, Switzerland and Turkey, refer to such comparisons. In Belgium, prices are based on improvement over existing products. In France, final prices are the result of negotiations with companies, which take into account similar products.

- reference to international comparisons

  This approach has been used by most OECD countries, but is particularly important in smaller or medium size OECD countries, such as Australia and Canada for patented products. In Australia prices are set with reference to European price levels, using a medium between high price and low price European countries. This also means that the world pharmaceutical market is in fact much more unified than would result from the autonomous operation of fragmented national markets.

- the contribution of the pharmaceuticals to the economy

This is done in Australia (Factor F scheme, see below), in Belgium, Hungary, Korea, Spain, Turkey and the United Kingdom. The extent to which such practices are followed implicitly in other countries remains unknown.

94. Countries differ in the extent to which prices are fixed:

- In Canada, maximum non-excessive prices have been established since 1987 for patented drugs. Firms may price their products up to this level for these drugs. (The Patented Medicine Prices Review Board was created for this purpose).

- Prices may be fixed at market entry and either frozen or increased afterwards. The issue of a proper adjustment for inflation is essential. Under-adjustment is equivalent to a price cut and may induce strategic withdrawal by firms, while over-adjustment may lead to excessive rents being given to providers.

95. When comparing prices, however, a major distinction has to be made between:

- countries considering the price of a standard "box".

  This is the standard approach, commonly used in France, Italy or Japan in the past.

- countries using sophisticated methods to obtain a proper price adjustment corresponding to the milligrams or daily defined doses of active ingredients. This approach has been used for some time in Canada or in Australia, and more recently in other countries, which have adopted reference pricing methods. Similar methods have been developed in New Zealand or in Italy more recently.

96. In the case of pricing by the "box", the price-fixing mechanism is highly vulnerable to manipulation (Abbott 1995): some minor changes of strength, packaging, or some recomposition in the chemical formula will help to make the product appear new. The new product can be artificially priced higher for the same therapeutic properties. This substitution results in disguised inflation, not measured by usual statistical indices (See box, the challenge of price measurement).

97. Reference price strategies have been developed for these reasons. They enable regulators to take account of only the real chemical contribution of a drug, and avoid the artificial substitution of more expensive products. This is comparable to the problem of price fixing, with an adjustment for quality: complex evaluation methods have been developed to surmount these shortcomings, including the use of at least some econometrics. As an example, in Canada, the guidelines of the Patented Medicine Prices Review board include several tests.

- For a similar chemical product, tests are performed to compare with products with a comparable molecular structure (i.e. a comparable drug denomination, with an adjustment for strength (Category 1).
- For breakthrough and substantial improvement products, international price comparisons using exchange rates averaged over the past 36 months. (Category 2).
- For similar or moderate therapeutic improvement products, therapeutic class comparison, with comparable medicines of comparable dosage. (Category 3).

98. In addition, there is an over-time adjustment using CPI and a benchmark. (See PPRMB in references for more details).

3.2.1.3 An assessment of the effects of price: some gains but also potential negative side effects

99. The effects of price controls on overall price differences have been ambiguous:

- prices tend to be lower in countries with fixed prices, much as one might expect.
- price controls may have created implicit incentives towards higher priced products, so that the price constraint is bypassed.

100. Traditional price comparisons which exhibit price differences of a general factor 2 to 3 between countries with high prices such as the United States or Germany and countries with relatively low levels such as Italy, France or Japan, are largely flawed. More work is necessary to correct the biases underlying these comparisons. More balanced results[21] from the first of these studies tend to show that:

- Price differences do exist but they are smaller than expected. There are three groups of countries:
  - the United States[22], Germany, Switzerland with relatively high prices[23].
  - the United Kingdom, Australia, Canada with relatively intermediate prices, well below the first group, with the United Kingdom at the lower end.
  - Italy, Spain, Portugal, Greece, and possibly Japan for lower prices;
  - France used to be in the third group, though at the higher end. Recently, prices have been adjusted closer to international price levels, particularly for more recent products. For example, a UK Department of health report issued in 1997 stated that French and UK prices were broadly comparable. The Netherlands used to be in the higher price group, but 1991 and 1996 reforms recent readjustments seem to have brought their situation in line with the intermediate group, with prices slightly above those of the UK in 1996. (UK Department of Health 1997).

Price differences are in fact highest for drugs introduced in the 1970s or the early 1980s. (This means that they may be more based on market power and historic brand names than on recent breakthrough research). On the other hand, price variations are less important for drugs introduced recently in the late 1980s or early 1990s, due to the increased international focus on prices for new drugs.

101. In terms of trends, prices have increased less than inflation in all countries with significant price control (Chart 17) (Italy, France, Greece, Spain, Australia, Belgium) and to a lesser extent in Sweden, Luxembourg and the Netherlands. The picture is more mixed for other countries.

Chart 17. Relative price trends for pharmaceuticals

21. See GAO 1994, Credes Lecomte Paris 1992, Danzon 1995 as examples, plus qualitative statements from Commonwealth Department of Health and Family Services (1998), or Pharmaceutical Patented Prices Review Board, 1996. See also the recent study by P. Danzon and L Chao (1998).

22. Some analysts have attributed some of the higher prices in the United States to product liability costs (Manning 1997).

23. Until recently, drug prices were relatively high in the Netherlands, approximately 20 % higher than in the rest of Europe (Ministry of Health Welfare and Sport October 1997). The Netherlands authorities hope that, following the Medicine Pricing Act introduced in 1996, these differences will be reduced.

102. Several explanations may be advanced to explain these trends. For example, unit-labour costs are generally higher and have increased in countries with free prices, as opposed to those with more stringent price mechanisms[24]. Since countries with free prices also have large pharmaceutical sectors, this suggests that free prices allow the pharmaceutical sector to attract a more qualified workforce and to invest more in RD. On the other hand, the monopoly power of producers could have led to overly generous pay settlements. Another important influence on price trends is the costs of RD. These soared at the end of the 1970s, and this may have been reflected in the price indexes.

103. In any event, one should remain cautious about the patterns apparently depicted by such traditional statistical indexes, as they suffer several biases. (See Box the challenge on price measurement). Studies have shown that there are two groups of countries:

- in a typical country with free prices, the United States, prices prove to have increased much less when a proper adjustment for quality is performed. In this respect, the pharmaceutical sector suffers from an under-evaluation of output, of both RD enhancement and price competition through generics[25]. Official statistical agencies in the United States, as well as in other countries, are trying to improve their measurement instruments.

- in a typical country with fixed prices, such as France, the price-fixing mechanism gave incentives to firms to bypass the process. The incentives built into the scheme favoured the development of "me too" products, with little innovation but higher prices. This is more significant for traditional multi-source drugs than for original new patented products. The overall effect is that a quality-adjusted price index would rise faster than does the published statistical index[26].

104. Hence measured prices have risen less in the last group than their "true" movement and more in the first group. Apart from the effects in terms of prices, the effects of price controls on spending and welfare should also be noted:

- Expenditure does not appear to be significantly lower, no matter what type of adjustment, in countries with the most stringent price control. Expenditure levels are rather high in Japan, France and Italy for example.

- Assessing welfare is more complex. Normally, consumer welfare is increased when a higher quantity of goods for a lower price is permitted. This remains however conditional on an appropriate use of medicine, and account needs to be taken of the fact that iatrogenic accidents are also a matter of frequent concern in OECD countries. The indirect effects on RD and innovation must be considered. If price-fixing policies had also been implemented in the major market for innovation in North America, the rest of the world might not have benefited from as many new products.

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24. OECD Health Data 98.

25. See the work presented for the Boskin Committee 1996, and also Berndt, Cutler, Griliches, Newhouse, Tripplett.

26. See Jacobzone (1998) for an evaluation of this phenomenon in the French context. Evidence is lacking for other countries. It appears that in countries like Australia or Canada since 1987, the possibilities for such strategic behaviour have been limited due to the way prices were fixed, whereas other countries, like Italy, may in the past have had an experience similar to the French.

3.2.2 Profit controls

105. Profit controls are used to a lesser extent (Table 14). In spite of its name, the Pharmaceutical Price Regulation Scheme in the United Kingdom has specified a permitted rate of return on capital, with an admitted rate around 17-21% with a 25% margin of tolerance, when companies submit new products. Prices for existing products cannot be raised. Drug companies are free to set their own prices but cannot exceed a predetermined profit ceiling. The government has lowered the rate of return over time and also adopted a restrictive approach as to which types of drugs would be admitted for reimbursement. Spain also relies to some sort of profit control, whereby costs are taken into account to determine prices since 1991. It was also considered in France at that time, although not formally implemented, and has influenced public policy through the subsequent implementation of the Pharmaceutical Economic Committee which is charged with undertaking global negotiations with companies. Apart from the United Kingdom and Spain, Korea, the Czech Republic, Mexico and Turkey reported that they relied on methods of profit control to regulate the industry. This applied only to domestic producers in the Czech Republic.

106. The UK scheme (Department of Health 1997) has given rise to a lot of comments, due to the very impressive performance of UK based firms in pharmaceutical markets over the last two decades, and also to the very low level of domestic expenditure handled at home by the NHS (GAO 1994a GAO 1994b, Thomas 1995). However, according to UK analysts (Bloom, Van Reenen 1998), the way the scheme is organised is not very transparent in practice. The scheme has been in operation in various forms since 1957 and does not cover generic products. It covers all licensed branded prescription medicines sold to the NHS (80% of the value of pharmaceutical sales to the NHS). Companies with annual sales to the NHS of over 20 million pounds are required to submit detailed annual financial returns (AFR) to the Department of Health. Defining the global business of a company is subject to negotiation. Return on sales is the basis for companies not based in the UK. In addition, strict restrictions on expenditure on subsidising promotion costs have been implemented. The scheme also seems to have been successful due to the ability of public authorities to establish a high quality and reliable relationship with pharmaceutical manufacturers. One should also note that it has turned the UK industry into one of the most concentrated of OECD countries, as smaller firms have almost disappeared in the UK. In addition, specific additional features of the NHS, namely a strict control of prescription, ensure that no expensive product will be unnecessarily prescribed. More recent agreements in the UK have involved some flexibility, particularly for newer products, in exchange for savings on existing drugs. (Department of Health 1997).

Table 14. Profit Controls

3.3 Public strategies for fiscal consolidation

107. With slower growth, governments have been faced with the challenge of high rising pharmaceutical expenditure, and the need to preserve financial balance in the short run. This has led to attempts at stabilising or reducing government spending on pharmaceuticals. Unilateral price freezes and price cut measures were common in the 1980s and 1990s (Table 15). They have affected countries with all types of schemes, as they occurred both in the United Kingdom, Germany, Switzerland and also in Mediterranean countries.

Table 15. Price freezes and cut measures in selected countries

108. However, even if prices were fixed, this would not necessarily control prescription volumes or spending. Hence, short-term fiscal consolidation sometimes involves levying specific taxes on the pharmaceutical industry (as such in France). In addition, in many countries, the management of the lists has been used as a tool for cost-containment. Delisting has occurred, particularly in countries with a

comprehensive scheme. For example, vitamins and various sorts of psychological stimulants were delisted in France in 1987. In addition, other demand-oriented tools have been used, such as sudden increases of co-payments. On the supply side, global expenditure ceilings have also been used (Germany). The effect of these has been ambiguous, as consumption has been substituted for products which remained subject to reimbursement, and which are sometimes more recent and expensive.

109. The overall effects of these short-term restrictions are unclear. They have largely resulted in a temporary curbing of the spending. Small reductions in public expenditure have occurred, but when these fiscal consolidation strategies were not associated with structural reforms of pharmaceutical regulation, longer term trends seem to have hardly changed. Chart 18 shows annual trends in the growth of total and public expenditure for six countries. Public spending growth has often been cut for one year: in Belgium in 1989, in Sweden in 1988, in Finland in 1992-1993, in Denmark in 1990 and in France in 1987 and 1994. In Germany, in 1989, the rise in drug expenditures by the health insurance funds was hardly noticeable as compared to the year before. This was mainly due to the reference pricing system and to a decline of reimbursed prescriptions. The significant decline in 1993 was due to several factors, including the price freeze for drugs not subject to reference pricing (price reduction by 5% and or 2% and prohibition on price increases for 1993 and 1994) and the introduction of a prescription budget. The legislative provision for compensatory payments by the pharmaceutical industry and the physicians when the budget is overrun could also have had an effect. In many cases however, public expenditure increased significantly the year after. In some cases, total expenditure on pharmaceuticals was not affected as much. The Finnish case is unusual as pharmaceutical consumption in this country, like other health care services, was affected by the very severe depression experienced by the country in 1993.

Chart 18. Trends in the measured growth rate of total and of public expenditures on pharmaceutical goods for selected countries

110. At first, global budgets may appear to be partly linked to these schemes. However, everything depends on the way they are formulated and for what medium term circumstances they were designed. Global budgets have been developed by two countries with high levels of expenditure, France and Germany, which otherwise had no specific "managed care" features, nor any stringent control of prescription. France mainly followed the German example (Schneider 1995). In both countries a national target for drug expenditure has been set, with a financial penalty to be shared by doctors and the pharmaceutical industry if pharmaceutical expenditure exceeds a specified target. The penalty applies when the total prescriptions, whether reimbursed or not, exceed a certain target in France -- in Germany it applies to the total payments by sickness funds for drugs. This seems to have led to a significant reduction in expenditure in the short term, as doctors in both countries have reduced prescribing or substituted lower priced forms of drugs in Germany in order to respect the target. This has generally been resented by the medical profession in both countries.

111. It seems difficult both to fix *ex ante* a national target and *ex post* to share it with individual physicians unless clear objectives have been fixed and a determined structural long-term strategy has been implemented to offer structural tools to regulate individual prescription. However, general budgets appear to be useful intermediary tools, in view of the progressive implementation of appropriate economic incentives to reorient the prescription at the level of the individual physician.

3.4 The search for social and economic efficiency: towards an information-based and outcome-oriented strategy

3.4.1 Reinventing the buyers while protecting patients

112. The role of demand and "buyers" has been traditionally weak on pharmaceutical markets: OECD countries have willingly limited the traditional role of demand on pharmaceutical markets, in order to ensure wide access to pharmaceuticals along with reasonable coverage. This results in a fairly low apparent price elasticity of demand on this market, once the role of insurance is taken into account. In view of these principles, price fixing has been the traditional answer developed by OECD countries, as in a market where there was no real demand, a public monopsony had to intervene to fix prices. This has not necessarily meant that co-payments would totally be waived for everybody. In some countries, these have been increased steeply and sometimes beyond what simple economic efficiency would have advocated in order to limit excess consumption. On the other hand, co-payments certainly remain limited in many countries.

113. However, while protecting patients, there is a need to promote a "demand curve" and "buyers" on pharmaceutical markets, in order to stimulate efficiency. Recent changes in the distribution systems of some pharmaceutical markets can be seen as a trend in this direction. (See section 2.4.2). In the United States, without a universal insurance and a single monopsony, analysts have argued that a similar result could be obtained through different means: it is necessary to have a buyer, who will act on behalf of the patient while protecting his interests. These organisations can be either the managed-care organisations themselves, or their partners in the field of pharmaceuticals, the Pharmaceuticals Benefit Managers (See paragraph 51 above). Some organisations have competed to obtain lower prices from the manufacturers. In the United States, federal facilities obtain up to 40% discount on drugs, and hospital and clinics around 10% (Table 16). HMOs obtain better and lower-priced drugs through the use of Pharmaceutical Benefits Management companies. Hence, there is an agent, on behalf of the patient, who negotiates *ex ante* the price and the type of drug to be used. There has been some concern over these price differentials: proposals for uniform pricing have been formulated, although some analysts have feared that they might have an anticompetitive impact (Berndt 1994).

Table 16. Average price differences for various types of purchasers in the pharmaceutical market

114. Evaluations of these market dynamics have also shown that cross subsidies occur among customer categories. Private customers in retail pharmacies pay more in order to compensate those whom prices are bargained down. When the Medicaid extension was established, non-Medicaid consumers had to pay higher prices than before.

115. Scherer (1997) has described this strategy as a third degree price discrimination: companies sell their products at a lower price to the patients who are the most sensitive and at a higher price to those with less demand elasticity. Hence patients in the managed care sector, in Medicaid or in Federal facilities are better off while other purchasers, and in particular retail customers, are at a disadvantage. That is, the market is characterised by private monopolistic pricing, with prices being set inversely to the demand elasticity of consumers in order to extract the maximum surplus from them. The price strategy of firms also takes into account the level of therapeutic advance embodied in a new product, with higher prices set for products which offer a higher therapeutic improvement and have less competitors (Lu and Comanor 1998).

116. In any case, the strategy of firms has to be anticipated in public regulation. For example, in France, the price fixing mechanism induced firms to introduce new products in a partly artificial way in order to smooth the price-fixing constraint (Jacobzone *et al.* 1997). In Canada the results displayed by Anis

(1998) suggest that firms may envisage a global strategy for prices and that constraints on some prices for new drugs may have an impact on other prices of existing drugs. These dilemmas are faced by many countries, and particularly the medium and smaller size countries, where national authorities have to negotiate with firms operating at the world level.

3.4.2 Rationalising payments under reference pricing

117. Reference pricing means that public reimbursement is made by reference to a lower-priced available drug which can be substituted for the intended drug. This reference may be the lowest-priced drug in a given therapeutic class or sub class but will not be in all cases. When defined strictly, reference pricing only compares branded products with their generic equivalents. In a more general sense, it may involve similar products, with similar therapeutic effects, though not necessarily the same chemical formula. It means that financial decisions on whether to buy a more expensive product are shifted to the patient, as the public reimbursement is only a flat "reference" rate. This mechanism was implemented both to empower the customer, to allow health insurance to provide necessary drugs and to improve price competition on the market. Demand is thus redirected, at the patient level, with a financial incentive for the consumer to choose the best-priced products, while ensuring that essential needs can be satisfied.

118. The implementation of reference pricing was done on a larger scale in Europe in Germany, under the "Festbetrag" system and also in Denmark, the Netherlands, New Zealand and Sweden. (Table 17). The reform implemented in 1996 in Italy involves reference pricing to a large extent. Hungary has also implemented some reference pricing. It has also been partly implemented in some Canadian provinces (British Columbia[27]). This approach might be seen as more "intelligent" price fixing, where prices are fixed according to the implicit characteristics of products. In the German scheme, reference prices are the prices at which the public is reimbursed. The difference between the branded price, or more expensive prices and the reference price of the drugs with the same active ingredients or a similar pharmacology, has to be borne by the patient. This should, in theory, give him a strong incentive to be a well-informed buyer, as he normally pays the difference between the flat rate price of the equivalent drug and the price of the drug actually chosen. However, when the ability of consumers to switch to generic products is limited for example due to lack of information, this mechanism risks putting some patients at risk. Therefore reference pricing needs to be linked with a substitution right and appropriate incentives for the pharmacist in the distribution system. Apart from the countries explicitly mentioned in the table, Spain also began reference pricing in 1999 for a limited number of drugs. In addition to these countries, a certain number of countries have been mentioned as having mixed systems in table 13 which describes price controls (Belgium, the Czech Republic, Norway), as their system is in fact hybrid and may involve some reference pricing for a share of the market.

Table 17. Reference Pricing

119. One of the key issues remains the extent of the reference range within which drugs are compared. If very large, it can be questioned in pharmacological terms, but it will also be more efficient, as strategic substitutions between drugs in favour of a more expensive alternative will be more difficult. If restricted to absolutely similar products, like generics, it will be less questionable in pharmacological terms but will have a smaller impact, as in Denmark.

120. In Germany the reference pricing system provides reference prices for drugs having the same active ingredients, ingredients which can be compared pharmacologically and therapeutically, particularly

27. In this Canadian province however, the scheme reimburses the full amount for non-reference drugs in the reference category if the drug is prescribed for patient specific reasons.

with substances which are chemically related and those which have a therapeutically comparable effect, especially drug combinations. As of 1 January 1999 the reference prices for drugs shall not exceed the price at the first tercile of the distribution of products within a given reference group. (For drugs without reference prices, the health insurance reimburses the price of the drug less a fixed amount, less a pharmacy discount of 5%). The introduction of this system led to very significant savings: several billion deutsche marks every year in Germany.

121. This system has been largely developed in countries with a large public reimbursement system, and strong pharmaceutical research oriented industry, mainly in Northern Europe. In these countries, pharmaceutical spending generally increased at the same pace as the OECD average in the 1990s (see Table 4). In other countries, particularly in Southern Europe, some analysts have claimed that the gains would be smaller, as original prices were not as high.

122. The possibility of extending further such policies depends on the size of the market, which goes to mature products, as opposed to the share going on innovative products "under patent". However, such comparisons across countries are very difficult to establish, as the extent and the signification of patents may differ. This is also directly linked with the possibility of putting some segments of the market under the pressure of generic competition, which depends to the space left to generics by national legislations and patents on existing drugs. Drugs from the same class may keep only a partial innovative character and still remain under patent in some countries and not in others.

3.4.3 Fostering the use of generic drugs

123. This section discusses policies to foster the use of generic drugs. (A description of recent trends in generic drug markets can be found in section 2.4.1). In the majority of OECD countries, there are now explicit policies in this direction (See table 18). These policies may rely on information and economic incentives. As far as information and education are concerned, this includes giving advice to consumers or prescribing physicians. In many cases, guidelines have been created, as for example in Austria, Germany, New Zealand, Sweden or Switzerland. These guidelines may exist in some more or less formal way in most countries that have developed policies towards generic prescription (See also table 11). Countries differ however to the extent to which financial incentives back up these guidelines. This is the case in Australia and New Zealand for example. As far as economic incentives are concerned, they may involve several aspects. Firstly, budgeting constraints act as a financial incentive for prescribing physicians, to increasing the prescription of generics, as has been the case for the United Kingdom. Budget constraints also play a role in France, Germany, Hungary, Mexico, the Netherlands and Norway. Secondly, these economic incentives may also have an impact on the consumer, as is the case in reference pricing systems, which also as a result increase the use of generics. On the whole, generics appear to have only developed where strong financial incentives had been implemented, with an impact on patients, pharmacists and/or prescribing physicians. This involves prescribing in International Common Denomination for physicians, substitution rights for pharmacists, and incentives for patients to buy generic drugs. The situation with generics may evolve very rapidly and the view depicted here using the answers to the OECD questionnaire offers only a partial picture, as this is an area of current policy development in many countries.

Table 18. Prescription of generics

3.4.4 Sharing the costs of RD and promoting future innovation

124. Following the discussion on the role of R&D and its costs (Section 2.2.1), this section discusses the need to find appropriate incentives to make sure that these costs can efficiently be met to promote future innovation. Governments are both price regulators and often, the dominant purchasers of new drugs,

on behalf of the patients in public health insurance systems. Hence, the market for patented drugs resembles a bilateral monopoly. Indeed, there might be incentives to "free riding" in paying for innovation across countries. In a bilateral monopoly context, there is a dilemma for governments on how to determine prices for patented drugs, taking into consideration both production costs and private monopoly prices. The regulation of this process and the pricing of patented drugs requires national authorities to balance their desire to disseminate important new drugs as quickly as possible at as low a price as possible with the need to allow profit rewards in the interests of preserving the long term incentives for important innovations.

125. The stock of past innovations can be considered as a public good, and a global fixed cost, that must be met in order to preserve future research. The fees for access to this public good are a condition for enjoying access to the flow of modern therapeutic innovation. From this perspective, the pharmaceutical industry can be seen as a "network" industry with RD as a core asset representing important fixed costs (Abbott 1995, Danzon 1995, Jacobzone 1998). In this respect, the regulation of the pharmaceutical industry bears some similarity to the regulation of traditional spheres of publicly regulated activities, with high fixed costs, such as electricity or telecommunications. As production costs by themselves are low, the issue is how to pay efficiently for R&D to reward important innovations. In theory, the problem is simple: one should try to obtain existing non-patented pharmaceuticals at their lowest cost, possibly the production cost, in a "cost plus" perspective. For patented drugs, in addition to production cost, a certain reward should be given for innovation, through a specific method of payment for reimbursing the fixed cost of innovation. Even if they cannot be implemented in practice, theoretically prices involve a binomial payment:

- a fixed charge, to be "connected" to the inflow of modern innovation.

- a fee according to the use, to meet production costs.

126. Several OECD countries are attempting to solve this problem. The reference pricing and the generics competitive approach represents an attempt to obtain the best possible prices for existing older products, while reserving all the consumer surplus to pay for the newer more expensive products. However, such buying does not help determine how to handle new products.

127. OECD countries differ greatly in their respective interest in the field of RD. Some have a large RD based industry, and are in part benefiting from higher prices while others, without a strong RD base, are tempted to refuse to pay for RD which does not promote their own scientific and production systems. In Australia, the payments for RD are allocated to the industry through the factor "F" scheme, introduced in 1988 and now called the Pharmaceutical Industry Investment Program (PIIP) (Pharmaceutical Benefits Pricing Authority 1997). The scheme gives explicit contracts to eleven companies, either local or based in other countries[28], granting additional support in the event of their locating part of their RD activities in Australia. Factor F scheme entitlements can be taken as such through a direct subsidy or can be obtained through higher prices for the companies participating in the scheme. Zeckhauser and Johnston (1991) provide an economic analysis of the scheme. Although similar policies could not be developed in Europe, due to EU common market rules, government decisions in many European countries have tried implicitly to exchange higher prices for location decisions in favour of their own country. In Canada, increases to patent protection were contingent on industry commitments to increase RD spending from 5% to 10 % of sales. In short, public authorities in OECD countries, are often ready to allow prices to reflect the high cost of RD, provided it benefits their own economy.

128. Specific mention should be made for the case of *orphan drugs.* These drugs usually concern too small a proportion of patients to give manufacturers strong market incentives to develop appropriate drugs.

28. Three other were refused and and have appealed to the Federal Court.

Hence, public authorities have had to develop explicit strategies to ensure that those fields of research were not neglected. In doing so, they have often followed United States guidelines for such drugs.

3.4.5 The contributions and limits of managed care strategies

129. The development of innovative forms of markets in the United States has often been used as a sort of *in vivo* social experiment by other countries. Most of the regulatory reforms driving pharmaceutical markets in the OECD area have been influenced by policies originating in the United States. The development of more aggressive buyers on the US pharmaceutical market has also stimulated the creation of actors such as PBMs. They have also brought about a more integrated view of the health care system, making extensive use of information by the HMOs.

130. Managed care organisations have both used older tools, developed earlier by public schemes in other countries and developed genuinely creative approaches for certain diseases. For example, in order to control cost, instead of specifying a standard co-payment for all drugs, they have designed a list of drugs through formularies and within this list have often determined the rate of co-payment according to the type of drug (generics or non-generic). Table 19 shows that use of formularies is associated with the extent of integration in the HMO. 66% of staff model original HMOs, the most cost saving-oriented form of managed care, had formularies recently but only 39% of the more attenuated Independent Practice Association (IPA) model of managed care controlled by physicians had it. They also intensively use positive lists and reference prices for reimbursement.

Table 19. Share of US HMOs with closed formularies

131. In the era of computerised information, another important strategy has been debated and implemented in the pharmacoeconomics arena: disease management. This is mostly appropriate for chronic patients, and aims at offering the best global answer to their structural health problems. This answer will aim at avoiding as much as possible unnecessary and costly hospitalisation, monitoring drug consumption to track adverse events, increasing prevention and improving patient compliance. To be implemented it requires a strong sharing of information on the distribution system, to allow the HMO to effectively monitor consumption. Not surprisingly, asthma and diabetes have been the main targets for such programs.

132. In spite of these efforts, financial pressure remains high for HMOs. They face similar problems to those faced by public schemes run by public authorities in other countries, and may have to either delist certain pharmaceuticals, raise premiums or increase co-payments.

3.4.6 Improving the cost-effectiveness of prescription and educating patients

133. Improving the appropriate cost-effective use of pharmaceuticals will only be possible through extensive collaboration with the medical profession. Many OECD countries have developed and improved their prescription guidelines (Mitchell 1996) without however strictly linking them in a systematic way to financial incentives in the way that Fundholding did in England. OECD countries have often fixed arbitrary limits of consumption, either per day, per episode of care or per physician, but no clear picture has emerged of the results (See Table 12). The OECD questionnaire reports explicit policies for the reduction of the volume of wasted drugs in a majority of countries. These may involve restrictions in the volume of prescription per episode, consumer education and rules regarding packaging by manufacturers (Table 20). On-the-job training for prescription in favour of more cost effective prescribing should be offered more extensively to doctors. In addition, in the majority of OECD countries, there is (at least in theory) an encouragement now for generics prescription (see section on generics).

Table 20. Reduction in the volume of wasted drugs

134. The cost-effectiveness of prescription can also be improved using prescription guidelines. These guidelines exist now in Australia, Austria, Denmark, France, Germany, Greece, Hungary, Japan, Korea, Mexico, the Netherlands, New Zealand, Norway, Sweden and the United Kingdom. Where sanctions are possible, more information is needed on their explicit roles and objectives, on how they are enforced and what are the precise economic incentives built into them. For example, in association with an improved economic evaluation for drugs, the Australian approach includes economic criteria in the prescription guidelines, in addition to their use in the drug market entry authorisation (Table 11).

135. Further efforts at improving the cost-effectiveness of prescribing require to study and influence the therapeutic decision making of physicians (Denig, Haaijer Ruskamp 1992). Several studies document the possibility that some feedback and co-operation with prescribing physicians may change their behaviour. This has been reported to be feasible in improving asthma treatment (Veninga et al. 1999). A review of the literature (Haaijer Ruskam and Denig 1995b) shows that several methods can be used to influence physicians' prescribing behaviour, including use of printed materials, one-to-one education, targeted lectures, and individual feedback combined with discussions in a peer group. However the type of feedback and evidence used to support the feedback are important in determining their impact on prescribing physicians (O'Connel et al. 1999). The results also show that the best way to drug education for general practitioners is a combination of different approaches.

136. Finally, cost-effectiveness of prescription can only be improved with patient participation and approval. Providing more quality information to patients and enabling them to make well-informed choices seems to be one of the challenges lying ahead. Some analysts have expressed fears that the regulation may have gone to far, denying consumer information rights and undermining consumer's self participation in the drug selection process (Temin 1990). The recent cases of AIDS-related drugs has shown the importance of powerful and well-informed consumers in the market. However, there is a need to channel information properly, in a context where marketing pressure can exert strong effects on public opinion.

Box: The challenge of price measurement

Although prices have always been a key factor in strategies for the regulation of pharmaceutical supply, their analysis requires complex investigation. In pure economic terms, the price of a pharmaceutical product is the price of a health gain, which is traded against production costs. In practical terms, people buy boxes or bottles, including certain quantities of composite elements. The whole difficulty lies in the fact that ordinary statistical measurement considers prices of boxes and their evolution rather than getting into the true nature of the product, taking into consideration its therapeutic properties. Normally, prices should make it possible to compare costs of drug therapy to customers. Therapies, however, are made up of heterogeneous elements.

The main point is to decide whether two different products, with similar therapeutic elements directed at common health-oriented diseases (e.g. antihypertensive drugs, aspirin and paracetamol, branded drug and generic) are essentially different or not. In fact, most traditional indices and international comparisons would consider them as different products, with the following consequences:

- *in terms of price indices, when new products enter the market, their price are not compared with existing products. Their entry and gains of market share have no impact on the evolution of prices.*

- *in terms of price levels across countries. Different structures of consumption of similar drugs for the same treatment, are treated as different baskets of goods, with no impact on price levels.*

For an economist these are false assumptions. If they are maintained, the dynamics of pharmaceutical markets and the impact of intense marketing will not be measured. The actual tendency has, in fact, been oriented towards:

- *the introduction of less priced identical products, with generics introducing competition in mature markets with high prices.*

- *the introduction of marginally different new products, in markets with regulated prices, with "me too" innovation, often pushing consumption towards similar, but more expensive products.*

Hence, the difficulty in understanding the true story behind international comparisons: why countries which supposedly have low prices,(apparently one-third or one-half of other countries, such as Italy, France, Portugal), have consumption levels closer to or higher than those observed in countries with high prices, such as Germany, the United States ? The reason is largely that the prices used in these comparisons are calculated using rough methods and do not allow for comparing heterogeneous products.

In more technical terms, traditional studies have often suffered from the following limitations:

- *weighting. They compared different aggregates of consumption but did not compare them with an adjustment for a common consumption structure. Also, packaging difficulties led to major weighting difficulties in comparing prices.*

- *selection bias. Comparisons were made using only particular products which had very different market shares across countries. For example, they do not include generics or parallel imports in*

high price level countries[29], as these products would be marketed through different distribution channels from those observed by the compilers of indexes[30].

- *not observing true final prices. This is particularly true for the United States, where different buyers pay different prices (see Table 11).*

- *integrating additional adjustments: litigation and distribution costs. Although there may be some discussion of the relevance of adjusting prices for such elements, it has been shown that distribution systems had different margins across countries and also that litigation costs can push prices up in some countries, particularly the United States. Hence, prescription drug price comparisons, through not taking into account the effects of different legal systems, can result in substantial bias (Manning 1997). However, the final consumer still has to bear these costs (e.g., through paying higher fees to physicians so they can pay liability insurance premiums), even if these do not accrue to the pharmaceutical producers themselves. Therefore, comparisons ought as much as possible to compare final prices of pharmaceuticals as well as production prices.*

Methodological problems in measuring price levels have been recognised both in academic and official reports. These difficulties are not unique to the drug industry and exist in most sectors where technological change plays an important role. However, they are felt more acutely for pharmaceuticals due to reimbursement systems and government intervention in the field of prices. This played a part in the discussions held under the Boskin Commission in the United States (Boskin et. al. 1996). In France, the French Health Accounts Commission held a working party on drug prices in 1993 (see references). The construction of better adapted price indices requires however very intense methodological development.

In the United States several official reports by the GAO (GAO 1992, GAO 1994) have addressed the issue of price comparisons. Individual analysts have themselves either criticised these or proposed alternatives (Danzon 1995). In Canada, the Patented Medicine Prices Review Board (PMPRB) has published results from international comparisons, (step I and II, see PMPRB (1993)a, (1993)b. It has also explicitly developed a methodology for international comparisons used in price fixing. The same is true for example for Australia (Australia Pharmaceutical Benefits Pricing Authority (1997) or Sweden (Ljungkvist 1997).

All these methodological efforts attempt to solve the mentioned difficulties by considering at some level the chemical properties of the drug itself. The studies have dealt with this at three levels:

- *comparing pure identical chemical substances. This is the case for generic drugs which are the same as the branded product. These comparisons are more limited and are concentrated on packaging and strength issues. They are often used in price-fixing mechanisms, whether in Germany (Reher* and *Reichelt 1993), Australia or Canada.*

29. Estimated at 6% of the market in the United Kingdom, 2 % in Germany, 3% in Denmark and 12% in the Netherlands, Mossialos (1997).

30. *For the US, for fiscal and historical reasons, roughly 20 to 25% of the US pharmaceutical production is manufactured in Puerto Rico (Berndt et. al. 1998), and was not integrated into the official production price statistics published in the past by the BLS.*

- *comparing similar chemical substances. This comparison aims at counteracting the partly artificial product differentiation embodied in some products, by considering them jointly. This has been done for international comparisons, by looking at the level of the sub-therapeutic class itself (e.g. for anti ulcer drugs, H2 blockers, proton pump inhibitors, etc. in Lecomte Paris 1994). This is also done by the Australian Pharmaceutical Benefits Pricing Authority to some extent, to avoid approving price increases for similar products.*

- *jointly integrating several chemical substances in a certain therapeutic class. This method makes it possible to consider multiple source and composite products, broken down for their elementary chemical properties expressed in Daily Defined Doses (DDDs). This is the strategy followed in Jacobzone et. al. (1998) but requires a potentially intensive effort to classify all drugs. This might be possible for a given country, but would require further consensus at an international level, although a model exists on existing standard agreements on the DDDs.*

International comparisons of price levels to be reliable should first use comprehensive statistical data, encompassing as many aspects of the market as possible. (For this, they may use the data produced by the company IMS Health in many countries, as this is often the official source of national studies themselves, and has been quite successfully used by Lecomte Paris 1994, but only for a single year and for a limited set of drugs, and a limited set of countries.) Second, they should aim at considering comparable "homogeneous" groups of products, to reduce product heterogeneity at a fair level.

In addition to the issues raised in terms of cross-section comparisons, these shortcomings may also affect the comparison of price trends themselves. Basically, a wealth of results has demonstrated that considering new products as different varieties leads to a bias in the price index (for a survey see Berndt, Cutler, Frank, Griliches, Newhouse, Triplett 1998)[31]. The price index is biased upwards when new products are similar and lower priced and it then overestimates the true rise in prices. On the other hand, when new products are similar and more expensive, the price index is biased downwards.

In countries where the problem was raised, the statisticians have acknowledged the difficulty both for producer and consumer price indices (e.g. in the US Fixler Ginsburg 1998, Ford I.K., Ginsburg D.H. 1998). They have addressed it mainly by proposing to treat generics as similar products and enhancing the composition of the basket of goods (Kelly 1997). These attempts are addressing the issue of generics but remain insufficient to address the issue of marginal innovation with similar goods, which requires further work (Jacobzone 1998) often too costly to be performed by statistical agencies themselves. Finally, a more ambitious study, encompassing other health related activities, has also advocated a cost of living approach, integrating all treatment components, together with a value for mortality reduction (Cutler, McClellan, Newhouse, Remler 1998). It refers, in theory, to the true "validity" of a price index, measuring welfare levels for a certain basket of goods. However, lack of data and operational problems mean this is only a long-term prototype.

31. For a list of the most significant of these studies, see Fisher F., Griliches Z. (1995), Griliches Z., Cockburn I. (1995), Berndt E., Cockburn I., Griliches Z., (1996), Suslow (1995), Griliches Z., Berndt E. (1993), Berndt E., Griliches Z., Rosett (1993), Cockburn I., Anis A. (1998).

CONCLUSION

137. Pharmaceutical consumption is affected by relative income levels and prices but also depends on national regulations. If pharmaceuticals represent a small share of GDP, they are a key component of health care systems and a significant component of both public and total health care expenditure. Their share is relatively higher in countries with lower relative income.

138. In the field of pharmaceutical activity, health policy and industry policy objectives have to be considered jointly. It is crucial to analyse both the role of RD and the evolution of company costs. While the costs of RD have certainly increased -- and part of this increase has been the result of stringent market entry regulation and technological progress -- marketing costs have also increased in many countries. Data on the market share of generics information remains insufficiently developed, although it seems that these drugs are more widely distributed in North America and in Northern Europe than in the rest of OECD countries.

139. In terms of policy to influence demand, this study shows that there seems to be a wide consensus. As demand by patients is price elastic, and as total coverage would be too costly, cost sharing is the rule in many countries, counter balanced by exemptions on the grounds of either health status or social need.

140. In terms of supply, most OECD countries regulate prices, and only a few regulate profits. The variety of institutional arrangements affecting prices is rather high. Two rather different groups of OECD countries with different interests can be identified. The first group of countries has strong RD based national pharmaceutical manufacturing sector, and has implicitly an interest in high prices, although it may be costly for some of its own consumers. Until recently, this first group of countries included some countries with free prices, some which regulate profits, and some with a looser form of price regulation. All these allowed important returns for manufacturers. The second group of countries includes all the countries without an important national drug industry. All these countries have a general interest in having lower-priced drugs, although some may wish to attract or to retain some pharmaceutical RD at the national level. Even if pharmaceutical prices could be harmonised, it should also be remembered that countries may differ in their ability to pay for pharmaceuticals. There are significant income disparities across OECD countries: the less privileged countries may need international prices to be adjusted to their own purchasing power. However, this should not hide the fact that financing RD and pharmaceutical innovation are analogous to a public good, which in some sense has to be shared at the international level. Therefore, preserving appropriate incentives for innovation should also be viewed as a fruitful area for international collaboration.

141. Important methodological progress has been made in recent years in understanding the effects of price fixing and in the issues of price measurement. When generics enter the market, prices measured by statistical indices are often biased upwards, while the contrary is possible where prices are theoretically fixed and the generics market share remains low.

142. A certain consensus is also emerging for public reimbursement of expenditure on existing non-patented drugs, even if the mechanisms used may differ. Under reference pricing related arrangements, the price subject to reimbursement, or the public subsidy for drugs, which are reimbursed, should be a function of the therapeutic properties of cheaper comparable alternative drugs. Countries differ greatly in the practical implementation of this principle depending on their social and economic system. Some countries have made it the mission of a public body, either the government itself or a publicly run agency to fix the

price using such standards (E.g. Australia). Some countries fix a level of public reimbursement, through a reference pricing mechanism. (e. g. Germany), although this applies only to a part of the market. The number of countries using reference pricing is growing, particularly in Europe. Some countries rely upon market mechanisms, ensuring for wide use of generics, through competitive pressure on prices by buyers acting on behalf of the patients (e.g. United States).

143. This leaves partly unsolved the issue of innovative patented drugs, which represent a real therapeutic breakthrough with few substitutes. Some countries have chosen to regulate their price, even if they do not regulate the price of other drugs (Canada). Some countries have left their prices free, as in the United States, in Germany and the United Kingdom. However, due to the high pressure on public funds, at times, prices have been arbitrarily cut for all these drugs even in these countries, as totally free prices are difficult to sustain. Most other countries regulate these prices. In this field however, international price comparisons are a key element used by all OECD countries in negotiating with pharmaceutical companies to obtain a "fair" price. Another way of looking at the issue is to ask: what should each country contribute to resources for future useful innovations, by paying for innovative drugs? This does not necessarily require homogeneous prices for all products at the world level. It may be achieved in different ways, such as fixed access fees, combined with proper adjustment for the relative wealth of countries. While amongst OECD countries this only has a major impact in a minority of relatively less wealthy countries, this is an area of major concern among developing countries.

144. Several areas could be investigated for future investigation following this report. At the international level, it seems important to further study the comparability of pharmaceutical markets across OECD countries, so that drugs are compared on the basis of their therapeutic properties, using common descriptive denominations at the international level. This would provide answers to the key issues surrounding quality-adjusted price comparisons. More detailed information about co-payments could be gathered, in terms of the special groups exempted and the global impact of out of pocket expenditure. A common international agreement on the definition and measurement of generics should be developed to supplement the existing uneven information.

145. As pharmaceuticals represent a significant cost driver in the health care systems of most OECD countries, it would be useful and important to build on this report. Future work could consist of monitoring the impact of introductory prices of new medicines on total drug expenditures, and evaluating the effectiveness or impact of price regulation and cost containment measures, e.g., controlling drug prices and utilisation, used by OECD countries to control rising drug expenditures. This would allow countries to benefit from others' experiences.[32].

146. This may help to further co-ordinate drug policies. Pharmaceutical pricing practices show a great diversity in the way they balance strategies for achieving common goals. The importance of these international aspects have been embodied in European policies, with pan European organisations such as the European Agency for the Evaluation of Medicinal Products (EMEA) and regulations for market access at the European level. At the same time, health policy retains distinctive national characteristics in European countries. Comparisons of national experiences and results can be useful for developing more efficient patient-oriented health care systems.

32. For example, international studies are underway in Canada, comparing the Canadian national system "Pharmacare" with other countries.

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ANNEX TABLES

Table 1. **Total and public expenditure on pharmaceuticals good as a percentage of gross domestic product (GDP)[1]**

	Total				Public			
	1970	1980	1990	1996	1970	1980	1990	1996
Australia	0.8	0.6	0.7	1.0	0.4	0.3	0.3	0.5
Austria	0.9	0.8	0.9	1.1	0.5	0.5	0.5	0.7
Belgium	1.1	1.1	1.2	1.4	0.7	0.7	0.5	0.6
Canada	0.8	0.6	1.0	1.2	0.0	0.2	0.3	0.4
Czech Republic	n.a.	n.a.	1.1	1.9	n.a.	n.a.	1.0	1.5
Denmark	0.6	0.6	0.6	0.7	0.2	0.3	0.2	0.4
Finland	0.7	0.7	0.8	1.1	0.2	0.3	0.4	0.5
France	1.4	1.2	1.5	1.6	0.9	0.8	0.9	1.0
Germany	1.0	1.2	1.2	1.3	0.6	0.9	0.9	1.0
Greece	1.4	1.2	1.3	2.0[2]	0.6[2]	0.8[2]	0.6[2]	1.2[2]
Hungary	n.a.	n.a.	0.3	1.9	n.a.	n.a.	1.6*	1.4[2]
Iceland	0.8	1.0	1.2	1.3	0.3	0.5	0.9	0.9
Ireland	1.2	1.0	0.8	0.7	0.6	0.5	0.5	0.5
Italy	0.7	1.0	1.5	1.4	0.7	0.7	1.0	0.6
Japan	n.a.	1.4	1.3	1.5	n.a.	n.a.	0.8	1.0
Luxembourg	0.7	0.9	1.0	0.8	0.6	0.8	0.8	0.6
Netherlands	0.4	0.6	0.8	0.9	0.3	0.4	0.5	0.6
New Zealand	0.7	0.8	1.1	1.1	0.5	0.6	0.8	0.8
Norway	0.3	0.6	0.6	0.7	0.1	0.3	0.4	0.6
Portugal	0.4	1.2	1.6	2.2	0.3	0.8	1.0	1.4
Spain	n.a.	1.2	1.2	1.5	0.8	0.8	0.9	1.1
Sweden	0.5	0.6	0.7	1.1	0.3	0.4	0.5	0.8
Switzerland	0.9	1.0	0.7	0.8	0.3	0.5	0.4	0.5
Turkey	n.a.	0.4	0.9[2]	1.1	n.a.	0.3	0.4[2]	0.9[2]
United Kingdom	0.6	0.7	0.8	1.1	0.4	0.5	0.6	0.7
United States	0.9	0.8	1.1	1.2	0.0	0.1	0.1	0.2
OECD average[3]	**0.8**	**0.9**	**1.0**	**1.2**	**0.4**	**0.5**	**0.6**	**0.7**

Notes: in percentage, n.a. non available, * data was interpolated.
(1) Korea, Mexico and Poland are not included due to lack of data.
(2) Data differ from OECD health database due to differences in concepts.
(3) The unweighted average does not include Czech Republic, Hungary, Japan, and Turkey.
Source of data: OECD Health data 1998.

Table 2. **Total expenditure on pharmaceutical goods as a percentage of total health expenditure**[1]

	Total			
	1970	1980	1990	1996
Australia	14.1	7.9	8.9	11.6
Austria	16.2	10.9	13.2	14
Belgium	28.1	17.4	15.5	17.9
Canada	11.2	8.4	11.3	13.6
Czech Republic	n.a.	n.a.	21	25.5
Denmark	9.1	6.4	6.7	8.5
Finland	12.6	10.7	9.4	14.4
France	23.2	15.9	16.7	16.8
Germany	16.2	13.4	14.3	12.3
Greece	25.5	18.8	16.9	23.8[2]
Hungary	n.a.	n.a.	5[2]	28.8[2]
Iceland	16.1	15.9	15.7	16.5
Ireland	22.2	10.9	11.7	10.6
Italy	14.5	13.7	18.3	17.9
Japan		21.2	21.4	21.2
Luxembourg	19.7	14.5	14.9	11.7
Netherlands	7.5	7.9	9.6	10.8
New Zealand		11.9	13.8	14.5
Norway	7.8	8.7	7.2	9
Portugal	13.4	19.9	24.9	26.3
Spain		21	17.8	20
Sweden	6.6	6.5	8	13
Switzerland	19.1	15.2	8.2	7.6
Turkey	n.a.	n.a.	25[2]	28.9[2].
United Kingdom	12.5	12.8	13.7	16.1
United States	12	8.7	8.6	9.4
OECD average[3]	15.4	15.4	15.4	15.4

Notes: in percentage, n.a. non available, * data was interpolated.
(1) Korea, Mexico and Poland are not included due to lack of data.
(2) Data is subject to revisions and may differ from OECD health data base due to differences in concept.
(3) The unweighted average does not include Czech Republic, Hungary, Japan, and Turkey.
Source of data: OECD Health data 1998.

Table 3. **Total and public expenditure on pharmaceutical goods per capita[1]**

	Total						Public					
	1970 (3)	1980 (3)	1990 (3)	1996 (3)	1990/1980 %	1996/1990 %	1970 (3)	1980 (3)	1990 (3)	1996 (3)	1990/1980 %	1996/1990 %
Australia	110.1	97.0	137.7	202.0	142.0	146.7	60.7	42.9	61.2	100.0	142.7	163.4
Austria	98.7	134.3	187.1	247.0	139.3	132.0	57.0	87.7	107.1	146.0	122.2	136.3
Belgium	140.5	186.5	228.3	306.0	122.4	134.0	83.5	108.2	107.1	139.0	99.0	129.8
Canada	106.3	111.9	224.8	258.0	200.9	114.8	3.8	28.0	73.0	93.0	260.8	127.4
Denmark	72.1	98.9	111.8	165.0	113.1	147.6	34.2	44.8	43.5	83.0	97.3	190.6
Finland	79.7	104.5	143.6	209.0	137.5	145.5	26.6	48.5	68.3	97.0	140.8	142.1
France	182.2	207.0	301.3	337.0	145.5	111.8	117.7	134.3	183.6	207.0	136.7	112.7
Germany	106.3	162.3	214.2	289.0	132.0	134.9	68.3	119.4	156.5	210.0	131.1	134.2
Greece	98.7	121.2	140.1	259.6 [2]	115.5	185.3	49.2 [2]	63.7 [2]	85.7 [2]	154.1 [2]	134.7	179.7
Iceland	83.5	171.6	254.2	312.0	148.1	122.7	38.0	87.7	178.9	205.0	204.1	114.6
Ireland	83.5	93.3	103.6	126.0	111.1	121.6	41.8	48.5	67.1	99.0	138.3	147.6
Italy	83.5	149.2	284.8	284.0	190.9	99.7	79.7	104.5	189.5	114.0	181.4	60.2
Japan	n.a.	207.0	273.1	349.0	131.9	127.8	n.a.	n.a.	167.1	230.0	n.a.	137.6
Luxembourg	110.1	164.1	262.5	250.0	159.9	95.2	91.1	141.8	222.5	202.0	156.9	90.8
Netherlands	57.0	98.9	149.5	193.0	151.2	129.1	41.8	67.2	100.0	124.0	149.0	123.9
New Zealand	91.1	111.9	164.8	194.0	147.2	117.7	68.3	91.4	122.4	137.0	133.9	111.9
Norway	38.0	102.6	115.3	174.0	112.4	150.9	15.2	42.9	90.6	137.0	211.2	151.2
Portugal	22.8	97.0	180.1	282.0	185.7	156.6	15.2	65.3	111.8	178.0	171.3	159.2
Spain	n.a.	126.8	170.7	223.0	134.6	130.7	64.5	82.1	122.4	166.0	149.1	135.6
Sweden	68.3	102.6	141.2	218.0	137.7	154.3	41.8	74.6	101.2	155.0	135.7	153.1
Switzerland	182.2	225.7	169.5	190.0	75.1	112.1	57.0	98.9	94.2	116.0	95.2	123.2
United Kingdom	68.3	106.3	155.4	218.0	146.1	140.3	45.6	69.0	103.6	138.0	150.1	133.2
United States	163.3	177.2	282.5	344.0	159.4	121.8	7.6	13.1	30.6	50.0	234.4	163.4
OECD average[4]	**97.5**	**134.5**	**188.2**	**239.7**	**141.6**	**131.3**	**47.7**	**73.1**	**106.7**	**136.9**	**154.9**	**133.4**

Notes: n.a.: not available. For each country, expenditure levels for the given years are calculated in US$ at current exchange rates. These are then expressed in constant 1996 US$.

(1) Czech Republic, Hungary, Korea, Mexico, Poland and Turkey are not included due to lack of data.

(2) Data differ from OECD health database due to differences in concepts.

(3) Constant 1996 US$ per capita.

(4) The unweighted average does not include Japan and Spain.

Source of data: OECD Health data 1998.

Table 4. **Non-prescription drugs, and over the counter drugs (OTC), 1996**

	Consumption		Share of non prescription drugs in total drug consumption	
	1996 US$PPP per capita		in %	
Australia	131	**	50	*1
Austria	31		12	
Belgium	57		19	
Canada	n.a.		29	***
Czech Republic	40		17	
Finland	27		13	
France	105		31	
Germany	103		35	
Hungary	29		17	
Ireland	22		17	
Italy	32		11	
Japan	n.a.		23	***
Netherlands	30		15	
Norway	13		7	
Portugal	33		12	
Spain	33		15	
Sweden	17		8	
Switzerland	84		44	
United Kingdom	44		20	
United States	110		32	
OECD average	**52**		**21**	

Notes: For most countries, the definition corresponds to non prescription drugs. For the United States, the definition may be a little different (OTC) due to specific market characteristics (see figure 2 and box 1 for definition of the pharmaceutical market).

(1) Denmark, Greece, Iceland, Korea, Luxembourg, Mexico, New Zealand, Poland and Turkey are not included due to lack of data.

(2) The unweighted OECD average does not include ...

n.a.: not available, *Data was interpolated, **data from 1995, ***data from 1994, ****data from 1993.

*1 The Australian data for the share of prescription in total drug consumption results from a slightly different definition (OTC) and should be treated with caution

Source of data: OECD Health data 1998.

Table 5. **Trends in pharmaceutical production, 1970-1995, (million US $, current exchange rates, constant 1995 dollars)[1]**

	Value	**Share**	**Value**	**Share**	**Value**		**Share**	**Value**		**Share**		**Evol.**	**in %**
	1970	(3)	1980	(3)	1990		(3)	1995		(3)		1990/1980	1995/1990
Australia	752	1.4	1412	1.4	1693		1.0	1777	***	0.9		119.9	105.0
Austria	372	0.7	1101	1.1	2115		1.3	2305	*	1.2		192.2	109.0
Belgium	1242	2.3	2298	2.2	2793		1.7	4520		2.3		121.5	161.8
Canada	1481	2.7	1951	1.9	3897		2.4	3540	*	1.8		199.7	90.8
Denmark	247	0.4	856	0.8	1707		1.0	2070	*	1.1		199.3	121.3
Finland	95	0.2	390	0.4	653		0.4	458	*	0.2		167.6	70.1
France	5437	9.9	12637	12.3	17361		10.5	20994		10.7		137.4	120.9
Greece	186	0.3	425	0.4	692		0.4	522	**	0.3		162.7	75.4
Japan	10388	18.8	23187	22.5	37475		22.6	47441	*	24.2		161.6	126.6
Korea	364	0.7	2000	1.9	5966		3.6	8471		4.3		298.4	142.0
Netherlands	1128	2.0	2410	2.3	2924		1.8	3178	**	1.6		121.3	108.7
Norway	68	0.1	218	0.2	520		0.3	611	***	0.3		238.4	117.4
Portugal	213	0.4	507	0.5	758		0.5	656	*	0.3		149.4	86.5
Spain	2274	4.1	5262	5.1	7627		4.6	7154	*	3.7		144.9	93.8
Sweden	478	0.9	1173	1.1	2398		1.4	3268	*	1.7		204.3	136.3
United Kingdom	4814	8.7	10586	10.3	14376		8.7	15183	***	7.7		135.8	105.6
United States	25598	46.4	36509	35.5	62620		37.8	73763	*	37.7		171.5	117.8
OECD sub total[2]	**55137**	100.0	**102923**	100.0	**165573**		100.0	**195911**		100.0		**160.9**	**118.3**
		(4)		(4)			(4)			(4)			
Germany	n.a.	n.a.	16008	15.6	20769		12.5	20268	*	10.3		129.7	97.6
Italy	6713	12.2	7842	7.6	12712	** **	7.7	n.a.		n.a.		162.1	n.a.
Mexico	n.a.	n.a.	3292	3.2	2768		1.7	3063		1.6		84.1	110.6
Switzerland	n.a.	n.a.	n.a.	n.a.	n.a.		n.a.	6472		3.3		n.a.	n.a.

Notes: For each country, production levels for the current year are expressed in US$ at current exchange rates.
These are then converted to constant 1995 dollars using the overall GDP deflator. n.a.: not available, * Data from 1994, **data from 1993, ***data from 1992, **** estimation from UNIDO, Balance 1992.
(1) Czech Republic, Hungary, Iceland, Ireland, Luxembourg, New Zealand, Poland and Turkey are not included due to lack of data.
(2) This sub total does not included Germany, Italy, Mexico and Switzerland to ensure time consistency.
(3) Percentage of OECD sub total bellow.
(4) Share as of above sub total.
Source of data: OECD Health data 1998.

Table 6. **Exports, imports and trade on pharmaceutical goods**

	1980			1985			1990			1996						
	Exp	Imp	Trade	Exp	Imp	Trade	Exp	Imp	Trade	Exp		Imp		Trade		
Australia	84	170	-86	83	242	-159	172	705	-532	705		1516		-812		
Austria	201	350	-149	254	340	-86	696	940	-245	1353		1975		-622		
Belgium	669	655	15	662	547	116	1632	1510	123	4302		3453		850		
Canada	114	356	-242	165	424	-259	229	860	-631	675		3024		-2349		
Czech Republic	m	m	m	m	m	m	m	m	m	152		659		-506		
Denmark	308	205	102	456	223	233	1183	515	668	2312		862		1450		
Finland	58	134	-75	63	149	-86	156	416	-260	205		631		-426		
France	1497	701	796	1536	787	749	3829	2651	1179	7247		5724		1523		
Germany	2272	1291	981	2368	1361	1006	5883	3469	2414	10552		6941		3612		
Greece	22	161	-138	37	123	-86	65	343	-279	70	**	645	***	-574	***	
Hungary	m	m	m	m	m	m	m	m	m	310		465		-155		
Iceland	m	11	m	m	12	m	1	30	-30	7		49		-42		
Ireland	166	156	10	198	179	20	960	425	535	2784		739		2045		
Italy	688	652	35	857	962	-105	1497	2794	-1298	4281		4617		-336		
Japan	295	1074	-779	391	1292	-901	877	2849	-1972	1889		4502		-2612		
Korea	56	126	-70	70	185	-115	191	515	-324	431	**	1162		-577	**	
Luxembourg	669	655	15	662	547	116	2	2	0	4	**	3	**	1	**	
Mexico	m	m	m	m	m	m	90	271	-181	423		698		-275		
Netherlands	619	569	50	610	581	29	1516	1450	66	3341		3243		97		
New Zealand	12	91	-79	24	111	-87	32	242	-209	80		372	**	-300	**	
Norway	36	138	-101	42	146	-104	135	364	-230	225		618		-392		
Poland	m	m	m	m	m	m	m	m	m	256		1068		-812		
Portugal	44	170	-125	47	125	-78	95	301	-206	170		710		-540		
Spain	191	245	-54	233	244	-11	633	989	-356	1414		2434		-1020		
Sweden	305	326	-21	405	332	73	1312	748	564	3190		1453		1737		
Switzerland	1615	411	1204	1604	493	1110	4361	1193	3167	8297		2839		5458		
Turkey	2	3	-2	4	13	-9	72	104	-32	71		412		-341		
United Kingdom	1734	517	1217	1845	761	1084	4041	2064	1977	8234		4755		3479		
United States	2020	803	1217	2790	1718	1072	4103	2540	1563	7160		7150		10		
OECD total[1]	**13677**	**9958**	**3719**	**15406**	**11884**	**3522**	**33673**	**27991**	**5682**	**68993**		**59780**		**9360**		

Notes: millions US dollars at current exchange rates. n.a.: not available, * data was interpolated, ** data from 1995, *** data from 1994.
(1) The total does not include Czech Republic, Hungary, Iceland, Mexico and Poland.
Source of data: OECD Health data 1998.

Table 7. **Market share and average retail prescription price, by type of drug, 1994**

United States	**Market share**		Average retail prescription price (dollars)
	Percentage of retail, pharmacy sales[a]	Percentage of prescriptions dispensed	
Innovator drugs			
Single source	55.5	37.5	53.8
Multiple source[b]	27.2	26.5	37.4
Generic drugs	17.3	36.0	17.4

Source: Congressional Budget Office (1998) based on tabulations retail pharmacy sales data from Scott-Levin.

a. Calculated at retail prices.

b. If generic versions of an innovator drug were available in any dosage form, then all sales of all dosage forms of the innovator drug were classified as multiple source. Hence, an extended-release dosage form that had no generic version available was classified as a multiple-source drug if generic versions of the original formulation were available.

Table 8. **Listing of drugs eligible for public insurance reimbursement**

Country	Listing of drugs	Comments
Australia	Yes	Listing according to medical needs and cost-effectiveness, updated every 3 months.
Austria	Yes	Listing according to medical and economic criteria. List updated every 3 months to reflect medical and market changes. There is a list of drugs reimbursable without prior approval by sickness funds
Belgium	Yes	List updated every month.
Canada	Yes(1)	Lists and formularies are part of the reimbursement system of provincial insurance plans. The criteria often include pharmaco-economic considerations.
Czech Republic	Yes	The general list of medicines available under prescription is issued by the Ministry of Health
Denmark	Yes	List constantly updated.
Finland	Yes	Listing according to effectiveness of drugs. Constantly adapted.
France	Yes	Listing according to the marginal improvement of health service allowed by the drug and the reduction in costs of medical treatments. Difficulties for proper update.
Germany	Yes(2)	Listing according to pharmacological criteria
Greece	Yes	The list was adapted and implemented in 1989/90, but physicians continue prescribing out of the list, justifying exemptions. Since 1995, a National Committee has the responsibility to adapt the list for all the insurance funds and the NHS. In 1997 a positive list was introduced by IKA and generalised to other insurance funds in 1998.
Hungary	Yes	Listing according to the indication and frequency of the illness.
Italy	Yes	Positive listing introduced in 1978 (Prontuario Terapeutico Nazionale). Important revision and de-listing in 1994 and 1995. Some products readmitted under conditions in 1998. .
Japan	Yes	Listing according to the effectiveness of drugs.
Korea	Yes	Listing according to criteria such as the therapeutic value of drugs, the cost of comparable treatments, and prices observed in foreign countries.
Luxembourg	Yes	List updated monthly.
Mexico	Yes	The list has to cover the existing pathologies at the lowest possible cost. It is adapted based upon medical progress and population health needs
Netherlands	Yes	Listing according to effectiveness. The list is updated regularly.
New Zealand	Yes(3)	
Norway	Yes	Listing according to type and seriousness of disease. Constantly adapted.
Spain	Yes(2)	Listing according to medical criteria, severity and time of the pathology, therapeutic and social use of the drugs; Socio-economic criteria include use of alternative drugs at lower prices, public expenditure fiscal constraints.
Sweden	Lists of recommended drugs set by country councils.	
Switzerland	Yes	Drugs listed must be effective, economically efficient and appropriate. Positive list updated twice a year.
UK	Yes	N/A
USA	Yes (HMOs, PBMs)	N/R.

(1) Most of the provinces and territories have established their own formulary for the provincial schemes. (2) Negative list. (3) List of subsidised items only, for reference pricing.

Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources.

Table 9. **Drugs in hospitals**

Country	Specific rules	Comments
Australia	Yes	Highly specialised drugs requiring monitoring are dispensed through hospitals e.g. drugs for AIDS.
Belgium	Yes	Some specialities are only reimbursed when administered in hospitals. Expensive drugs for AIDS are dispensed by hospital pharmacists for the moment. The hospitalised patient pays a fixed amount of 25 BEF per day for drugs, not depending on the amount of drugs provided.
Canada	Yes	Drugs administered in hospital are part of insured hospital services under federal health care legislation, the Canada Health Act. When in hospital for necessary care, Canadian residents are entitled to medications without financial charges of any kind.
Czech Republic	Yes	In practice, the expensive drugs are usually applied in a specific treatment and are mainly distributed through specialised in-patient facilities. However, in principle, dispensation through outpatient facilities is also possible.
Denmark	Yes	In hospitals, there are specific guidelines for prescription by physicians.
Finland	Yes	High-cost experimental drugs can be dispensed only through hospitals. AIDS medicines are dispensed from public hospitals without any cost for the patient.
France	Yes	Some expensive and particularly innovative drugs are dispensed only by hospitals. However the government has decided that such drugs will gradually be obtainable at a pharmacy with a prescription initiated in hospital. Prices for hospital drugs are free and subject to a biding process. There are calls for tender to supply such drugs and negotiation over prices between hospitals and manufacturers.
Greece	Yes	Expensive medicines (AIDS etc.) and medicines for the poor or unemployed are distributed through hospitals or health centres which are related to hospitals. There is a program recently run for hospital drugs (15% of the drug market) to implement a unit dose (per patient/per day) system to monitor all hospital drug stores.
Hungary	Yes	The extremely expensive but indispensable pharmaceuticals are financed from a separate source of the National Health Insurance Fund Administration, under the auspices of an expert panel. The number of patients treated is limited.
Italy	Yes	A minimum 50 % rebate on the market price is applied to drugs used in hospital settings.
Luxembourg	Yes	Medicines used for in-patient care are completely refundable. Expensive medicines are distributed in hospitals and outside.
Mexico	Yes	Since the public health sector in Mexico has many competing demands for its limited resources, so that in general basic health care is prioritised. For this reason, the availability of these medicines is limited, so that the supply is very far from satisfying the demand. Generally, costly treatments are only available in specialised hospitals, which are only located in highly populated urban area.
Netherlands	Yes	Hospital guidelines on medicine dispensation exist. Individual hospitals receive sometimes subsidies specifically intended to finance expensive medication, such as for the treatment of AIDS.
New Zealand	N/A	Drugs are included in hospital global budgets. Hospital drugs are not subsidised through the reference-pricing regime discussed above.
Spain	Yes	Some drugs are dispensed only through hospitals.
Sweden	Yes	Since 1993, Apotekslaget keeps right to negotiate direct agreement with manufacturers for the price of these drugs.
Switzerland	N/A	The Sickness Law relates only to ambulatory setting. Medicines in inpatient care are included in a global payment a day. Nevertheless ambulatory treatment with very expensive drugs may be started and supervised by university hospitals.
Turkey	Yes	Although, according to certain insurance policy organisations (such as SIO), certain medications should be prescribed only by specialists and be used in hospitals, only blood and some blood products are implemented, dispensed and distributed through hospitals.
UK	Yes	Medicines in hospitals are not covered by the PPRS. Hospital drugs are treated as other inputs to hospital care. Specific drugs are not restricted to hospitals, but while patients are under the care of hospital consultants, the cost of these drugs will fall to hospital budgets. As a consequence some pharmaceuticals - including some for AIDS - will often be prescribed by hospitals. New and expensive drugs need to be limited to the hospital sector with specific arrangements and co-operation between Health Authorities and GPs.

Austria, Germany, Japan, Korea, Norway, Sweden and the United States have no specific rules for drugs in hospitals.
Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources

Table 10. **Co-payments and Patient Cost-Sharing Policies in OECD Countries**

Country	Differentiation	Method	Modifications	Reinsurance of second-tier co-payment allowed?	Does reinsurance offset co-payment?
Australia	By type of beneficiary	Fixed amount depending on beneficiary type Max 11 $ per prescription. Waiver for concessional cardholders, low income, chronically sick.	Changes regularly in line with Federal Budget decision.	Private insurance but mainly for hospital care.	Not usually
Austria	By type of beneficiary	Fixed amount per package 5$. 43 ATS in 1998	Yearly adjustment according to inflation	No	NR
Belgium	By type of drug and of beneficiary	Percentages depending on the category of the active person and of his dependants. (100/80/60/50 0%)	News categories defined in 1980	In hospital only by non-profit insurance, profit insurance is allowed.	N/A
Canada	By type of drug and beneficiary	Most provinces use a combination of co-payments and deductibles as part of cost sharing with beneficiaries. Overall 88% of Canadian have coverage, 62 % private plans, 19 % provincial plans, 7% under both, Universal coverage in Alberta, British Columbia, Quebec and Saskatchewan.		Yes	NR
Czech Republic	By type of drug	N/A	Changes almost every year to reflect change in drug prices and structure of drug consumption	Yes	N/A
Denmark	By type of drug and partly by beneficiary	50.2% for drugs with definite and valuable therapeutic effects, 25.3% for drugs used for the treatment of well-defined and often life-threatening diseases. 0% for insulin preparation.	Yes, in January 1996, 50% and 25% were changed in order to finance the compensation of iatrogenic diseases. The rule of 0% co-payment for insulin came into force in January 1990.	Yes	In some cases
Finland	By type of drug and beneficiary	A fixed deductible different for each of the three categories of reimbursement. Co-payment 60% in excess of 8$. Level of co-payment also influenced by the categories.	Fixed deductible was changed several times, and the categories were changed in 1986, 1992 and 1994.	Yes	Yes
France	By type of drug and beneficiary	A percentage of the price of the drug, according to the type of drug. Waivers for certain beneficiaries 0/35/65% co-payment.	The reimbursement level was decreased several times. Last 5 % decrease was in 1993.	Yes	Yes, almost fully, this is usually the case.

N/A: not available, NR: not relevant. Amounts in USD or national currency. **Source:** OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table 10. **Co-payments and Patient Cost-Sharing Policies in OECD Countries (follows)**

Country	Differentiation	Method	Modifications	Reinsurance of second-tier copayment allowed?	Does reinsurance offset co-payment?
Germany	By size of the prescription and beneficiary	By law in 1992. Since July 1997 copayment of 9/11/13 DM (5 to 7$) in relation to package-volume (DM 8/9/10 since January 1999); exemptions, e.g. chronic diseases. (For drugs under the reference pricing scheme, patients also pay the difference between the reference and the actual price).	Yes, increase of 1 DM from 1 January 1997	No	NR
Greece	Very partial	Fixed contribution of 25% of the total drug value, but only 10% for pregnant women, 0% for chronic diseases	Before 1992, level was 10-15%. No change since then.	Yes	No
Hungary	By type of drug and beneficiary	A percentage of the price of the drug from 0% to 100% depending on the type of drugs.	Yes, year by year, depending on the deficit.	Yes, for non-profit insurance company	N/A
Ireland	By type of beneficiary	GMS patients are exempted, mx 90 £(Irl) per quarter for category II patients		NA	NA
Italy	By type of drug and beneficiary	Prescription charge of 3 $ plus percentage of the price. Three main drug categories (0, 50, 100 %). Moving towards more prescription charge and reduction of the share of drugs with patient charge (more or nothing). Exemption according to income, age and health status.	First introduced in 1978. Revised in 1983,	NA	NA
Japan	By type of beneficiary	Fixed amount. From 0 to around 1$ for three internal or six external drugs. Special rules for the elderly and certain diseases. Waivers for elderly, children and low income.	1984. Additional patient participation added in 1997, but with some wavers.	No	N/R
Korea	Not by type of beneficiary or size.	Differentiated percentage of co-payment by type of medical facility: in-patient: 20%; outpatient: pharmacies: 40%, Local clinic: 30%, Hospital: 40%, General Hospital: 55%.	No	Yes	Yes
Luxembourg	By type of drug and beneficiary	According the type of drugs (0, 20, 60 and 100%). 20% is the normal level of co-payment applied for majority of drugs. Pharmaceutical products are totally reimbursed for in-patient care.	Yes, in 1994 for cost containment/ budgetary reasons.	Yes	N/A
Mexico	By size of the prescription and beneficiary	Public insurance: co-payments according to income and geographical/rural area. Private health insurance plans have their own co-payments.	No	Yes	Yes

N/A: not available, NR: not relevant. Amounts in USD or national currency.
Source: OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table 10. **Co-payments and Patient Cost-Sharing Policies in OECD Countries (follows)**

Netherlands	No	20% co-payment, with a ceiling on the total annual co-payment (67$). Income-adjusted stop-loss annual ceiling.	No. The policy is very recent.	Yes	N/A
New Zealand	By type of beneficiary	Partial insurance for the most needy persons means tested. Difference between actual price and reference price, and co-payment. 2 to 8$ co-payment	Waivers for children have been added	Yes	No
Norway	By type of beneficiary	50% co-payment. Waiver for children and elderly. Maximum 43 $ per prescription.	No	Yes	N/A
Portugal	By type of beneficiary	0/30/60% of price, reduced for low income			
Spain	By type of drug and beneficiary	Based on the price of the drug. 0 or 40%. Exemptions for pensioners and chronically ill.	Changed 6 times.	No	Yes
Sweden	By prescription size and beneficiary	Fixed amount, SEK 160 for first item and SEK 60 for further items. Percentage of the cost. , Stop loss 1800 Skr per 12 months, amount per prescription item.	Yes, since 1968, the co-payment has been changed about 15 times. last changed in 1995.	Yes	Yes
Switzerland	Partly by beneficiary	Franchise 230 SFr, plus 10 per cent of the costs, with annual stop loss ceiling 600 NCU SFr per year. Exemption for children.	Sickness Law 1994. Franchise and co-payment rates were raised in 1995.	No	NR
Turkey	By type of beneficiary	10% retired 20% active.		Unknown	N/A
UK	By type of beneficiary	Fixed amount charge, currently £ 5.5 per prescription. Many waivers(1)	Fixed amount re-valued on an annual basis. Increased in real terms over the 1980s.	Unknown	N/A
USA	NR	Drugs not included in Medicare but may be covered if HMO. Most private insurance plans have co-payment requirements. 60% of retail sales paid by third parties to some exempt. Fixed prescription charges in HMOs, against co-payments plus a deductible in Fee For Service Planes, Medicaid Covers Some Drugs.		Yes	N/A

(1) In 1995, 16% of the total number of the prescriptions carried a prescription charge, and 22% of the value of total prescriptions carried a charge.
N/A: not available, NR: not relevant. Amounts in USD or national currency.
Source: OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table 11. **Guidelines for prescription**

Country	Guidelines	Comments	Possible Sanctions
Australia	Yes	Advisory guidelines, including newsletter to prescribers, and feedback to prescribers on their performance against the average. State guidelines also.	No
Austria	Yes	The guidelines apply to the whole range of medical treatment options.	Yes, contractual obligations include refunds or termination of contracts.
Canada	Not at federal level but in most provinces have	Most provinces have a clinical practice guideline activity underway, including prescribing guidelines.	N/A/
France	Yes	Negative Reference Mandatory Guidelines for certain drugs.	Yes, in theory, there are financial and contractual sanctions.
Germany	Yes	In fact, physician prescription is reviewed ex post at the level of sickness funds.	Yes, prescriptions are examined by sickness funds.
Greece	Yes	IKA doctors have to follow the list of drugs and they are reviewed ex-post to detect over-prescribing physicians.	Yes, IKA Board of Directors and the Governor of IKA normally give fines to doctors who over-prescribe and in very few cases fire them.
Hungary	Yes	Therapeutic protocols exist for the treatment of the most frequent pathologies. These protocols suggest effective and cheap medicines.	Yes, financial sanctions from the Insurance Fund Administration.
Japan	Yes	There are guidelines for the treatment of the elderly high blood pressure.	No
Korea	Yes	Guidelines from medical insurance to restrict use of treatments with limited efficacy.	No
Luxembourg	Yes	"Transparency list" and negative mandatory medical guidelines, following the French model.	Yes in theory. R.M.O. guidelines regulation in preparation. Close to the French model.
Mexico	Yes	Therapeutic-Diagnostic guides are distributed to physicians.	No
Netherlands	Yes	Guidelines are set both for general practitioners and specialists. National network of 650 local groups participating in pharmaco-therapeutic consultation.	No, used by the insurers mostly for feedback
New Zealand	Yes	Information is distributed by the pharmaceutical agency to physicians.	No
Norway	Yes	There are broad guidelines	No
Sweden	Yes	Information is distributed to prescribing physicians. (guidelines for 11 common diseases).	No
UK	Yes	Advice issued across a wide range of practices in line with policy towards clinical and cost effectiveness. Relevant professional body also issue advice to their members. Computer aided prescribing system under trial within the NHS should provide detailed information on cost-effectiveness.	No
USA	Yes	There are various publications available for use by physicians. Guidelines are set by managed care organisations.	Yes, according to the type of managed care setting.

At the time of this questionnaire, No data is available for Spain. No guidelines were reported in Belgium, the Czech Republic, Denmark, Finland, Spain, Switzerland, and Turkey. There may however exist in these countries other types of incentives to prescribe cheaper drugs.
Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources

Table 12. **Fixed budgets, direct limitations of volume and expenditure**

Country	Fixed budgets Global volume targets	Some type of individual control per physician, episode or per day	Comments
Austria	No	Yes, per episode	Limitations on volume per individual drug and per episode of care.
Belgium	Yes, global indicative target	Yes, various limitations, per episode, per physician, or per day, but only for expensive specialities	Limitations for expensive specialities are applied per day and per episode, with reference to the period of treatment and the posology. These specialities represent 30% of the annual expenditure and are under the control of medical advisors of the mutual sickness fund.
Canada	No	Yes, supply days per script	Some provinces limit the supply days per scrip. In many cases the limit is set to around 30 days for episodic medicines, and 100 days for maintenance medicines. However physicians are able to provide automatic repeats on scrip enabling a patient to refill the order without a new prescription.
France	Yes, since 1996	Yes, guidelines for specific drugs	The National Target of health care expenditure (ONDAM) includes a target for reimbursement of pharmaceutical prescriptions. In addition, three-year agreements are signed with pharmaceutical companies, with expenditure targets. Higher taxes on pharmaceutical companies when targets were not respected. Rather limited control is exerted on individual prescriptions except for specific drugs included in guidelines.
Germany	Yes	N/A	Global budgets at the national level, which are translated into prescription targets for physicians in a defined region. "Contracts" between sickness funds and physicians' organisations.
Greece	Yes, but only for the main social insurance fund	Yes, per day, per physician	For IKA social insurance fund, 50% of the insured people) The mean average of all the doctors' prescriptions.
Hungary	No	Yes	Volume prescribed at the time. Physicians are allowed to prescribe pharmaceuticals for 30 days period only.
Italy	Yes, set up in 1994, effective in 1996	Yes, for exempted patients.	Delisting occurred in 1996 to prevent budget overrun. For exempted patients, maximum 16 prescriptions, introduced by law in 1992, abolished in 1993 and reintroduced in 1994. Payback decided in 1998 : in case of global budget overruns, 60% of the deficit borne by industry and distribution. Expenditure targets for GPs since the reform.
Mexico	Yes	N/A	Through pharmaceutical budget ceilings, which are set for every medical unit on an annual basis. Once the annual health global budget is determined, a certain proportion is destined to pharmaceutical expenditures, based on medical experience and expected price increases.
Netherlands	No	Yes, some limitation per episode	The volume of prescription should not last more than 3 months (except for some classes of medicines).
New Zealand	No	Yes, Some limitation per episode	1. Volume per month (dispensing limits), the maximum prescription is for 3 months. 2. Dosage strength and period of dosage for some pharmaceuticals. The pharmaceutical agency, PHARMAC, negotiates with drug companies according to decision criteria set by government.
Switzerland	No	Yes, some volume controls per episode for specific therapeutic groups of drugs of the specialist list. Some expenditure control, per day and per episode	By number of packages or number of points within three months.
UK	Yes, at a decentralised level per physician, (1991)		General Practitioners can become fund-holders, and receive a budget covering some elective care and also prescription. Non-fundholding GPs (a minority) were set indicating prescribing budgets. All physicians have now to participate in some form of fundholding, within primary care groups.

The following countries did not mention official control of the volume of prescription or specific limitations on expenditure per day, per episode or per physician. This does not necessarily mean that strong influences may not be used to invite physicians to prescribe in a rigorous way. These countries are Australia, Czech Republic, Denmark, and Finland, Japan, except for some expenditure targets, Korea, Luxembourg (except for exceptional drugs such as Sumatriptan), Norway, Spain, Sweden, Turkey, United States (except for some State Individual Medicaid Agencies). Information was not available for Ireland, but drug budgets for doctors have been reported in this country.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table 13. **Price controls**

Country	Control	Since	Characteristics taken into account to fix the price				Comments
			Therapeutic value of the drug	Cost of comparable treatments	Pharmaceutical contribution to the economy	Price in other countries	
Australia	Yes	1951/1986	YES	YES	YES	YES	Various references used to set reimbursement and price level: this applies to 48 % of the market. Price according to volume and cost-effectiveness. Price level linked to market approval, with economic guidelines..
Austria	Yes	1976				YES	See Öbig 1998.
Belgium	Yes	1963/1995-	YES	YES	YES	YES	Distribution and manufacturing costs.
Canada	X[4]	1987		YES		YES	For patented drugs only (PMPRB duty). Price related to cost-effectiveness.
Czech Republic	Mixed	1992[1]/1995	YES	YES		YES	For both producers and importers. Domestic producers must submit their production-cost-formula; importers must submit their price list.
Finland	Yes	1968-1993 [2] 1994-[3]	YES	YES		YES	Trade off: cost of treatment, manufacturing and R&D costs vs. available funds for reimbursement.
France	Yes	1945	YES	YES		YES	Since 1994, joint negotiation on volumes. Innovative value
Greece	Yes	≅1978				YES	Imported drugs: cheapest price among the three lower prices of EU. Domestic drugs: individual product price setting cost-based plus an index of international prices.
Hungary	Mixed	1990	YES	YES	YES	YES	Price negotiation between manufacturers and public health insurance body. Impact of currency devaluation of currency and different duties integrated. International reference to Spain, France, Greece and the Czech Republic.
Italy	Yes/mixed	1978, 1995 ref.				YES	Before 1995, prices according to cost information, after "free prices" under Average European Price. Price negotiated since then for innovative products.
Japan	Yes	1950	YES	YES		YES	Weighted average of the prices at which a brand is transacted in all available packaging forms.
Korea	Yes	1977	YES	YES	YES	YES	
Luxembourg	Yes	1964				YES	With reference to the price existing in the respective country of origin (Belgium, France, Germany and Switzerland)
Mexico	Yes	1993				YES	Self-regulating formula taking into account the firm's operating costs. 50 % is sold in a private sector in a free basis. In the public sector, basic list of medicines with competitive bidding by firms.
Netherlands	Mixed	1996				YES	Since 1996, for 3000 products maximum authorised prices.
Norway	Mixed	always/1993	YES	YES		YES	Specific reimbursement following generic prices plus 5 % in 1993. RD and manufacturing costs
Spain	Yes	unknown	YES	YES	YES	YES	
Sweden	Mixed	1993	YES	YES		YES	Direct negotiations with central public pharmacy body (Apoteksbolaget) until 1993 and National Social Insurance Board since 1993. Partial reference pricing scheme 1993.
Switzerland	Yes	1962	YES	YES		YES	Public price integrates manufacturer's price, distribution margins and VAT. Price revisions for older products in 1995, comparisons with other countries
Turkey	Yes	1928	YES	YES	YES	YES	Real manufacturing costs

Mixed means that the control may apply only to part of the prescription market. Germany Denmark, the Netherlands and the United States have very little or no price control. In the United Kingdom price considerations are not absent from negotiations between NHS authorities and manufacturers. Apart from the general profit control target, prices in other countries and the pharmaceutical contribution to the economy are also taken into account in this country. In addition, prices were not adjusted for inflation in years of high inflation. In Germany, price cuts have also been enforced (see table 14). (1) Price control also existed in Czechoslovakia before 1992. (3) From 1994 only price negotiation with companies that want to include their products in the National Drug Reimbursement Scheme. (2) Direct price control on all medicines. (4) Pharmaceutical policy depends on the provinces. Reference pricing in British Columbia. Price controls in all provinces for patented drugs. In the UK existing drug prices cannot be raised but new products are priced subject to profit constraint.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources

Table 14. **Profit controls**

Country	Profit Control	Date	Method
Czech Republic	For domestic producers	1992	30% profit for domestic producers, 35% margin for pharmacists and distributors
Korea	Yes	1997	Determine the ceiling level or the range through consultations with the institute authorised by the government. For instance, Korean productivity centre and etc.
Mexico	Yes	1993	Each firm's operating costs. There is an self-regulated formula that considers each pharmaceutical firm's operating costs, and according to the governmental pricing policy, price increment ceilings are set.
Spain	Yes	NA	Prices based on "cost". Includes a ceiling of promotion expenditure (12 to 14 % of retail price).
Turkey	Yes	1984	15% of annual profits, based on annual net profit
UK	Yes(1).	1957(2)	The target rate of return was set at 17-21% return on capital employed with a 25% margin of tolerance and a system of allowances such as R&D allowance. Includes a ceiling on promotion expenditure

(1) The Pharmaceutical Price Regulation Scheme (PPRS) in the UK is a profit control scheme. The overall aims of the system were outlined in the 1993 agreement: 1. To secure the provision of sale and effective medicines for the NHS at reasonable prices; 2. To promote a strong and profitable industry in the UK capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; 3. To encourage in the UK the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries

(2) Re-negotiated on a period basis since that time. Other analysts date it to 1969. Most recent: 1993 and should run for 5 years.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table 15. **Price freezes and cut measures in selected countries**

Country	Price Freeze	Date	Method/Intensity	Comments
Austria	Yes	1997	Price reduction, agreement of the social insurance and the industry to reduce the manufacturers' prices.	
Belgium	Yes	1993, 1996, 1997	Prices frozen on the level of 1 January 1993 or 1996 and 2% price cut in June 1996.	General consultation was organised with the pharmaceutical industry, medical associations, mutual funds, trade unions, etc…
Canada	No at the federal level but in two provinces	N/A	These two provinces have either cut or frozen prices on drugs for their insurance programs, which is reimbursement levels and not actual price control.	
Czech Republic	Yes, but not applied	N/A	The Ministry of Finance sets up the maximum prices.	Maximum prices are re-valued each year and may be slightly under-re-valued. If the general effect may be rather limited, individual changes may be more pronounced.
Denmark	Yes	From 1994 to 1997	Price freezes from January 1994 to 1st April 1995. Cut prices in April 1995 and frozen prices until April 1997.	From April 1995 to April 1997, agreement with the pharmaceutical industry. Target for reduction in public pharmaceutical expenditure in the State Budget. According to this agreement, general price reduction of 5% on prescription drug covered by the reimbursement scheme. Prices of prescription drugs not covered by the scheme and OTC products were lowered by 2%.
France	Implicit		Prices may be under-re-valued with the annual changes.	This had a stronger effect in years of accelerating inflation, at the beginning of the 1980s
Germany	Yes	1993 for 2 years	For prescription drugs by 5% and for over the counter drug (OTC) by 2%.	Consultation process.
Greece	Yes	Several times	Price freeze	Consultation process.
Italy	Yes	1995, 1996	Price cut of 2.5% in 1995, price freezes in 1996.	
Korea	Yes	1977		Consultation process.
Luxembourg	Yes	N/A	Price cuts from neighbouring country, applied in Luxembourg.	
Netherlands	Yes	1994		Negotiations with pharmaceutical industry.
Spain	Yes	1993	Price cut of 3% for 3 years.	Consultation with pharmaceutical industry.
Switzerland	Yes	1992-96, 1997	1992-96, price freeze for specialist list products. From 1997, new Sickness Law.	
UK	Yes	Oct-93	2.5% price cut was determined at the time of the re-negotiation of the Pharmaceutical Price Regulation Scheme in 1993.	Consultation with pharmaceutical industry, companies could choose the method to obtain an average 2.5% price cut. (They could also choose to return their profit).

Price cuts or price freeze were not reported in Australia, Austria, Finland, Hungary, Japan, Mexico, New Zealand except for incidental effects of reference pricing, Norway, Sweden, Turkey and the United States. N/A not available

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table 16. **Average price differences for various types of purchasers in the pharmaceutical market**
(percent)

United States	Average invoice price paid for 100 brand-name drugs (as a percentage of the average invoice price to pharmacies)		Market share by type of purchaser (%)
Type of purchaser	1993	1994	1994[a]
Retail pharmacies	100	100	85.6
Hospitals	91	91	4.2
Long-term care facilities	96	95	3.4
Health maintenance organisations	80	82	2.7
Federal facilities	65	58	2.6
Clinics	95	91	1.6

Notes: These figures are based on the average prices of 100 top-selling brand-name drugs sold primarily through retail pharmacies.
The prices do not include manufacturer rebates or other discounts not appearing on the invoice.
a. Calculated as a percentage of total sales revenues for the 100 drugs (valued at invoice prices) after excluding sales to mail-order pharmacies.
Source: Congressional Budget Office (1998) based on IMS America

Table 17. **Reference pricing**

Country	Reference pricing	limited to therapeutic classes with competition	Date	Proportion of the pharmaceutical market for which reimbursement is governed by reference pricing.	Reference formula	Used in conjunction
Canada	Yes, British Colombia	Yes	N/A	20% prescription 30% of costs	Daily cost basis	Generic prescription.
Denmark	Yes	No	1993	33% of global market	Average of the price of the two cheapest productions in the group under consideration...	Positive list, generic prescription and de-listing to OTC.
Germany	Yes	No	1989	66 % of global market	Average of cheaper drugs in the therapeutic class	Generic prescription and de-listing to OTC.
Hungary	Yes	Yes	1990	Unknown	Fixed support for identical active substances	
Italy	Yes	Yes	1996	Unknown(2).	Equal price for same drugs, with same active ingredient, European countries and generics.	De-listing.
Netherlands	Yes	Yes	1996	N/A.	Weighted average of prices in the therapeutic class, including price in four other countries.	Positive list, generic prescription and de-listing to OTC.
New Zealand	Yes	No	late 80's	Almost all	Lowest priced pharmaceutical in a therapeutic group, including price in other countries(3)	Positive list and generic prescription.
Sweden	Yes	Yes	1993	10 % of the market in 1994	50 groups, reference price set at lowest price plus 10%.	

Reference pricing corresponds to a system whereby public reimbursement is set according to the chemical properties of comparable drugs.
(1) In addition, there are access restrictions, guidelines, budget holding, and prescription education. (2) If drugs have prices above the same active ingredient, same or comparable therapeutic form, but possibly different dosages, drugs are de-listed and not reimbursed. As a result, products were either de-listed or had their prices reduced by an average of 7%. This does not apply to products registered at the European level by EMEA, or since 1998 at national level.
(3) A few contracts are negotiated with companies for supply of pharmaceutical at a fixed price according to health needs, availability and suitability of existing medicines, therapeutic medical devices or related product to meet those needs, clinical benefits, risks and costs of new product, global cost-effectiveness and overall budgetary impact.
Note: Some reference pricing is to be adopted in Spain and has begun in 1999 for 50 drugs.
Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table 18. **Prescription of generics**

Country	Explicit policy	Type of incentives	Comment
Australia	Yes	Consumer education and financial incentive	Patient payment if drug chosen at any higher price than generic base. (Close to reference pricing system).
Austria	Yes	Guideline for prescription by physicians	Doctors are regularly informed with lists of low cost generic drugs.
Canada	Yes except in one province		Lowest cost alternative: stipulating that for drugs where generics exists, reimbursement rates will be set at the cost of the least expensive bio-equivalent. In some provinces, pharmacists are able to substitute with a generic alternative, provided there aren't any explicit instructions from the physician.
Czech Republic	Yes	Information	Generics are included in the general list of drugs available under prescription, however there is a lack of incentives for physicians to prescribe them.
Denmark	Yes	N/A	The prescription scheme of generics, called "G" scheme, was introduced in November 1991 and includes most of the pharmaceuticals for which synonymous drugs exist. When a physician prescribes a drug covered by the G scheme, he may write a "G" on his prescription to indicate to the pharmacists that this should be filled with generics, unless the consumer refuses.
Finland	Yes	No explicit incentives	From March 1996, prescribers are able to write their prescription in generically written form. Pharmacists have then to dispense the cheapest product.
France	Yes	Global budgets on physician prescription, information for physicians	Implementation of stronger incentives for generic prescription is underway in the main action plans presented by the Ministry of Social Affairs.
Germany	Yes	Global budgets for physicians and guideline on prescription for physicians	
Greece	Yes	N/A	The policy included 14% price reduction of all the generic related to the similar branded drugs.
Hungary	Yes	Budget constraints, guidelines for prescriptions and consumer education	
Italy	Yes		Introduced in Italian law in 1996. Negligible market.
Mexico	Yes	Budget constraints, guidelines for prescription, consumer education, and manufacturing side	
Netherlands	Yes	Some budget constraints, guidelines for prescription and consumer education	In order to encourage generic delivery, pharmacists can share some of the savings they generate and they receive a fraction (currently 33.3%) of the price difference, if the product delivered is cheaper than the "reference price" for that group of medicines.
New Zealand	Yes	Guidelines for prescription, consumer education and economic incentives	Consumer has to pay the difference between generic product and branded product if the latter is chosen.
Norway	Yes	Budget constraints and guidelines for physicians	Physicians have to take economic considerations when prescribing, and prescribe the cheapest alternative.
Sweden	Yes	Guidelines for prescription	
Switzerland	Yes	Guidelines for prescription and consumer education	There are legal incentives to prescribe generics (art. 52, al.1 of the Sickness Law) which have to be 25% cheaper but there is a lack of effective economic incentives for doctors and pharmacists to deliver them. Substitution right for pharmacists to be introduced in 2000.
UK	Yes	Incentives for GP fundholders and prescription guidelines. From 1985, all but the generic forms of a number of widely used medicines were excluded from NHS reimbursement.	Possibility to write prescriptions in generic format.
USA	Yes	Prescription guidelines and consumer education	In private sector, most insurance plans require generics rather than brand name drugs

Generics are only virtually present in Belgium, with only 36 generic specialities available. Japan, Korea, Luxembourg and Turkey had no explicit policy for generics at the time of the survey. There was no explicit policy in Spain also, but recent changes in the legislation were about to consider it.

Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources

Table 19. **Share of US HMOs with closed formularies**

HMO type	*Share with closed formularies*
Staff model	66.7
Group model	53.8
Independent Practice Association model	38.7
Network model	40.0
Total	**47.8**

Managed care organisation with open formularies impose no penalty to the enrolee for getting a prescription that is not on the formulary. Managed care organisations with closed formularies do. The staff model HMO is the more traditional and vertically integrated model of managed care, while the Independent Practice Association and network models are looser forms of managed care. The group model is intermediate.
Source: Datamonitor, CibaGeneva Pharmacy Benefit Report.

Table 20. **Reduction in the volume of wasted drugs**

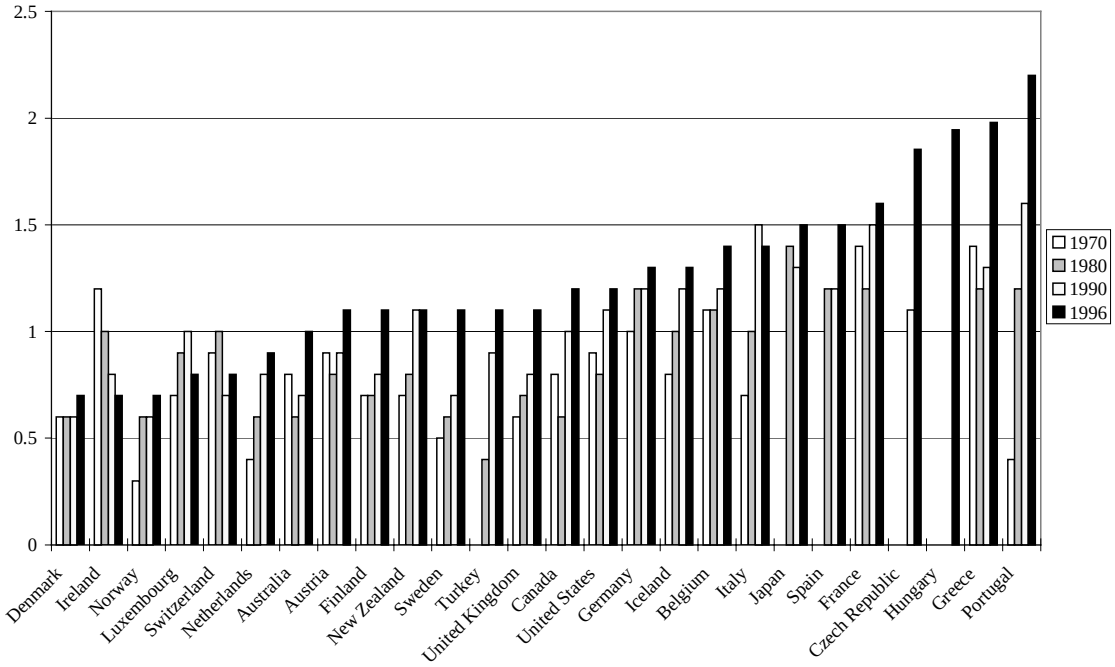
Country	Restriction on the volume of prescription per episode	Consumer education	On packaging by the manufacturers
Australia	Yes	Yes	
Austria	Yes, for a single drug.	Yes	Yes
Belgium	No	No	Yes
Canada[(1)]	Yes, by using the reimbursement mechanisms.	Consumer education programs aimed at improving compliance may also reduce wastage.	
Czech Republic	No	No	Yes, integral part of registration process
Finland	Yes, maximum period of three months per purchase	No	No
Germany	N/A	N/A	Yes, in 1993, copayment based on package size, to reduce wasted drugs.
Hungary	Yes	Yes	No
Italy	Yes, cap introduced in 1993, for exempted patients, 16 prescriptions maximum, and abolished in 1994.		
Mexico	Yes	Yes	Yes
Netherlands	Yes	Yes	No
New Zealand	Yes	No	No
Norway	Yes, maximum period of three months per prescription	No	No
Spain	No	Yes	No
Switzerland	Yes	No	Yes, for certain groups of medicines, manufacturers have to offer different size of packages.
Turkey	Yes	No	Yes
UK		YES	
USA	Yes	Yes	No

(1) Some provinces in Canada. There was no explicit policy in Denmark, France, Japan, Korea, Luxembourg and Sweden. The situation for the United Kingdom and Greece were unknown.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

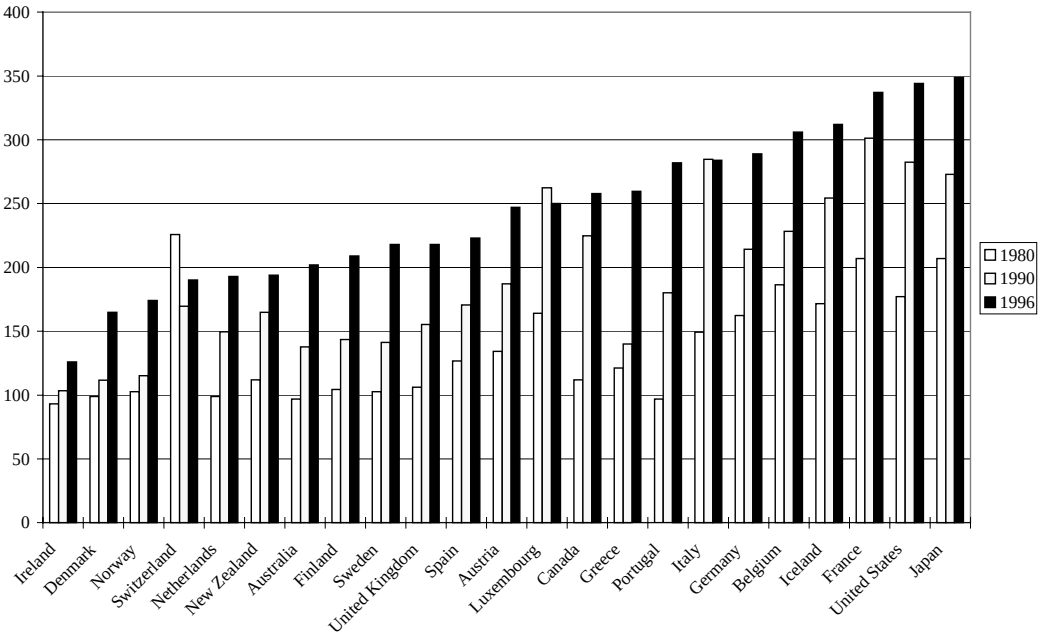
CHARTS

Chart 1. **Total expenditure on pharmaceutical goods as a share of GDP**



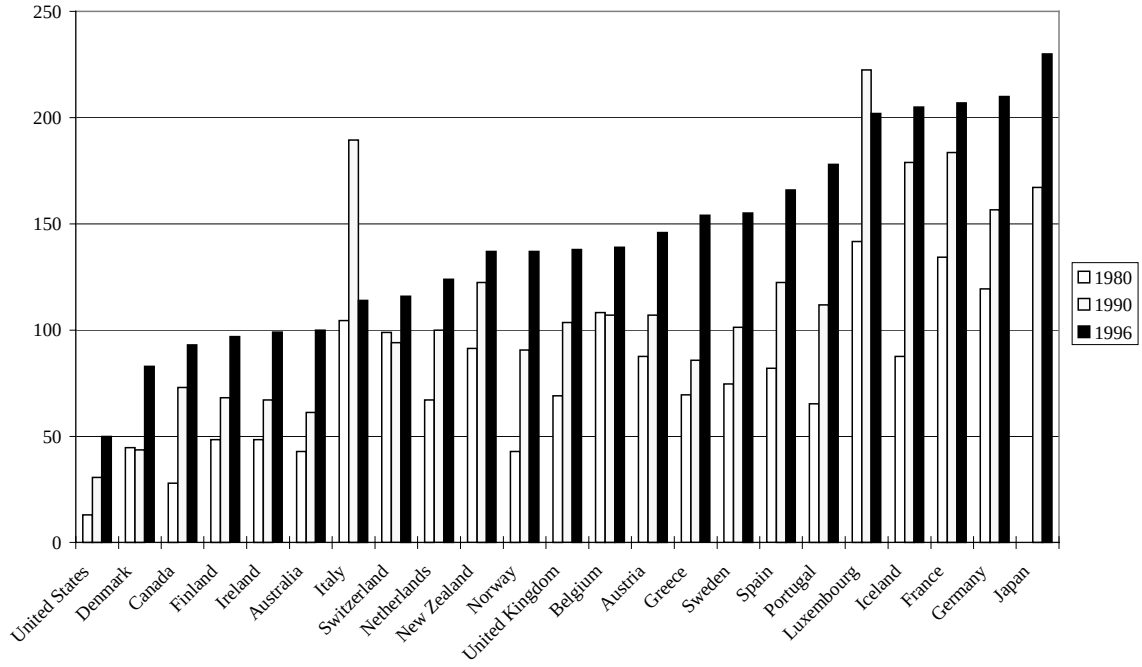
Source: OECD HEALTH DATA 98.

Chart 2. **Total expenditure on pharmaceutical goods per capita**
constant US dollars, current exchange rates



Source: OECD HEALTH DATA 98.

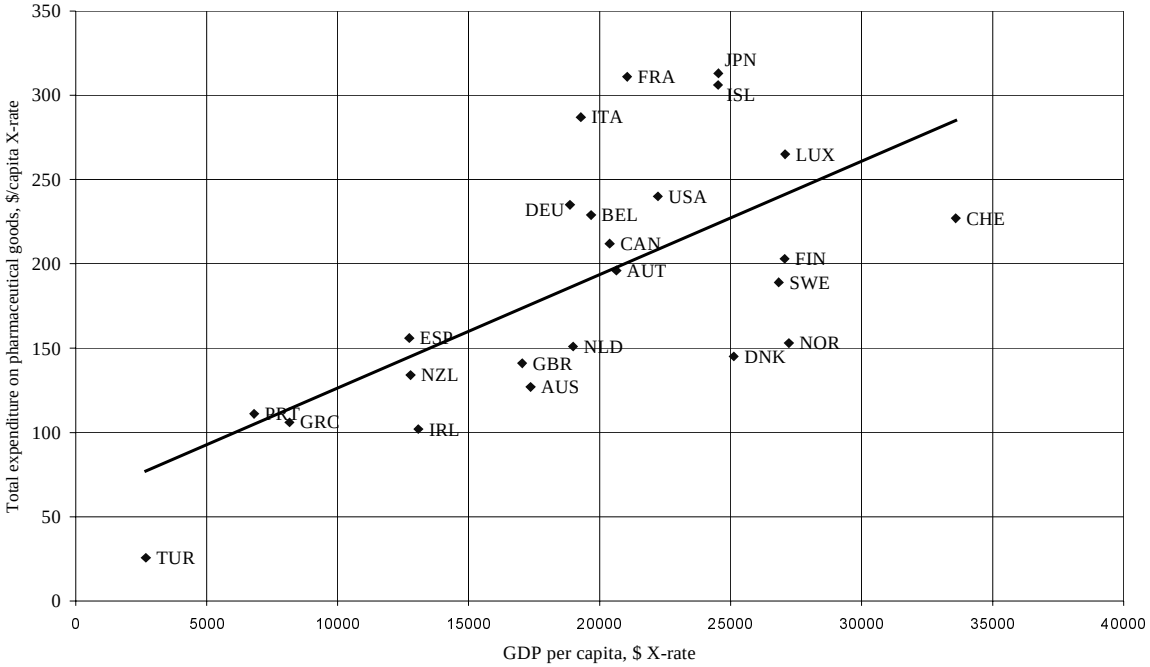
Chart 3. **Public expenditure on pharmaceutical goods per capita**
constant US dollars, current exchange rates



Source: OECD HEALTH DATA 98.

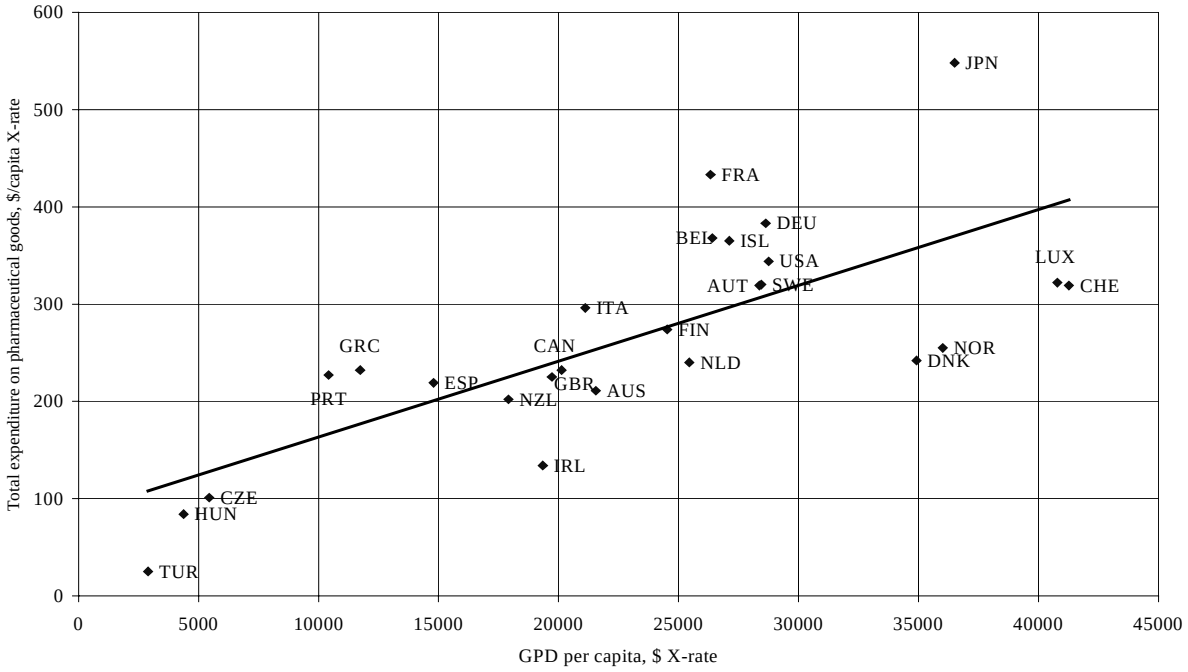
Chart 4. **Link between total expenditure on pharmaceutical goods per capita and GDP per capita at current exchange rates,**

1990



r^2:0.66 *Source*: OECD HEALTH DATA 98.

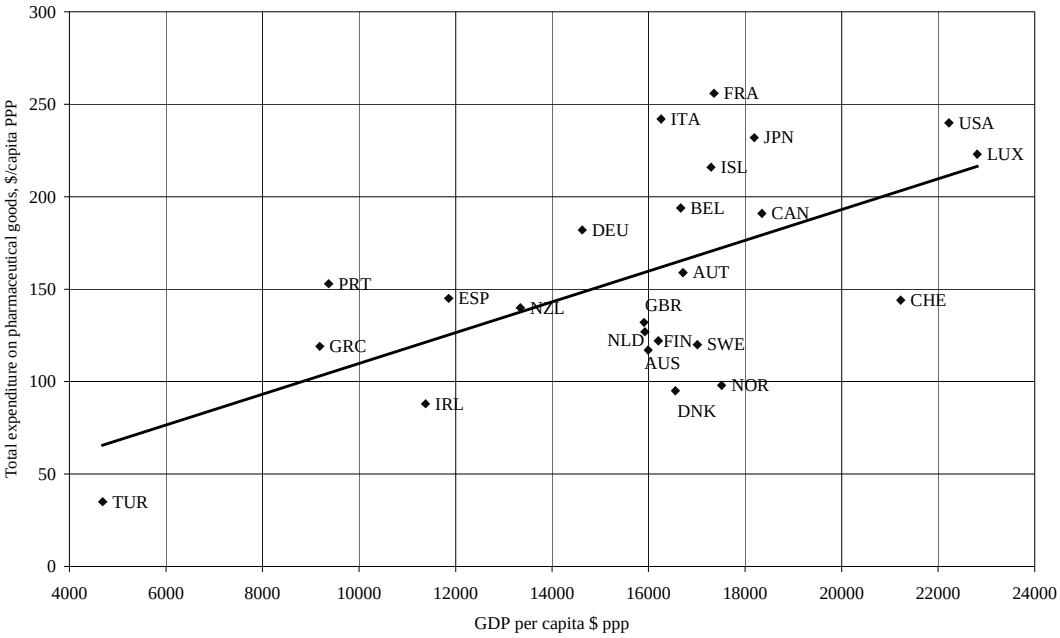
1996



r^2: 0.74 *Source*: OECD HEALTH DATA 98.

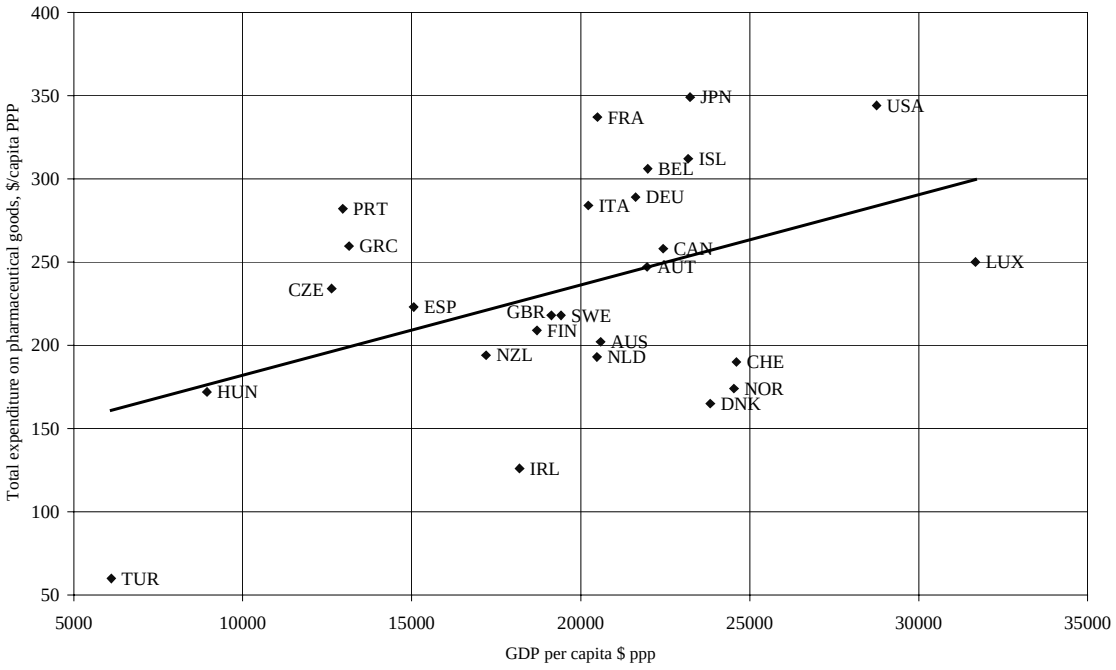
Chart 5. **Link between total expenditure on pharmaceutical goods per capita and GDP per capita at purchasing power parities**

1990



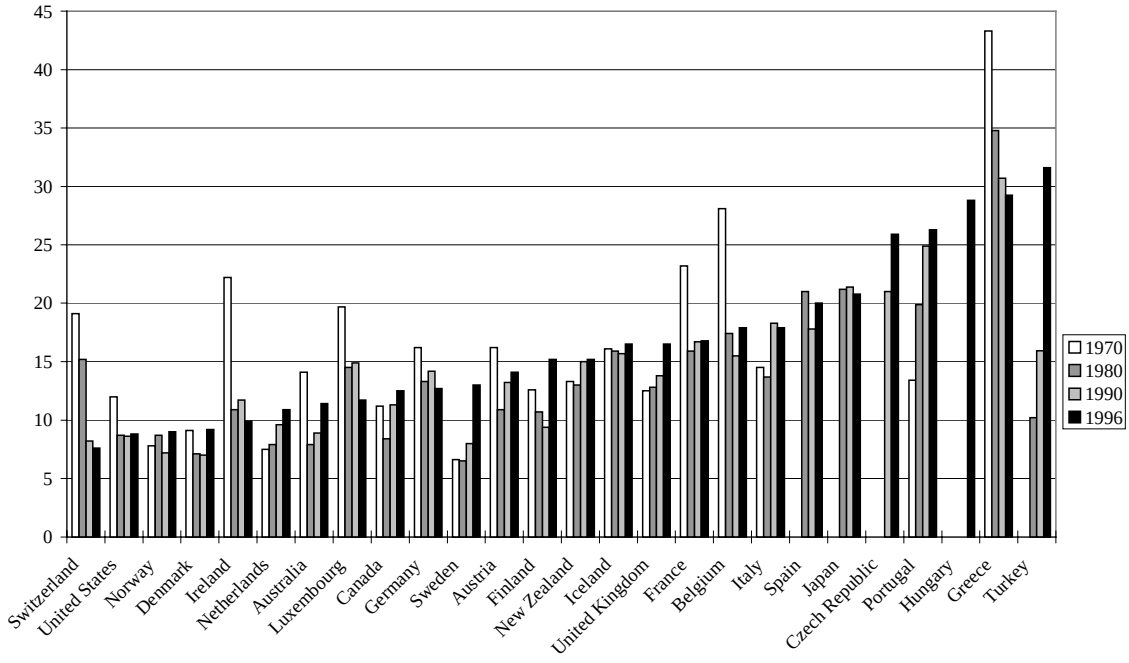
r^2: 0.60 *Source*: OECD HEALTH DATA 98.

1996



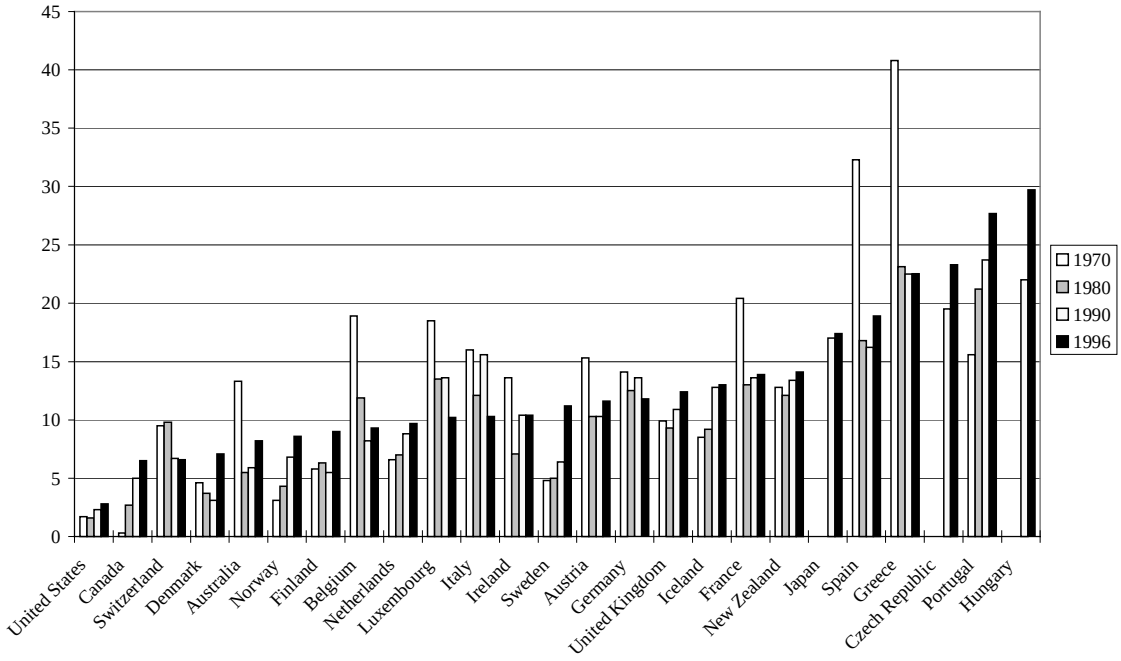
r^2: 0.45 *Source*: OECD HEALTH DATA 98.

Chart 6. **Total expenditure on pharmaceutical goods as a percentage of total expenditure on health**



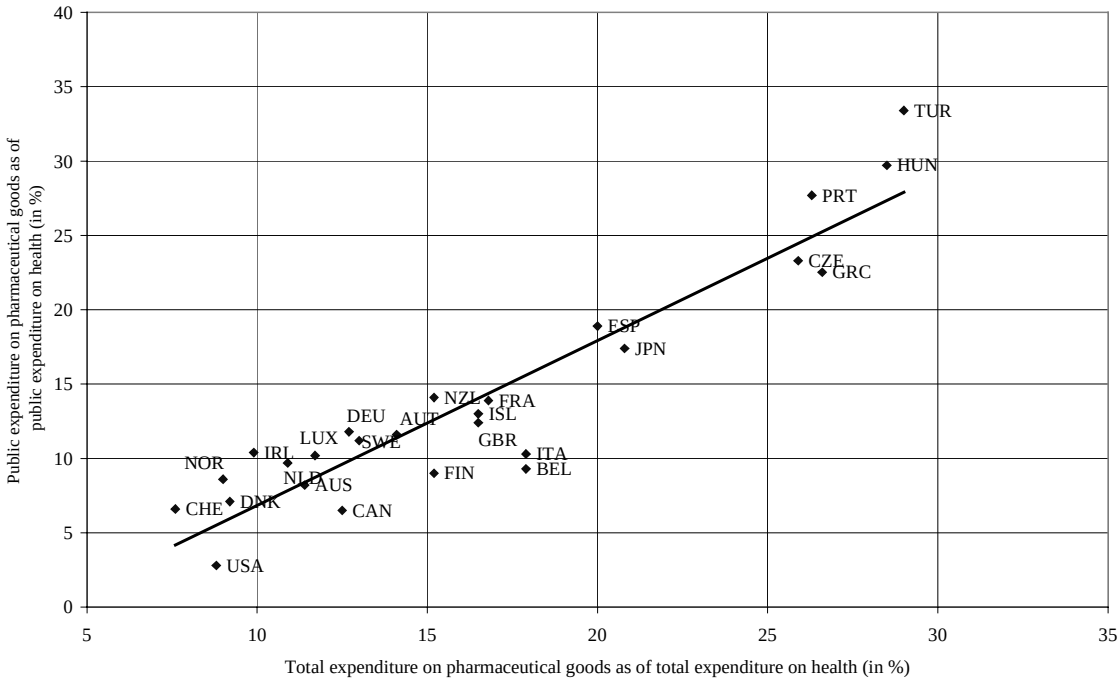
Source: OECD HEALTH DATA 98.

Chart 7. **Public expenditure on pharmaceutical goods as a percentage of public expenditure on health**



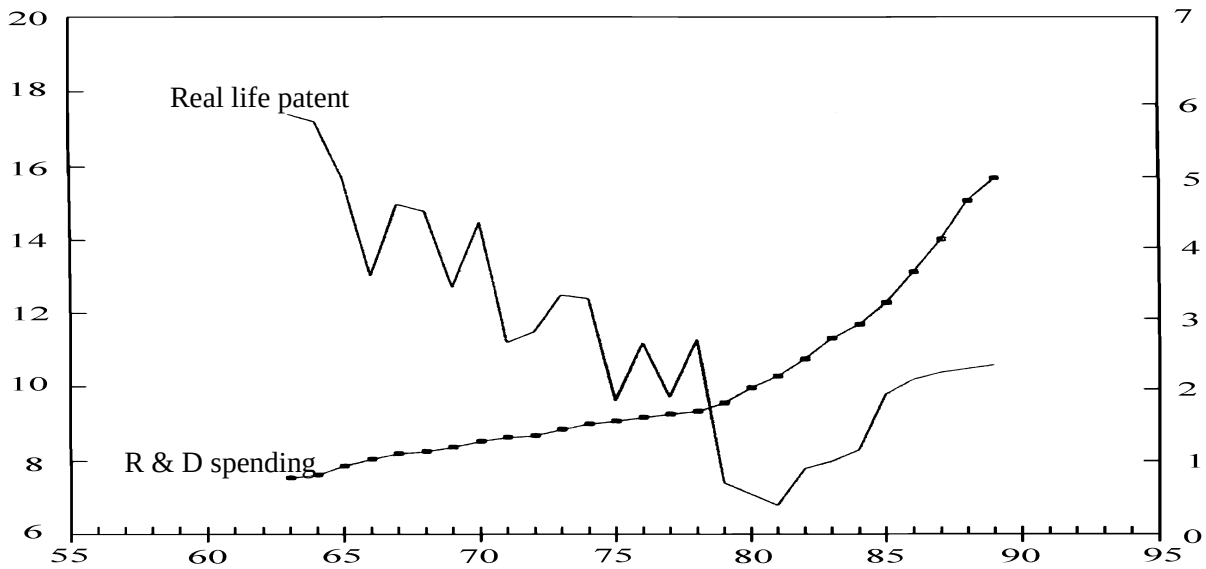
Source: OECD HEALTH DATA 98.

Chart 8. **Public expenditure on pharmaceutical goods versus total expenditure on pharmaceutical goods as of public and total health expenditures, 1996**



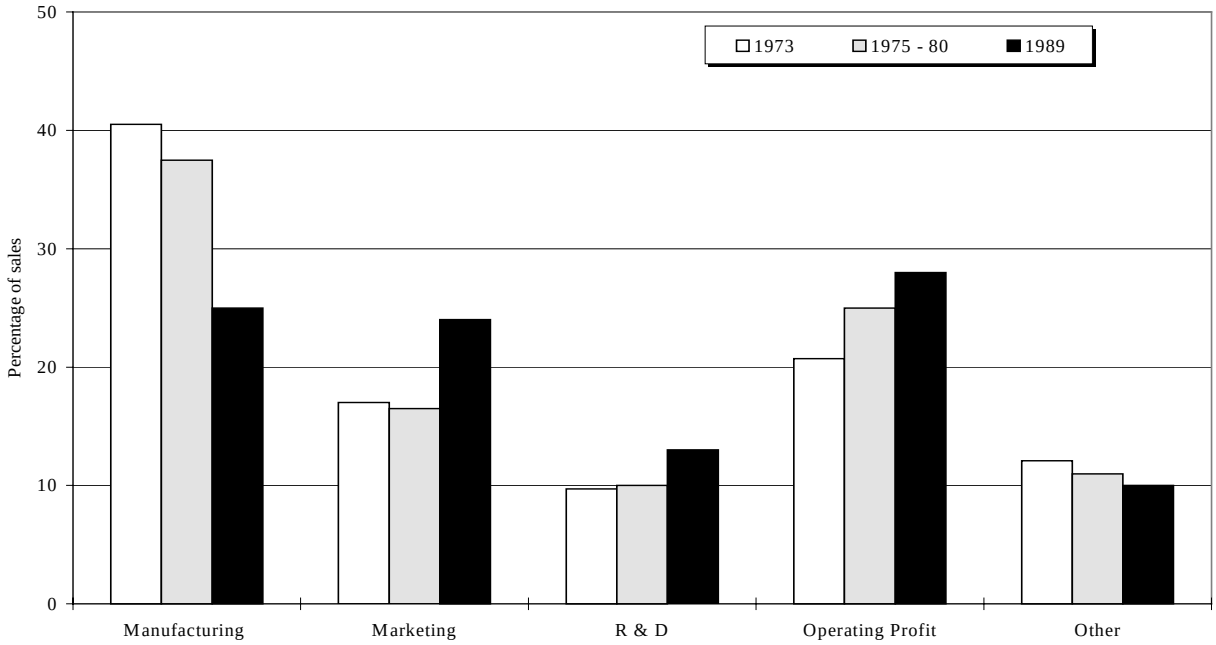
Source: OECD HEALTH DATA 98.

Chart 9. **R & D expenditures and effective patent life of NMEs in the United States, 1963-89**



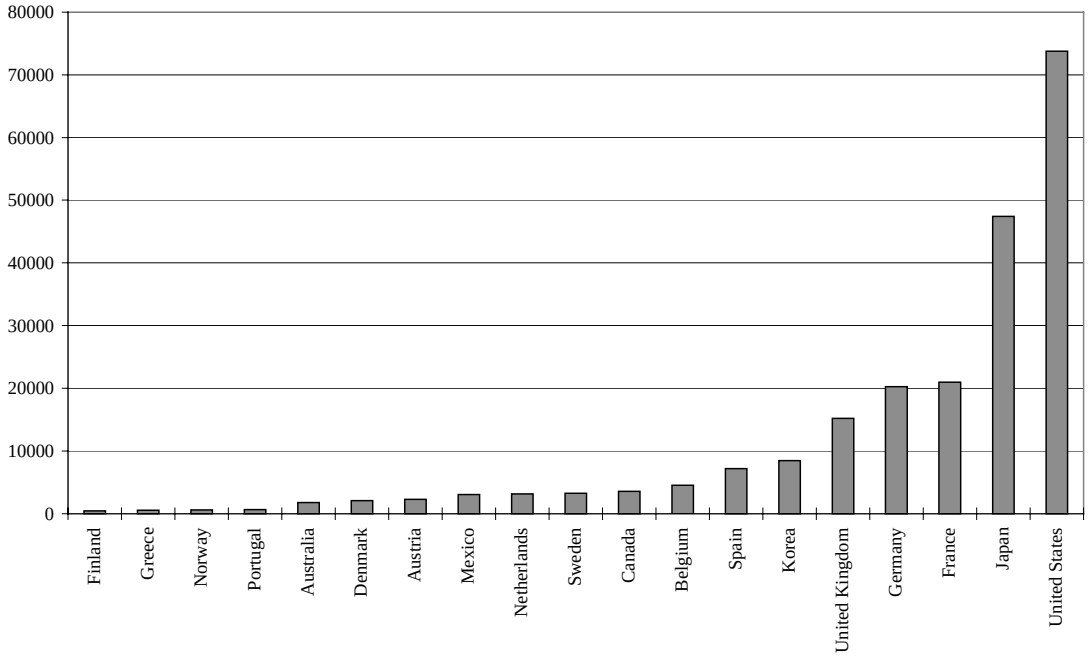
Sources: Estimates of patent life for 1963-81 were taken from Grabowski and Vernon (1983). Estimates for later years were done by UNIDO using average approval times reported by the United States Food and Drug Administration. Expenditure on R & D in current dollars were taken from Annual Survey Reports of the American Pharmaceutical Manufacturers Association and deflated to 1980 dollars by UNIDO.

Chart 10. **The changing structure of company costs in the pharmaceutical industry, 1973-89**



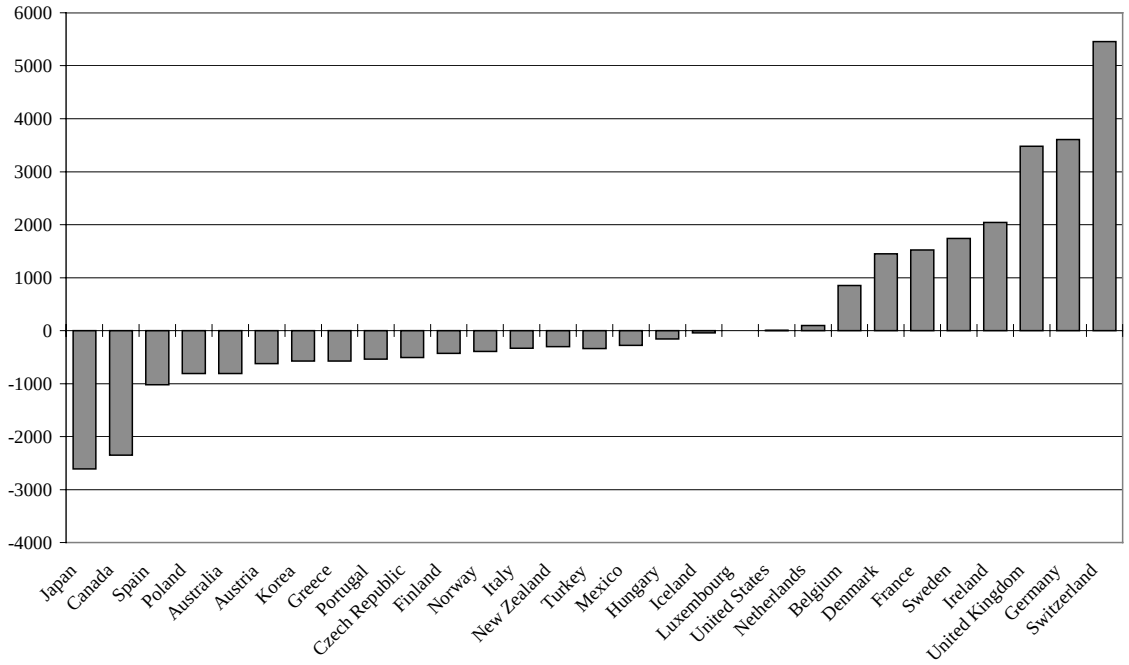
Note: Figures are based on data for research-oriented firms only. This means that these figures represent mainly the large pharmaceutical industries based in the main exporting countries.
Sources: based on Cooper, M. and A. Culyer (1973); OECD, 1975, p. 19; 1981, p. 31 and pp. 47-8; pharmaceutical company reports UNIDO estimates.

Chart 11. **Pharmaceutical production in 1995**
million US dollars, current exchange rates



Source: OECD HEALTH DATA 98.

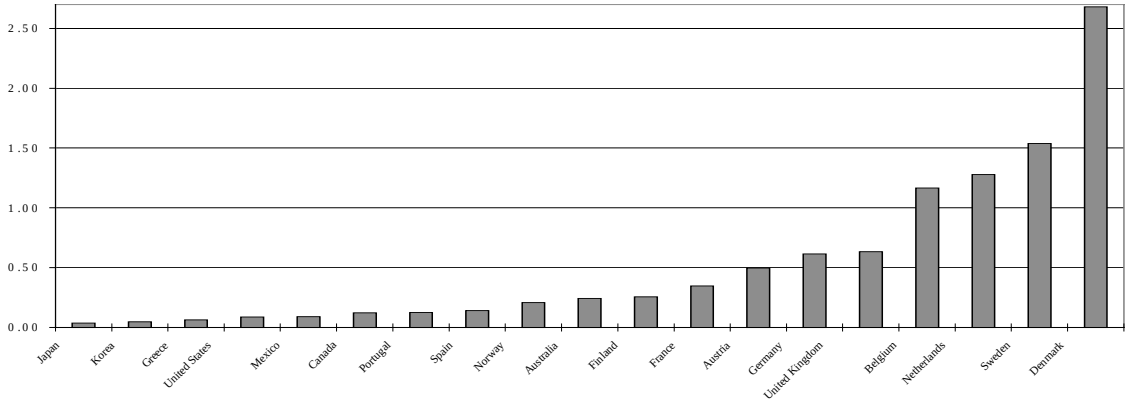
Chart 12. **Net pharmaceutical trade balance, OECD countries**
million of US dollars, current exchange rates, 1996



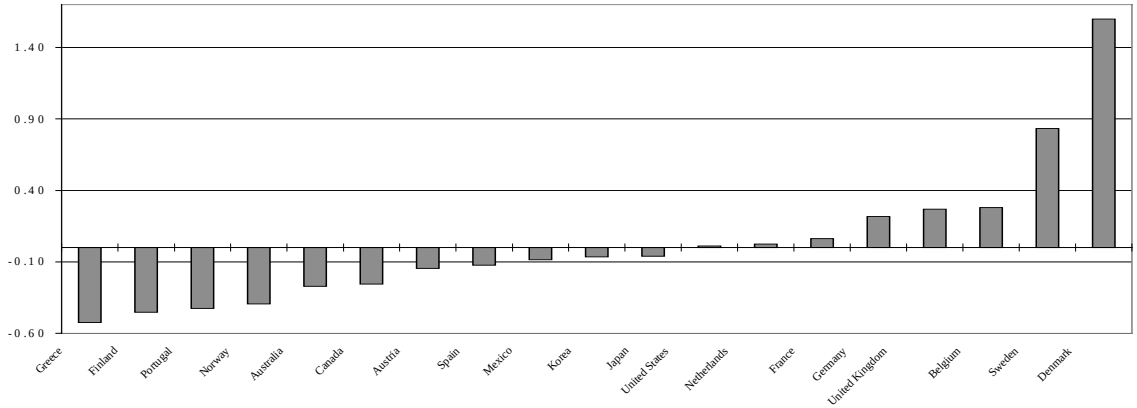
Source: OECD HEALTH DATA 98.

Chart 13. **Exports, imports and trade over domestic market, 1996**

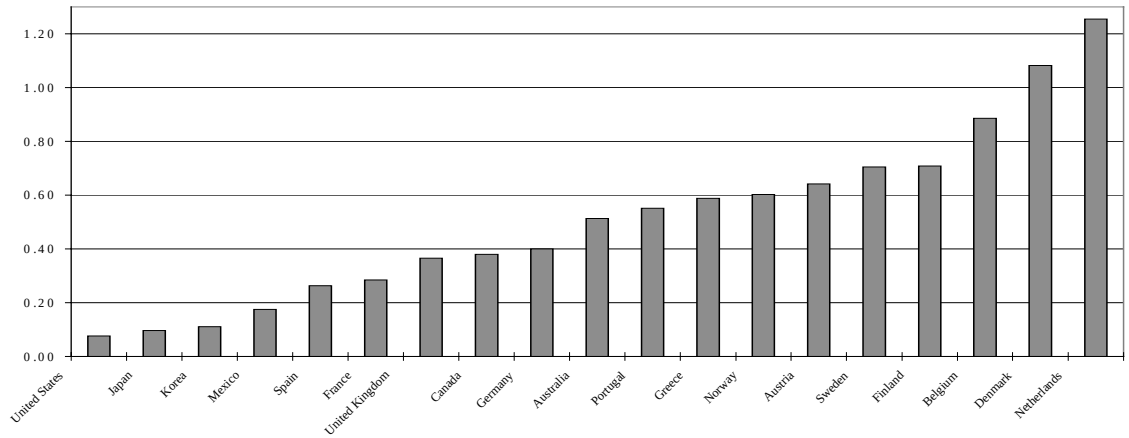
Exports / domestic market



Trade / domestic market



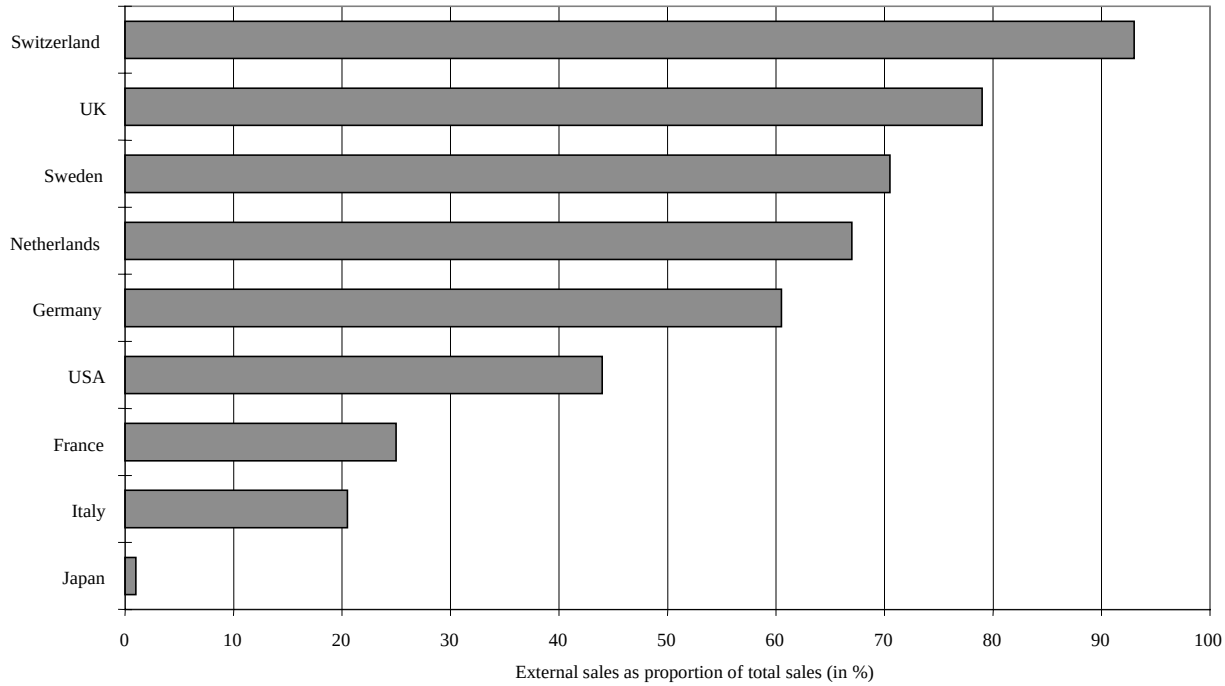
Imports / domestic market



Note: the domestic market is defined as production plus import minus export.

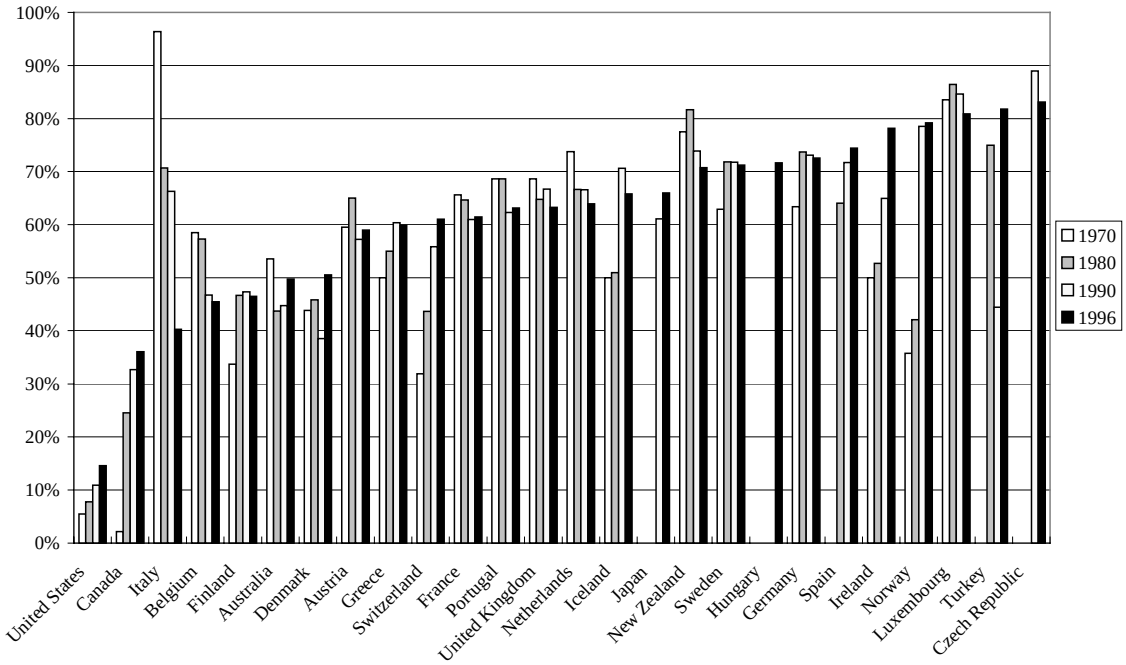
Source: OECD HEALTH DATA 98.

Chart 14. **Share of Multinational Drug Company Sales Outside Home Market**



Source: Thomas (1996)

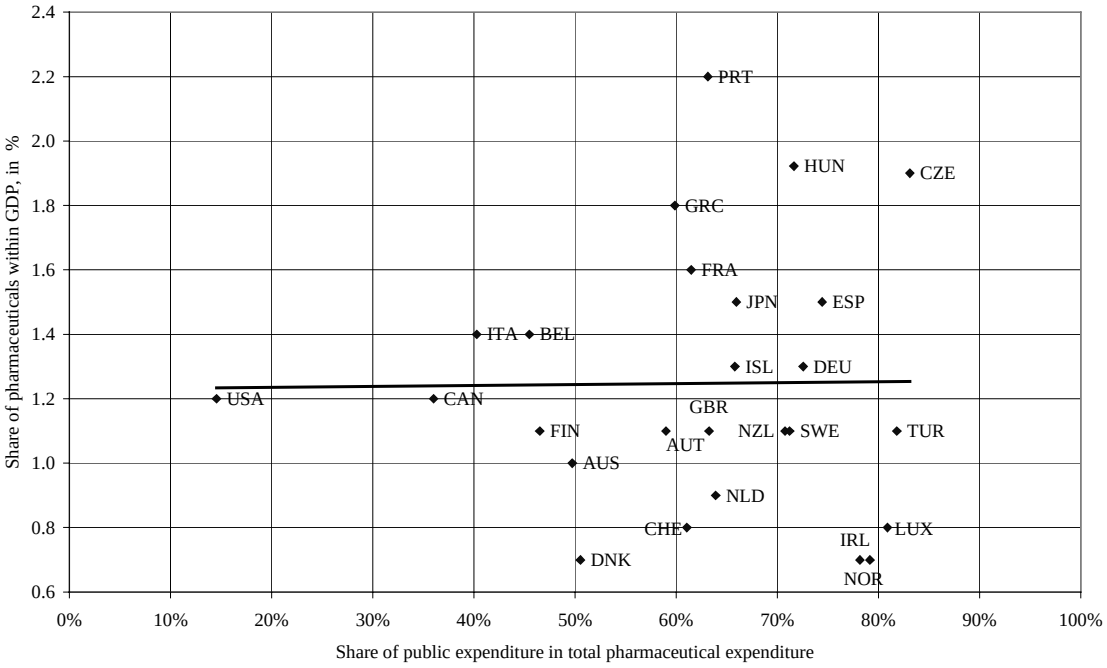
Chart 15. **Public pharmaceuticals expenditure within total pharmaceutical expenditures**



Note: data for Turkey needs further examination.

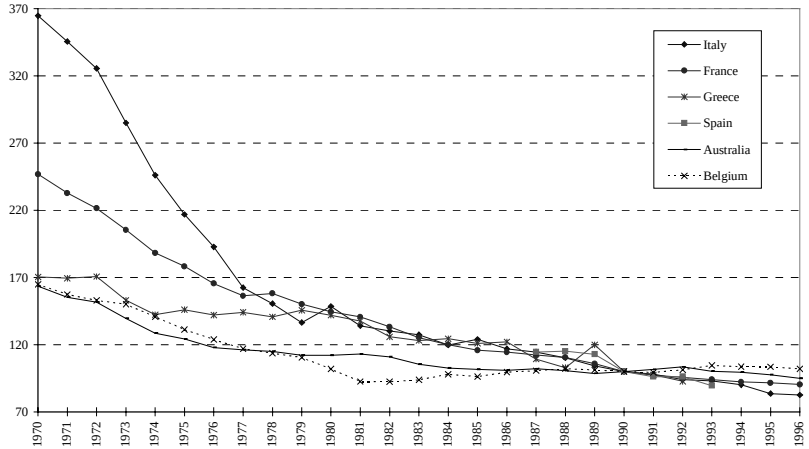
Source: OECD HEALTH DATA 98.

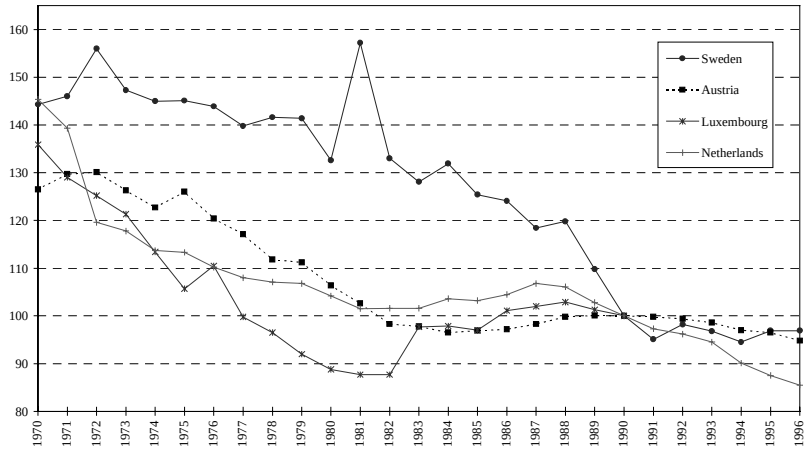
Chart 16. **Share of GDP and public coverage for pharmaceutical consumption, 1996**

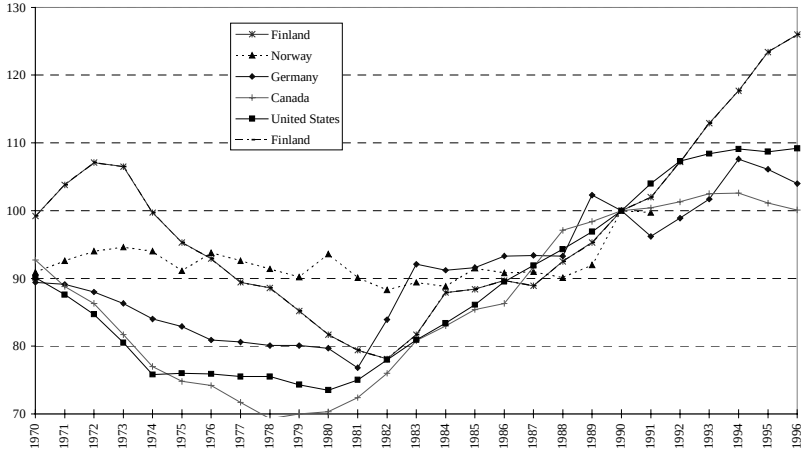


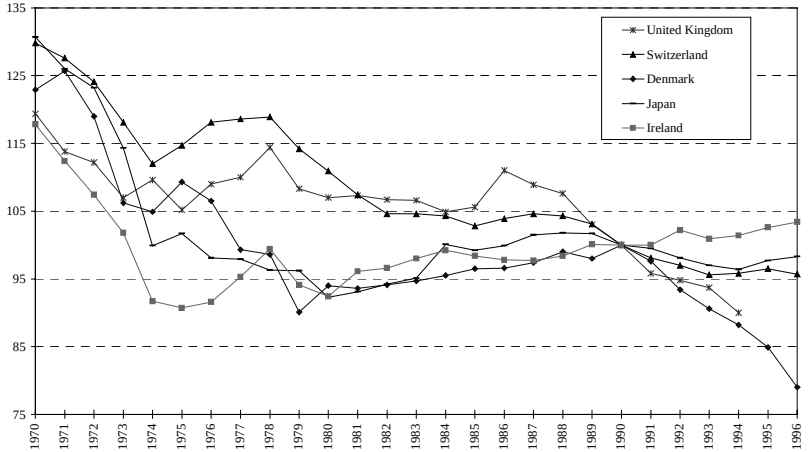
Source: OECD HEALTH DATA 98.

Chart 17. **Relative Price trends for pharmaceuticals**
(relative price compared to GDP deflator)



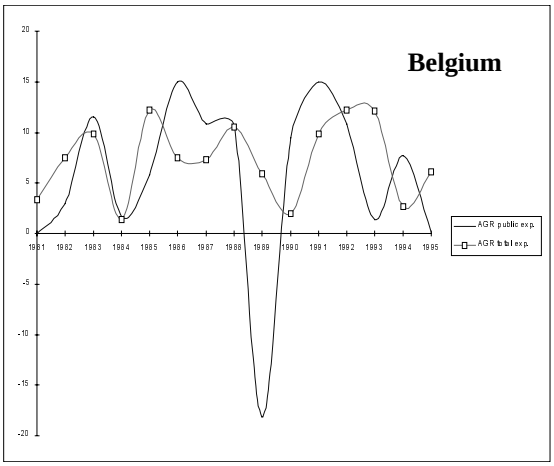


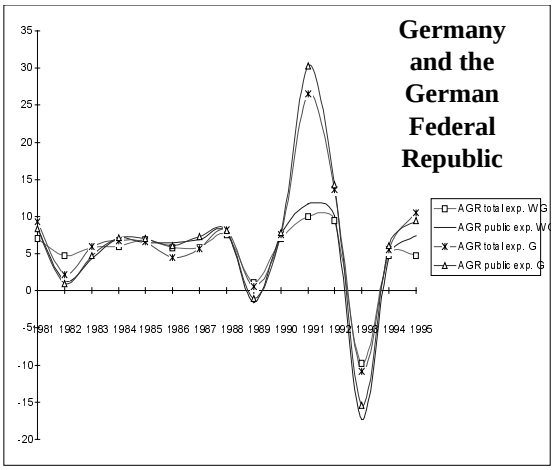


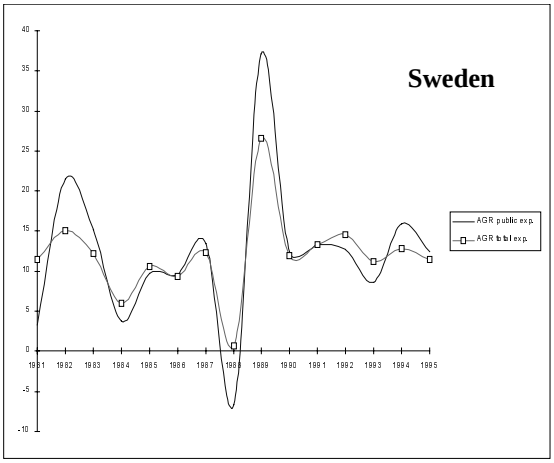


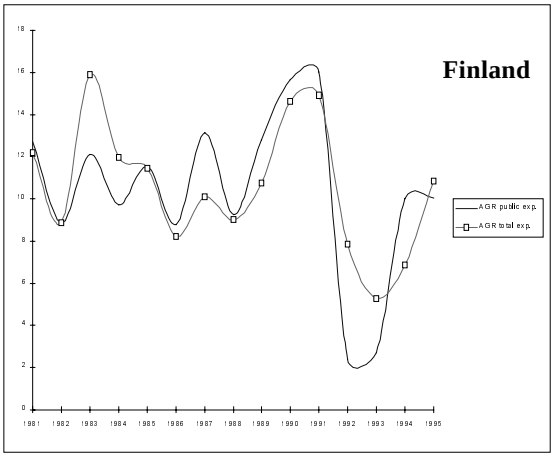
Source: OECD HEALTH DATA 98.

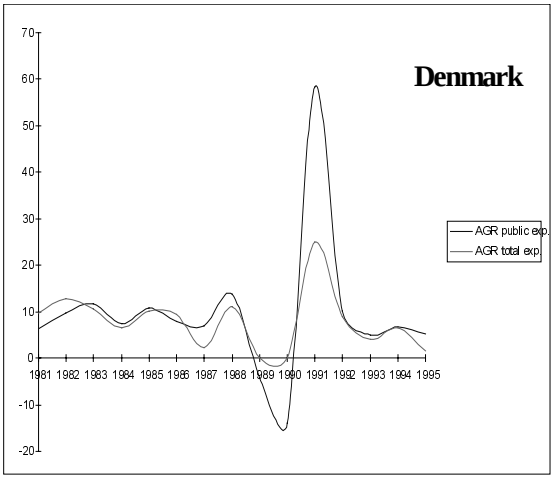
Chart 18. **Trends in the measured growth rate of total and of public expenditures on pharmaceutical goods for selected countries, 1980-1996**

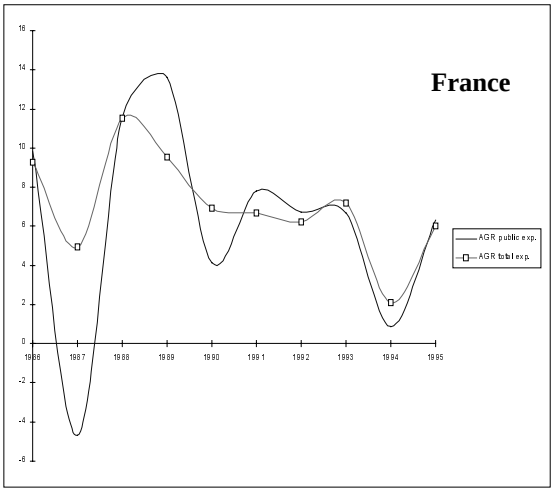






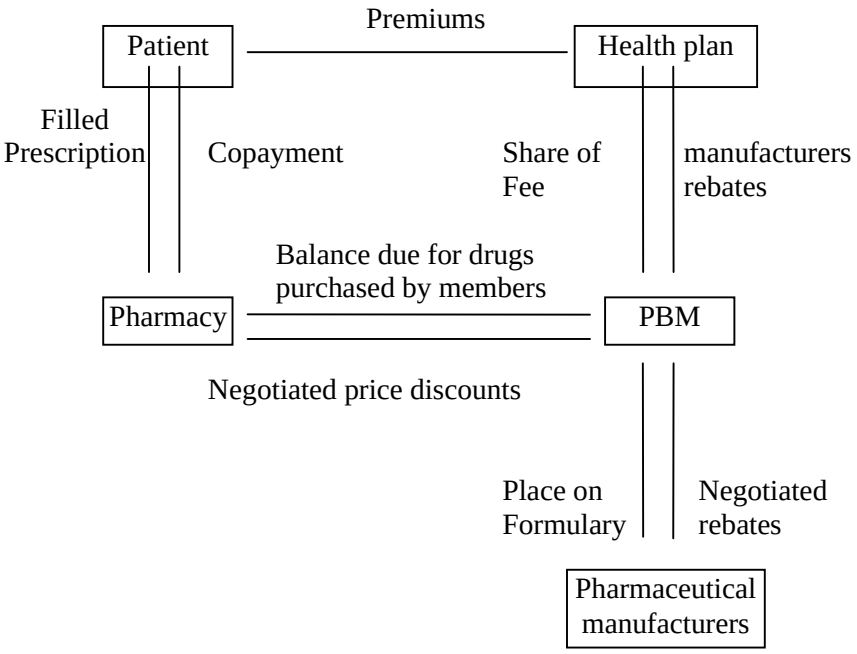






Source: OECD Health Data 1998

Figure 1. **How PBMs fit into the payment system for prescription drugs**



This refers to the United States
Note: PBMs= pharmaceutical benefit management companies.
Source: General Accounting Office, Pharmacy benefits managers: early results on venture with drug manufacturers, GAO/HEHS-96-45 (November 1995).

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