

C THE REGULATION OF PHARMACIES ABROAD

- C.1 This annexe provides a descriptive overview of how community pharmacies are regulated around the world with a particular focus on the impact on competition. This study was commissioned for the investigation. It is the responsibility of the authors and any views expressed in them are those of the authors and not necessarily of the OFT.
- C.2 The OFT commissioned Dr Elias Mossialos and Dr Monique Mrazek from the London School of Economics to undertake a study of pharmacy regulation in six OECD countries.
- C.3 In addition, a brief overview of the pharmacy regulations in the Republic of Ireland is presented. The Irish regulations can be described as being in a state of flux. The regulations that were put in place in 1996 were ruled to be ultra vires earlier this year and a Review Group has been set up to recommend a way forward.
- C.4 Overall, pharmacy regulations vary considerably around the world, reflecting differences in healthcare systems, the financing of those healthcare systems and historical trends.

Pharmacy regulation changes in the Republic of Ireland

- C.5 There are around 1,280 pharmacies in Ireland (or one per 3,040 people).
- C.6 Medicines in Ireland have broadly similar regulations on distribution as does the UK. That is, some are only available on prescription, some can only be purchased in the presence of a pharmacist while some OTCs (e.g. aspirin, paracetamol and cough medicines) are available in non-pharmacy outlets. However, whereas around 75 per cent of non-prescription medicines in the UK are sold in pharmacies, the figure for Ireland is almost 90 per cent.²⁹
- C.7 Ownership regulations are also similar to the UK – corporate bodies are allowed to own community pharmacies and there is no restriction on the number of outlets per owner. However, until recently, there have been tight restrictions on the location of pharmacies.
- C.8 In 1996, regulations were introduced making entry to the General Medical Services (GMS) dispensing market more restrictive.³⁰ For example, under the

²⁹ AESGP (2001).

³⁰ Broadly, the GMS is the Irish equivalent of the NHS. As with the UK and the NHS, there are few restrictions on setting up a non-GMS dispensing pharmacy in Ireland. But also like the UK and NHS, in the large majority of cases pharmacies need a GMS dispensing contract to be viable (Competition Authority, 2001).

new regulations, pharmacies could not open within 250 metres of an existing pharmacy in urban areas or within 5 kilometres in rural areas. In addition, pharmacies were required to pass a 'needs test'. In urban areas, the pharmacy applying for a contract must have been able to prove that at least 4,000 people in the area were not being adequately served by existing pharmacies (2,500 people in rural areas). Further, the new pharmacy must be 'viable' and not adversely impact on the viability of existing pharmacies.³¹

- C.9 In 2001, the Organisation for Economic Co-operation and Development (OECD) raised competition concerns about some of the regulations governing Irish professions.³² These included pharmacy, with particular criticism directed at the restrictive location requirements of new pharmacies and the ownership requirements (pharmacists not trained at Trinity College, Dublin, were prevented from opening a pharmacy within their first three years of working in Ireland).
- C.10 Around the same time a number of pharmacists, as well as the Irish Consumers' Association, challenged the legality of the location and ownership restrictions in the Irish courts. In January 2002, the Irish Attorney General ruled the regulations to be ultra vires.³³
- C.11 At present, no regulations are in force. Health Boards across the country have had various responses to this – some have stopped issuing new contracts until new regulations are issued.
- C.12 In the meantime, a Pharmacy Review Group has been established, comprising officials from across Government and pharmacy representative organisations. The terms of reference of the group is to review the pharmacy regulations with (among others) a view to:³⁴
- maximising the potential to increase competition within the sector with a view to ensuring lower prices and improved services to the consumers
 - assessing and responding to the recommendations in the OECD report on restrictions on the location of pharmacies while ensuring, in so far as is possible, a reasonable spread of pharmacies so that the service is convenient to the consumer
 - ensuring a high quality pharmacy service in remote and deprived areas (to include an assessment of the dispensing doctors scheme)

³¹ Competition Authority (2001).

³² OECD (2001).

³³ The Department of Health in Ireland has not released the details of the ruling.

³⁴ Department of Health (Ireland) (<http://www.doh.ie/aboutus/groups/revphar.html>)

- Ensuring that the opening hours of pharmacies facilitate consumers and meet all reasonable health needs of the population in its area, and
- Considering how a universal service and public service obligation can be identified and met and assessing any funding consequences which may arise.

The Regulation of Pharmacies in Six Countries

Report prepared for the Office of Fair Trading

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**LSE Health & Social Care and the
European Observatory on Health Care Systems**

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1.0 INTRODUCTION AND COMPARATIVE OVERVIEW

The aim of this study is to provide a brief overview of the laws and regulations governing the retail pharmacy sector that impact on competition between pharmacies in six OECD countries. As part of the Office of Fair Trading investigation into the entry controls to the retail pharmacy market in the United Kingdom, this study describes how retail pharmacy is governed in other countries, in particular the extent to which entry is controlled and pharmacies compete. The countries covered by this study are Canada, France, Germany, the Netherlands, Norway and the United States (USA). The countries were selected on the basis of the diversity of their systems for financing and delivering health care, as well as for the structure and extent of regulation in their pharmacy market. This report covers developments in the pharmacy markets of these countries up to June 2002.

This study examines the retail pharmacy sector in each of the selected countries along four main parameters: pharmacy numbers, restrictions of entry, restrictions of ownership and restrictions on price. The first section in each country case-study looks at the relationship between the ratio of pharmacies and pharmacists to population. Where the data is available, a time trend for comparison is included. This is followed by the examination of restrictions of entry in each country including whether there are restrictions on the location of new pharmacies and whether a licence or contract is required for dispensing prescribed drugs. Questions such as whether there are restrictions on ownership structure or the number of pharmacies per owner are examined in the section on restrictions of ownership. Finally, regulations limiting the retail prices of prescribed drugs are considered.

An appendix (Appendix A) to this study provides a brief overview of the mechanisms for financing and delivering health care in the selected countries. It includes requirements for co-payments and the limits to product reimbursement.

Comparative findings of country case-studies

Each case study in this report examined the pharmacy market in the selected countries that considered market structure, regulation and competitive potential. Key differences between countries were observed in terms of market structure and the extent of regulation in the markets. Market structure and the extent of competition in the market are extensively determined by the regulations in place. For example, regulations that limit the chaining of pharmacies and the location of pharmacies are important determinants of the extent of competition in the retail pharmacy market.

The results of this study are summarised in the table below.

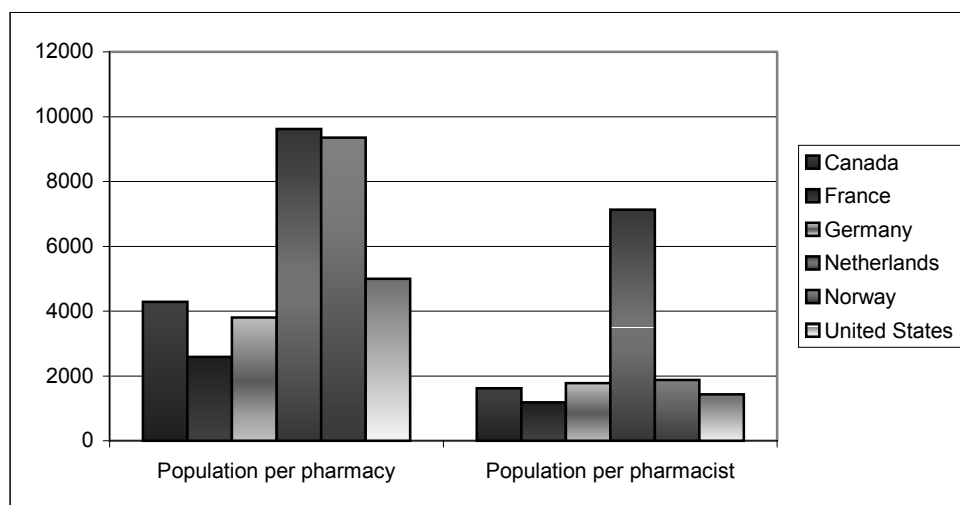
Table 1.1. Regulation of pharmacies in six countries

	France	Germany	Netherlands	Norway	USA	Canada
License or contract required?	Yes	Yes	Yes	Yes	Yes	Yes
Location of new pharmacies restricted?	Yes	No	No	Yes	No	No
Ownership structure restricted?	Yes	Yes	No	No	No	No
Number of stores per owner restricted?	Yes	Yes	No	Yes	No	No
Regulated prescribed drug price a price maximum?	Yes	No	Yes	Yes	No	Yes

Pharmacy and pharmacist numbers

The first comparison was made in terms of the population relative to the number of pharmacies and pharmacists (Figure 1.1). In terms of the number of pharmacies as compared to the population, both the Netherlands and Norway seem to be outliers relative to the other study countries. Since the deregulation of the pharmacy market in Norway the number of pharmacies has increased and consequently this ratio is decreasing. Only the Netherlands is a relative outlier when considering the population to pharmacist ratio. This is likely because other health professionals including chemists and pharmacy assistants are involved in the dispensing of OTC medicines.

Figure 1.1. Comparative population to pharmacy and pharmacist ratios



Source: Authors' estimates based on country reports that follow

Note: Population to pharmacy ratios based on data from 2002 Norway, 2001 Germany and 2000 all other countries. Population to pharmacist ratios based on data from 1996 USA, 1998 Canada, 1999 Netherlands, and 2000 all other countries.

The number of pharmacies was increasing in all countries except the USA since the early 1990s. The number of pharmacies was found to be decreasing in the USA mainly due to an increase in the number of chained pharmacies, as well as an increase in the market share of sales in the pharmacy market due to mail order pharmacies. Although pharmacy numbers are increasing in Germany this is occurring at a decreasing rate, possibly because of the high number of pharmacies particularly in some urban areas. Pharmacies numbers in France are tied to population numbers.

Licensing

All countries examined in this study require pharmacists and pharmacies to be licensed. In some countries the licensing of either or both pharmacists and pharmacies is at the national level while in others licensing is at the regional level as in Canada, Norway and the USA; however, even when licensing is a regional responsibility requirements are fairly uniform between the regions. All countries require a licensed pharmacist to manage the dispensing medicines in a licensed pharmacy. In Norway, a pharmacist may be granted a licence to manage only one pharmacy but can also manage up to 3 branches.

Location

The location of pharmacies is not geographically restricted nor are the number of pharmacies restricted in most of the study countries. In Canada and USA pharmacies can be located in supermarkets or in mass merchandiser stores. The location of pharmacies was restricted in France in an attempt to secure certain geographic pharmacy to population ratios. The other exception is Norway and despite significant recent deregulation of the pharmacy market a remaining restriction in terms of the location of pharmacies is that they must be physically separated from the prescribing

doctor's practice. Prior to 2001, the Norwegian government regulated who could own a pharmacy, how many pharmacies there could be and where they were to be located.

Although there is no restriction of pharmacy numbers or locations in the Netherlands, to some extent the structure of the health care market itself does impose certain restrictions. For a single pharmacist or a group of pharmacists the barrier to market entry is obtaining a contract of service with a principle insurer in the area, as loans to open a new pharmacy are often tied to this condition. As well, entry of new pharmacies, even larger established corporations, may be impeded by customer loyalty to a particular pharmacy that is generally established through the relationship with the patient's insurer and encouraged to ensure the continuity of care for the patient. Patients are able to obtain their prescription drugs free at pharmacies where they have an established relationship and it is the pharmacy that then sends in the prescription for reimbursement to the insurer. Relationships between existing pharmacies in an area (i.e. the exchange of patient information) and the opposition of general practitioners also serve as barriers to entry to the Dutch retail pharmacy market.

Certain categories of OTC medicines can be sold outside pharmacies or in the absence of pharmacists in Canada and the USA, as will soon be the case in Norway. Currently in Norway a limited range of OTCs are available in medicine outlets located in more remote areas, but these are owned and the responsibility of a licensed pharmacy. In Germany, only OTCs that are considered 'harmless' such as herbal teas and vitamins can be dispensed outside of a pharmacy in for example supermarkets, but even then staff has to receive some training. OTC medicines are sold only in pharmacies in France.

Despite the large geographic distances in Canada and the often sparse rural populations, there are no subsidies for rural pharmacies. Nevertheless, there are some provisions that allow for physicians to dispense in rural areas in Canada; this is also the case in the Netherlands. Also in France and the USA there are no subsidies for rural pharmacies. In Germany, although there are no direct subsidies for rural pharmacies, an exception may be made in rural areas to the single pharmacy ownership rule allowing a pharmacist owner to own a second pharmacy in a remote, less profitable and designated location. Only Norway maintains operational subsidies for pharmacies in rural areas.

Mail order pharmacies are allowed in Canada and shipping is allowed across provincial and national borders. Prescription medicines may only be sent across state lines in the USA if the pharmacy is licensed to dispense to residents of that particular state. In Norway, mail order dispensing is only allowed within a pharmacy's geographic area. Dispensing by mail in France is only allowed if a patient is unable to travel to a pharmacy, however internet pharmacies are not allowed. Despite attempts to dispense drugs in Germany via the internet, this approach to dispensing, as well as the concept of mail order drugs in general has been met by much resistance from the pharmacists' association. Mail order drugs in Germany are allowed for immobile patients, however there is no attempt to verify the patient's status. Although mail order and internet pharmacies are allowed in the Netherlands they have yet to capture a significant share of the market generally because patients would have to pay out-of-pocket to be

reimbursed rather than be able to obtain their prescription free of charge at their local pharmacy where they have an established relationship.

Ownership

Most countries in this study including Canada, Netherlands, Norway and the USA do not restrict the ownership structure of pharmacies and do permit corporations to own pharmacies and for pharmacy owners to own more than one pharmacy. The ownership structure of pharmacies is restricted in France as well as in Germany. In both France and Germany, ownership of a pharmacy is restricted to a registered pharmacist and a pharmacist is allowed to own only one pharmacy. This gives pharmacists in both countries a monopoly on dispensing. Interestingly, France and Germany collectively had just over 40 per cent of all pharmacies in Europe in 2001 (Luckenbach, 2001). Although in both France and Germany the pharmacy may be owned by a group of pharmacists, this is rare in the case of the latter. These regulations are similar to those that were in place in Norway prior to market deregulation in 2001.

Therefore, given the restriction on ownership in France and Germany, neither country has pharmacy chains. In Norway, although pharmacy chains are permitted, no single chain can own or manage a group of pharmacies whose combined turnover exceeds 40 per cent of the total sales turnover of all private pharmacies in the market. In all other countries, pharmacy chains form an important part of the market and secure competitive forces within the pharmacy market environment.

Retail price and payment of pharmacists

The regulation of drug prices differs between countries. Only the USA does not have any type of centralised price regulatory system for pharmaceuticals. Nevertheless within the heterogeneous health care market of the USA, both private health care payers, as well as public payers mostly at the state level do use various incentives and requirements to obtain lower drug prices and discounts from manufacturers, wholesalers and pharmacists. These cost-control initiatives, particularly those undertaken by PBMs have resulted in decreasing margins right across the distribution chain.

The other countries in this study do apply some form price regulation to prescription medicines. Germany is the only country other than the USA not to regulate the price of in-patent drugs. However Germany does indirectly regulate the price of off-patent (generic) drugs through a reference price scheme. A reference price scheme for off-patent drugs is also applied in the Canadian province of British Columbia, Netherlands and Norway, although the Dutch scheme includes some in-patent drugs as well. Canada regulates only the prices of patented drugs Federally although the provinces and territories apply different price controls and incentives that limit the prices of off-patent drugs. Only in France are OTC drugs subject to price controls if they are reimbursed as with all other reimbursed drugs whether in-patent or generic.

Wholesaler margins are competitive in Canada, the Netherlands and USA. Regulated margins are applied to wholesalers in Germany although some discounting to the pharmacist is allowed.

Both France and Germany pay pharmacists with digressive margins scaled to price bands that decrease as product price increases. Although these margins are scaled digressively the overall effect is that pharmacists receive a higher margin from dispensing a more expensive medicine. The objective of the regulated pharmacist margins in Germany is to ensure uniform retail prices.

Despite market deregulation in Norway, the payment of pharmacists is still centralized. Pharmacy owners are paid through a progressive annual fee. Subsidies are still given to pharmacies not generating a surplus in order to ensure a reasonable return. This payment approach is contrary to the competitive incentives that were introduced and that should exist for payment within the Norwegian market. Restrictions are also placed on Norwegian pharmacies in terms of how they generate their turnover and what percentage of that should be generated by the sale of medicines.

Pharmacist margins in the Netherlands and the USA are determined to a greater extent by the market. In the Netherlands, pharmacists are reimbursed at the list price of regulated drugs but often agree to discounts below the list price through a negotiated clawback in order to secure contractual arrangements with insurers. Dutch pharmacists also have financial incentives to dispense generics and are able to retain up to one-third of the price differential. This is also the case in Norway where pharmacists can retain up to 50 per cent of the difference between the maximum price and the actual price of the drug. A perverse incentive does exist for pharmacists in the Netherlands to dispense smaller pack sizes particularly for repeat prescriptions as they are paid a fee each time a prescription is dispensed.

Pharmacist margins are unregulated in Canada. In Canada, pharmacists are generally paid either for the actual acquisition cost of the drug or the maximum list price plus a dispensing fee. These dispensing fees are negotiated with the main public provincial insurer although the fees may differ for private insurers or may be discounted to encourage patients to shop around. Provinces set dispensing fees in different ways including having a flat fee, a digressive fee scaled to product price bands or as a percentage of the drug price.

Regulation Versus Deregulation

This study finds that there are benefits to deregulation and the increased competition in pharmacy markets. Benefits can be generated in terms of cost savings both to patients paying at source and to health care payers through lower retail prices. As well, ease of access to pharmacies located in supermarkets or mass merchandisers may potentially reduce transaction costs for some consumers although in so doing may transform the market characterised by independent pharmacy retailers.

The extent of competition as well as the payment methods, are linked to incentives for discounting in the distribution chain and the dispensing of cheaper multi-sourced drugs. Fixed reimbursement prices that give pharmacists incentives to dispense the cheapest multi-sourced drug while retaining a higher margin for doing so encourages competition and discounting of a product's price. Margins linked to product price even if these are scaled digressively encourage dispensing of more expensive drugs as pharmacists retain a higher margin. Chaining of pharmacies is also associated with discounting of pharmacists' margins.

Evidence of competition in the more deregulated pharmacy markets is clear. Where chaining of pharmacies is permitted (i.e. in Canada, the Netherlands, Norway and the USA) horizontal integration continues. In both the Netherlands and Norway, increasing competition has led to forward integration of wholesalers purchasing pharmacies. Also in the Netherlands, insurers have increasingly moved to operate their own pharmacies in an attempt to better position themselves for discounts from manufacturers.

It is interesting to consider the extent to which the relationship between insurers and pharmacies does or does not generate beneficial outcomes. On the one hand the close relationships between an insurer and a pharmacy chain can create barriers to entry to new pharmacy chains and could to some extent limit competition. On the other hand leverage is created by the size of the insurer/purchaser to motivate discounted dispensing fees which can generate cost savings for the payer and end consumer; this has been an important part of the cost-saving strategy of PBMs in the USA (NACDS. 2002). If patients visit the same pharmacy as in the Netherlands or network of pharmacies as in the USA it can also be beneficial to the continuity of care. In Canada, the consumer is encouraged to shop around to obtain a discounted dispensing fee; but to the extent this occurs or whether consumers would benefit more from the organized leveraging of size of insurers as in the USA or Netherlands would certainly merit further consideration. Some pharmacy chains in Canada do motivate consumer loyalty through promoting the concept of continuity of care in having prescriptions dispensed at the same pharmacy or with the same chain.

Certainly there would be both cost savings to consumers and efficiency gains to retailers through deregulation and increased competition in the pharmacy markets in both France and Germany. The Federal Ministry of Health in Germany has indicated that it considers the number of pharmacies in Germany to be too high. It is not clear however, that deregulation would necessarily mean a decrease in the number of pharmacies. Although the experience in the USA has been for a decrease in the number of pharmacies primarily driven by the expansion of pharmacy chains and mail order pharmacies, the situation in Norway has been the opposite, since deregulation, with an increase in the number of pharmacies. In the case of Norway it is likely that this increase in the number of pharmacies subsequent to deregulation was due to an under supply in the number of pharmacies in the market as the number was previously regulated. It is likely that as France has a regulated system of pharmacy to population numbers that is similar to that which was in place in Norway prior to deregulation that the French experience in a deregulated pharmacy market may be similar to that in Norway. However, as Germany does not regulate pharmacy numbers but only restricts ownership it may follow the experience of the USA and possibly see a decrease in the number of pharmacies through both pharmacy chaining and also if the market for mail order/internet pharmacies is allowed to expand. Vertical integration could also be anticipated in Germany in particular given that German wholesalers have actively engaged in the purchase of pharmacies in other markets namely Norway.

As the retail pharmacy market is a heavily under researched area, the conclusions given here should be treated with some caution. Certainly, how these markets operate and particularly the approaches taken in different countries is important. More research is needed on the pharmacy markets particularly differences in terms of regulation and deregulation, as well as on the relationships between key actors in this market.

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2.0 CANADA

2.1 Pharmacy numbers

Both the number of pharmacies and pharmacists have increased in Canada during the 1990s as shown in tables 2.1 and 2.2. The number of pharmacies in Canada increased by 9 per cent between 1995 and 2000 (3.8 per cent 95/98) while the number of pharmacists increased by 12 per cent between 1990 and 1998 (4.95 per cent 95/98). The population of Canada increased by 10.1 per cent between 1990 and 2000 (3 per cent 95/98). This suggests that at least between the 1995/98 period that the number of pharmacists were increasing faster than both the number of pharmacies or the Canadian population. The ratio of pharmacies to population increased by only 0.8 per cent between 1995/98 while the ratio of pharmacists to population increased by 2.1 per cent.

Table 2.1. Number of pharmacies in Canada, 1995 - 2000

Year	Number of Pharmacies ⁽¹⁾	Population ⁽²⁾	Number of community pharmacies per 100000 population
1995	6527	29354000	22.24
1996	6529	29672000	22.00
1997	6584	29987000	21.96
1998	6786	30248000	22.43
1999	6918	30493000	22.69
2000	7175	30750000	23.33

⁽¹⁾ Source: IMS HEALTH Canada, 2000

⁽²⁾ Source: OECD Health Data, 2001

Table 2.2. Number of pharmacists in Canada, 1990 – 1998

Year	Number of Pharmacists	Population	Number of community pharmacists per 100000 population
1990	16458	27701000	59.41
1991	15468	28031000	55.18
1992	16090	28377000	56.70
1993	16484	28703000	57.43
1994	16986	29036000	58.50
1995	17808	29354000	60.67
1996	18358	29672000	61.87
1997	18203	29987000	60.70
1998	18735	30248000	61.94

Source: OECD Health Data, 2001

2.2 Restrictions of entry

A licensing system exists for dispensing prescribed drugs (NAPRA, 2002a). The licensing and registration of persons who engage in the dispensing and sale of pharmaceuticals to the public and operate pharmacies is the responsibility of Canada's provincial and territorial Pharmacy Regulatory Authorities. In general, to become a licensed pharmacist in a Canadian province an individual needs: a bachelor's degree in Pharmacy from a Canadian University; must complete a national board examination of the Pharmacy Examination Board of Canada; have a particular level of fluency in English or French; and pay a licensing fee. Pharmacies in Canada must be accredited. Again the accreditation is done at the provincial level. Most provinces require an initial pharmacy licensing fee and an annual renewal fee.

Only registered and licensed pharmacists can dispense prescription medicines as defined in provincial 'health professions' legislation. These registered pharmacies may be located within supermarkets, department stores or other retail outlets. However, a registered pharmacy must have a pharmacist managing the pharmacy and the dispensing of prescription medicines. There are some restrictions on who can sell OTC medicines. Certain classes of OTC medicines can be sold at locations other than pharmacies where no pharmacist needs to be present. What pharmaceutical products can be sold and where is governed by two federal pieces of legislation: *Controlled Drugs and Substances Act*; and *Food and Drugs Act*.

Mailing of drugs to customers is allowed and may even be sent across provincial or Canadian borders. However, the prescription must be written by a professional licensed to prescribe in Canada.

There are no special provisions made to encourage pharmacies to locate in rural areas. Some exceptions are made for very remote rural areas where physicians in some cases can dispense. Also in some areas dispensing fees may be higher to support rural pharmacies.

Pharmacies are not restricted in number through being subject to a test of community need. There is no restriction on where pharmacies may locate in relation to other pharmacies or prescribing doctors.

2.3 Restrictions of ownership

There are no restrictions on pharmacy ownership. The only restriction is that a licensed pharmacist must manage the pharmacy (NAPRA, 2002b). Nor are pharmacy owners restricted in the number of pharmacies they can own. Pharmacy chains are common in Canada, as are pharmacies located in supermarkets and in mass merchandisers. Nationally 14 per cent of pharmacies are located in supermarkets or in mass merchandisers but this figures rises to 24 per cent in British Columbia (Pharmacy Post, 2000). In Ontario 42 per cent of pharmacies were independent in 2000, compared to 30 per cent in British Columbia, 25 per cent in Atlantic Canada and 11 per cent of pharmacies in Quebec.

2.4 Restrictions on price

There are restrictions on pharmaceutical prices in Canada. The maximum price at which a manufacturer can sell a patented drug to wholesalers, hospitals or pharmacies (i.e. ex-manufacturer, ex-factory price) is regulated in Canada at the federal level. There is no regulation of non-patented medicines, although some provinces do limit the reimbursement prices of generic medicines. Wholesalers margins are also not restricted. Pharmacist margins (i.e. professional fees) vary from province to province and consequently so does the final retail price of drugs. Retail prices of OTC medicines are not regulated unless they are in-patent or listed on a drug plan's formulary.

At the federal level, the manufacturers' selling price is regulated by the Patented Medicine Prices Review Board (PMPRB). The PMPRB is a quasi-judicial body that regulates the maximum prices charged by manufacturers for patented medicines for human and veterinary use from their market launch (Anis, 2000). New 'breakthrough' drugs are set so as not to exceed the median of average ex-factory prices of the product of the same strength and dosage form of Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the USA. If a new drug is not considered to be a significant breakthrough then its introductory price must not exceed the maximum price of other comparable drugs in the same therapeutic class in the relevant market. Any subsequent changes to drug prices are limited to changes in the Consumer Price Index. If the price of a patented drug already being sold is found to be excessive, then the patent holder may be required to reduce the price of the drug and offset any excess revenues.

Provincial drug formularies are an important locus of drug price and reimbursement control for the public insurance plans. Public drug benefit plans in Canada use formularies to list the prescription and non-prescription drugs reimbursed under the given plan and is a mechanism of cost control. Provincial formulary submissions must include information on the efficacy, effectiveness and in some cases must give the lowest price for their product in Canada as an indicator for comparison or provide evidence of the cost-effectiveness of the new drug to be listed compared to alternative products (Laupacis, 2002). Although companies normally do not lower their prices to ensure a formulary listing, if a product with limited therapeutic advantage or value is priced too high it may not be listed. In Alberta, for example, generics must provide at least a 25 per cent savings over the brand name product and for a 30 per cent savings will be fast-tracked for a formulary listing. All provinces have an interchangeable formulary for bioequivalent products.

The provinces normally reimburse the pharmacy acquisition cost plus a dispensing fee as set through a contract for patients covered under provincial drug plans. The pharmacy acquisition cost may be less than the price listed in the provincial formulary and in theory the price listed in the formulary is the maximum reimbursement price. Most provinces pay the actual acquisition cost up to a Maximum Allowable Cost except Quebec, Ontario, Newfoundland and Prince Edward Island (Jacobs and Bachynsky, 2000). Audits are conducted to ensure that pharmacies are complying with maximum acquisition cost policies. The Drug Benefit programme in Ontario for example pays the pharmacist for the lowest cost interchangeable generic drug listed on the provincial formulary (Ontario Ministry of Health, 2002a) and prohibits pharmacists from charging the patients of the Ontario Drug Benefit Programme more than the listed price

unless the person indicates no substitution (*Ontario Drugs Benefit Act, 2002*). The listed price for generic drugs in Ontario, as well as in Quebec are set following bids from manufacturers to get the Best Available Price. The lowest cost in Ontario is restricted to 70 per cent of the brand price for the first generic listed generating savings for the programme (Jacobs and Bachynsky, 2000). Negotiated list prices are determined in Newfoundland and Prince Edward Island giving pharmacist the opportunity to earn a higher margin from dispensing a product at a cost below the list price on interchangeable products.

The province of British Columbia controls drug costs for the publicly-funded drug insurance programme Pharmacare through both the Low-Cost Acquisition Programme and the Reference Drug Programme (reference pricing) that was introduced in 1995 and now applies to six categories. The Reference-Based Pricing scheme only pays the cost of the cheaper drug leaving the consumer to pay the difference between the price of the least expensive therapy and the one dispensed. Reference pricing has been associated with cost-savings to Pharmacare without an adverse impact on health outcomes (Cassels, 2002; Schneeweiss et al., 2002).

Pharmacist professional fees can vary between provinces and also within provinces between public and private insurers. Table 2.3 shows that most provinces reimburse pharmacists on a fee per prescription dispensed bases (McDonald et al., 1999) but in some provinces, pharmacists are reimbursed as a percentage of the prescription dispensed: Saskatchewan, Ontario, Quebec, Prince Edward Island, the Yukon and the Northwest Territories. Fee schedules are not negotiated regularly.

Table 2.3. Schedule of provincial dispensing fees, 2000

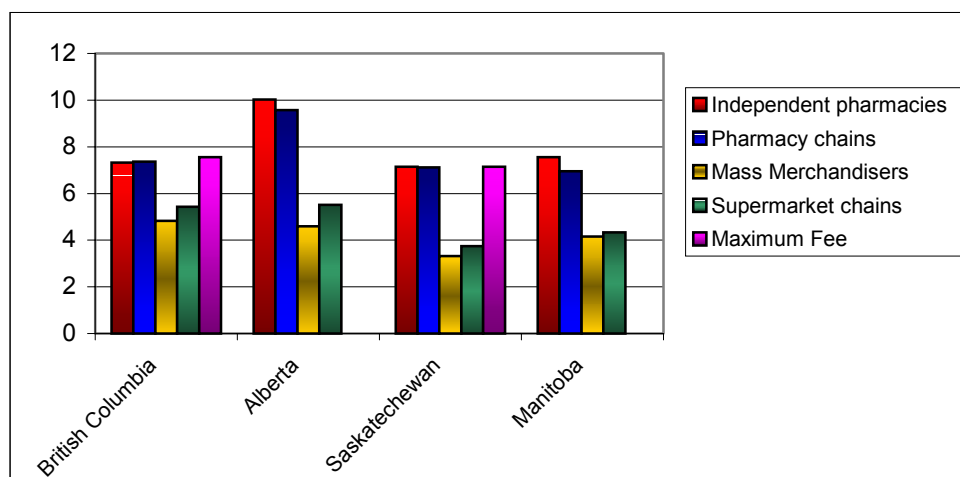
Fee schedule 2000	
British Columbia	Flat fee up to \$7.55
Alberta	\$9.70 + \$0.20 inventory allowance for Actual Acquisition Cost of \$0-\$74.99 \$14.70 + 04.75 inventory allowance for Actual Acquisition Cost of \$75-\$149.99 \$19.70 + \$2.15 inventory allowance for Actual Acquisition Cost of \$150+
Saskatchewan	Max \$7.15
Manitoba	No Cap on Fee
Ontario	6.47 per item dispensed
Quebec	7 for first 23400 prescriptions per pharmacy per year, then \$6.54
New Brunswick	Starts at 7.40 for prescription drugs under \$100. Fee is higher for compounds and rises according to the cost of prescription.
Nova Scotia	For prescriptions with an ingredient cost up to \$115-8.52. For prescriptions with an ingredient cost more than 115-13.48.
Prince Edward Island	Maximum 7.00 for disease-specific programs. Seniors plan: 7.85, social assistance plan: 7.25
Newfoundland	Social services max 5 plus 10% of medication cost when cost is greater or equal to 30. Seniors there is no reimbursement fee.

Adapted from Peartree Solutions Inc., 2001

In Ontario the ‘usual and customary’ dispensing fee for cash paying customers must be registered with the Ontario College of Pharmacists and clearly displayed for all customers (Ontario Ministry of Health, 2002b). The fee per item dispensed in Quebec decreases once the number of prescriptions dispensed by the pharmacy exceeds the limit imposed by the government (Pharmacy Post, 2000). Alberta introduced the concept of an unbundled fee in 2000 separating the payment for dispensing from that of business costs. Private dispensing fees negotiated by some payers have been capped at particular levels requiring either the pharmacist to accept the negotiated level or charge the patient an additional amount out-of-pocket (Jacobs and Bachynsky, 2000).

Often there is discounting of dispensing fees to encourage patients to shop around and obtain discounts especially since the emergence of super-market/mass pharmacies in the mid-1990s. Figure 2.1 shows how dispensing fees vary in western Canadian provinces depending on the pharmacy type. The lowest fees in these provinces were found at pharmacies located in mass merchandisers. The extent to which patients are likely to shop around is assumed to be low given that many patients are covered by insurance which pays all or high proportion of their prescription cost (Blomqvist and Xu, 2001) but also because discounted dispensing margins are not well advertised. A number of pharmacy chains have loyalty programmes for patients such as the Healthwatch System® operated by Shoppers Drug Mart which maintains computerized medication profiles of individual patients (Shopper Drug Mart Inc, 2001).

Figure 2.1. Dispensing fees by pharmacy type in Western Canada, 2000



Adapted from BenefitsWorld.com, 2000a,b,c

In the hospital sector, discounts are possible. Hospitals often negotiate specific arrangements with individual companies. In Ontario, drugs used in hospital are paid for out of the hospital global budget and each hospital's Pharmacy and Therapeutics committee decides on what drugs will be available (Laupacis, Anderson and O'Brien, 2002).

- Interviewees

Interview conducted with Mr. D Bougher, Director Pharmaceutical Policy and Programmes, Alberta Health and Wellness and Ms K Smilski, Pharmaceutical Policy Consultant, Alberta Health and Wellness.

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3.0 FRANCE

3.1 Pharmacy numbers³⁵

The population to pharmacies ratio in 2000 was 2578 inhabitants per pharmacy. The ratio of population to pharmacists who own a pharmacy in 2000 was 2144 inhabitants per pharmacist. The ratio of inhabitants to qualified pharmacists (owners and assistants) 1190 to 1.

Pharmacy owners and pharmacy assistants hold the same diploma that they obtain after six years of studies (CNE, 1998). Usually pharmacists begin their careers as pharmacy assistants.

The pharmacist's professional organisation is the French National Chamber of Pharmacists (the Conseil National de l'Ordre des Pharmaciens (CNOP)). It includes all qualified pharmacists with the exception of a small number of pharmacists employed by the Civil Service. The *Ordre des Pharmaciens* is divided into seven categories, from A to G, which are devoted to the different professional activities in which pharmacists may specialise. In 2000, Category F was abolished.

There were 66694 pharmacists in France in 2002, (although, as pharmacists may be counted in more than one category, there appear to be 67,062) as registered with CNOP (CNOP, 2002) (see Table 3.1).

Table 3.1. Number of pharmacists in France, 2000

A	B	C	D	E	(Ex) F	G
Community pharmacists (owning a pharmacy)	Manufacturers (industry employees, pharmacists working in production)	Wholesalers	Employees in all subsections: Assistants ^a ; Hospital dispensaries ; Health Insurance Funds and Miner's societies; Other ^b	Overseas departments	Overseas territories	Clinical biologists (laboratories)
27 290	990	361	29 279	1 121	176	7, 845
40.7%	1.5%	0.5%	43.6%	1.7%	0.3%	11.7%

^aNumber of assistant pharmacists: 24,893; Number of assistants in a community pharmacy: 18,878; Number of temporary assistants in a community pharmacy: 3,005.

^bOther refers to pharmacists exercising a variety of pharmaceutical functions such as pharmacists for humanitarian associations. (CNOP: 1/1/2001)

³⁵ Figures are from the Conseil National de l'Ordre des Pharmaciens (CNOP), the French National Chamber of Pharmacists. All statistics refer to January 1, 2001.

As shown by Table 3.2³⁶, the total number of pharmacy owners (pharmacist owners) increased from 20,923 to 27,290 or 30.43 per cent during the 20 year period, 1980-2000. Similarly, the number of pharmacy assistants also increased significantly during this period, from 10,425 in 1980 to 24,893 in 2000, an increase of 138.73 per cent.

Table 3.2 Evolution of pharmacist numbers in France, 1980 – 2000

Year	A	B	C	D				E	(Ex) F	G
	Community pharmacists (owning a pharmacy) ¹	Manufacturers	Wholesalers ²	Pharm. Assistants	Hospital dispensaries	Health Insurance Funds	Other ³	Overseas depts.	Overseas territories	Clinical biologists
1980	20 923	600	104	10 425	2 889	128		483	55	5 849
1985	23 127	586	123	14 075	3 240	141		591	67	6 369
1990	25 179	592	136	17 232	3 405	146		705	85	7 390
1995	26 503	950	236	20 120	3450	143		867	111	7 604
1996	26 684	956	260	21 079	3 532	141		916	114	7 692
1997	26 837	967	262	22 215	3 664	142		943	125	7 742
1998	26 949	982	287	23 334	3 704	139		1 001	149	7 838
1999	27 129	991	327	24 245	3 788	140		1 074	165	7 847
2000	27 290	990	361	24 893	3853	139	394	1 121	176	7 845
% 1980 /2000	+30.43	+65.0	+247.12	+138.78	+33.37	+8.59	ns	+132.09	+220.0	+34.13

1. **Total number of pharmacists owning a pharmacy (associated and non-associated). Pharmacists with co-ownership, limited responsibility, liberal practice and collective ownership are all considered to be associated pharmacists.**
2. **Industry employees, pharmacists working in production.**
3. Other refers to pharmacists exercising a variety of pharmaceutical functions such as pharmacists for humanitarian associations.

3.2 Restrictions on entry

The number of pharmacies depends on population numbers. In 1941, a law was passed to institute a system of licensing community pharmacists on the basis of population figures, to ensure satisfactory coverage of the whole of France. This provision is still in force and tends to restrict commercial competition and the use of advertising.

- For a district with 30,000 inhabitants or more, a new pharmacy is only allowed when the number of people per pharmacy is 3000 or above.

³⁶ All statistics from January 1, 2001. Source: CNOP (<http://www.ordre.pharmacien.fr>).

- For a district with a population between 2500 and 30 000 inhabitants, a new pharmacy is allowed when the number of people per pharmacy is 2500 or above.
- No new pharmacy is allowed in a district with less than 2500 inhabitants:
-If there is already one pharmacy.

-If there is no pharmacy but the population has already been taken into account in a decision to establish a new pharmacy in another district.

- For districts with less than 2500 inhabitants with no pharmacies and with a population that has not been or is no longer counted elsewhere, a new pharmacy can be permitted in a geographical area which includes adjoining districts, if the total of the population in the specified area is at least 2500.

The representative of the State in each *departement*³⁷ determines which districts are taken into account when allowing a license to establish a pharmacy. The licence fixes the location of the pharmacy. The State representative can impose a minimum distance between a proposed new pharmacy and an existing one. Moreover, to ensure optimal service coverage for the population residing within proximity of the proposed location of new pharmacy, the licence may also stipulate in which neighbourhood the pharmacy must be located.

The opening of a dispensary is subject to a license granted by the prefect of the *departement*. The licence is specific to the stipulated 'place of business' and should the place of business close down, the licence must be returned to the prefect. Moreover, should a licence be rendered invalid for any reason (for example due to a court decision) the 'place of business' also ceases to exist.

Community pharmacists in France enjoy a monopoly in the dispensing of medicines. However, doctors in an area where there are no community pharmacies may be authorised by the state representative of the *departement*, after consulting the health and social affairs regional director, to keep a stock of drugs and to be able to deliver these to their patients. There is a list of drugs for which this can be done and this is drawn up by the Minister of Health, the French National Chamber of Pharmacists and the French National Chamber of Doctors.³⁸ This group also decides in which areas to allow doctors to deliver medicines to patients' homes. These arrangements are revoked in the event that a pharmacy that is open to the public is established in the specified district. Doctors who are given dispensing rights must adhere to the same rules as pharmacists and such doctors cannot own a community pharmacy. They can only deliver the drugs that they themselves prescribe to their patients.

Hospital dispensaries are required by law to have at least one qualified pharmacist present to oversee the dispensing of pharmaceutical products. Hospital pharmacies are chiefly concerned with the needs of patients being treated in the establishment, but they may also provide drugs to outpatients who are undergoing certain forms of treatment with medicinal products that are not available through the network of community pharmacists (for example AIDS medication).

³⁷ A *departement* is a regional and administrative subdivision of France. There are 96 *departements* within France and four French overseas *departements*.

³⁸ <http://agmed.sante.gouv.fr/hm/5/avisct/act0000c.htm> (Legifrance Article L4211-3).

If a patient is unable to travel for reasons related to health, age or geographical location, the community pharmacist may dispense prescribed drugs by mail or courier. Solicitation on the part of pharmacists is not permitted, but under clearly defined conditions, delivering drugs to the patient is allowed. This must be done by a pharmacist or an intermediary with legal and patient authorisation to do so. The drugs must be contained in an opaque package with the specific patient's address marked. The package must be closed in such a manner that the patient can ensure that a third party has not opened it. The pharmacist must ensure that the medicine will be well conserved and provide the patient with all necessary explanations and instructions. The person in charge of delivering the drugs must guarantee that they are well conserved and that they are given directly to the patient.

There are no subsidies to encourage pharmacies to locate in rural areas. Under special circumstances doctors are sometimes allowed to dispense drugs to patients if no pharmacies exist in their area (see above). However, a 'numerus clausus' (quota) has ensured a balanced geographical distribution of dispensaries; approximately one third of them are in rural areas.

3.3 Restrictions of ownership

Only qualified pharmacists or a company engaged in running pharmacies may own dispensing pharmacies. A few exceptions aside (hospital pharmacies, social insurance fund pharmacies³⁹ and mining company pharmacies), all pharmacies must be the property of one or more pharmacists or of a company constituted solely of pharmacists. Therefore, ownership and management of a dispensary are inseparable. As of 1st January 2001, there were 27,290 pharmacists who owned a pharmacy in France. Of those, 10,380 were 'associated pharmacists' with joint ownership of a pharmacy. The proprietor of a dispensary employs a number of salaried pharmacists depending on the size of the pharmacy's business (based on turnover). In 2000, the law required that pharmacies with an annual revenue of Euro 823,000 (FF 5.4m) or less, had to have one permanent pharmacist working in the pharmacy; pharmacies with annual revenues of between Euro 823,000 and 1.64m had to have two permanent pharmacists; for pharmacies with an annual revenue between Euro 1.64m and 2.47m, three permanent pharmacists were required, after which, for every Euro 823,000, one further permanent pharmacist must be employed.

In France, the majority of pharmacies are 'small' community pharmacies. Figures for 2001 were as follows:

29.06 per cent of community pharmacies had one permanent pharmacist
45.75 per cent of community pharmacies had two pharmacists with a degree: a permanent pharmacist with an assistant or two permanent pharmacists
25.19 per cent of community pharmacies have at least three qualified full-time pharmacists

OTC medicines are only available in community pharmacies, thus a pharmacist is always present during a sale of these types of medicines. The pharmacist is

³⁹ Social insurance funds may be the proprietors of internal pharmacies for the use of their members.

responsible for avoiding errors due to ill-advised, self-medication, and must ensure the best possible management of the small degree of risk involved with OTCs. For this reason, pharmacists are opposed to OTC medical products being freely available in other retail environments. In their view, selling a medical product, albeit an OTC, still requires that proper advice be given to the purchaser – sometimes referred to a ‘pharmacy consultation’. Also pharmacists cannot sell over the Internet in France (Resplandy, 2000).

A pharmacist or a company can own only one pharmacy. There are no pharmacy chains France.

3.4 Restrictions on price

In the case of reimbursable drugs, prices are fixed. The Minister of Health, the Minister of Finance and the Minister of Social Security are responsible for determining prices. Prices are fixed for reimbursable drugs on sale to the public through a system based on a six-level of profit margin, the margin percentage decreasing as the industrial price increases. The applicable rates in this regressive profit margin have not been revised since 1990, neither to compensate for inflation nor to allow for modifications in packaging (principally a tendency to replace boxes of 30 tablets by boxes of 60). The largest levels of medical sales are reimbursable products (82 per cent), followed by non reimbursables (9 -10 per cent) and parapharmaceuticals and cosmetics (8 - 9 per cent).

Pharmacy margins are regressive and calculated according to 3 price bands based on the ex-factory price. The average mark-up is around 26 per cent (Blanchier and Kanavos, 2001). However mark-ups on some non-prescription drugs that are purchased directly from the manufacturer may be closer to 60 per cent of the retail price (AESGP, 2001). Wholesalers are restricted to granting pharmacists a maximum discount of 2.5 per cent. However, loyalty by wholesalers is promoted through other service packages such as computerised purchasing and sales links as well as offers to attend professional conferences (Gehe, 2002).

Prices of OTCs are not fixed or regulated for products that are not reimbursable. Prices are determined by the pharmacist as long as they within a reasonable range. Manufacturers may decide to impose a ceiling price on their product as long as it does not lead to the pharmacy incurring sales losses. However, all drugs sold in a community pharmacy can be reimbursed if they are prescribed by a doctor. In these cases, the drug prices are fixed by the Ministry of Health.

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4.0 GERMANY⁴⁰

4.1 Pharmacy numbers

The number of pharmacies in Germany has been growing steadily over the last 50 years and thus, the pharmacy to population ratio has decreased. However, the rate of growth has diminished in the last few years, and between 2000 - 2001, for the first time, the number of pharmacies decreased slightly by 23 (Federal Association of German Pharmacists' Organisations (ABDA), 2002). In 2001, there were 21,569 pharmacies providing drugs in Germany, giving a population to pharmacy ratio of 3,800:1. The number of pharmacists has also increased over the last two and a half decades but again at a decreasing rate (See Table 4.1). In 2000, 46,078 pharmacists worked in German public pharmacies, giving a population to pharmacist ratio of 1,780:1. In addition to these, approximately 7,000 pharmacists work in hospital pharmacies, within the pharmaceutical industry or within public administrative bodies. This brings the total number of pharmacists to 53,000.

Table 4.1. Number of people employed in the German pharmaceutical sector 1975-2000

Type of Position	1975	1980	1985	1990	1995*	1996*	1997*	1998*	1999*	2000*
Pharmacists (male and female)	24678	27693	31068	35118	42790	43629	45271	45465	46064	46078
% of female pharmacists	50.2	51.8	53.6	57.3	61.7	62.3	62.5	62.6	62.8	65.3
Pharmacy trainees	344	1113	1585	1899	1660	1758	1859	1780	1750	1649
Pharmacy assistants	5340	4542	4500	4168	11501	11344	11313	11367	11141	10835
PTA ^a (incl. PTA trainees)	6811	11920	19015	25009	32102	33809	35150	37149	37821	39792
Pharmacy employees ^b	36115	35733	37660	33416	38483	39748	38814	39030	38116	38116
Total	73288	81001	93828	99610	12653	13001	13240	13479	13489	13647

⁴⁰ The information provided refers only to privately run pharmacies outside hospitals - known in Germany as 'public pharmacies' (ABDA 2000). On 22nd April 2002, the Federal Ministry of Health and the major health sector organisations (known as the Round Table for Health Sector Reform) met to release a reform paper on pharmacies. In principle, the Federal Ministry of Health is in favour of legalising mail-order drugs on the condition that patients' security is guaranteed and that any mail-order system has comprehensive geographical coverage. Such conditions will not allow mail-order pharmacies to cream skim. Moreover, mail-order pharmacies will not be allowed to offer only highly profitable drugs, with the burden of providing advice (counselling) and supplying less profitable drugs falling on the shoulders of normal pharmacies. The Federal Ministry of Health fears that such a situation would drive most normal pharmacies into bankruptcy and would jeopardise appropriate geographical coverage. The Round Table is not expected to produce a legislative proposal but a list of recommendations resulting from its discussions on how the above aims might be achieved. The Ministry of Health may then prepare a bill on the basis of these recommendations but this is not expected to occur before the federal elections in September.

Employment					6	8	7	1	2	0
% change over previous year	-	+3.7	+2.0	+1.1	+1.8	+2.8	+1.8	+1.8	+0.1	+1.2

Source: ABDA, 2001

Note: ^a pharmaceutical technical assistants, ^b sales assistants (in pharmacies and supermarkets), and * after unification with East German

The population to pharmacy ratio varies widely (but not in a systematic way) between different Länder – from 2,990:1 in the Saarland to 4,600 in Mecklenburg-Vorpommern (Table 4.2).

Table 4.2. Number of pharmacies and pharmacy to population ratios in the Länder

Länder	Number of pharmacies in 2000	Number of people per pharmacy
Baden-Wuttemberg	2827	3710
Bayern	3419	3560
Berlin	875	3870
Brandenburg	523	4970
Bremen	181	3660
Hamburg	462	3690
Hessen	1639	3690
Mecklengurg-Vorpommern	389	4600
Niedersachsen	2118	3730
Nordrhein	2562	3720
Westfalen-Lippe	2256	3750
Rheinland-Pfalz	1179	3420
Saarland	359	2990
Sachsen	938	4750
Sachsen-Anhalt	598	4430
Schleswig-Holstein	726	3830
Thuringen	541	4530
Total	21592	3800

Source: ABDA, 2001

Note: * Based on end of year figures

4.2 Restrictions to entry

There are no restrictions on the number of pharmacies which may operate in an area. Nor are there any restrictions on where pharmacies may locate. Thus pharmacists may open a pharmacy wherever they wish.

The German Pharmacists' Association (DAV)⁴¹ and the Pharmacists' Associations of the Länder negotiate contracts with the many Social Health Insurance Funds' associations according to § 129, 2-5 SGB V (Social Code Book, No. V)⁴². These contracts regulate the reimbursement of prescribed drugs for patients who are members of a Social Health Insurance fund. Members of private sickness funds pay for their drugs and are reimbursed later by the fund.⁴³

Around 90 per cent of pharmacies are members of the Pharmacists' Associations and hence are automatically covered by the contract. Non-members have to make declarations to the several Social Health Insurance Funds' associations that they will comply with existing contracts if they wish to dispense prescription drugs to patients who are members of a Social Health Insurance fund.

Generally, pharmacies are the only entities that are allowed to dispense prescription drugs and so called 'OTC-drugs for sale in pharmacies only' (for example, aspirin). Only 'harmless' OTC-drugs such as herbal teas or weak-dosed vitamin pills are available freely and can be dispensed by non-pharmacies such as supermarkets. An exemption to this rule exists in cases where the pharmaceutical industry provides small samples of new drugs free of charge to physicians as a marketing measure. Physicians are allowed to give these samples away to their patients but they are not allowed to charge for them.

In general, mailing prescription drugs and pharmacy-only OTC-drugs is not allowed and the pharmacies' lobby, the ABDA, has acted strongly to prevent any changes. Nevertheless, one exemption already exists: according to the regulation on pharmacy operation, in 'justified cases of exemption' a pharmacy may send drugs by a courier - to an immobile patient, for instance. According to a Federal Ministry of Health official, this exemption rule is often used, and drugs are sent over considerable distances. For many chronically ill patients, even if they are not immobile, the mailing of prescriptions is a convenient and useful service.

ABDA has proposed that the regulation outlined above should be clarified. It suggests that instead of allowing transport by non-specified couriers, only trained pharmaceutical employees should be allowed to transport drugs to immobile patients in order to increase the safety and quality of counselling to patients. This proposal is likely to affect small pharmacies in particular, and may make them less likely to be

⁴¹ This organisation is not to be confused with the Federal Association of German Pharmacists' Organisations (ABDA). The DAV is the peak organisation of the Pharmacists' Associations of the Länder. In addition, a Federal pharmacists' association exists which is the peak organisation of all the pharmacists' associations. Both the Federal pharmacists' association and DAV are members of the ABDA, making it the overall peak organisation for all organisations dealing with pharmacists' affairs in Germany.

⁴² Available online at <http://www.bmgesundheit.de/rechts/gkv/sgb/sgbv.htm>.

⁴³ The overall framework contract negotiated between all the peak organisations of the Social Health Insurance funds and the German Pharmacists' Association can be found at http://www.vdak.de/apotheken/rahmenvertrag_129_%20060801.pdf. An example for one of the additional contracts negotiated between a particular Social Health Insurance funds' association and the German Pharmacists' Association is available at http://www.vdak.de/apotheken/alv_020201.pdf.

involved in mail ordering because of the extra costs in employing the necessary staff to transport drugs.

There are no subsidies for pharmacies in sparsely populated areas. However, the Pharmacies Act contains one special rule for remote areas. Normally, pharmacists are only allowed to own only one pharmacy but in very remote and sparsely populated areas, such as the islands in the Northern Sea, there would be no incentive for a pharmacist to open their sole pharmacy under the one-pharmacy rule. Therefore, in these rare cases, pharmacists are allowed to run two pharmacies – their main pharmacy in a more profitable area and a second in the designated remote area.

Apart from special provisions for remote areas, the Federal Ministry of Health puts its faith in market forces with regard to where pharmacies are located. According to the ABDA, to date there have been no complaints regarding shortcomings in the provision of drugs. On the contrary, the Federal Ministry considers the number of pharmacies in Germany to be too high, particularly in densely populated areas. German Pharmacist's Law restricts hospitals to purchase from their own or adjacent area (de Paoli and Schreiber, 2002).

4.3 Restrictions on ownership

A pharmacist may only own one pharmacy, except in the rare case of very remote areas (see above).

A pharmacy can only be owned and run by a pharmacist – that is, a person who has studied and passed examinations in pharmacy both at University and at a German pharmacists' association ('approbation'). The Pharmacies Act provides detailed regulation of the profession. Potential pharmacists need to demonstrate that they are trustworthy (with no criminal record) and are not overly incapacitated by mental or physical disease; they must also prove that appropriate premises to run a pharmacy are available. Pharmacists must be a citizen of one of the member states of the European Union or a stateless foreigner (e.g. political refugees). A special rule applies to non-German citizens from other EU member states that have qualifications from their own country but do not have a German pharmacists' licence (for example, a registered pharmaceutical chemist from the UK); such professionals are only allowed to run pharmacies that have been operating for at least three years.

Pharmacists must be personally and fully responsible for the economic viability of their enterprise. Should pharmacists wish to run a pharmacy jointly (Section 8, Pharmacies Act) they are required to establish one of two types of corporation - a 'OHG' (a general partnership) or a 'GmbH' (a private limited liability company). These are the only legal entities that are allowed. Even in these circumstances, each partner pharmacist can only own the one pharmacy; hence, jointly owned company pharmacies are very rare.

Only pharmacy trained staff are permitted to undertake pharmaceutical activities. These activities include the development, production, testing and dispensing of drugs (prescription drugs as well as pharmacy-only OTC drugs) and providing information and counselling to patients. So-called 'pharmacists' assistants' and pharmacy technicians are the only professionals allowed to perform these activities. Other pharmaceutical

staff (so-called 'pharmaceutical-technical assistants', for example, must be supervised by a pharmacist. Non-pharmaceutical staff in pharmacies are only allowed to dispense freely available OTC drugs such as herbal teas which can also be sold in supermarkets. However, in order to undertake these tasks all such assistants (as well relevant supermarket staff) must attend a special training course.

4.4 Restrictions on price

The price for prescription drugs and OTC-drugs for sale in pharmacies is only partly regulated in the Drug Price Regulation⁴⁴. Manufacturers are free to set prices. However drug prices are indirectly regulated through the reference price scheme. A reference price scheme was introduced in 1989 setting a maximum price for the reimbursement of certain prescription medicines through SHI funds. The reference price is a statistically derived median price for the therapeutic category. The reference price scheme was introduced in three stages and in-patent medicines were initially included but fully exempted by 1995 (Schneeweiss, Schoffski and Selke, 1998). The patient must pay the difference between the price of the prescribed drug and the reimbursement limit, if the former is higher; this led to patient switches away from drugs priced above the reference price and a subsequent decrease in the price of medicines towards the reference price if previously priced above (Litsch, Reichelt and Selke, 1990; Zweifel and Crivelli, 1996).

Regulated wholesaler and pharmacy margins are added to the manufacturer's price. Wholesalers may remain under their margin and offer pharmacies a rebate. Wholesale margins vary inversely with the manufacturer's price (from 12 to 21 per cent). The actual margin pocketed by the wholesaler is generally less than the mark-up as there is some discounting to pharmacists. Discounts to pharmacies are estimated to be on average no more than 6 per cent (Selke and Schroder, 1997). On average, the wholesale margin accounts for 8.9 per cent of the retail price (Association of Danish Pharmaceutical Industry, 1997). Quantity discounts from wholesalers are also limited by the requirement of unit pack dispensing that prevents pharmacists from splitting large packs.

The margin to the pharmacy falls with price - the higher the price, the lower the margin. Nevertheless, in absolute terms, profits are higher with more expensive drugs. Consequently, it is contrary to the profit interests of pharmacists to substitute a cheaper medicine as this would reduce their income (Schoffski, 1996). In 1999, the average margin was 20.3 per cent (Friese 2001). The fixed mark-ups ensure that retail prices of pharmaceuticals are uniform across Germany, preventing competition in terms of price. Pharmacies are required by law to charge their full margin, in whose calculation any wholesalers' rebates are ignored..

The retail prices of OTC drugs are not regulated.

⁴⁴ Available online at <http://www.uni-leipzig.de/~vetppt/recht/AMPreisVO.pdf>.

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5.0 THE NETHERLANDS

5.1 Pharmacy numbers

There is no accurate data on the pharmacist to population ratio. In terms of pharmacy numbers, a representative of KNMP (Royal Dutch Society of Pharmacy) estimated the total number of pharmacies to have been 1500 in 1990 and 1650 in 2000, a 10 per cent increase over this 10 year period. There were a total of 1,956 pharmacists in 1995 and 2,217 in 1999. The total number of pharmacists' assistants was 10,709 in 1995 and 12,220 in 1999.

5.2 Restrictions to entry

There is no government planning system to regulate the number of pharmacies nor are there any formal restrictions on where pharmacies may locate in relation to other pharmacies or prescribing doctors. Thus in theory, a pharmacist can set up a pharmacy anywhere. However, in practice, this is not the case due to following factors:

- Pharmacists need a contract with the principal health insurer in the region.⁴⁵ According to new regulations, pharmacists must contract with all insurers in order to stimulate market competition. Thus, insurers will operate as purchasers of pharmacy services. Since 1992, insurers have been given the right to deny granting a contract to a pharmacy. In the negotiating process, they may consider factors such as community need and desirability. Recently, there has been an interesting development in Amsterdam where the principal insurer (AGIS) organised a competitive bidding process to set up a new pharmacy in a newly developed district in the city. Another insurer (CZ) recently also announced that it will develop a strategy of competitive bidding. A further development is that the purchaser may negotiate, for example, a 10 per cent discount on the official price (*taxe*)⁴⁶ that it must pay to the pharmacy for prescription drugs. This discount can be considered to be an additional clawback on top of the clawback that is implemented by the state. The insurer's clawback needs to be seen as part of the process of market competition. In fact, this is a counter-strategy on the part of the health insurers against the process of 'forward or vertical integration' pursued by wholesalers (see below).
- Setting up a pharmacy in the Netherlands is an economic undertaking requiring huge levels of investment and thus, lenders want to ensure that an undertaking will be financially viable. For this reason, a contract with the principal insurer (or some large insurers) is an absolute prerequisite for loan applications.
- Furthermore, it is important to note that good relationships with neighbouring pharmacies are essential, particularly for the purposes of co-ordinating night and weekend-service facilities and to exchange information on patients' drug

⁴⁵ Under Dutch legislation on social health insurance (ZFW, AWBZ) health care can only be delivered by providers who have a contract with an insurer. A pharmacy is considered to be a health care provider. Regulation cannot be separated from the benefit-in-kind system that applies in social health insurance systems.

⁴⁶ This price must be approved by the Authority on Health Care Tariffs (CTG). The prices are ceiling prices.

consumption. Established pharmacies in an area may informally obstruct the establishment of a new pharmacy by withholding such collaboration or information. Without a strong relationship with neighbouring pharmacies and a clear position in the local health care delivery chain, a pharmacy cannot, in effect, survive. It has been difficult for new pharmacy entrants to move customers from their existing pharmacies, as although customers could go to any pharmacy they do not given that many have membership cards that link their insurer to a named pharmacy. Patients in the Netherlands tend to visit one pharmacy (Mason, 2000). This factor probably also explains why the establishment of pharmacies within supermarkets has not been very successful in the Netherlands.

- General practitioners with a pharmacy of their own can be vehement opponents of any plans to establish new pharmacies in their area.
- In the past, wholesalers also played a part in counteracting the establishment of mail order pharmacies (e.g. Caremark). By not delivering drugs to the pharmacy, the wholesalers' strategy resulted in the failure of the enterprise. Such overt strategies of abuse of power are no longer possible as the practice contravenes market competition regulations; it should be noted that pharmacies now are also considered to be economic undertakings which must compete with each other.
- A final practical problem relates to the scarcity of pharmacy assistants (apothekers-assistent). However, this may be only a temporary problem.

Several new developments within the pharmacy sector are now taking place. These include:

- Foreign wholesalers or investors are seeking to break into the Dutch market; for example, Alliance – Unichem (French/British) and GEHE (German).
- Wholesalers are buying pharmacies (known as 'forward' or 'vertical' integration) in order to control the local market (which is particularly important for generics) and to be in a stronger position to negotiate lower prices with the pharmaceutical industry. The wholesaler OPG's aim is to run 150 pharmacies by the end of 2002. Other wholesalers are now also following a strategy of forward integration. Alliance-Unichem owns 30 pharmacies and Brocacef 45. Thus, by the end of 2002 some 17 per cent of pharmacies will be in the ownership of the major wholesalers. Forward integration has obviously driven up prices and the insurer-related clawback can be considered a counter-strategy to reduce cost increases.
- There is also a trend towards 'horizontal' integration whereby pharmacies become part of a chain of pharmacies. Approximately 50 per cent of pharmacies are estimated to be part of a horizontal or vertical chain.
- Another development relates to the establishment of group practices that also include a pharmacy. GPs may own pharmacies and such pharmacies are particularly desirable to wholesalers because they enable them to influence the delivery of prescription drugs. It should be noted that doctors' prescriptions only include the active substance; and pharmacists are encouraged through financial incentives to deliver the cheapest effective drug available (generic instead of brand-name).

- Recently, the Prescription Drugs Provision Act (Wet op de Geneesmiddelenvoorzieningen) has been reformed to stimulate market competition and to remove some of the traditional legal measures that have regulated pharmacists. Three reforms are of particular importance in this context:
 - i) The first reform introduced the possibility that pharmacists may be employed by other non-pharmacists (e.g. supermarkets) to run a pharmacy. Previously, this was not allowed.
 - ii) The second reform allows hospitals the option of setting up a hospital-related pharmacy for outpatient prescription drugs. Again, until recently, this practice was not allowed. Regulations also forbid hospitals to run a pharmacy for inpatient prescription drugs if the number of hospital beds is less than 300. Currently, there are four such hospital (outpatient) pharmacies; health insurers support their further development and there are more such pharmacies planned.
 - iii) The reform of the Prescription Drugs Provision Act has also created the option for insurers to run their own pharmacies (the assumption is that they are in a stronger position than local pharmacists to negotiate lower prices with the pharmaceutical industry). This change in the law may be the first step to abolishing the traditional, strict institutional separation between health insurance and health care delivery.⁴⁷

Mail order drugs are not forbidden in the Netherlands but, as yet, this is only a small-scale phenomenon. A few years ago, an initiative to set up a mail order system failed because of market abuse by wholesalers (it should be noted, however, that technically pharmacists may own shares in wholesalers). Some patients have shown an interest in using the Internet provider (www.medicijnen.nl), particularly if they are of the opinion that their use of prescription drugs is a strictly private affair (e.g. in cases where drugs such as Viagra, contraceptives and anti-depressives have been prescribed). In such cases, patients just need to send their prescription to the mail order company.

There are further reasons why mail order drugs are not (as yet) very popular in the Netherlands:

- With the benefit-in-kind system under the social health insurance system, patients wanting to use the mail-order system would have to first pay out-of-pocket and then be reimbursed.
- Many private health insurers have also developed a benefit-in-kind system. They offer their insured the possibility of registering with a particular pharmacist and when a prescription is required, the patient obtains it free from the pharmacist with whom he or she is registered, who then sends the bill directly to the insurer. The

⁴⁷ AZIVO – a health insurer in The Hague – has always run a pharmacy of its own in The Hague, but this was a unique exception.

insurer may bill the insured in cases where co-payments or deductibles are payable (depending on the policy the insured has purchased). If patients with private insurance go to a pharmacy other than the one where they registered, the normal reimbursement system applies i.e. the patient pays the pharmacist and then is reimbursed by their insurer. From the insured patient's perspective the latter may be unattractive.

Doctors with licenses to dispense drugs are found only in rural areas (about 550 in total). A Government proposal to abolish the system of doctors with drug dispensing licenses was defeated due to strong and effective opposition by MPs. There are no subsidies to set up pharmacies in rural areas.

5.3 Restrictions of ownership

In the Netherlands only qualified pharmacists are allowed to dispense prescribed drugs but some changes have taken place recently (Bellingham, 2001). Under the old regulations, only one pharmacist was allowed per pharmacy. Under new rules, it is possible to employ a 'superintendent pharmacist' who is responsible for more than one pharmacy. Companies with a superintendent pharmacist can own pharmacies. Moreover, there are no restrictions on the number of stores a pharmacist can now own. Over-the-counter medicines can only be sold by pharmacists (who may run a shop for OCTs), by a chemist (*drogist*) or by a pharmacist assistant (*apothekersassistente*).

5.4 Restrictions on price

Retail prices are determined twice a year and are regulated by the government through two laws: Healthcare Tariff Act (price reference system) 1991 and the Medicine Pricing Act 1996 (Jansen and Hermans, 2001). The Medicine Pricing Act stipulates that the maximum price the pharmacist is allowed to pay for each medicine must be the average of the prices in Belgium, France, the UK and Germany (de Vos, 1996). Consequently, this leaves the determination of the wholesaler's margin to the market (Oxera, 2001).

The Healthcare Tariff Act limits the amount that can be reimbursed to the pharmacist by and insurer for a drug. The maximum reimbursement price is equal the cheapest list price of the supplier that can supply the whole market. Insurers may negotiate a lower price though a clawback with is set at 6.82 per cent (Ministerie van Volksgezondheid, 2002). The patient is required to pay the difference between the maximum reimbursement price and the actual price of the drug.

Prices (*taxes*) are ceiling prices to be paid by the insurer to the pharmacist under a remuneration fee contract that includes both a fee for dispensing plus reimbursement for the cost of the drug. The fixed price fee is set by the government for the dispensing of each prescription. The average gross profit in community pharmacies in 2000 was estimated at 23 per cent including purchasing rebates (Stichting Farmaceutische Kengetallen, 2000). The pharmacist's margin is on average 33 per cent of the retail price (AESGP, 2001).

The major sources of revenue for pharmacists are:

- A fixed price for the dispensing of each prescription approximately €6 in 2002 for medicines included under the Medicines Pricing Act (Ministerie van Volksgezondheid, 2002). In effect, this payment scheme provides the pharmacist with an incentive to reduce the number of actual drugs dispensed (i.e. smaller packet size) to a patient per prescription. If a patient needs drugs for a longer period of time, he or she would be required to return to the pharmacist and request a new packet, for which the pharmacist would receive a further fixed dispensing price. It should be noted that the fixed price for dispensing does not vary with the costs of the prescription drug. Therefore, pharmacists' revenues do not depend upon the prices of the prescription drugs sold but on the total number of prescriptions dispensed.
- Pharmacists also may receive (or negotiate) a discount on prescription drugs from wholesalers or pharmaceutical companies. This means that the price (*taxe*) that the insurer pays to the pharmacist may be higher than the price the pharmacist pays to the wholesaler. Not surprisingly, the pharmaceutical industry has a great interest in influencing pharmacists' dispensing behaviour now that doctors no longer prescribe specific drugs but only the chemical substance of the drug to be given to patients.
- The clawback system introduced by the state social insurance funds is an attempt to claw back part of these additional revenues from pharmacists.
- Pharmacists also receive an incentive bonus if they dispense cheaper generic and parallel imported drugs. This is because if the drug dispensed is less than the reimbursement limit, the pharmacist is then entitled to a third of that price differential (Oxera, 2001).

Retail prices of OTC medicines are not regulated nor are prices of products prescribed and consumed in hospital (Jansen, 1999).

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6.0 NORWAY⁴⁸

6.1 Pharmacy numbers

Since the introduction of the new Pharmacies Act in 2001, 81 new pharmacies were established in Norway between 1 March 2001 and 1 May 2002; however, six of these subsequently closed. By contrast, in 2000 only five new pharmacies were established.

In May 2002 there was a total of 483 pharmacies in Norway, giving an approximate average of 9 350 inhabitants per pharmacy (geographically this figure ranges from 8000 – 16 000 inhabitants per pharmacy). At the end of 2000, the population to pharmacy ratio was 11,280:1. The more recent decrease in the pharmacy per population ratio is consistent with the trend that has been observed over the last 12 years, where the number of inhabitants per pharmacy has been steadily declining. For example, in 1990 there were only 320 pharmacies in Norway, with approximately 12 800 inhabitants per pharmacy.

The moderate but steady increases in the number of new pharmacies during the pre-2001 period was mainly due to an increase in the number of branch pharmacies (see below for a description of 'branch pharmacies'). When the new Pharmacies Act came into force in 2001, Norway had a total of 402 pharmacies: 374 privately owned and 28 hospital pharmacies (26 public and two private hospital pharmacies). Of the privately owned pharmacies, 260 were licensed pharmacies and 114 were branches. (See Table 6.1). Branches are often similar to their parent licensed pharmacy, except that they have restricted space, sometimes shorter opening hours, and they cannot manufacture drugs. Branch staff are employed by the main licensed pharmacy and branches draw upon the services of the main pharmacy, including staff, in cases of leave of absence.

⁴⁸ The regulatory situation for pharmacies has recently changed in Norway. The new Pharmacies Act, that somewhat liberalised the highly regulated pharmacy sector, came into force on 1 March 2001. With the new legislation only one year old it is still too early to say whether liberalisation will have the expected effects on availability, service and prices. The new Pharmacies Act also allows for the sale of certain OTC-medicines in other shops as well as in pharmacies. There is no single pharmaceutical association in Norway which is mandated to oversee the pharmaceutical profession. Two such professional associations are the Association of Proprietor Pharmacists (NAF) and the Norwegian Association of Pharmacists (NFF). Since 1 January 2001, the authorisation of pharmacists and inspection fall under the responsibility of the Pharmacy Inspectorate, which is part of the Ministry of Health's Medicines Agency.

Table 6.1. Number of pharmacies in Norway, 1990-2002

Type of Pharmacy	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	May 2002
Pharmacies	259	257	256	254	252	250	247	249	249	254	256	260	353
Branches	42	47	55	66	70	78	90	97	107	110	113	114	102
Hospital Pharmacies	19	22	24	25	26	27	27	28	28	28	28	28	28
Total	320	326	335	345	348	355	355	385	392	392	397	402	483

Source: Authors' calculations based on Norwegian Association of Pharmacists (NAF), 2002.

There are two categories of pharmacists in Norway: university graduates (with a MscPharm degree) and pharmacy technicians, who have 2.5 years' education in pharmacy (there are plans to increase this training to three years).

An accurate figure on the number of pharmacists in Norway is not available but some estimates can be made⁴⁹. In 1990, there were approximately 2000 pharmacists, giving a ratio of 2110 inhabitants per pharmacist; in the year 2000 there were approximately 2400 pharmacists, yielding a population to pharmacy ratio of 1880 inhabitants per pharmacist. (See Table 6.2).

There is a serious shortage of pharmacists in Norway and it is expected that this shortage will affect the speed of pharmacy expansion. The Pharmacies Act reserves the right to restrict the number of licences issued in certain areas if this is deemed necessary to ensure acceptable pharmacy staffing throughout the country as a whole.

Table 6.2. Number of pharmacists in Norway, (estimate) all sectors, 1990-2000

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Number of Pharmacists	2006	2018	2071	2080	2171	2218	2221	2329	2309	2321	2380

Source: Authors' calculations based on Norwegian Association of Pharmacists (NAF), 2002.

6.2 Restrictions to entry

Under the new Pharmacies Act, there is no longer a national plan and the Ministry of Health no longer assesses the overall need for pharmacies. Thus, the allocation of pharmacies is now left to the market. There are no requirements regarding distance

⁴⁹ Pharmacist numbers are calculated from membership numbers published by the Norwegian Association of Pharmacists (2002) and from estimates (e-mail correspondence 22 April 2002) given by Martin Bjerke, the Associations' chairman. The Association's membership figures take into account an estimated number of non-members working in the pharmaceutical industry (approximately 200) and the number of pharmacy owners (equal to the number of pharmacies).

from existing pharmacies but there is a restriction stipulating that that pharmacies must be physically separated from a prescribing doctor's practice.

The new Pharmacies Act contains no incentives to encourage opening pharmacies in remote areas. Operational subsidies may be given under certain strict conditions but only a small number of pharmacies qualify. The new Act does not include any provision for dispensing doctors.

With the liberalisation of the pharmacy sector, one of the fears which arose was that there might be a drain of pharmacists from rural districts to urban areas where an expected sharp increase in new pharmacies was expected to occur. In response to this potential problem, the government contracted with the former state wholesaler, NMD, (now a private chain owned by Gehe) which committed the chain to maintaining pharmacies in Norway's rural districts. NMD's main competitor followed suit, committing themselves (from 1 March 2001) to taking over vacant licences within municipalities with only one pharmacy when the current owner resigns (unless there are other interested parties). These contracts are valid for three years. In cases where a pharmacy cannot make a profit, a system of economic support based on subsidies raised from pharmacy annual fees revenue continues to operate (see below).

Because of Norway's geography, containing small settlements in isolated places, the Medicines Agency may also allow 'medicines outlets' in places where this is considered to be necessary to secure access to medicine (evaluation criteria include the distance to the nearest pharmacy and the level of transport services available). These outlets, approximately 1200 in total, are located in shops of various kinds (although some 20 of them have their own premises) and stock a limited range of OTC-drugs. The medicines outlet(s) belong to a local pharmacy, which is responsible for the quality of products and for training the personnel running the outlet. The pharmacy and the municipal medical officer provide the list drugs that will be sold in an outlet. In addition, many of these outlets distribute prescription medicines, which have been forwarded in packages from the local pharmacy, to individual patients.

Mail order to patients is restricted to the local area, i.e. patients in a pharmacy's geographical impact area may have their prescriptions filled either by a doctor contacting the pharmacy to forward a prescription or patients sending their prescription to the pharmacy and receiving a parcel by mail. Hospital pharmacies are allowed to sell drugs to former patients outside their area when this is considered to be the best option for the patient.

6.3 Restrictions on ownership

The first pharmacy in Norway was opened in 1595. During most of the 20th century, and until the new Pharmacy Act came into force in 2001, all pharmacies (except hospital pharmacies) were privately owned by university graduates with a degree in Pharmacy (MScPharm). However, the government (through the Norwegian Board of Health) regulated who could own a pharmacy, how many pharmacies there should be and where they should be located. No owner-pharmacist could have more than one licence but pharmacists could open branches in places where the government felt there was a need for a pharmacy, albeit one that provided reduced services.

Under the pre-2001 system, pharmacies were individual enterprises with the pharmacy owner having economic and administrative responsibility for the enterprise. A national plan ensured that even small communities would have a pharmacy and the plan restricted the number of pharmacies that could be located in cities. Under this system, when a local government (known as a municipality) wanted a new pharmacy to be established, it would send an application to the Board of Health; the application would include information that appropriate premises and facilities were available for a new pharmacy. There was no explicit policy on location within a given community/local area but populated areas such as shopping centres and busy streets tended to be preferred over locating pharmacies within GP practices.

A progressive fee on annual sales was (and still is) used to ensure a minimum income for pharmacy owners and to minimise the divergence in income between pharmacy owners which otherwise would occur. Based on pharmacies' annual account statements, a subsidy is granted to pharmacies that do not make a surplus high enough to ensure the owner a reasonable income. Part of the funds created by these fees are used for other purposes such as postgraduate training, part-funding of the Medicines Agency and, latterly, for establishing regional drug information centres and the national forensic laboratory.

The licensing system for pharmacies changed on 1st March 2001. Licences are issued by the Pharmacy Inspectorate, which is located within the Medicines Agency, in the Ministry of Health (previously licences were issued by the Norwegian Board of Health).

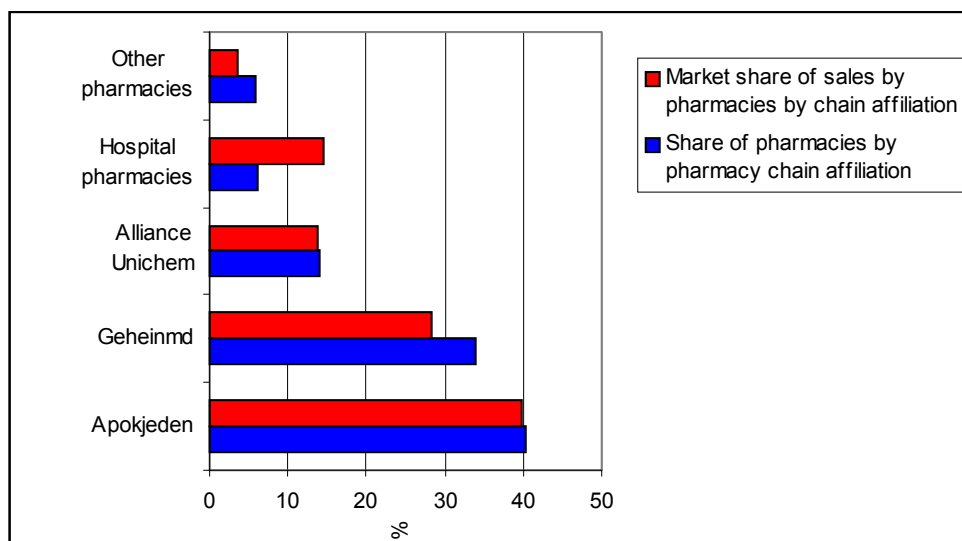
A licence is valid for a specified municipality. Before a licence is issued by the Medicine's Agency, the municipality will be consulted. Conversely, municipalities may initiate discussions with the Medicines Agency where there is a perceived need for pharmacy services in areas that currently lack them. Whilst there is no restriction on who may apply for a licence, people who obtain a licence must employ a licensed pharmacy director with an MScPharm degree. This pharmacist has full responsibility for the professional running of the pharmacy in question. Moreover, the Medicines Agency may grant a licence with attached conditions, e.g. it may attach conditions on co-operation with local health services, opening hours or the provision of pharmacy services to nursing homes.

There is no longer the requirement that a pharmacy owner should have a professional qualification or background in pharmacy in order to be granted a licence. Thus, in principle, anyone may obtain a licence, with the exceptions of pharmaceutical manufacturers, prescribers (doctors, dentists, veterinarians) and their close relatives, or persons close to manufacturers or health establishments treating ill people. The law is very complex on this point and has not been given in detail here.

Under the new Act, companies may also own pharmacies. Currently, 265 (59 per cent) pharmacies are fully owned by pharmacy chains (such as *Vitus 99*, *AllianceUniChem Norway 71*, and *Apokjeden 95*). The remaining pharmacies (excluding hospital pharmacies) are owned by private individuals, and there are a few small chains. As figure 6.1 shows, the pharmacy market is currently dominated by three chains that are owned by the three large European wholesalers Alliance-Unichem, Gehe and Phoenix. The largest of these wholesalers Gehe acquired NMD from the Norwegian government in 2001 as part of the privatisation process and have 52 per cent of the wholesale market (Gehe, 2002). There is a restriction on chain ownership however, no single

chain can own or manage a number of pharmacies whose combined turnover exceeds 40 per cent of the total sales turnover of all private pharmacies in the market; as the figure below shows it appears that Apokjeden is approaching this threshold. Apokjeden was founded in 1995 originally as a buying alliance for member pharmacies and in 2000 entered into an ownership agreement with Tamro Distribution AS that integrated the pharmacies with the wholesaler (Stokke, 2001). Wholesalers such as Gehe have customer loyalty programmes that include purchasing advantages, training opportunities and support in designing and fitting their pharmacies (Gehe, 2002).

Figure 6.1. Distribution of market share by pharmacy chain affiliation, 2001



Source: LMI, 2002

As mentioned above, each pharmacy owner must employ a pharmacist as the director of the enterprise. This person must have a MScPharm degree or equivalent two years' practice and authorisation. Individuals may only hold one licence at any time, which allows them to run their main pharmacy and up to three branches. Each of these branches must have its own non-licensed qualified pharmacist as a manager. There are some restrictions on establishing branches, with the licensed pharmacy director having to be present for at least half of the branch's annual working hours. As only a qualified pharmacist may dispense drugs, a pharmacist must be present during the full opening hours of a pharmacy. In Norway, the minimum pharmacy opening hours is 35 hours per week.

Pharmacies may not enter into a contract with a prescriber (GPs, dentists or veterinarians) that would have the effect of a) restricting a patient's right to the free choice of pharmacy or b) would link discounts given to the prescriber with the value or number of prescriptions received by the pharmacy.

Pharmacies are required to stock and supply, on demand, all medicines with market authorisation in Norway. Pharmacies have a monopoly on the sale of medicine but currently discussions are underway to allow the sale of OTC products in other retail locations 'to increase availability'. The new Pharmacies Act opens up the possibility of

selling OTC-products in ordinary shops. The original timetable was to allow such sales after the first three years that the new Act had been in operation (i.e. in 2004).

At least 85 per cent of pharmacy turnover must derive from medicines and medical supplies, with 75 per cent coming from prescription-only medicines. The remaining percentage of turnover should derive from goods that have traditionally been sold in pharmacies and conveniently compliment the sale of medicines and medical supplies. However, 1 per cent of turnover should be from products produced within the pharmacy. Estimates in 2001 found that 72.3 per cent of private pharmacy sales came from prescription drugs, 12 per cent non-prescription drugs and 15.7 per cent non-pharmaceuticals (LMI, 2002).

6.4 Restrictions on price

Prescription-only medicines have a maximum price set by the regulatory authority (price to pharmacy and pharmacy sales price). The Norwegian Medicines Agency sets the pharmacy purchase prices as the mean of the 3 lowest prices in a group of Northern European countries. OTC medicines have no price control. Pharmacists are obliged to inform patients about the cheapest alternatives available and, with patient or doctor agreement, they may dispense a different product to that listed in the prescription if there is a cheaper alternative on the official list of interchangeable products. Norway reimburses the cost of medicines for a defined number of diseases, chronic or life-threatening. This means that not all medicines with market authorisation are reimbursed and a medicine may be reimbursed only if used for certain conditions.

The pharmacy margin is digressive and has been reduced every year by the government. From 1999 to 2000 the margin, after director's salary (defined by the employer) and tax, fell from 3.7 to 3.1 per cent. A dispensing fee per prescribed item is charged and an additional fee is allowed for narcotics and psychotropic medicines. There is a 24 per cent VAT on all medicines. Privately owned pharmacies pay a fee on annual sales to the government. In 2002, this fee was changed from a progressive fee to a flat fee and is currently 1.4 per cent of the pharmacy purchase price of all medicines sold. Pharmacists have the incentive to substitute parallel imports and generics as part of a discount sharing model which allows them to retain up to 50 per cent of the difference between the maximum price and the actual price (Haga and Sverre, 2002).

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7.0 UNITED STATES

7.1 Pharmacy numbers

The number of pharmacies in the USA decreased by over 6 per cent between 1990 and 2000 reaching its lowest number in 1997 and rising again by 2000 but still reaching a lower number than in 1990. Between 1990 and 1996 the number of pharmacists increased by 9.9 per cent. The population of the USA increased by 5.9 per cent between 1990 and 1996, and grew a further 3.6 per cent by 2000. This suggests that between the 1990/96 period that the number of pharmacists was increasing faster than the USA population while the number of pharmacies was decreasing. The ratio of pharmacies to population decreased by 2.1 per cent between 1990/96 while the ratio of pharmacists to population increased by 4.2 per cent.

Table 7.1. Number of pharmacies

Year	Number of Pharmacies (1)	Population (2)	Number of community pharmacies per 100000 population
1990	58642	249464000	23.51
1991	57495	252153000	22.80
1992	54053	255030000	21.19
1993	54021	257783000	20.96
1994	53243	260327000	20.45
1995	52155	262803000	19.85
1996	51377	265229000	19.37
1997	51170	267784000	19.11
1998	51966	270248000	19.23
1999	53832	272691000	19.74
2000	55011	275130000	19.99

(1) Source: National Association of Chain Drug Stores (2002) citing IMS Health and NACDS Economics Department (http://www.nacds.org/user-assets/PDF_files/Pharmacy_Sales.pdf)

(2) Source: OECD Health Data, 2001

Table 7.2. Number of pharmacists

Year	Number of Pharmacists	Population	Number of community pharmacists per 100000 population
1990	166700	249464000	66.82
1991	169400	252153000	67.18
1992	172000	255030000	67.44
1993	175400	257783000	68.04
1994	178800	260327000	68.68
1995	182300	262803000	69.37
1996	185000	265229000	69.75

Source: OECD Health Data, 2001

7.2 Restrictions of entry

Pharmacies are not restricted in number through being subject to a test of community need.

A licensing system exists for dispensing prescribed drugs. The practice of pharmacy is regulated at the state level including state laws on the licensure for pharmacy practice. To practice in any state, a pharmacist must become a licensed and registered pharmacist with the State Board of Pharmacy. Requirements vary somewhat from state to state but in general a pharmacist must: graduate from an accredited college of pharmacy; participate in residency or internship programmes to acquire direct, hands-on patient care experience; and pass rigorous examination, known as the National Association of Boards of Pharmacy Licensing Examination. Pharmacies are also licensed by the state boards of pharmacy that routinely inspect pharmacies to ensure that pharmacists and pharmacies comply with state laws.

As well, 40 states require that out-of-state pharmacies (i.e. non-resident pharmacies) be licensed or registered if they dispense prescriptions to state residents. Some states have also attempted to regulate Internet pharmacies according to the same standards but this has been difficult (see below). The sale of prescription drugs between states or as the result of importation is the jurisdiction of the federal government.

Pharmacies are not restricted on where they can locate in relation to other pharmacies or prescribing doctors.

Registered licensed pharmacists can dispense medicines in accordance with state laws. There has been a clear problem faced by regulators in the USA over Internet pharmacies where prescribing and dispensing are not necessarily in compliance with state laws. A study by the GAO (2000) reported that there were 111 Internet pharmacies that required a prescription from a physician, 54 that would provide a prescription if a consumer completed an online questionnaire and 25 that did not require a prescription. Many websites did not provide enough information to determine whether medicines that were being sold were approved in the USA and dispensed according to state and federal laws. The monitoring and prosecution of these websites has been difficult. The National Association of Boards of Pharmacy now makes available a list called the Verification of Internet Pharmacy Practice Sites (VIPPS) of Internet pharmacies that comply with existing state laws and rules. Pharmacy technicians assist pharmacists but currently they are not certified or registered.

Some physicians also dispense medicines. This is regulated by the state boards of medicine.

Mailing direct to customers is allowed so long as the mail order pharmacy is registered by the state pharmacy boards. A mail order pharmacy (also called non-resident or out-of-state pharmacy) is defined as a pharmacy operating outside a given state that delivers, dispenses or distributes by shipping, mailing, delivering or any other method prescriptions or devices to residents of the state. Both mail order and Internet pharmacies are common along-side chain, independent, mass and supermarket pharmacies. Many traditional pharmacies now have Internet connections. Mail order pharmacies use the Internet as the primary method of ordering prescription medicines. There is also a problem with so called 'rogue sites' that allow ordering of prescription

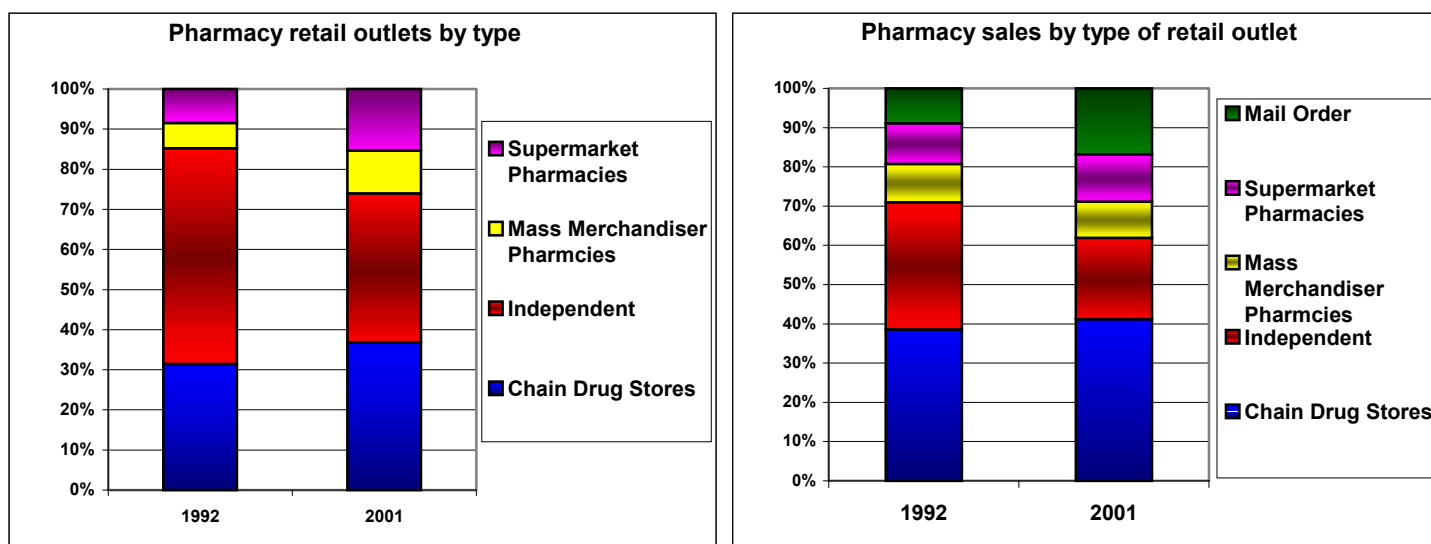
through online assessment and prescriptions to be filled by either domestic or foreign pharmacies.

There are no special subsidies for rural areas and there are often difficulties for rural areas to attract and retain staff.

7.3 Restrictions of ownership

There are no restrictions on ownership or corporate structure. As shown in figure 7.1 corporate ownership of pharmacies and chaining is common and has increased during the 1990s. The impact of this has been both a decrease in the number of independent pharmacies, as well as their share of overall pharmacy sales. The share of pharmacy sales accounted for by mail order pharmacies also increased during the 1990s. The only restriction is that the pharmacies must be licensed and that a pharmacist must be in charge of the dispensing of prescription medicines.

Figure 7.1. Pharmacy retail outlets by type and pharmacy sales by type of retail outlet



Adapted from : (1) National Association of Chain Drug Stores (2002) citing IMS Health and NACDS Economics Department (http://www.nacds.org/user-assets/PDF_files/Pharmacy_Sales.pdf) and (2) National Association of Chain Drug Stores (2002) estimates based on IMS Health, NCPCP and American Business Information Data (http://www.nacds.org/user-assets/PDF_files/Retail_Outlets.pdf)

There is no restriction in the number of stores pharmacy owners can own. Retail pharmacy chains are common since they were first introduced in the 1970s.

OTC medicines can be purchased with self-selection at any and all retail outlets including pharmacies, discount stores, supermarkets without a pharmacy, convenience stores etc. Some individual States do limit the sales to pharmacies only of certain non-prescription controlled substances with a low level of potential abuse. These are generally classified as Schedule V substances according to the Controlled Substances Act of 1970. Schedule V substances have a recognized abuse ability and approved medical use but are generally available without a prescription. The Drug Enforcement

Administration is the primary federal agency charged with enforcing these drug schedules. There is an ongoing discussion in the USA about establishing a so called third class of drugs that would be available only through a pharmacist.

7.4 Restrictions on price

Neither the retail prices of prescribed medicines nor the prices of OTC medicines are regulated. Retail pharmaceutical expenditure in the USA was estimated to have increased by 17.1 per cent between 2000 and 2001 to US\$154.5 billion (NIHCM, 2002). By April 2002, 31 states enacted or authorized some type of programme to lower prescription costs through discount programmes, bulk purchasing programmes, expanded manufacturer rebates, forms of price negotiation or price controls, and reducing pharmacy reimbursement (NCSL, 2002). These measures have included mandatory special discounting of products for companies participating in Medicaid in Florida, restricted access to expensive drugs for Medicaid patients in Maine and a low-cost drug matching scheme for state programmes in Michigan. Maine also threatened to introduce price regulation if companies did not offer residents without drug coverage discounts. At the federal level, Congress is examining closing loopholes on patent extensions so as to increase generic competition (New York Times, 2002).

Retail discounts vary depending on group insurer, employer or other third-party payers at the point of sale. Pharmacy Benefit Managers (PBMs) often manage prescription claims for employers, unions, and health plans. They are known for negotiating discounts from manufacturers and with networks of retail pharmacies, giving pharmacies financial incentives to dispense generics and ensuring tighter control of pharmaceutical use through drug formularies (Cook, Kornfield and Gold, 2000).

Pharmacies that join the networks agree to accept discounted dispensing fees in return for the higher volume that follows from the participation in the network. The networks have added to the price sensitivity of pharmacists. The dispensing fee on generics may be 25 to 50 cents higher to encourage generic substitution by pharmacists (DHHS, 2000). Pharmacy networks have put pressure on wholesalers to offer discounts on the average wholesale price, the benchmark for reimbursement, in order to compete. The average wholesale price is the average list price that a manufacturer suggests wholesalers charge pharmacies and is typically less than the retail price which will include the pharmacy's own price margin.

The reimbursement limits for products listed on a plan's formulary are often limited through the setting of a Maximum Allowable Cost price. For example, the Medicaid programme incorporates MAC prices, for products with generic substitutes for retail pharmacies. Medicaid MAC rules stipulate that the maximum reimbursement level should be no more than the published average wholesale price of the lowest priced version of the drug, in general a generic equivalent, plus a dispensing fee. States such as Illinois have gone further reducing its payments to pharmacists for Medicaid recipients to average wholesale price minus 11 per cent for brand-name drugs and average wholesale price minus 20 per cent for generics, while increasing dispensing fees by \$0.55 for brand-name drugs and \$1.35 for generics (Bruen, 2002). Many private insurers have also adopted fixed reimbursement levels. Approximately three-fourths of generic drugs are reimbursed through MAC limits, that are established by PBMs, based on the lowest estimated acquisition cost for any generic equivalent of a

given drug and are 50 to 60 per cent below the average wholesale price (DHHS, 2000).

Drug discount cards are another approach to lower retail pharmaceutical prices for consumers. After payment of an enrolment fee, the enrollee receives a discount card on prescription drugs purchased from certain independent retail, chain and mail order pharmacies. As table 7.3 shows, the card programmes differ across a number of dimensions that also includes enrolment fee, size of the price discount and by whom the cards are organized (i.e. state, insurer, PBM, retail stores, drug companies) (Health Policy Alternatives, Inc., 2002).

Table 7.3: Characteristics of drug discount cards

- | |
|---|
| <ol style="list-style-type: none">1. Hundreds of different discount cards on the market2. The discount card market is unregulated3. Markedly different discounts depending on type of card4. Many target uninsured, those without prescription coverage and Medicare patients5. Some have age and income restrictions6. Not all cards cover all drugs7. Not all pharmacies accept all cards8. Some discounts available only in certain cities on certain days9. Price may change frequently |
|---|

Source: Adapted from Brubaker, 2002

In April 2002, seven large pharmaceutical companies - Abbott Laboratories, Aventis, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, and Novartis - announced the 'Together Card' offering discounts of 20 to 40 per cent on 130 prescription drugs to Medicare recipients with incomes below US\$28000 and who are uninsured (Financial Times, 2002). Other similar schemes were previously introduced to aid Medicare recipients and a broad scheme in 2001 had been proposed to offer drug discount cards to older Americans. An analysis of current prescription card discount plans found that minimal discounts were offered for seniors and some card plan schemes were found to be fraudulent and subsequently banned in some states (US House of Representatives, 2001).

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APPENDIX A: OVERVIEW OF HEALTH CARE FUNDING AND DELIVERY

The objectives, financing, structure and coverage of health care systems of countries included in this study are strongly influenced by their historical context and cultural values. Table A.1 compares selected health care system indicators of the countries included in this study. Health care spending as a percentage of GDP is roughly similar in all these countries but is highest in the USA and Germany. Expenditure on pharmaceuticals as a percentage of health care expenditure and per capita is highest in France. Public expenditure on pharmaceuticals is highest in Germany and lowest in the USA. Spending on over-the-counter (OTC) medicines is highest in Germany followed by the USA. Both Germany and France have the highest rates of practicing physicians per 1,000 population.

Table A.1. Health system and pharmaceutical indicators, 1999

Country	Total Expenditure on Health % GDP	Total Expenditure Pharmaceuticals % Total Expenditure on Health	Public Expenditure on Pharmaceuticals % Total Expenditure on Health
Canada	9.3	15.4	32.2
France	9.4	22.8	58.6
Germany	10.3 ⁽¹⁾	12.7 ⁽¹⁾	69.2 ⁽¹⁾
Netherlands	8.7	11	59.9 ⁽²⁾
Norway	9.3	9.1 ⁽²⁾	64.2
United States	12.9	11	17.6
Country	Total Expenditure Pharmaceuticals per capita (US\$x-rate)	Total Expenditure OTC Medicines % Total Expenditure Pharmaceuticals	Practising physicians per 1,000 population
Canada	297	12.2	2.1
France	521	12.2	3 ⁽¹⁾
Germany	343 ⁽¹⁾	28.9 *	3.4 ⁽²⁾
Netherlands	240	15.4*	3.1
Norway	258 ⁽²⁾	9.1*	2.8
United States	478	23.6	2.7 ⁽¹⁾

Source: OECD Health Data 2001 (except * sourced AESGP, 1999)

Note: All data 1999 except ⁽¹⁾ 1998 and ⁽²⁾ 1997

Principles of social solidarity and welfare are important in all countries where the public system can be characterized as providing universal or near-universal health care coverage although the extent of coverage may differ; the USA is the exception. The health care system in Norway is built on the principle of equal access and all inhabitants have access to the same service (European Observatory on Health Care Systems, 2000a). The public health care systems in France and Germany cover 96 per cent and 90 per cent of the population respectively (Dixon and Mossialos, 2002). Universal coverage in the Netherlands is limited to long-term care and exceptional medical expenses. Health care coverage in Canada is founded on five principles enshrined in the Canada Health Act: public administration, comprehensiveness, universality, portability and accessibility. Nevertheless, health care coverage in Canada excludes some benefits such prescription medicines and dental care.

In the USA, those who do not have either commercial health insurance, or the means to pay out-of-pocket, may apply to a means tested public welfare programme. The

largest of these is Medicaid which covered approximately 44 million low-income individuals (i.e. families with dependent children, the elderly poor, the disabled) in 2001 (KKF, 2001a). Medicaid covers basic health services (i.e. hospital, physician, nursing home, prescription drugs), as well as, other services such as long-term care; states are given the flexibility to decide on eligibility, benefits and provider payment policies. The Medicare programme provided benefits to 34.4 million elderly (65 years and older) and 5.5 million disabled people in 2000 (HCFA, 2000). All those 65 and older are entitled to be insured by Medicare, consisting in part of hospital insurance and in part of supplementary medical insurance. Other Federally funded programmes include Federal Employees Health Benefits Programme, CHAMPUS for military families, Veterans Affairs and Indian Health Services. There are 38.4 million people without health insurance coverage (KFF, 2002) either because their employer does not offer insurance, they cannot afford to pay for that which is offered, or because they do not meet the income and eligibility criteria of the Medicaid programme. Hospitals are required by law to treat those with life threatening or urgent conditions even if they are uninsured.

The mechanisms for financing health care in each of the study countries differs. Health care in Norway is predominantly financed through general taxation. Taxation is also used as the predominant method of paying for health care in Canada, France and the Netherlands but the former may require residents to pay premiums at the provincial level, while the latter two countries are funded additionally through social health insurance contributions. Health care in Germany is predominantly financed through statutory social health insurance (SHI) contributions as the financing of the public health care system is viewed as the social responsibility of those who can afford to pay (i.e. the employed population), based on their ability to pay jointly with employers (European Observatory on Health Care Systems, 2000b). By contrast, health care in the USA is predominantly privately funded at 54.8 per cent of total health care expenditure in 2000, but with the remainder coming from public funds that nevertheless represent a significant portion of the health care spend (Centres for Medicare and Medicaid Services, 2000). Public spending in the USA extends beyond direct expenditure and includes tax subsidies such as those for employer-based insurance schemes.

In the study countries with predominantly public systems, health care is considered a social good where health benefits are distributed according to need. This is in contrast to the USA where health care can essentially be considered a market commodity. The private health sector is often described as a market-driven industry, particularly as the number of health plans, hospitals, or other providers that are for-profit increases; in 1997, for-profit managed care plans represented 63 per cent of enrollees compared to 12 per cent in 1981 (Levitt and Lundey, 1998). However, increasingly health care is being market driven in other countries as well. For example, in Germany, reforms in the mid-1990s to increase competition among sickness funds included allowing insured persons to freely choose between sickfunds which led to a series of mergers between funds to achieve economies of scale (Kamke, 1998).

All systems examined in this study do have some form of private insurance operating in their health care markets. As previously mentioned, health care in the USA is predominantly privately financed and delivered through more than 1,100 private insurance programmes covering 85 per cent of the non-institutionalised population (DFAIT, 2000). Traditionally, health insurance in both the public and private sectors has been provided by fee-for-service (FFS) (i.e. indemnity) plans. FFS plans provide health services to enrollees who pay an initial deductible and a coinsurance for any amount above the deductible. The need to control rising health care costs led to the significant expansion of managed care, in both the public and private health sectors in the USA, particularly during the 1990s. By 1996, 56 per cent of the population in the USA was covered by a managed care plan and 85 per cent of those with employer-based insurance funds (Levitt and Lundey, 1998).

Voluntary health insurance plays a smaller role in funding health care in the European countries examined in this study and in Canada. In the Netherlands, normal medical expenses are covered through private voluntary complementary or supplementary health insurance as approximately a third of the population is excluded from statutory coverage for these benefits (Mossialos and Thomson, 2002). Voluntary complementary health insurance is common in France with over 90 per cent of the population opting for additional coverage (Dixon and Mossialos, 2002). Although those with higher incomes representing about 20 per cent of the working population in Germany can opt out of the SHI scheme, only 23 per cent choose to do so (Mossialos and Thomson, 2002). It is possible to purchase voluntary insurance in Norway to avoid waiting for hospital treatment for example, however the penetration of this type of private coverage has been limited (European Observatory on Health Care Systems, 2000a). Private health insurance in Canada is supplementary and used to cover benefits excluded from the public system including dental care and pharmaceutical coverage. It is estimated that in 2001 public sector spending per capita was CND\$2,396 compared to CND\$902 in the private sector (CIHI, 2002a).

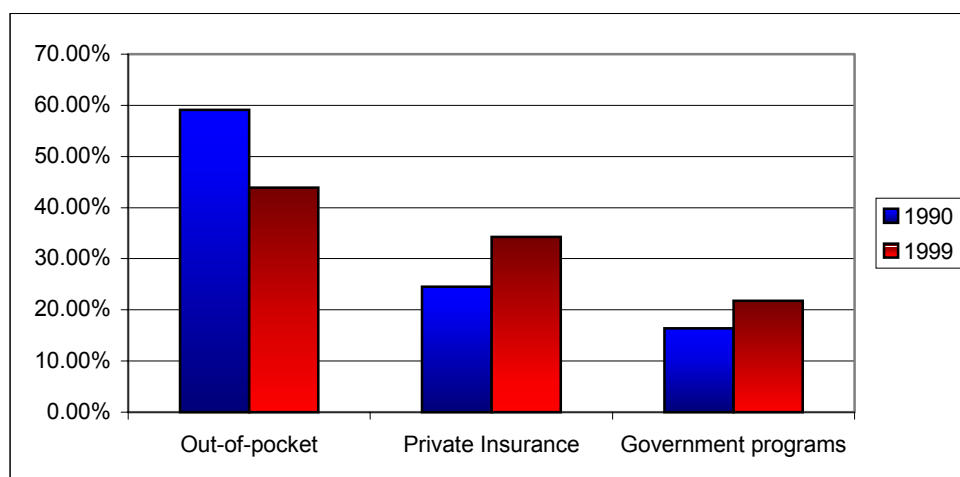
- Coverage of pharmaceuticals

In most of the study countries that have a predominantly publicly funded health care system, pharmaceuticals are covered as part of the benefits package; this is not the case in Canada. The type and level of out-patient prescription coverage in Canada differs from province to province but in general supplementary insurance is provided through government plans, employee benefit plans and individual insurance policies (Applied Management, 2000). Canadian federal, provincial and territorial governments all sponsor drug insurance arrangements for groups of their citizens. Public expenditure in 2000 on prescribed drugs paid for by provincial and territorial governments accounted for on average 38.2 per cent of total expenditure on prescribed drugs while drug expenditure financed from private sources accounted for on average 34 per cent of total private sector health spending (CIHI, 2002b). It is estimated that 75 per cent of Canadians aged 12 and older had some insurance for prescription drugs but young adults and those with low incomes were least likely to have insurance reflecting the fact that private insurance is often a benefit of employment (CIHI, 2002a).

In the USA, there has been a shift in prescription drug coverage since the early 1990s that has seen a significant rise in the coverage of prescription drugs by private insurers

as shown in Figure 1.1. Traditional FFS plans in the USA did not cover pharmaceuticals. With the spread of managed care, prescription drug coverage was gradually added by a number of Health Maintenance Organizations (HMOs) as a competitive strategy (Lyles and Palumbo, 1999). Strategies used by private insurers to secure more affordable drugs for their patient populations has meant that cash customers were often paying more than those insured for the same drugs at the point of sale (DHHS, 2000) and has subsequently led to prescription discount card programmes in an attempt to ease some of the burden of the cost of prescription drugs on those paying out-of-pocket (KFF, 2002). As well, political debate in the USA often turns on the issue of a lack of prescription drug benefits for senior citizens (Wechsler, 2002).

Figure 1.1. Prescription drug expenditure in the USA by source of funds, 1990 and 1999



Adapted from: Kaiser Family Foundation, 2001 citing Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group (www.hcfa.gov, March 2001).

Prescription drug coverage in all the countries in this study is subject to varying degrees of co-payment. In France patients are required to pay a co-payment of 35 per cent of the cost of the drug, although for some drugs there are no co-payments while for others considered to be of debatable therapeutic value the co-payment is 65 per cent; however, more than 90 per cent of the population has supplementary insurance to cover these co-payments (Mossialos and Thomson, 2002). Prescription drug plans in Canada generally require individual co-payments as a percentage of the total cost of the product dispensed and/or deductibles (National Forum on Health, 2001). The extent of cost sharing across public prescription drug plans in Canada varies considerably: all residents in Saskatchewan, British Columbia and Manitoba are covered by the public plan but must pay a relatively high deductible; and all residents

in Quebec without a private plan are covered by the public plan but must pay a monthly deductible (CIHI, 2002a). In the Netherlands, patients are only required to pay the difference between the reference price and the actual cost of the medicine. By contrast, in both Germany and Norway, patients must pay both a co-payment and any difference between the price of the medicine and the fixed reimbursement level (reference price). In Norway, medicines covered by the National Insurance System are subject to a co-payment limited to 36 per cent of the prescription fee up to a ceiling of Nkr 1320 (£115) per year (European Observatory on Health Care Systems, 2000a). The co-payments in Germany are flat-rate per pack size and there is both an annual upper limit that varies depending on the level of individual income, marital status and the number of children, as well as exemptions from co-payments on socio-economic grounds, pregnancy and for those under 18 years. In the USA, the co-payment rates vary particularly between formulary and non-formulary drugs and between brand names and generics. For example, in 2000 the average co-payment per prescription required for outpatients by HMOs was US\$22.97 for non-formulary brand names, US\$12.90 for formulary brand names and US\$6.67 for generic drugs (SMG Marketing Group, 2001).

Most health care payers and insurers limit what is reimbursed. Drugs in France are reimbursed only if they are included on a positive list that is established and updated by the Economic Committee for Medical Products. Most provincial public drug plans in Canada have a formulary, but how drugs are selected, what is included and the conditions under which certain drugs may be used varies from province to province (Anis, Guh and Wang, 2001). Provincial drug formularies in some Canadian provinces such as Ontario, consider both clinical and economic evidence in determining a formulary listing (Laupacis, 2002). Most private plans do not use a defined list of drugs, but in cases where they do, often follow the approach of the province (Applied Management, 2000). A negative list was introduced in Germany first in 1983 and later extended to exclude from reimbursement drugs considered uneconomic and were mainly off-patent OTC products: (i) medicines indicated for colds and influenzal infections; (ii) preparations for treatment of the mouth and throat; (iii) laxatives; (iv) medicines designed to combat travel sickness (Marx, 2000). Norway has both a positive list of drugs that are reimbursed but subject to a co-payment, and a negative list of drugs that can be prescribed but must be paid for in full by the patient. Formularies were used by 99 per cent of HMOs in the USA in 2000 and only 10.3 per cent of prescription drugs were filled outside a formulary (SMG Marketing Group, 2001).

Direct to consumer (DTC) advertising of prescription drugs is not permitted in any of the study countries except the USA and Canada. DTC advertising in Canada must promote disease awareness, help-seeking or promote a company but it cannot be used to directly promote drug sales. Since the Food and Drug Administration in the USA eased regulations on television advertising of prescription drugs in 1997 expenditure on DTC has risen (Public Citizen, 2002). In 2000, US\$2,467 million was spent on DTC in the USA with 63.3 per cent of promotional spending on television advertising (KFF, 2001b). The European Commission had proposed relaxing restrictions on DTC to allow companies to provide information to the public about HIV/AIDS, diabetes and asthma; however the proposal is currently being debated by the European Parliament.

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