

# Annexe G

International survey

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# **Study of Medicines Distribution in Other Countries**

**Report prepared for the Office of Fair Trading**

**Donald Macarthur**  
Global Pharmaceutical Business Analyst

[don.macarthur@btinternet.com](mailto:don.macarthur@btinternet.com)

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The views expressed in this Annex are the author's, and do not necessarily reflect those of the OFT.

### EXECUTIVE SUMMARY

1. Most medicines, in most European countries, follow a distribution pathway that goes from manufacturer to patient via a prewholesaler, a wholesaler and then a community pharmacy.
2. Medicines are unlike most other goods in that the time between first prescribing them and first consuming them must be as short as possible, and administering a substitute may not be clinically acceptable. It is also illegal for wholesalers or pharmacists to supply a medicine containing a different active ingredient, even one with a very similar effect, as a substitute for the one ordered.
3. Wholesalers have long been employed by manufacturers as the most efficient and cost-effective way for the product to reach the point of dispensing. In two European countries, Hungary and Norway, national legislation requires all medicines to be distributed to pharmacies by wholesalers.
4. Most wholesalers are either private companies or co-operatives (owned by the pharmacists they supply). Most are full-line, stocking almost every medicine that is available on the market regardless of whether it is a commonly-used medicine or one that is only rarely in demand. In some countries, short-line wholesalers exist. These offer lower prices as they concentrate on a limited range of fast-moving lines and hence have lower costs. Pharmacies use an average of two full-line wholesalers (one as a back-up) and receive on average two deliveries a day from each, sometimes just a matter of hours after an order has been placed, and at worst the following day. Short-liners deliver less frequently and may impose other conditions, such as a minimum order size or a carriage charge. Wholesalers do not distinguish in their deliveries between prescription medicines and over-the-counter products for self-medication (OTCs) as it would not be efficient.
5. A common feature is for the wholesaler to take title to the goods it sells, and by this gain the right to dispose of them as it chooses, as well as carrying the risk of loss or damage and bad debt.
6. Every European country has more than one pharmaceutical wholesaler and Italy still has 200 wholesaler branches. Competition for pharmacy accounts is based on discounts, service and value-added. Numerically, regional wholesalers dominate but, except in Spain, national wholesalers take the greatest market share.
7. Under a so-called 'public service obligation', wholesalers are required by national law in Belgium, Finland, France, Greece, Italy, Norway, Portugal and Spain to stock a full range of medicines and deliver any within a short period of time to any of their usual customers. There is also an obligation on both manufacturers and wholesalers in EU Directive 2004/27 to ensure adequate and continual supplies 'so that the needs of patients in the member state in question are covered'.
8. In all but two European countries wholesaling is predominantly multichannel, with each wholesaler stocking products from every supplier. In Finland and Sweden single channel distribution is found, by which manufacturers enter into exclusive, renewable one-year contracts with one or other of the two wholesalers to supply the entire national market.
9. Wholesalers usually receive a fixed or regressive mark-up on the purchase price or a margin on their selling price, set as a maximum gross profit per transaction by law,

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though in the Netherlands and all the Nordic countries this margin is freely negotiable. In regulated markets, the margin is sometimes limited to a maximum in value terms for very expensive products; wholesalers in any case discount to pharmacies for competitive purposes and this reduces the margin they actually receive.

10. For dispensing social health insurance prescriptions, pharmacies are paid a fixed fee per item, a certain percentage of the cost (on a progressive or regressive scale), or some combination of the two. Again, the margin may be capped in value terms, and may be further eroded by a clawback (to part recover procurement discounts), compulsory rebates or special taxes.

11. Mainly because of a margin squeeze and government-imposed price cuts, wholesalers have made changes to their business model to stay profitable. Efficiency gains and diversification into new products and markets have been followed by horizontal integration (nationally and internationally in Europe) and vertical integration (backwards into prewholesaling and forwards into retailing).

12. Mergers and acquisitions have resulted in three wholesalers – Celesio, Phoenix and Alliance UniChem – forcing their way into at least one of the top-five rankings in most European countries. EU-wide, the 'big three' have a combined 46% market share, and this share is higher in the larger markets. The 'big three' also own or franchise pharmacies in 11 European countries, including most of the largest pharmacy chains. Many other independent pharmacies are financially tied to wholesalers.

13. Significant direct-to-pharmacy (DTP) distribution by manufacturers to the retail market is largely limited to France (where DTP has a 19% market share), Spain (20%), Germany (16%), Italy (11%) and Switzerland (10%). Growth in DTP over the past four years has been most evident in France, the Netherlands and Spain. While there seems little or no DTP in some countries, including Finland, Hungary and Norway, Europe-wide DTP is a slowly growing trend. Much is believed to be accounted for by OTCs and generics, though some will be an attempt by brand manufacturers to counter parallel trade. DTP in Italy (by the regions) and in the Netherlands (by homecare companies) occurs with expensive high-tech products. Large volume intravenous infusions are also distributed direct in Sweden.

14. France shows a highly traditional system with only full-line wholesalers, no pharmacy chains and a pharmacy monopoly for the sale of all medicines. Four groups – OCP (Celesio), Alliance Santé (Alliance Healthcare), the co-operative CERPs and Phoenix – account for 98% of ex-wholesaler sales with market shares between them fairly stable over recent years.

15. Four national wholesalers operate in Germany: Phoenix (28% market share), Gehe/Celesio (18%), Anzag (17%) and a co-operative Sanacorp (13%). Officially there are no pharmacy chains or franchises but affiliations are beginning to appear. Mark-ups for the wholesaler are on a regressive scale and pharmacies receive a flat €8.10 dispensing fee plus a 7% mark-up, but have to rebate €2.30.

16. The Dutch market is the most liberal as regards distribution and is most akin to the UK environment with a large number of pharmacy chains, high generic and parallel import use, and a significant dispensing doctor sector. The main difference is that Dutch wholesalers have retained the bulk of distribution to hospitals while in the UK much goes direct. There are four Dutch full-line wholesalers: OPG (28% market

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share), Alliance UniChem (27%), Brocacef/Phoenix 18% and a co-operative Mosadex (13%).

17. Sweden is unusual in having single channel distribution. It is unique in having a state-owned pharmacy chain, Apoteket, that monopolises retail and hospital distribution. There are just two wholesalers and the market is currently split 54% to Tamro, 42% to KD, with the 4% balance going direct. Manufacturer contracts have switched between the two wholesalers increasingly in recent years with resultant variations in market shares. The pharmacy sector is soon to be liberalised but it is as yet unclear what the outcome will be. If wholesalers are allowed to own pharmacies this is likely to result in the demise of single channel distribution.

18. Wholesaler and pharmacy respondents in the four markets studied strongly defended their own systems, highlighting the fact that these systems worked to the benefit of the patient.

19. GSK is thought to have tried to duplicate its UK agency distribution scheme in the Netherlands but failed; it is not known to use DTP currently in any other European country except the UK. 15 years later Pfizer sought to introduce DTP in Germany, but it also failed. Pfizer is reportedly trying again and was in talks with wholesalers in early 2007. Pfizer was stopped by the government from using DTP alone in Spain, and now uses a mixed DTP/dual pricing scheme with wholesalers to reach the market, but DTP is believed to only account for 5% of its sales. Pfizer has also recently changed single channel distributor in Sweden, and this change might have been associated with a change to more of a DTP model, but this could not be confirmed.

20. Direct distribution is far more common in the hospital market.

21. The risk of counterfeit medicines entering European markets is not seen as a priority issue and past examples of known counterfeits reaching patients or pharmacies are exceptionally rare.

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*Summary of main features of wholesale markets in France, Germany, the Netherlands and Sweden*

	France	Germany	Netherlands	Sweden
Distribution type	Multichannel	Multichannel	Multichannel	Single channel
Leading wholesalers (market shares)	OCP (38%) Alliance Santé (28%) CERP Rouen (14%)	Phoenix (28%) Gehe (18%) Anzag (17%) Sanacorp (13%)	OPG (26%) Alliance Healthcare (23%) Brocacef (18%) Mosadex (13%)	Tamro (54%) KD (42%)
Total number of full-line wholesalers	9	15	6	2
Wholesaler-owned pharmacy chains?	No	No	Yes	No
Level of price regulation for reimbursed products	Manufacturer selling price	None (free pricing for manufacturer)	Pharmacy purchase price	Pharmacy purchase price
Which margins are regulated by law?	Wholesale mark-up & pharmacy mark-up	Wholesale mark-up & pharmacy mark-up	Pharmacy dispensing fee	Pharmacy mark-up
DTP	20% (mainly OTCs, generics)	15% (brands at risk from generics & PIs)	More than 6% (homecare products)	4% (IV infusions)

### 1. EUROPEAN OVERVIEW

It is well known that the market for prescription medicines throughout Europe is not a normal one. The consumer does not make the product selection, does not normally pay the full market price for it, and is not in the position to substitute one product for another. Instead, the prescriber (the doctor) decides what product the actual consumer (the patient) receives, with price not the key consideration for this choice, and a third-party reimburses all or a large part of the cost. The third party payer, depending on the country, is either a national health service or statutory social health insurance scheme. This system has been a major contributor to the growth of the pharmaceutical manufacturing and distribution industries in Europe as it has made medicines affordable to patients at the time they need them.

#### 1.1 Distribution Chain

Everywhere in Europe, most medicines are prescribed by GPs and dispensed to patients by community pharmacies. Patients expect and typically need to obtain any medicine prescribed for them with the minimum of delay. In some countries (e.g. France, Germany, Spain, Sweden), as part of their cost-containment policies, pharmacists are allowed to substitute a prescribed brand with a cheaper generic (containing the same amount of the same active ingredient), but only if the doctor agrees and the patient does not object. In all other cases, the pharmacist must dispense the exact product – by brand, dosage form, unit strength and pack size – prescribed. This is because even closely-related but different active ingredients, or even different formulations of the same active substance, can never be assumed as having the exact equivalent effect in every patient.

Pharmacies could not possibly have the space to stock (or afford to purchase) the tens of thousands of different forms of medicines (known as stock keeping units or SKUs) available on each national market, and therefore depend on well-functioning distribution system. While a manufacturer may sometimes undertake to ship its products to pharmacies via a logistics service provider (LSP), a system known as direct distribution, more usually goods pass through one or more middlemen (known as indirect distribution)

The standard distribution chain for the retail market is:

Manufacturer → prewholesaler → wholesaler → community pharmacy → patient.

Prewholesalers (known in France and Italy as depositaries) have largely replaced manufacturers' own logistics functions, a trend accelerated by increasing concentration of manufacturing sites into specialised 'centres of excellence' supplying all or large parts of Europe with particular dosage forms in country-specific packs. Prewholesalers do not purchase the stock they handle, but wholesalers and pharmacies do.

The most important middlemen between Europe's 3,500 pharmaceutical manufacturers and its total of 140,000 dispensing points are wholesalers, numbering around 600. These have two main functions:

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- To maintain an economical and efficient distribution network to supply pharmacies and other dispensing points with medicines and related products sold into the market by manufacturers and importers.
- To simplify customers' restocking by providing an efficient order and supply service through which they can obtain all the products needed.

*Dispensing points in main European countries (latest available year)*

Country	Community pharmacies	Population/pharmacy	Hospital pharmacies	Self-dispensing doctors
Belgium	5268	1948	344	-
Denmark	284	18835	18	-
Finland	797	6512	24	-
France	23000	2609	3052	few
Germany	21651	3822	550	-
Greece	9350	1198	70	few
Ireland	1268	3084	155	140
Italy	17524	3336	800	-
Netherlands	1625	9810	85	480
Poland	9693	3945	690	-
Portugal	2557	4013		-
Spain	19766	2044		-
Sweden	800	11125	76	-
Switzerland	1679	4347		3928
UK	12250	4798	332	2225
Total Europe	134825	3367		

Sources: Pharmaceutical Group of the European Union/European Association of Hospital Pharmacists

The use of wholesalers by manufacturers in most countries is a matter of choice, based on economics and efficiency. Because incoming orders are pooled by wholesalers, complexity is minimised and there is a reduction in transaction costs between parties at either end of the chain. In a November 2005 paper for the European Association of Full-line Pharmaceutical Wholesalers (GIRP), Clement and co-workers at the Institute of Pharmacoeconomic Research in Vienna estimated that the 28 billion pharmaceutical distribution transactions a year in the EU countries would increase to an unlikely 528 billion without the involvement of wholesalers. It should be noted that national legislation in both Hungary and Norway requires all medicines to be distributed to pharmacies via wholesalers.

In wholesaling and pharmacy terms each national market is considered discrete. A wholesaler in country X orders medicines from a manufacturer or its agent in country X, and a wholesaler in country Y orders similar ones from a manufacturer in country Y. All pharmacies place their orders locally, these are processed locally and delivered in vans in familiar local liveries from local warehouses.

Community pharmacies are the most important customer group for wholesalers.

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*Share (%) of sales from wholesalers by customer group, 2006*

	Community pharmacies	Hospital pharmacies	Dispensing doctors	Drugstores	Other
Belgium	97	3	-	-	-
Denmark	70	30	-	-	-
Finland	76	24	-	-	<2
France	99	1	<1	-	-
Germany	99	1	-	-	-
Greece	100	-	-	-	-
Ireland	84	16	-	-	-
Italy	98.5	1	-	-	0.5
Netherlands	79	8	6	-	7
Portugal	98	<1	-	2	-
Spain	99	1	-	-	-
Sweden	87	13	-	-	-
Switzerland	54	19	25	3	-
UK	82	10	8	-	-

Source: GIRP

The average size of population served by one community pharmacy is highly variable, but care must be used in interpreting this. There are often additional retail outlets in which certain over-the-counter (OTC) medicines may be purchased for self medication as well as prescriptions handed in for dispensing elsewhere and collection later. Rural populations in some countries have access to self-dispensing doctors, and mail order/internet pharmacies have started to appear in Denmark, Germany, the Netherlands, Sweden and the UK

### 1.2 Wholesaling

The wholesaler takes title to the goods it sells, and by this gain the right to dispose of them as it chooses. In the normal course of events, a wholesaler purchases products from a manufacturer and resells them to community pharmacies. The wholesaler is responsible for ordering and holding stock to enable predicted levels of demand to be met, as well as for the collection of debt resulting from these transactions. The manufacturer pays for his goods to be transported to the wholesaler; the wholesaler pays for their onwards delivery to each pharmacy account. Very occasionally, with a manufacturer start-up, goods will be stocked by wholesalers on a consignment basis until demand for the products is proven.

There is competition between wholesalers in all European countries ranging from one to more than two hundred competitors. Norway's NMD lost the last national monopoly in western Europe one year after the European Economic Area agreement came into force in 1994. A similar fate befell the once state-owned wholesalers in the former Soviet Union satellite countries of central and eastern Europe.

Overall, following the global trend, numbers of wholesaling companies are falling. The concentration process is largely as a result of mergers and acquisitions (M&A);

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relatively few wholesalers cease trading after bankruptcy. Warehouse numbers have fallen significantly in some countries but not in others, reflecting the stage of rationalisation the industry has reached, and, a certain minimum number of strategically-sited warehouses being needed to deliver to every pharmacy quickly. Pharmacy numbers have remained largely steady over the past decade.

*Numbers of wholesalers and pharmacies in 2004 (compared to 1995 figures in parentheses)*

Country	Wholesalers	Warehouses	Community pharmacies
France	10 (16)	187 (210)	23000(22300)
Germany	16 (19)	106 (104)	21350 (21000)
Italy	136 (215)	254 (312)	16800 (15500)
Spain	49 (106)	190 (202)	20400 (18400)
UK	11 (21)	59 (63)	12200 (12200)

Source: GIRP

Most wholesalers are either private companies or co-operatives owned by their pharmacy customers. Co-operative wholesalers are a strong market feature in Belgium, France, Greece, Italy, Portugal and Spain. Manufacturer-owned wholesalers are a rarity. Two examples are Hungaropharma (Hungary) and Oriola-KD (operating in both Finland and Sweden).

Wholesalers do not normally market prescription medicines, they merely respond to orders from pharmacies, whose orders in turn are triggered by doctors writing prescriptions.

Pressure on dispensing remuneration has resulted in pharmacies making extra demands of their wholesalers. Orders are smaller, more frequent, less regular and there is more shopping around for special offers and 'cherry picking' for higher discounts. There are no contracts as such between the parties and in an attempt to win and retain customer loyalty wholesalers offer pharmacies a number of added-value services, ranging from special promotional deals, finance, loan guarantees, merchandising, own brands, training, market information, to computers and pharmacy software.

### 1.2.1 National/Regional Wholesalers

In numerical terms, most wholesalers (about 70% of the European total) only operate in distinct regions of their country, though the most important wholesalers are active nationally.

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*Numbers of pharmaceutical full-line wholesalers in main European countries, 2006*

Country	Nationwide wholesalers		Local/regional wholesalers	
	Companies (wholesaling market share)	Warehouses	Companies (wholesaling market share)	Warehouses
Belgium	3 (65%)	20	8 (21%)	7
Denmark	2 (95%)	7		
Finland	2 (99%)	6		
France	3 (94%)	180	2 (6%)	13
Germany	4 (>75%)	78	12 (<25%)	30
Greece	7 (33%)	7		
Ireland	3 (90%)	10		
Italy	81 (89%)	214		
Netherlands	5 (86%)	15		
Norway	3 (100%)	7		
Portugal	2 (40%)	14	8 (46%)	15
Spain	3 (38%)	64	55 (62%)	127
Sweden	2 (96%)	6		
Switzerland	4 (80%)	9	30	
UK	3 (91%)	46	11 (11%)	11

Source: GIRP

### 1.2.2 Full/Short-Line Wholesalers

Full-line wholesalers distribute the full range or nearly the full range of prescription medicines. German wholesalers hold the largest number of different SKUs, some 80,000 (30,000 of which represent medicines), while Hungarian full-line wholesalers stock fewer than 7,000.

Delivery frequency averages twice each day (once on Saturdays), throughout the year and in all weathers. Pharmacies in Belgium, Germany, Greece, Ireland, Italy, Portugal and Spain are daily supplied more frequently than the EU average, and those in Denmark, Finland, Lithuania, Netherlands, Norway, Slovenia and Sweden are supplied less frequently. As pharmacies use an average of two wholesalers this means a total of eight deliveries per day are possible in Germany (i.e. two wholesalers each making four deliveries per day), or two in Sweden (i.e. two wholesalers each making one delivery per day), for example.

Almost all orders (more than 90%) are placed via electronic data interchange (EDI) terminals in the pharmacy in the larger countries, and generally are delivered within a few hours, or overnight at the latest. There is no minimum order size or delivery charge.

Short-line wholesalers deal only with a limited range of fast-moving lines. They do not offer an emergency service or handle 'problem' or rarely-used products. With lower costs, short-line wholesalers can offer pharmacies preferential terms, but allied

to a lower level of service (e.g. minimum order, carriage charge, at best overnight delivery via third-party carrier).

### 1.2.3 Public Service Obligation

Several countries – Belgium, Finland, France, Greece, Italy, Norway, Portugal & Spain - have national legislation that precludes the existence of short-line wholesalers. Under the so-called 'public service obligation', every wholesaler serving that market is required to deliver virtually any product within a certain time period to its usual customers within the wholesaler's geographical reach. In practice, even where there is no obligation enshrined in law, competitive pressures on full-line wholesalers and voluntary codes of practice ensure pharmacies receive a comparable service.

Similar supply obligations on pharmacies apply, either in professional codes of practice or in contract terms with their health insurance agencies.

On the European level, Article 81 of EU Directive 2004/27 introduced an obligation on both manufacturers and wholesalers to ensure adequate and continued supplies:

*'The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a member state shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the member state in question are covered'.*

### 1.2.4 Multichannel/Single Channel

Most wholesalers, full- or short-line, supply products from a number of different manufacturers in competition with other wholesalers operating in the same market. In Finland and Sweden, an alternative approach to this traditional multichannel system has developed, single channel distribution. In this case, a manufacturer makes an exclusive distribution arrangement for a period of time with one wholesaler, which alone is responsible for meeting all demands in the country for the affected products.

### 1.3 Margins

The base price, set by the authorities, on which distribution margins are added for reimbursed medicines is for most countries the manufacturers' selling price (MSP) or import (cost for insurance and freight; CIF) price. Throughout Scandinavia and also in the Netherlands, however, it is the pharmacy purchase price that acts as the base for the pharmacy's selling price, with the wholesale margin subject to free negotiation between each manufacturer and each wholesaler.

#### 1.3.1 Wholesaler margin

Superficially simple methodologies applied in setting gross wholesaler margins often preclude effective international comparison. Terms such as mark-up on the MSP, margin of the wholesale selling price (WSP) to pharmacies, or margin of the final public price – with or without value-added tax (VAT) – are not synonymous but are sometimes translated that way. Price levels, discount and settlement terms, the types

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and numbers of products handled, the density of pharmacies, the delivery frequency and the geography of the country all also have an impact.

The percentage component can be fixed or regressive (i.e. varying inversely with the cost of the drug), and is sometimes combined with a flat fee. In some countries there is a ceiling or cap on wholesaler earnings for very high cost drugs.

Quite apart from these differences in definition and interpretation, it is important to recognise that the gross margin wholesalers receive – on whatever basis – does not constitute their net margin as in many countries they may offer significant discounts to pharmacies in order to gain their business. So for example in the UK, while full-line wholesalers may buy medicines at the PPRS price less 12.5% discount, they do not see the full 12.5%: typically they offer most branded medicines to pharmacies at 10% or 10.5% discount, leaving a net margin of 2 – 2.5%. Also, of course, they must still meet their costs out of the net margin.

### *Summary table of wholesaler margins/mark-ups*

Country	Unregulated	Percentage-based	Regressive	Flat fee	Capped
Austria			O		
Belgium		O		O	
Denmark	O				
Finland	O				
France			O		
Germany			O		O
Greece		O			
Ireland		O			
Italy		O			
Netherlands	O				
Poland		O			
Portugal		O			
Spain		O			O
Sweden	O				
UK		O			

Source: author

Owing to fear of downwards pressure on their margins from manufacturers and/or governments to some European 'norm', wholesalers often feel that transparency is not in their interests. If any figures are quoted, these are invariably gross, and not net margins and, depending on the country, can be the average for the mix of all goods handled, apply just to medicines (prescription and OTC), or just to reimbursed products.

Differences often can be explained by differences between the markets. Whether or not discounts are routinely offered to customers is the most important factor. The density of population or pharmacies is another. For reasons of geography, climate and terrain, wholesalers in some countries have higher operating costs than elsewhere. In addition, there are often very large differences between the types and numbers of

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products handled and, to a lesser extent, in the delivery frequency. This heterogeneity has long been recognised by the European Commission, which has no plans to harmonise or approximate conditions and margins.

In some countries (e.g. Belgium, Spain, UK), for the sake of simplicity, manufacturers offer wholesalers the same margin for non-reimbursed prescription drugs as for reimbursed ones, even if it is only the latter that are government-regulated. However in Italy, the wholesale margin for non-reimbursed prescription drugs may be freely set.

The following table gives average gross wholesale margins for different European countries in 1995 and 2005 (source: GIRP). It must be stressed that as margins are worked in different ways, and based on different figures, the figures do not admit to straight comparison.

*Average gross wholesale margins (%), 1995 vs 2005*

Country	1995	2005
Denmark	7.3	6.25-6.75
France	8.5	6.5
Germany	13.7	6.2
Greece	NA	4.5
Hungary	NA	6.2
Poland	NA	8.9
Portugal	10.0	7.5
Spain	12.0	<4
Sweden	3.4	NA
UK	12.5	12.5

### 1.3.2 Pharmacy Margin

Pharmacists are paid on a fee-for-service basis and in addition are reimbursed for the acquisition costs of the medicines they dispense less the prescription charges or co-payments they collect from patients. The calculation of the remuneration component for dispensing social health insurance prescriptions differs in every European country, and is often highly complex.

Pharmacy remuneration is usually based on:

- a fixed fee per item, or
- a certain percentage of the cost or the delivery price of the item, or
- some combination of the two.

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*Summary table of pharmacy margins/mark-ups*

Country	Percentage-based	Regressive	Flat fee	Capped
Austria		O		
Belgium	O		O	
Denmark	O		O	
Finland		O	O	
France		O	O	
Germany	O		O	
Greece	O			
Ireland			O <sup>1</sup>	
Italy	O			
Netherlands			O	
Poland		O		
Portugal	O			
Spain	O			O
Sweden		O		O
UK			O	

<sup>1</sup> General Medical Services prescriptions only

Source: author

The gross dispensing margin may be eroded by compulsory rebates to social health insurance or by special taxes. As well, as described above, the precise price paid by the pharmacy for the medicines depends in many – but not all – countries on the level of discount offered by the wholesaler. These factors mean that, as with the wholesaler margin, it is often difficult to measure the net margin pharmacies obtain.

Dispensing margins for private prescriptions in some countries (e.g. France, Italy, Poland, UK) are free from government interference. In Belgium, Denmark, Germany, the Netherlands, Spain and Sweden, however, the margin scales are common for reimbursed and non-reimbursed prescription products alike.

### 1.4 Evolutionary Changes by Wholesalers

Wholesaling is basically a local business and the opportunities for expansion of any wholesaling operation in its own domestic market are often limited. Wholesalers cannot increase the demand for prescription products and are vulnerable to government-imposed margin and/or price cuts, or manufacturer price adjustments.

The first step taken to restructure the business was to seek productivity improvements. Greater efficiency meant considerable investment in computer technology and automation – investment, wholesalers argue, that is analogous to manufacturers' investment in R&D – which in turn meant fewer and larger units dependent on a high volume throughput.

Diversification into new product areas, such as OTCs, generics, parallel imports, cosmetics, toiletries and baby products (everything that a community pharmacy sold and therefore needed), helped feed the volume as well as providing sales with higher

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margins. Wholesalers also sought new markets (such as hospitals, clinics, nursing homes and home healthcare) and new business areas (such as medical and surgical supply, contract sales, data processing and pharmacy finance).

Expansion by wholesalers into other national markets is a more recent phenomenon. Though legally possible, it is not usually sensible to try to set up a new wholesaling operation from scratch – as it would need to build up customers from a zero base. There is normally some form of tie-up with an existing local wholesaler. Originally, this took the form of joint ventures and international alliances, but the strategy of the larger players today is on overseas acquisition of other wholesalers, and vertical integration – especially backwards into prewholesaling (e.g. Movianto/Celesio, Alloga-Europe/Alliance UniChem and Phoenix) and forwards into pharmacy retailing.

The UK's 'big three' wholesalers – AAH (Celesio), UniChem (Alliance UniChem – the wholesaling division of Alliance Boots) and Phoenix - are also the big three across much of Europe. In 2004, according to IMS, together they held a 46% market share across the EU, with in excess of 55% in the largest national markets of Germany, France and the UK. Based on information provided by GIRP it is estimated that by 2006 their combined market shares reached 100% in both Denmark and Norway, 92% in the UK, 70% in France and 63% in Germany.

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Leading five wholesalers by sales by country, 2006

Country	1st ranked	2nd ranked	3rd ranked	4th ranked	5th ranked
Austria	Herba Chemosan <b>(Celesio)</b>	Kwizda	<b>Phoenix</b>	Jacoby	Richter
Belgium	Febelco	Aprophar/Alpha Répartition	Pharma Belgium <b>(Celesio)</b>	CERP Phardip (CERP Lorraine)	Laboratoria Flandria (OPG)
Bulgaria	Libra <b>(Phoenix)</b>				
Czech Republic	<b>Phoenix</b>	<b>All. UniChem</b>	Pharmos	Gehe Praha <b>(Celesio)</b>	
Denmark	Nomeco <b>(Phoenix)</b>	Max Jenne <b>(Celesio)</b>	KV Tjellesen <b>(Celesio)</b>	-	-
Estonia	Tamro <b>(Phoenix)</b>				
Finland	Tamro <b>(Phoenix)</b>	Oriola (Oriola-KD)	-	-	-
France	OCP <b>(Celesio)</b>	Alliance Santé <b>(All. UniChem)</b>	CERP Rouen		
Germany	<b>Phoenix</b>	Gehe <b>(Celesio)</b>	Anzag	Sanacorp	Noweda
Greece	Prosyfape	Lavifarm	Syfa Salonica	Stroumas	Marinopoulos
Hungary	Hungaropharma (Richter/Egis/Béres)	<b>Phoenix</b>	Humantrade	Medimpex	Euromedic Pharma
Ireland	United Drug	Cahill May Roberts <b>(Celesio)</b>	Uniphar	-	-
Italy	Comiphar <b>(Phoenix)</b>	Alleanza Salute <b>(All. UniChem)</b>	Farmintesta (Secof)	Unico	So Farma Morra
Latvia	Tamro <b>(Phoenix)</b>	Limedika	Medikona		
Lithuania	Tamro <b>(Phoenix)</b>				
Netherlands	OPG	InterPharm <b>(All. UniChem)</b>	Brocacef <b>(Phoenix)</b>	Mosadex	Regifarm
Norway	NMD <b>(Celesio)</b>	Tamro <b>(Phoenix)</b>	Holtung <b>(All. UniChem)</b>	-	-
Portugal	<b>Alliance UniChem</b>	OCP <b>(Celesio)</b>	Codifar	UFP	Cofanor & Cooprofar
Slovakia	<b>Phoenix</b>				
Slovenia	Kemofarmacija <b>(Celesio)</b>	Salus	Farmadent	Pharmakon	Gorpharm
Spain	Cofares	Safa <b>(All. UniChem)</b>	Hefame	Cecofar	Federció
Sweden	Kronans Droghandel (Oriola-KD)	Tamro <b>(Phoenix)</b>	-	-	-
Switzerland	Galenica <b>(20% stake by All. UniChem)</b>	Amedis <b>(Phoenix)</b>	Voigt	Unione	-
UK	AAH <b>(Celesio)</b>	UniChem <b>(All. UniChem)</b>	<b>Phoenix</b>	Mawdsley- Brooks	NA

Source: GIRP

## Medicines Distribution in Other Countries

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James Dudley Management estimated that 13.5% of pharmacies across Europe's 18 leading countries are already in chains of two or more outlets, and many are wholesaler-owned. This figure largely reflects the position in the UK, with more than half of the 16,974 pharmacies belonging to chains among the 126,152 pharmacies in the 18 countries.

*Share of community pharmacies in actual or virtual chains by country*

Country	Pharmacy chain (%)	Virtual chain (%)
Austria	1.6	2.1
Belgium	22.0	3.8
Czech Republic	9.9	0
Denmark	18.4	0
Finland	19.4	0
France	0	60.0
Germany	5.7	62.4
Hungary	0	0
Italy	8.8	0
Netherlands	19.2	11.2
Norway	98.1	0
Poland	10.0	0
Slovakia	5.6	0
Slovenia	0	0
Spain	0	1.0
Sweden	100.0	0
Switzerland	18.0	44.0
UK	73.0	49.0
18-country total	13.5	27.3

Source: OTC Distribution in Europe 2007, James Dudley Management

In countries where multiple ownership is currently forbidden (and even where it is allowed), so-called 'virtual chains' sometimes exist. These are independently-owned pharmacies gathering together under a common, recognisable brand to share the benefits of bulk purchasing, common marketing and in-store merchandising, often under the direction of a wholesaler. Dutch wholesaler OPG both owns 220 pharmacies and runs a franchise for a similar number, giving it effective control of 30% of the market

In other cases, independent pharmacies are effectively tied to dealing with a particular wholesaler for a high percentage of the pharmacy's needs over a period of time, as the wholesaler has either acted as a loan guarantor or provided finance.

Wholesaling and community pharmacy, previously mutually dependent, are increasingly integrated with each other. Wholesalers own the largest pharmacy chains in Bulgaria, Czech Republic, Estonia, Hungary, Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Romania, Switzerland and the UK. Apart from countries where chains are forbidden by law (e.g. France, Germany, Italy) – where wholesalers either manage pharmacies on behalf of municipalities (Italy) or act as the

## Medicines Distribution in Other Countries

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focus of buying groups of independent pharmacies, in the other countries, Belgium, Greece, Portugal and Spain, pharmacists as co-operatives own the major wholesalers.

Between themselves, the 'big three' wholesalers own a total of about 6,000 community pharmacies in 11 European countries. Norway, with just 15 of the country's 559 pharmacies independent of the 'big three, is an extreme example, but considerable inroads into pharmacy ownership have been made in every European country that allows this.

*Extent of pharmacy ownership by Alliance Boots, Celesio and Phoenix*

Country	Alliance Boots	Celesio	Phoenix
Austria			O
Belgium		O	
Czech Republic		O	
Estonia			O
Ireland	O	O	
Italy	O	O	O
Latvia			O
Lithuania			O
Netherlands	O	O	O
Norway	O	O	O
UK	O	O	O

Source: Wholesaler annual reports

With recent or pending changes to pharmacy ownership in a number of countries (e.g. Germany, Hungary, Portugal, Sweden), challenges to the status quo by the European Commission in others (e.g. Austria, France, Italy, Spain), and depending on the outcome of the *DocMorris* (joined cases C-171/07 & C-172/07) before the European Court of Justice, the size and number of chains could grow greatly over the next few years. Where new opportunities for ownership emerge, it seems certain that wholesalers will be the first to exploit them.

### 1.5 Direct-to-Pharmacy Distribution

Direct distribution, cutting out the wholesaler as intermediary, has always occurred to a varying extent across Europe. It is most prevalent in the hospital market, especially in Belgium, France, Germany, Greece, Italy and Spain. In the retail sector, most direct distribution has traditionally occurred with OTCs. Demand here is more predictable and often seasonal, and hence purchases can be made by pharmacies in larger volumes at certain times of the year to attract the best terms. Unlike prescription medicines, there is no particular need for urgent delivery. Some generic companies also deliver direct as do some parallel importers. Again these products are generally bought in greater volume than domestic originator brands, as well as being effective duplicates of brands already on the pharmacy shelves, so urgency with delivery is not paramount.

To the dismay of wholesalers, direct-to-pharmacy (DTP) distribution has grown in importance in some European countries, though this is neither a generalised nor

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constant phenomenon. If a pharmacy is unable to obtain a particular product from its regular wholesalers and makes an enquiry of the manufacturer concerned, it often will offer to supply direct. While there appears little or no DTP in Finland, Hungary and Norway, for example, overall the trend to mid-2006 with DTP across Europe as a whole has been slowly upwards.

*Evolution of DTP sales in Europe as a percentage of total sales of medicines to community pharmacies, 2003-2006*

Country	2003	2004	2005	2006 first half
Germany	12.7	13.0	14.2	15.7
France	13.4	12.5	17.7	NA
Italy	10.1	8.2	9.0	9.8
UK	2.2	2.3	3.1	3.0
Spain	2.4	2.3	2.9	3.3
Belgium	5.6	5.4	5.5	6.0
Switzerland	6.9	7.3	8.9	8.1
Austria	5.8	6.3	6.0	5.4
Ireland	3.6	3.5	4.8	5.6

Source: IMS Health

As a cost containment measure under Law 405/2001, Italian regions started in 2002 to purchase a limited range of medicines directly from manufacturers and supply these to patients discharged from hospital or attending out-patient clinics through local health authorities and hospital pharmacies. Purchases by the regions are entitled to a minimum 50% discount on the public price, so there is a big saving compared to sales through community pharmacies. In practice, affected products follow a twin distribution route as some wholesalers and community pharmacies have agreed to handle regional purchases at much lower margins than normal in order to limit their volume losses. According to the Italian wholesaling body ADF, full-line wholesalers account for 84% of pharmacy sales, while 6% is distribution through the regions, and the remaining 10% (which is mostly OTCs) is direct distribution.

Other national-specific features are discussed in the country sections below.

### 2. FRANCE

#### 2.1 Healthcare System

France's health insurance system (*Assurance Maladie*) is characterised by freedom of access for users and a high degree of professional freedom and independence for providers (*médecine libérable*), whilst at the same time being *dirigiste* (heavily regulated by government). From a consumer perspective it has been rated the best in the world, though the system has a chronic huge deficit financed by debt. Funding is by compulsory payroll contributions (60%) and a special tax (40%) paid by all those in employment. The government pays the premiums for non-working people, including the retired and the unemployed.

#### 2.2 Pharmaceutical Market

The total out-of-hospital pharmaceutical market (prescription and OTC) at public price level in 2006 was €29,500 million, according to IMS. France is the second-largest pharmaceutical market in Europe, more than 50% larger than the UK's market.

#### 2.3 Supply Chain

retail: manufacturer – wholesaler – pharmacy, or  
manufacturer- prewholesaler – wholesaler – pharmacy  
hospital: manufacturer-prewholesaler – hospital pharmacy

Of manufacturer output for the retail prescription market, 88% goes to wholesalers and 12% goes to wholesalers via prewholesalers (*dépositaires*). Virtually all sales from wholesalers (99.5%) go to community pharmacies. Wholesaler sales (by value) can be broken down as 89% prescription medicines, 5% OTCs, and 6% other products.

#### 2.4 Distribution Model

This is multichannel.

#### 2.5 Players

##### 2.5.1 Wholesalers

Merger and acquisition activity and rationalisation has resulted in a marked fall in the number of wholesalers to just seven major companies in four groups: Office Commercial Pharmaceutique or OCP (Celesio), Alliance Santé (Alliance UniChem), Coopérative d'Exploitation et de Répartition Pharmaceutiques (better known as the CERPs), and Phoenix. A family-owned firm, RBP Pharma, and another co-operative, Giphar Sogiphar, are the two remaining much smaller players. The CERPs, which are a network of pharmacist-owned, financially-independent co-operatives, operate in distinct regions of the country, i.e.

- CERP Rouen: greater Paris, northern France, Normandy, south-west, central France, Lyon and Macon

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- CERP Rhin Rhône Méditerranée : Alsace, Bourgogne, Rhone Alpes and south east France
- CERP Lorraine: east, central and south west France
- CERP Bretagne-Nord: Brittany.

The other large wholesalers all operate nationwide.

*Wholesalers in France, 2007*

Group	Number of warehouses	Market share (%)
Groupe OCP (Celesio)	51	38
Alliance Santé (Alliance UniChem)	62	28
Reseau CERP		28
- CERP Rouen	31	14
- CERP Rhin Rhône Méditerranée	17	8
- CERP Lorraine	13	4
- CERP Bretagne Nord	8	2
Phoenix France (Phoenix)	7	4.
Giphar Sogiphar	1	0.5
RBP Pharma	1	0.3
Total	191	98.8%

Source: CSRP

The combined market shares of France's 'big four' have been almost constant at 98-99% for the past ten years, with relatively little shift between them.

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### *Trends in wholesaler market shares*

Year	OCP	Alliance Santé	CERP Rouen	CERP RRM	CERP Lorraine	CERP Bretagne	Phoenix	Total
1996	40.5	30.3	13.1	6.6	3.9	2.0	3.3	99.7
1997	40.5	29.7	13.0	6.6	3.9	2.1	3.4	99.2
1998	40.4	29.4	12.9	6.7	3.9	2.1	3.3	98.7
1999	40.4	29.3	12.8	6.8	3.9	2.1	3.4	98.7
2000	40.0	28.7	13.1	7.0	4.0	2.1	3.6	98.5
2001	40.1	28.3	12.8	7.1	4.0	2.1	3.3	97.7
2002	39.9	28.3	13.0	7.1	4.0	2.1	3.4	97.9
2003	39.6	28.2	13.2	7.3	4.0	2.2	3.4	97.9

Source: Decision No. 07-D-22 of 5 July 2007 by *Conseil de la Concurrence*

### **2.5.2 Community Pharmacies**

At the end of 2006 there were 22,561 privately-owned community pharmacies in France, a number that has been fairly stable for several years.

Despite long and constant pressure from supermarkets, the profession has successfully maintained its monopoly over the supply of all medicines (including OTCs, herbal and homoeopathic products) granted it under an 1803 law. The monopoly also extends to medical devices, dressings, lens cleaning solutions, insecticides, and even food supplements, cosmetics and dietetic products when they meet the definition of a medical product laid down in the Public Health Code.

Only pharmacists or partnerships of pharmacists may own a pharmacy and the main owner must always be on the premises during opening hours. Two-thirds of outlets are in fact owned by a single pharmacist. There are also a small number of member-only pharmacies owned by mutual insurance funds (68) or miners' welfare societies (68).

While the law does not allow for private chains or franchises of pharmacies, aggregation around wholesaler-affiliated buying groups (*groupements*) and networks ('pools') is growing.

### **2.5.3 Other**

There are just a handful of self-dispensing doctors (*propharmaciens*), and should a pharmacy open in their area then the physicians have to cease dispensing. Mail order or supply of medicines via the internet is not allowed.

## **2.6 Performance**

All wholesalers in France are full-line, holding 25,000 SKUs (of which 8,700 are medicines). A public service obligation (Article R 5115-13 of the *Code de la Santé Publique*) ensures full-line status. It requires every wholesaler to:

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- Communicate to the national Medicines Agency (AFSSAPS) details of the territory the company covers (every district containing one or more pharmacies where sales are normally made by the wholesaler must be included).
- Hold in stock at least 90% of all medicines used in France, whether reimbursed or not.
- Have a two-week supply capacity for their usual customers.
- Supply the orders of any pharmacy within its territory. Pharmacies outside the territory can (and on decision of the authorities must) be supplied under exceptional circumstances.
- Be able to deliver within 24 hours at a maximum.
- Inform the public authorities as soon as there is a reduction in stockholding.

When no other source of supply is available, the Director General of AFSSAPS can, as an exception, require a wholesaler to deliver to a pharmacy outside its normal territory.

Their public service obligation is reportedly taken very seriously by French wholesalers, though no instance of prosecution for infringement could be found.

There are no supply obligations in law on community pharmacies.

In practice, deliveries are made at least twice per day, in both rural and urban areas, and with prescription and non-prescription medicines alike. Almost all orders by pharmacies are electronically transmitted and are usually prepared and delivered within four-six hours of being placed (three hours for OCP), although a two-hour turnaround is sometimes possible if this is necessary. 95% of orders are filled from stock. On average, one warehouse supplies 140 pharmacies, although there are great regional differences, e.g. Ile-de-France, one warehouse per 260 pharmacies; Champagne-Ardennes, one warehouse per 56 pharmacies.

Pharmacies choose which wholesalers they purchase from primarily on the basis of service and added-value provided. They receive delivery statements every 10 days, summarising deliveries made during this period, and are required to pay wholesalers within 30 days of statement receipt. Wholesalers are on average required to pay manufacturers 38 days after goods receipt.

Products shortages do 'sometimes' occur, the wholesaler association CSRP reports. It attributes these primarily to manufacturer supply quotas, and also to production failures.

As measures of wholesaler performance, OCP cites the following:

- less than one mistake in deliveries per customer per month;
- cost of wholesale distribution less than 3% of the public price;
- fewer than 0.5% of products not immediately delivered (unless unavailable from manufacturer).

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### 2.7 Direct Distribution

This is primarily limited to generic and OTC manufacturers.

### 2.8 Medicine Pricing

For coverage under statutory health insurance, the manufacturer's selling price (MSP) for each medicine must be agreed through negotiation with the Economic Committee for Health Products (CEPS) after taking account of the views of the Transparency Commission, part of the Agency for Quality of Care (HAS). Presentations containing off-patent ingredients are clustered together in reference price groups with the amount reimbursed per group capped. Prices of non-reimbursed products and OTC are free.

Public prices can be found at [www.theriaque.org](http://www.theriaque.org)

### 2.9 Components of the public price

The final reimbursement or public price (*prix public toutes taxes comprises*; PPTTC) is equal to the MSP (*prix fabricant hors taxe*; PFHT) plus the wholesale mark-up, plus the pharmacy mark-up, plus VAT (TVA, at 2.1% on reimbursed medicines and those used in hospitals)

#### 2.9.1. Payment to Wholesalers

For reimbursed products, wholesaler mark-ups are fixed according to a regressive scale, last revised early in 2004. When the MSP is at or below €22.90, the mark-up on the MSP is 10.3%. It is 6% for the part of the MSP between €22.91 and €150.0, and 2% for that part above €150.

*Wholesaler mark-up for reimbursed medicines in France*

MSP (€)	Mark-up (%)
that part less than 22.90	10.3
that part between 22.91 and 150.0	6.0
that part greater than 150	2.0

Source: *Comité Economique des Produits de Santé*

Wholesaler discounts to pharmacies are limited by law to 2.5% of the wholesale selling price, apart from generics where they can reach 10.74%. Based on the level of monthly purchases, discounts on reimbursed medicines average 1.8%, according to the CSRFP.

An exceptional new tax on wholesalers, at 0.21% of pretax turnover, was introduced in 2006. It generated €35 million for the government that year. This tax had been expected to continue but the 2008 budget statement made provision for a cut in the wholesaler margin instead. Details, yet unavailable, are expected to be announced in a ministerial order.

Compared to the UK, the French market has a different product mix, with fewer generics and OTC products, virtually no parallel imports, lower prices, and its larger

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geographic size means that more warehouses etc are required.

### 2.9.2 Payment to Pharmacies

The pharmacy mark-up for reimbursed products is applied in a similar manner to wholesalers i.e. different rates are applied and added according to the MSP. There is in addition a flat fee of €0.53 per item dispensed paid to pharmacies.

*Pharmacy mark-up scale for reimbursed medicines in France*

MSP (€)	Mark-up (%)
that part less than 22.90	26.1
that part between 22.91 and 150.0	10.0
that part greater than 150	6.0

Source: *Comité Economique des Produits de Santé*

For generics not included in the reference price system, the mark-up is adjusted so that pharmacies receive the same cash amount had the originator brand (whose price is usually 30-40% higher) been dispensed.

Pharmacies are not required to pay any rebate or clawback to social security, though they can offer discounts to their customers as long as these do not exceed the same discount ceilings that apply to wholesalers (i.e. 2.5% of the MSP for originator products and 10.74% of the MSP with generics).

One source has put the average gross pharmacy margin on medicines as 24% in 2001 and 23.8% in 2004, but the definition of these figures is not clear.

Both wholesaler and pharmacy margins are free for products outside the reimbursement system. This often results in widely different charges on patients for private prescriptions in different pharmacies.

### 2.10 Price Paid by Patients

Except for the chronically ill, the poor, the handicapped and expectant mothers, patients are required to make a 35% or 65% co-payment (*ticket modérateur*) of the public price for reimbursed prescription medicines that are not 'irreplaceable and particularly expensive' (these are 100% reimbursed).

Ambulatory patients suffering from 30 specified chronic diseases that require 'prolonged and costly treatment', with another critical illness known as the '31st disease' (on demand, and on examination of the medical file) and those with multiple pathologies ('32nd disease') are exempted for any co-payment liability for the exempting condition(s) only. They receive a two-part prescription form; one is for medicines directly linked to the exempting condition (zero co-payment) and the other for non-related conditions (35% or 65% co-payment).

Four main disease groups – cardiovascular disease (2.1 million patients), malignant tumours (1.3 million), diabetes (1.2 million) and chronic psychiatric conditions (900,000) – account for the overwhelming majority of the 30 chronic diseases.

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Because chronic disease patient numbers have grown by more than 50% over the past decade, containing the burgeoning cost has become a political priority. Patients with chronic diseases must now agree a treatment protocol with a primary care physician. Healthcare products prescribed outside the protocol are reimbursed at lower rates.

For more than 90% of French people, supplementary health insurance from mutual funds or private insurers and provided as an employment benefit generally meets any co-payment liability under social health insurance. This covers not just the 35% or 65% drug co-payment that would otherwise be due but also charges for ambulatory doctor visits, the per diem charge for accommodation in hospital, and extra billing authorised for a small number of ambulatory doctors. It also covers the difference between actual prices charged and official reimbursement tariffs, which are particularly high for dental prostheses and spectacles.

Patients do not even need to make separate claims for social and supplementary insurance. Under the *tiers payant* system, patients register their details with local pharmacies of their choosing. The pharmacy obtains all reimbursement directly from social security, the mutual funds and/or private insurers as appropriate, making patients completely insensitive to cost.

It should be noted that if a medicine is not part reimbursed by social health insurance supplementary cover does not generally apply and full payment must come out of pocket.

The pharmacy margin is free for non-reimbursed products and while it can be highly variable (to the frustration of patients) local sources suggest an average of around 15% is often applied. To add to the patient's cost burden, TVA is levied at 5.5% for non-reimbursed private prescriptions and on OTCs.

Across all types of medicines in France (including OTCs and non-reimbursable prescription drugs), social insurance pays on average 67% of the cost, out-of-pocket payments by patients account for 13%, and the mutual/private health insurers for 12%.

### 2.11 Hospital Market

Drug procurement by public hospitals is conducted either by central bodies in Paris, Marseilles and Lyon or at the regional level. Unless a drug cost is included in the all-in package for diagnosis-related patient care, maximum selling prices have to be agreed with CEPS in the normal way, with individual city/regional buying groups expecting a discount on these. Virtually all distribution to hospitals is direct using prewholesalers. France has 2,268 hospital pharmacies, eight-times the number in the UK. Sales to hospital pharmacies only account for 0.5% of wholesaler turnover.

### 2.12 OTC Market

French sales of non-prescription medicines that are non-reimbursable in 2006 amounted to €1,989 million at public prices. This is equivalent to less than 7% of the total medicines market.

### 2.13 Parallel Trade

France used to be a major parallel exporter, involving full-line wholesalers as well as specialist exporters, but this activity has greatly declined as a consequence of manufacturer supply quotas and favourable treatment of new drug prices by CEPS (a higher 'facial' price is sometimes allowed with subsequent offsetting annual rebates). France was one of the last EU-15 countries, in 2004, to make legal provision for incoming parallel trade, and this only after pressure over many years and a fine from the European Commission. There are just a handful of parallel imports marketed by two traders, with their combined penetration of total market less than 1 %.

### 2.14 Counterfeit Entry

There have been no cases of counterfeit medicines appearing on the French market (though some has been detected in transit), according to the CSRP.

To complement strict checks on all incoming products, CSRP members have now adopted even stricter conditions regarding accepting returns from pharmacies.

### 2.15 Pending Changes

The official position is that improvements need to be sought within the current framework and there is no need for radical reform.

From 2011, each wholesaler will be required to track the distribution of its sales.

### 3. GERMANY

#### 3.1 Healthcare System

Statutory health insurance (GKV) covers about 90% of the population, with just some high earners choosing to opt out and take out private health insurance (PKV) instead. Decision-making is shared between the federal government and the 16 states, but it is self-governing bodies that effectively run the system. Employee (50%) and employer (50%) contributions to individual sickfunds (totaling some 250) are the main method of funding the GKV, with sickfund associations empowered to agree contracts with provider groups and provide services to their members.

#### 3.2 Pharmaceutical Market

The total out-of-hospital market in 2006 at public price level amounted to €35,100 million, with the costs to the sickfunds of €23,951 million. Germany is the largest pharmaceutical market in Europe, more than 50% larger than UK's market.

#### 3.3 Supply Chain

retail: manufacturer- prewholesaler – wholesaler – pharmacy  
hospital: manufacturer-prewholesaler – hospital pharmacy

Almost all sales by wholesalers (in excess of 99.5%) are to community pharmacies. Sales (by value) can be broken down as 78% prescription medicines, 12% OTCs, and 10% other products.

#### 3.4. Distribution Model

This is multichannel

#### 3.5. Players

##### 3.5.1 Wholesalers

Four wholesalers have nationwide coverage: Phoenix (28% market share);<sup>1</sup> Gehe (Celesio) (18%); Andrae-Noris Zahn – better known as Anzag (17%) and Sanacorp (13%) The remaining 11 are regional players, the largest being Noweda (10% national market share). Gehe's market share reportedly slipped at the beginning of 2007 as some of its customers took their business elsewhere in protest of the wholesaler's acquisition of controversial Dutch mail order pharmacy DocMorris, though Gehe may have since regained some losses with a policy of more aggressive discounting.

Altogether these companies have 106 warehouses and 13,000 employees, and all are represented at national level by the association PHAGRO.

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<sup>1</sup> All market share figures relate to the first half of 2007.

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Financial holdings can be complex. Sanacorp owns a 25% stake in its rival Anzag. Noweda sold 19% of its 25% stake in Anzag to Alliance UniChem. Sanacorp has now merged with fellow co-operative, France's CERP Rouen.

The gross profit of pharmaceutical wholesalers in 2006 amounted to €980 million, or 4.1% of sickfund expenditure on drugs.

### 3.5.2 Community Pharmacies

At around 21,500, community pharmacy numbers have remained steady for several years. Their main representative body at national level is ABDA.

For many years, only pharmacists were able to own pharmacies, and then just one pharmacy (the so-called *mehrbesitzverbot* rule). The 2004 Health Reform Act changed the situation so that a single pharmacist or partnership of pharmacists was allowed to own one main pharmacy and up to three branch pharmacies all located within one *landkreis* (administrative district) or in adjacent ones. Germany has 313 *landkreise* and therefore large-scale, nationwide pharmacy chains are effectively prohibited.

Just as in other countries, a large number of independent German pharmacies (possibly half the total) participate in co-ordinated marketing and buying activities, some managed by wholesalers.

The most controversial event in recent years was the Dutch mail order pharmacy, DocMorris, creating an actual walk-in pharmacy in Saarbrücken; this is the only non-pharmacist owned pharmacy in Germany. DocMorris further upset ABDA by establishing a German DocMorris 'franchise' among independent community pharmacies. These outlets carry the DocMorris logo, have a standardised appearance and sell OTCs at discount prices. Unlike DocMorris' mail operation in the Netherlands, however, these pharmacies are not allowed to waive 50% of the patient co-payment for prescription drugs under GKV. About 40 pharmacies have so far signed up to the initiative. A similar number of independent German pharmacies belong to the AVIE 'franchise' organised by the leading parallel importer, Kohlpharma.

There are no demographic or geographic criteria for the establishment of pharmacies.

### 3.5.2 Other

In principle, all medicines should be sold in pharmacies. While this still holds true for prescription-only medicines, certain OTCs are more widely available from around 3,800 drugstores, 2,500 health shops and 7,000 other outlets (food stores, supermarkets, etc). PHAGRO members do not deliver to these outlets

A change in the law in 2004 allowed the first mail order/internet pharmacies. There are a large number of domestic sites selling discounted OTCs but sales with prescription drugs are dominated by Dutch-based DocMorris which with sickfund encouragement has become the largest pharmacy serving Germans. Its main

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competitors are another Dutch-based firm Europa Apotheek and Swiss-based Apotheke Schweiz.

There are no dispensing doctors in Germany.

### 3.6 Performance

German wholesalers each hold 60,000-80,000 different SKUs, of which about 30,000 represent medicines.

Pharmacies must hold sufficient stock to cover the average demand over two weeks (Section 15, Ordinance on the Operation of Pharmacies). In an appendix certain drugs are listed that must be stocked or be obtained in a short period of time. Section 17 of the Ordinance requires pharmacies to deliver medicines without any delay.

Concerning mail order pharmacies, the requested items must be dispatched within two days. While the Federal Civil Court has noted that public pharmacies depend on full-line wholesalers to fulfil their supply obligations, due to insufficient storage capacity within pharmacies, general public service obligations for wholesalers are not yet implemented.

Three-quarters of pharmacies deal with two wholesalers each, an equal proportion (12%) are supplied by either one wholesaler or by three, with the remaining few pharmacies supplied by four or five different wholesalers. Almost all orders that Gehe receive are placed electronically; Gehe offers order assembly and ready for delivery times averaging one hour. Payment terms are a matter of individual agreement. Customers of Gehe receive a single invoice each month that is payable within 14 days. Supplier payments average 8 days after good are received by wholesaler.

In terms of total numbers of wholesaler deliveries per day, the breakdown by share of pharmacies is as follows:

1/day	<1%
2/day	15%
3/day	23%
4/day	38%
5/day	12%
6/day	6%
>6/day	6% (declining)

Product shortages are said by ABDA to be 'extremely uncommon', though Gehe says they do occur – primarily with about 300 SKUs from 8 manufacturers – due to supply quotas within Germany (i.e. manufacturers supply wholesalers with just enough products to meet local market need). Wholesaler service levels – the percentage of orders that can be delivered immediately from stock - overall exceed 97%.

If a product is not immediately in stock at one wholesaler it should theoretically be delivered to the pharmacy within hours by another wholesaler, with 85% of deliveries by wholesalers being made at least three-times a day. There have been some problems with obtaining specific generics in 2007 (if a generic company has a contract with a sickfund to offer it rebates then all patients insured with that sickfund have to receive

## Medicines Distribution in Other Countries

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that manufacturer's version), but this is a production and not a distribution problem, PHAGRO explains.

According to ABDA, wholesalers provide their members with the following added-value services:

- exchange of stock if damaged, expired or ordered in error
- product recall in emergencies
- compensation for stock bought at high prices if prices are reduced
- support for manufacturers' promotions
- possibility for delayed interest-free payment for deliveries
- training, business advice
- website support
- acting as focus for buying groups

### 3.7 Direct Delivery

15% of all pharmaceuticals are delivered direct to community pharmacies, according to ABDA, but it had no details on the breakdown. Gehe attributes most direct deliveries to originator products subject to generic and PI competition within Germany and to products at risk of parallel exporting from Germany as it provides the manufacturer with full transparency and control over stockholding. Celesio has commented that these deliveries constitute a supplementary – rather than alternative – channel to the usual wholesaling system. The manufacturer makes a special deal with the pharmacy and the pharmacy designates a wholesaler to deliver at these terms, though the same products are still available from a wholesaler in the normal way. The cost to pharmacies of directly-delivered drugs ranges anywhere between the MSP and the MSP plus the wholesale mark-up.

Speaking at a SMi conference in London in February 2007, Stefan Rinn (Head, Corporate Division, Prescription Medicines Europe, Boehringer Ingelheim) gave an account of how parallel exports from Germany with Spiriva (tiotropium) were being tackled. Spiriva is Boehringer's leading brand with 2005 sales of €951 million (81% up on 2004).

Rather than loss of profit ('loss of 2% when you are earning 25% is manageable'), the main concern was shortages in Germany leading to a loss of patients treated, he explained. A volume of 18% above domestic demand was supplied to the market in 2006. This was allocated as broadly and fairly as possible to wholesaler warehouses using a stock management system. Internally, there was no incentive to generate exports to hit a sales target to qualify for a bonus, as 'he who generates the prescription gets credit for the sale'.

If any pharmacy complains of an out-of-stock situation then deliveries direct from the manufacturer are offered even if its costs Boehringer more. It might be inefficient for pharmacies, he explained, 'but it was still preferred to losing patients'. On average 600 direct orders for Spiriva are handled per day, with two-thirds of all pharmacies already have been supplied in this way. Wholesalers had 'abandoned' up to 30% of their Spiriva business in Germany as a result, he estimated.

### 3.8 Medicine Pricing

For all medicines there is free pricing at the manufacturer level. Every prescription medicine has to have a fixed, common public price in all pharmacies across the country in accordance with the *Arzneimittelpreisverordnung* (price regulation). This price, listed in the *Lauertaxe*, is used for reimbursement and can be found at <http://rote-liste.de/online/login.html>.

Admission to reimbursement is generally automatic. Exceptions are most non-prescription bound medicines, drugs for 'trivial' diseases (e.g. common cold), 'inefficient' drugs (e.g. homoeopathic products) and 'lifestyle products' (e.g. for erectile dysfunction). The Institute for Quality and Efficiency in Healthcare (IQWiG) performs benefit and (since April 2007) cost-benefit assessments on selected marketed products and can recommend removal from reimbursement or prescribing restrictions to the Federal Joint Committee (G-BA) which takes the actual decision.

Presentations containing ingredients considered therapeutically interchangeable (including some patented ones) are clustered together in reference price groups, with the amount reimbursed per group capped.

### 3.9 Components of the public price

The final reimbursement or public price (*apothekenverkaufspreis*) is equal to the MSP (*herstellerabgabepreis*) plus the wholesale mark-up, plus the pharmacy mark-up, less the statutory rebate, plus VAT (MwST, at 19%).

#### 3.9.1 Payment to Wholesalers

Different mark-up scales for wholesalers apply depending on whether the medicine is a prescription-only product or a non-prescription bound product that it reimbursed as an exception (e.g. for children). The current scale for the former group runs from +6% to +15%, with a minimum mark-up of €0.45 and a maximum of €72.0 (prior to 2004, the scale went from +12% to +21%, with mark-ups for products costing more than €684 capped at 3% plus €61- this scale still applies to the latter group of products). Between each band there is a narrow price range for which a fixed cash mark-up is given. This is to ensure smooth progression across bands.

Wholesalers then compete with each other to provide medicines to pharmacies, and this in effect erodes the net margin they receive.

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### *Wholesale mark-up scale for reimbursed prescription medicines in Germany*

MSP (€)	Wholesale mark-up as % of MSP	Maximum wholesale mark-up (€)
less than 3.00	15.0	-
3.01-3.74	-	0.45
3.75-5.00	12.0	-
5.01-6.66	-	0.60
6.67-9.00	9.0	-
9.01-11.56	-	0.81
11.57-23.00	7.0	-
23.01-26.82	-	1.61
26.83-1,200	6.0	-
more than 1,200	-	72.00

Source: *Arzneimittelpreisverordnung*, 2004

### *Wholesaler mark-up scale for exceptionally reimbursable non-prescription bound medicines in Germany (i.e. the former scale)*

MSP (€)	Wholesale mark-up as % of MSP	Maximum wholesale mark-up (€)
less than 0.84	21.0	-
0.85-0.88	-	0.18
0.89-1.70	20.0	-
1.71-1.74	-	0.34
1.75-2.56	19.5	-
2.57-2.63	-	0.5
2.64-3.65	19.0	-
3.66-3.75	-	0.7
3.76-6.03	18.5	-
6.04-6.20	-	1.12
6.21-9.10	18.0	-
9.11-10.92	-	1.64
10.93-44.46	15.0	-
44.47-55.58	-	6.67
55.59-684.76	12.0	-
more than 684.77	3.0	61.63

Source: *Arzneimittelpreisverordnung*, 2004

Mark-ups for non-reimbursed non-prescription bound medicines (including OTCs) were freed at the beginning of 2004.

### **3.9.2 Payment to Pharmacies**

Pharmacies receive for each medicine dispensed under GKV a fixed €8.10 plus a 3% mark-up on the wholesale selling price. This is quite a change from the pre-2004 situation when the mark-up scale went from +30% to +68%, with products costing more than €543 limited to an 8% mark-up plus €118.

## Medicines Distribution in Other Countries

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A regressive pharmacy mark-up scale applies with reimbursable OTC products.

### *Pharmacy mark-up scale for reimbursable OTC medicines in Germany*

WSP (€)	Pharmacy mark-up as % of WSP	Maximum pharmacy mark-up (€)
less than 1.22	68.0	-
1.23-1.34	-	0.83
1.35-3.88	62.0	-
3.80-4.22	-	2.41
4.23-7.30	57.0	-
7.31-8.67	-	4.16
8.68-12.14	48.0	-
12.15-13.55	-	5.83
13.56-19.42	43.0	-
19.43-22.57	-	8.35
22.58-29.14	37.0	-
29.15-35.94	-	10.78
35.95-543.91	30.0	-
more than 543.92	8.263	118.24

Source: ABDA

Pharmacies have to pay statutory rebates to the sickfunds of €2.30 per prescription medicine and 5% of the value at public prices of reimbursable OTC medicine dispensed.

Under the 2006 Drug Savings Law (AVWG), pharmacies lost the right to obtain 'natural rebates' from manufacturers and wholesalers. This practice usually involved the provision of free stock or other non-monetary rebates for bulk orders from predominately generic companies, which pharmacies could subsequently claim full reimbursement for.

Wholesalers compete to gain pharmacy business by offering discounts and therefore in effect reducing the net margin they receive. Wholesaler rebates to pharmacies are now limited by law to a maximum that is equal to the wholesaler's statutory mark-up. These rebates are made either in return for ordering efficiency (electronic placement of orders, placement of many orders at once, or ordering large volumes), or to reward or obtain customer loyalty. Cash discounts are also provided to reward early payment of bills. There is no specific measure to claw back procurement discounts or rebates.

The net result for a reimbursed product with a public price of €100 splits as follows:

- manufacturer	€63.7
- wholesaler	€3.8
- pharmacy	€18.7
- tax	€13.8

Pharmacy mark-ups on non-reimbursed OTCs are free, though price competition is said to be more evident with online rather than with community pharmacies.

### 3.10 Price Paid by Patient

For medicines prescribed under the GKV, patients are required to pay 10% of the public price, with a minimum charge of €5 and a maximum outlay of €10 (in no case paying more than the public price) plus any reference price excess (this latter is rare in practice). Only certain types of chronically-ill patients and the severely disabled are routinely exempt from payment.

Across all products and all sickfunds the charge averaged €5.53 in 2004. Even this modest amount is waived if the prescribed product is in the reference price system and is priced at least 30% below the reimbursement ceiling. Physicians have a legal obligation to inform their patients of any reference price excess that is due. Under the 2007 health reform law, sickfunds are also allowed to drop the statutory co-payment for products (mainly generics) for which they have negotiated an individual rebate agreement with the manufacturer concerned.

### 3.11 Hospital Market

Manufacturers supply the 550 hospital pharmacies direct, with an estimated 150 community pharmacies having agreements to supply smaller hospitals without their own in-house pharmacy. Wholesalers do less than 0.5% of their business with hospitals.

### 3.12 OTC Market

Sales at public prices of all medicines bought for self medication by German consumers in 2006 were €4,530 million. This equates to 13% of total pharmaceutical sales. This relatively high figure is due to the fact that most medicines that do not legally require a prescription to purchase (not just advertised OTCs) have been taken out of GKV reimbursement.

### 3.13 Parallel Trade

Despite having existed since the 1970s, parallel importing into Germany has been low in percentage if not in absolute terms. Its level has clearly responded to domestic trigger points, one of the first being a 1995 Supreme Court decision requiring the major wholesalers to stock parallel imports. Another was an obligation on pharmacies to use parallel imports if certain conditions were met.

Under the threat of financial sanctions, pharmacies are currently required to dispense parallel imports to the value of 5% of their sickfund prescriptions. To count towards this target parallel imports have to offer a minimum 15% or €15 saving compared to their domestic equivalent. Actual PI penetration today is about 8%.

Traders use a mix of direct and indirect distribution, with the latter dominating. The leading importer has two sister companies, Kohlpharma (which uses wholesaler distribution) and MTK-Pharma (which uses direct distribution). The main strategy employed by manufacturers against German PI has been to limit supplies in the exporting markets, primarily Spain.

Once one of Europe's highest priced markets, the seemingly endless stream of health reform legislation has lowered some prices, opening up opportunities for traders to parallel export from Germany into the UK and Scandinavia.

### 3.14 Counterfeit Entry

Although Gehe has stated that it has detected counterfeit medicines in its incoming stock, ABDA has no information that any has ever appeared in community pharmacies. There is concern, however, that counterfeit medicines are traded through internet pharmacies. In 2003, the federal Ministry of Health confirmed that no counterfeits had appeared in Germany as PI.

### 3.15 Pending Changes

Pfizer was rebuffed by all the main German full-line wholesalers when it sought bids for its planned DTP scheme in 2005 (see annex). The company has recently announced its determination to press ahead with this again but so far has not issued any call for tenders. None of the other manufacturers has stated any intention to change the present system.

The European Commission's DG Competition has for some time been pressurising the German government to liberalise the pharmacy market. The government has resisted this and criticised the Commission's purely economic approach.

A final decision on the status of the DocMorris pharmacy in Saarbrücken is pending before the European Court (ECJ joined cases C-171/07 & C-172/07).

### 4. NETHERLANDS

#### 4.1 Healthcare System

There is a single, universal government-regulated health insurance scheme with competing private insurers and a choice of plans. All residents are required to purchase a basic insurance package covering essential healthcare (including prescribed drugs) but insurers have some freedom to decide which providers to contract and what type of extra care to cover. Each plan has a basic premium rate (averaging €1,050) and for employed persons there is a contribution of 6.5% of income up to an income ceiling of €30,000/year. Everyone can also purchase a plan complementary to the basic one to insure against other risks, and over 70% of the population has done so. Switching to an alternative insurer or plan is possible once a year.

#### 4.2 Pharmaceutical Market

Total out-of-hospital sales in 2005 at public price level were €5,119 million. The Netherlands is the 7th largest pharmaceutical market in Europe, one-quarter of the size of the UK's market.

#### 4.3 Supply Chain

retail: manufacturer- prewholesaler – wholesaler – pharmacy  
hospital: manufacturer-prewholesaler – wholesaler - hospital pharmacy

#### 4.4 Distribution Model

This is multichannel.

#### 4.5 Players

##### 4.5.1 Wholesalers

There are four nationwide full-line wholesalers: OPG (2006 total pharmaceutical market share 26%), Alliance Healthcare (formerly known as Interpharm and part of the Alliance UniChem group, with 23% market share), Brocacef (Phoenix; 18%) and Mosadex (13%). Mosadex is owned by pharmacists and only supplies community pharmacies; the others are private companies and supply pharmacies, dispensing doctors and hospitals. The balance is made up of smaller pharmacist-owned self-distributing groups (13%), including Regifarm and Plurifarm, and direct distribution (7%).

Very roughly, 80% of wholesalers' sales go to community pharmacies, 10% to dispensing doctors and 10% to hospital pharmacies.

##### 4.5.2 Community Pharmacies

There are 1,810 community pharmacies, at least one-third of which are part of chains – there were no chains prior to 2001. Ownership structure varies. Some multiple

## Medicines Distribution in Other Countries

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pharmacy groups like Mediveen (currently being branded as 'Mediq health centres') and Lloyds are 100% owned by wholesalers, while in others non-pharmacists have minority shares. Even drugstore groups (formerly) and a health insurance fund have opened their own pharmacy chains. There are also two 100% pharmacist-owned chains (Prickartz and Thio Pharm).

### *Leading multiple pharmacies in the Netherlands*

Pharmacy chain	Owner	Owner type	Number of outlets
Mediveen/Mediq	OPG	Wholesaler	223
Farmassure/Escura	Brocacef (Phoenix)	Wholesaler	90
De Vier Vijzels	Alliance Boots	Wholesaler	75
Lloyds Apotheken	Celesio	Wholesaler	56
Apotheken in Overdracht	Regifarm	Wholesaler	37
VNA	VNA	Foundation	80
DSW	DSW	health insurance fund	5
Prickartz	Pharmacists	co-operative	21
Thio Pharm	Pharmacists	co-operative	16
Total			603

Source: updated from Vogler S et al, Community Pharmacy in Europe: Lessons from Deregulation, ÖBIG for PGEU, February 2006

There are also several large wholesaler-affiliated symbol groups to which independent pharmacies are invited to join. Described as 'soft franchises' these are:

- Kring Apotheken (302 pharmacies; Alliance Boots is 51% owner of Kring)
- Mediq (pharmacies linked to OPG)
- Service Apotheek (185 pharmacies linked to Mosadex)
- Escura 115 pharmacies linked to Brocacef)
- Medsen (68 pharmacies linked to Regifarm)
- Lloyds (60 pharmacies linked to Celesio)

86% of turnover by the average pharmacy comes from dispensing medicines and almost all stock is purchased from wholesalers. Clearly the pharmacies that are owned or franchised by wholesalers order from the wholesaler concerned, but it appears that these do not receive preferential treatment compared to independent pharmacy customers, and the same discount structure applies. As Celesio does not have a wholesaling presence in the Netherlands its Lloyds pharmacies order from OPG and Brocacef.

### 4.5.3 Other

While Dutch patients are 98% loyal to an individual pharmacy, the medicines supply chain to ambulatory patients is one of the most liberal in Europe. The sale of OTC medicines by non-pharmacies has been allowed for more than a century and drugstore chains like Kruidvat, Etos and DA today account for 80% of all OTC business. While

## Medicines Distribution in Other Countries

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Brocacef, alone of the major pharmaceuticals wholesalers, supplies drugstores, it is basically a separate market altogether.

480 doctors dispense for about 8% of the population. This is allowed if the distance to the nearest pharmacy is more than 4.5 kilometres. Numbers of self dispensing doctors have fallen by 11% over the past decade, whilst pharmacy numbers have grown by 14%.

The Netherlands hosted Europe's first mail order pharmacy in the early 1990s and what is now Europe's largest internet pharmacy, DocMorris, was founded there in 2000 (though German patients have always made up the majority of its customer base, and most of its products are not Dutch but sourced in Germany).

Along with the UK, the Netherlands is apparently the only EU market in which homecare services modelled on US specialty pharmacy lines is legally possible. Homecare involves delivery of medicines and associated support to the patient's home where treatment is undertaken. Because this is costly, the service is largely restricted to high cost/low volume injectable biological products that require special handling, including maintenance of the cold chain. As well as a 24-hour telephone helpline, support comes in the form of specialist nurses who offer counselling and either train the patient to self-administer (e.g. with subcutaneous injections) or administer the drug themselves (e.g. with intravenous injections). A pharmacy licence is required to supply any prescription medicine to patients in Europe, therefore a homecare company has to have its own in-house pharmacy, as well as usually its own van transport and nurses.

Homecare providers normally purchase the drug from the pharmaceutical company they contract with and negotiate additional fees for the requested package of support services.

### 4.6 Performance

There are no regulatory obligations on holding stock or delivery time imposed either on wholesalers or pharmacies in the Netherlands.

Dutch pharmacies are relatively large by European standards and normally keep four-six weeks' anticipated stock. Wholesalers deliver once-per-day, to pharmacies and to hospitals, with prescription and non prescription medicines alike. Other possible reasons why Dutch pharmacies require only one wholesaler delivery per day include:

- patients are very loyal to their own particular pharmacy in the Netherlands, where their medication records are retained, so pharmacies do not get many unexpected prescriptions or requests for unusual items from prescribers in other parts of the country;
- generic substitution by the pharmacies is allowed;
- regular pharmacotherapeutic meetings are held between local doctors and pharmacists at which therapeutic rationalisation decisions are taken so that pharmacies can reduce the number of different items they can stock.

## Medicines Distribution in Other Countries

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Orders placed electronically up to about 6pm will be delivered during the same night (wholesalers have keys to access lockers when the premises are closed) ready for dispensing the following morning. Emergency deliveries can be arranged from wholesalers 24 hours a day, but this service carries an additional charge which is non recoverable by the pharmacy.

Pharmacies bill the health insurers at the end of each month, are paid by the 21st of the following month and have to pay their wholesalers around the 25th. When wholesalers have to pay manufacturers is a matter of individual negotiation.

Shortages of medicines on the Dutch market are described by KNMP as 'uncommon', though the wholesalers complain of fairly frequent problems due to manufacturer supply quotas.

### 4.7 Direct Distribution

IMS has estimated that homecare accounts for 6-7% of the Dutch pharmaceutical market (and 8% in the UK). Affected supplies bypass Dutch wholesalers (though two of the commercial homecare providers are owned by wholesalers) and the business has been variously described as either direct-to-pharmacy or direct-to-patient. Providers include ApotheekZorg (Mosadex), Red Swan (OPG), Medizorg, Klinerva and Prevent Care. According to KNMP, ApotheekZorg has exclusive Dutch distribution rights for Abbott's Humira (used primarily for rheumatoid arthritis), and half of Enbrel (also for rheumatoid arthritis) is routed through Red Swan with the other half dispensed from community pharmacies.

### 4.8 Medicine Pricing

Non-reimbursed medicines can be priced freely. Entry to reimbursement is controlled by the Ministry of Health, Welfare and Sport (VWS). It considers clinical and cost effectiveness aspects though the final decision, residing with the Minister, also depends on whether there is a budget for the newly-admitted product.

Products deemed to be interchangeable are clustered together in annex 1a of the reimbursement list (GVS), irrespective of active ingredient or patent status, with the maximum reimbursement amount based on the price of the product immediately below the average price of the cluster. Innovative products unable to be clustered in reference price groups are in principle listed in annex 1b and are fully reimbursed at the manufacturer's asking price (as long as this respects the Drug Prices Act, i.e. wholesale selling price at or below the arithmetic average of the wholesale selling price of comparable medicines marketed in Belgium, France, Germany and the UK). In practice, annex 1b applicants must show greater efficacy than existing listed products and cost-effectiveness advantages.

Prices are set at the pharmacy purchase level. These are published in the tariff (*taxe*) of the KNMP and can be found at [www.fk.cvz.nl](http://www.fk.cvz.nl).

Excluded from reimbursement are OTCs (unless the doctor has endorsed the prescription that it is for chronic use and the patient pays for the first 15 days),

## Medicines Distribution in Other Countries

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homoeopathic products, lifestyle drugs, and obsolete and irrational combinations (i.e. an unscientific combination of ingredients).

### 4.9 Components of the Public Price

The final reimbursement or public price is equal to the pharmacy purchase price plus the pharmacy dispensing fee, less the statutory rebate, plus VAT (BTW, at 6%).

#### 4.9.1 Payment to Wholesalers

The wholesale margin is unregulated, even for reimbursed medicines. It is based on individual manufacturer/wholesaler agreements and varies greatly between the different types of prescription products handled: margins on Dutch domestic specialities are much less than those with PIs and especially those with generics. Much is given away, as discounts or rebates, to pharmacies/dispensing doctors, with the value dependent on the mix of goods purchased. Manufacturer-wholesaler agreements are normally for a one-year term.

#### 4.9.2 Payment to Pharmacies

Pharmacies receive the maximum pharmacy purchase prices listed in the *taxe* and a flat rate dispensing fee of €6.10 per item (a level unchanged since 2004). This fee applies irrespective of the product cost or the quantity supplied (though, depending on the product, supply is limited by all the insurers to 15, 30 or 90 days, or 1 year for oral contraceptives only).

Dispensing doctors do not receive a per item dispensing fee but instead are given a basic annual fee of €8.60 per insured patient, which is increased by €0.60 for every patient younger than 65 years and by €20.80 for every patient older than 65 years.

Procurement discounts or rebates provided by wholesalers have been a recurring topic of discussion, negotiation and even legal challenge over the years. Originally, they could be retained in full but a form of clawback was introduced by the VWS Ministry in 1999 to recover part. Towards the end of 2002, an outgoing minister announced the clawback would be increased from 6.82% (to a maximum of €6.80/dispensed item) for all products to 8% (maximum €9.00) for single source products and 40% (maximum €20) for off-patent multisource products – including the originator brand. This differentiated clawback was widely criticised and successfully challenged by the KNMP in the courts. The original 6.82% clawback (maximum €6.80) was re-introduced and additionally it was agreed that generic list prices would be cut by an average of 40% from January 2004. Prices of branded originals with marketed generics were also cut by 40% a year later.

KNMP estimates that pharmacies retain an average 25% margin from dispensing.

It is understood that in autumn 2007 the KNMP agreed to a temporary (7 month) increase in the clawback to recover past overpayments to pharmacies.

### 4.10 Price Paid by Patient

The only patient contribution to GVS treatment costs is any reference price excess. The Dutch are very keen to avoid paying even this, so inevitably manufacturer's price below the reference ceiling. What little co-payment that applies only accounted for 0.5% of the €4.1 billion reimbursed drugs bill in 2005.

When the reimbursement limits were first lowered in 1999 (to reflect price movements since 1991) there was such a public concern that patients would be faced with higher reference price excess payments that the Health Ministry had to set up a special telephone line to deal with queries and complaints. In fact, there were hardly any consequences for the patient because most manufacturers readjusted their prices to the new reference price ceilings. Most of the reference price excess is accounted for by oral contraceptives.

### 4.11 Hospital Market

The Dutch hospital (or intramural) pharmaceutical market accounts for about 17% of the total. Hospitals procure medicines either individually or as buying groups. Distribution is most frequently via wholesalers, with 1-2 daily deliveries.

### 4.12 OTC Market

Sales at public prices of non-prescription medicines bought OTC by Dutch consumers in 2005 amounted to €568 million. This equates to 11% of total pharmaceutical sales, but is mostly achieved by drugstores not pharmacies.

### 4.13 Parallel Trade

The Netherlands was the birthplace of pharmaceutical parallel trade and it has achieved double-digit penetration there for decades. Its share of the prescription market in 2005 was over 15%. Paradoxically, relations between manufacturers and traders are better than elsewhere, and there are unconfirmed reports of dialogue even collaboration. Two of the main importers (Polyfarma, Stephar) are owned by vertically-integrated full-line wholesalers (OPG and Alliance Healthcare respectively) which allows ready access to pharmacy customers. The main driver to parallel import use is the high level of discounts on offer, much of which can be retained by pharmacies and dispensing doctors.

### 4.14 Counterfeit Entry

Apart from lifestyle drugs purchased via the internet, there was officially only one recorded case in regular supply channels and this was several years ago. One wholesaler, with 40 years' experience, said he had never heard of a confirmed counterfeit case in the Netherlands.

### 4.15 Pending Changes

None known.

### 5. SWEDEN

#### 5.1 Healthcare System

A statutory system provides coverage for all residents. The 21 county councils own and run most of the hospitals and primary care centres, and part-subsidise the cost of prescribed medicines in ambulatory care and fully subsidise inpatient treatment costs. To fund these activities they levy income-related taxes and user charges on their populations and also receive block grants from the government.

#### 5.2 Pharmaceutical Market.

Total out-of-hospital pharmaceutical sales in 2006 at pharmacy purchase price level were SEK 26,421 million. Annual market growth, in double digits throughout the 1990s, has been curtailed to 2-5% since 2002, primarily because of the new price-setting body and introduction of mandatory substitution by the pharmacist with the cheapest generic or parallel import equivalent.

The Swedish market is the 12th largest in Europe, less than 20% the size of the UK market.

#### 5.3 Supply Chain

retail:            manufacturer - wholesaler – pharmacy  
hospital:        manufacturer - wholesaler – hospital pharmacy

#### 5.4 Distribution Model

Wholesaling is managed on a single channel basis, with one of two companies – Tamro and KD - each having exclusive distribution contracts with manufacturers for the entire country for different products. As this model contains some potential competition restricting elements, both distributors separately applied to the Swedish Competition Authority (*Konkurrensverket*) for negative clearance. This was denied, but the Authority reportedly found the model acted as a positive 'counterforce' to the pharmacy monopoly held by Apoteket and to prevent Apoteket from entering wholesaling as well it granted individual exemptions. The exemptions were initially valid until 30 June 1998, with three five-year extensions granted since, the last of which expired (for Tamro anyway) on 31 December 2006. It was then agreed that all actors would continue to apply the model until the market structure changed significantly.

Most of the manufacturer-wholesaler contracts are valid for one year but some renew automatically unless one party requires re-negotiation. Prior to 1995, the contracts covered each manufacturer's entire product portfolio but following the 1991 Competition Act and review of the single channel system by the Competition Authority the contracts shifted to a product-by-product basis.

While the supplier has the right to split distribution of its assortment, in practice few do this. Pfizer was one of the exceptions. From 2005 until early 2007, most of its

## Medicines Distribution in Other Countries

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products were distributed by Tamro and a few were handled by KD. Pfizer has now switched distribution of all its products to KD.

Swedish wholesalers describe themselves as service providers, a sort of hybrid between traditional wholesalers and LSPs. Unlike LSPs they take ownership of the stock and also invoice pharmacies. They also bear responsibility for loss or damage on their premises and for bad debt (although with a single state-owned customer debt is not an issue for now), but they do not set their selling prices, this being the responsibility of the LFN (the Pharmaceutical Benefit Board) (see below).

Wholesalers supply community pharmacies, healthcare centres, hospitals and veterinarians. They are not allowed to supply the public.

### 5.5 Players

#### 5.5.1 Wholesalers

There are two wholesalers - Tamro (2007 market share 54%) and Kronans Droghandel (KD, 42% market share). Direct delivery makes up the balance with 4%. Tamro is owned by Germany's Phoenix and KD is part of the Finnish/Swedish Oriola-KD group, itself owned by a consortium of manufacturers: Orion (85.6%), Merck Sharp & Dohme (12.5%) and Organon (1.9%).

Despite the limited competition, market shares have clearly shifted over time. Merger activity among manufacturers is one factor. If two companies using different logistics partners merge, one distributor will lose out post-merger (e.g. Tamro lost its Sanofi business to KD after Sanofi's merger with Aventis).

Tamro had a 70% market share in 1992. This fell to 48% by 2004, but – loss of Pfizer business earlier in 2007 notwithstanding - it has slowly re-established its leading position, with a 50% market share in 2005, 53% in 2006 and 54% in the first half of 2007. Though it has never handled any of the products from KD's three principals, Tamro describes competition as 'working perfectly' with several major contracts shifting between KD and itself over the past three years.

Since 1970, Apoteket AB, a company under state control, has had exclusive rights to supply all types of medicines to the public. It operates a chain of 875 community pharmacies, 76 hospital pharmacies, and 30 Apoteket shops for OTC and other healthcare purchases. Community pharmacy numbers have fluctuated between 810 and 850 over the past decade, though there has been a recent surge. It is notable that 62% of prescriptions are transmitted electronically from the prescriber to the pharmacy of the patient's choosing (the comparable figure for England is 11%).

Pharmacies are located within shopping centres or close to primary healthcare centres or hospitals. In rural areas, Apoteket arranges with owners of 875 grocery and convenience stores to act as Apoteket representatives. As well as obtaining small packs of about 20 common OTC preparations from a cupboard owned by Apoteket, patients can drop off their prescriptions and collect the medicine later after it has been dispensed at an Apoteket branch.

### 5.5.2 Other

Apoteket has run a mail order pharmacy for prescription medicines and OTCs since August 2006. Orders are placed either by phone or at [www.apoteket.se](http://www.apoteket.se). There are no dispensing doctors in Sweden.

### 5.6 Performance

There is no public service obligation in law on the level of stockholding or required service level of either wholesalers or pharmacies.

Both wholesalers deliver to every pharmacy once-a-day, both prescription medicines and OTCs. There is a cut-off point for each wholesaler and pharmacy computer systems automatically place orders at this time. Wholesalers recheck their systems just before goods are dispatched to see whether there have been any late orders, and in some cases pharmacies can also place these by phone. Different product types (prescription drugs, narcotics, OTCs and parapharmaceuticals) arrive in different boxes which makes checking and handling in the pharmacy easier.

An Apoteket spokesperson said that pharmacies have adapted to single channel distribution and once-daily deliveries, and neither caused any particular difficulties. She also found little to distinguish between the two wholesalers.

Whereas added-value services of the type provided by UK wholesalers do not seem to exist, given Apoteket's size, resources and state-backing, these are probably not needed.

Apoteket has a data system that counts stock levels. If an acute situation should arise any pharmacy can see the stock level in any other pharmacy in the country, and either patients are asked if they want to visit another pharmacy or arrangements are made to bring the drug to the first pharmacy by car or bus. There is also a large pharmacy, Apoteket CW Scheele in central Stockholm, that holds more extensive stock and unusual medicines, and arrangements can be made by it to ship by post or air anywhere in Sweden.

Like any monopoly, Apoteket has had its critics, though surveys conducted by the company itself show a growing level of customer satisfaction. It has opened more stores and customer service points in response to complaints about long waiting times and poor, even rude service. Opening hours have been lengthened too. Outlets used to be open from 10am to 6pm during the week; a few opened on Saturday, but only until 2pm, and all pharmacies were closed on Sundays (an estimated 10% even closed throughout the summer holiday season).

### 5.7 Direct Delivery

As far as community pharmacies are concerned DTP is unheard of, though as both Tamro and KD act in part as LSPs not as classical wholesalers, the entire retail market might actually be considered to be served direct.

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An estimated 4% of total pharmaceutical sales are delivered direct via third-party LSPs. Affected products are mainly bulky liquids to hospitals, including large volume intravenous solutions.

### 5.8 Medicine Pricing

Prices for prescription medicines eligible for reimbursement are set at pharmacy purchase price level by an independent government agency, the Pharmaceutical Benefits Board (LFN), prior to market introduction on a product-by-product basis. LFN decisions are primarily based on whether the new drug brings a clinical improvement over existing treatments and if it is cost-effective. Generics and PIs can be priced freely up to a maximum of the originator's price. Approved pharmacy buying and selling prices can be found either at [www.lfn.se](http://www.lfn.se) or [www.fass.se](http://www.fass.se)

Prices for all other medicines other than reimbursed ones, including hospital-only products and those bought OTC for self-medication, do not involve intervention by the LFN.

### 5.9 Components of the Public Price

The final reimbursement or public price (*apotekens utförsäljningspris*; AUP) is equal to the pharmacy purchase price (*apotekens inköpspris*; AIP) plus the pharmacy mark-up.

Prescription medicines are zero-rated for VAT, while OTC medicines attract the standard rate of 25%.

Public prices for all medicines from community pharmacies have to be the same across Sweden.

#### 5.9.1 Payment to Wholesalers

The distribution mark-up is not regulated but based on free agreements between suppliers and the two wholesalers, and is not made public. On average, it is estimated to be 2.7% of the MSP (*droghandelns inköpspris*; DIP) - it is percentage-based and not fee-for-service.

#### 5.9.2 Payment to Pharmacies

Pharmacies have two statutory mark-up scales – one for prescription medicines and the other for OTCs - both set and revised by the LFN after discussions with Apoteket. Revisions to the scale are usually annually, with the last change made in January 2006.

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### *Pharmacy mark-up scale for prescription-only medicines in Sweden*

AIP (SEK)	AUP (SEK)
less than 75.00	$AIP \times 1.20 + SEK\ 31.25$
74.00-300.00	$AIP \times 1.03 + SEK\ 44.00$
300.00-6000.00	$AIP \times 1.02 + SEK\ 47.00$
more than 6000.00	$AIP + SEK\ 167.00$

Source: LFN

### *Pharmacy mark-up scale for OTCs in Sweden*

AIP (SEK)	AUP (SEK, including VAT)
less than 20.00	$AIP \times 1.42 + SEK\ 4.10 \times 1.25$
20.01-50.00	$AIP \times 1.40 + SEK\ 4.50 \times 1.25$
50.01-100.00	$AIP \times 1.12 + SEK\ 18.50 \times 1.25$
100.01 – 1000.00	$AIP \times 1.11 + SEK\ 19.50 \times 1.25$
more than 1000.01	$AIP \times 1.10 + SEK\ 29.50 \times 1.25$

Note: multiplication by 1.25 is to account for VAT

Source: LFN

Pharmacies receive no discounts, rebates or free stock from manufacturers or wholesalers, and so there is no clawback.

## 5.10 Price Paid by Patient

Sweden, like Denmark, operates a needs-based system of patient co-payment for reimbursed medicines. All patients (including the elderly and the unemployed) pay in full the cost of any drug prescribed when the total cost incurred in a 12-month period beginning with the first consumption does not exceed SEK 900. Thereafter, reimbursement increases in cost bands up to 100% reimbursement for an annual out-of-pocket spend in excess of SEK 4,300. Extra costs may be incurred if a patient refuses a generic or parallel import substitute.

### *Swedish reimbursement rates, 2007*

Accumulated total spend (SEK)	Reimbursement rate (%)	Maximum patient outlay/12 months (SEK)
less than 900	0	900
901-1700	50	1300
1701-3300	75	1700
3301-4300	90	1800
more than 4300	100	1800

Source: LFN

All children under 18 years of age within a family unit are considered a single beneficiary and costs may be added together. The only product type that does not attract any co-payment is insulin. On average, Swedes pay 30% of the total drugs bill, or 21% of the cost of prescribed medicines alone. In-patients pay a 'hotel charge' of SEK 80/day which covers everything including all treatment received.

### 5.11 Hospital Market

Sales of medicines to the 76 hospital pharmacies managed by Apoteket account for about 16% of the total drugs bill.

Manufacturer selling prices to hospitals are negotiated with the county councils, who usually expect a discount averaging 8-10% from the AIP. The county councils have the legal right to operate their own hospital pharmacies but so far none has done so, instead entrusting this to Apoteket. Apoteket receives the hospital purchase price plus a fixed fee for its services.

Unusually for Europe, Swedish hospital pharmacies supply out- as well as in-patients, in fact half the total number of Apoteket branches are situated within or near hospitals or health centres. The two wholesalers supply the vast majority of hospital drugs.

### 5.12 OTC Market

Sales at AIP of all non-prescription medicines, including OTC purchases, in 2006 amounted to SEK 2,485 million. This equates to just over 9% of the total pharmaceutical market. Apoteket, through its pharmacies, mail order operation, Apoteket shops and Apoteket representatives, has a total monopoly of OTC supply. Manufacturer prices may be freely set, but public prices have to be the same across Sweden.

### 5.13 Parallel Trade

Following Sweden's accession to the EU, parallel imports first emerged in 1997. Penetration grew very rapidly at first and has now stabilised at 11-12% of the prescription market by value over the past three years. In contrast to the UK, relatively few brands are affected, but those that are have very high parallel import penetration rates. The main driver for use has been mandatory generic/parallel import substitution. Parallel imports like direct imports are distributed entirely through one of the two wholesalers.

Single channel distribution is an obstacle to parallel exporting, Swedish trader Medartuum (a daughter company of UK wholesaler and parallel importer Munro) alleged. It filed a complaint in 2003 with the European Commission on this, with, to date, no outcome.

### 5.14 Counterfeit Entry

No counterfeit medicines have been found in pharmacies, Apoteket reports.

### 5.15 Pending Changes

The Swedish distribution model is 'under threat' with a few (unnamed) companies moving to DTP, using Tamro or KD for logistics services 'and nothing more', according to a Tamro spokesman.

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Apoteket's monopoly has been discussed for the past decade but it first came under serious scrutiny when in 2005 the European Court in case C-438/02 'held that the Swedish state monopoly on retail sales of medicinal preparations is contrary to European law'. The following year a new centre-right government gained power and reform was announced.

As the first result, nicotine-based smoking cessation aids will shortly be available from non-pharmacy outlets subject to these holding a permit from the Medical Products Agency. Of greater significance, deregulation of the pharmacy sector (or 're-regulation' as Apoteket describes it) has been promised as early as 2009. The stated objectives are to guarantee a safe and secure supply of medicines, increase accessibility and the degree of service as well as to increase price pressure.

A 'special investigator' was appointed by the government to propose how competition to Apoteket (which is expected to remain in state ownership) could occur with both prescription and OTC medicines. His report is due by the end of 2007. As a second step, he is due to propose by April 2008 a limited range of OTCs to be available from non-pharmacy outlets.

Apoteket has a strong market position, *Konkurrensverket* noted in a February 2007 press release, and when phasing out the monopoly 'special requirements should be introduced to ensure efficient competition'. As an example it said that Apoteket 'should not be allowed to amalgamate its pharmaceutical activities with the wholesale trade soon after deregulation, as such a move would represent a serious obstacle to market entry for new pharmacies'. To ensure proper competition, the state may have to sell pharmacies, it added.

Liberalisation of the retail environment might be accompanied by a change from single channel wholesale distribution to multichannel, as the former was effectively maintained through Apoteket's monopoly. However, if wholesalers are disallowed from pharmacy ownership (as is the case in Finland) then single channel might continue. Prior to 1970, KD operated as a traditional wholesaler.

While new players are expected to enter and Apoteket may have to divest some outlets, current players – the two existing wholesalers and Apoteket - are reportedly keen to compete vigorously in all sectors if allowed to i.e. prewholesaling, wholesaling and retailing. KD and Tamro fear that if Apoteket entered the domestic wholesaling market aggressively it would soon dominate. Apoteket's strategy documents also reveal proposals to buy pharmacies in other EU countries and to develop a European supply chain. Under its former name, Apoteksbolaget (National Corporation of Swedish Pharmacies), Apoteket previously owned the wholesaler Apotekarnes Droghandelsakliebolag (ADA), which achieved a Swedish market share in excess of 60%. ADA was sold by Apoteksbolaget to Tamro in 1995.

### 6. AUSTRALIA

Though there has been talk of consolidation and takeovers, Australia has long had three main nationwide full-line wholesalers - Sigma, Symbion (formerly called Mayne) and API. Traditionally these shared 90% of the market. More recently there has been a fourth entrant, a joint venture between DHL (Excel) and Australian generic company Alphapharm. Sigma is now estimated to hold a 27% market share, with API and Symbion accounting for 25% each, DHL/Alphapharma about 17%, with shortliners and small wholesalers operating within state boundaries for the remaining 6%.

The leading regional wholesaler, operating only in the states of South Australia and Victoria, where it owns a number of pharmacies, in the Friendly Societies Medical Association (also known as National Pharmacies). Short-line wholesalers tend to handle the top-300 lines. Among the major manufacturers, only GSK and Sanofi-Aventis distribute direct via LSPs, as do several generic companies (including previously Alphapharma).

The Commonwealth (national) government pays community pharmacies for supplying prescription medicines under the country's reimbursement system, the Pharmaceutical Benefits Scheme (PBS). These payments cover:

- the cost of the medicine;
- the cost to have the medicine delivered to the pharmacy by a wholesaler;
- a retail mark-up to cover pharmacists' costs in storing and handling medicines;
- a fee for the pharmacist's professional advice and services in dispensing the medicine to the patient.

All government payments for PBS medicines are made only to pharmacies. Pharmacies, wholesalers and manufacturers determine terms of trade between themselves.

Under the fourth community pharmacy agreement (effective 1 July 2006 and to run for four years) a total of AUD 11.1 billion in payments for supply of PBS medicines has been budgeted, compared to AUD 7.9 billion under the third agreement.

The main features of the fourth agreement are:

- Reduction in the allocation set aside for wholesaler costs. The wholesale mark-up on the MSP is reduced from 11.1% to 7.5%. A 7.5% mark-up equates to a 7.0% wholesaler margin on the pharmacy purchase price.
- An increase in the pharmacists' dispensing fee from AUD 4.75 per item to AUD 5.15 per item.
- Establishing a new Community Service Obligation (CSO) pool to provide additional payments to wholesalers, over and above their 7.5% mark-up, that agree to supply the full range of PBS medicines to pharmacies across Australia (or for state wholesalers any pharmacy within their state) within 24 hours of a pharmacy's regular order cut-off time. Initial annual funding for the pool is AUD 150 million (£61 million); this will be increased to AUD 173 million

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(£70.5 million) from August 2008. Payment will be made directly to wholesalers.

Wholesalers will be eligible to access CSO payments from the pool if they can demonstrate:

- infrastructure capacity to meet required service standards;
- purchase of 100% of the PBS range of products supplied through pharmacy (about 4,600 items), directly from the manufacturer; and
- at least 12 months of sales records showing that at least 30% of sales are to rural and remote pharmacies, and at least 30% of sales are for low-volume PBS medicines. New entrants without 12 months of sales records only need to show they have the capacity to meet the service standards.

Though CSO payments will largely be split four ways (National Pharmacies will only get an estimated AUD 1 million) and the wholesaler mark-up has been cut, wholesalers hope the new operating arrangements will discourage more manufacturers from shifting to direct distribution. Nevertheless, wholesalers in Australia as elsewhere have been diversifying. All three leading ones own pharmacies. Sigma merged with Arrow, which has a range of generics and OTC products. API acquired the health and beauty chain New Price Retail and formed a joint venture with ABM AMRO to set up a hospital supplies division.

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### ANNEX 1: SUMMARY OF PHARMACY OWNERSHIP RULES

Austria	Only pharmacists or partnerships where pharmacist's share is 51%
Belgium	No specific regulations
Czech Republic	No specific regulations
Denmark	Only pharmacists
Finland	Pharmacist owner may run up to three branch pharmacies.
France	Only pharmacists or partnerships of pharmacists
Germany	Pharmacist or partnership of pharmacists may own up to four pharmacies in local or adjacent administrative districts.
Greece	Only pharmacists or partnerships of pharmacists
Hungary	Fully liberalised since end 2006
Ireland	No specific regulations
Italy	Private pharmacies can only be owned by pharmacists.
Netherlands	No specific regulations
Norway	No single chain to include more than 40% of total pharmacies. No ownership by manufacturers or prescribers.
Poland	No single owner to have more than 1% of pharmacies in any of country's 16 regions.
Portugal	No single owner to have interest in more than four pharmacies. Prescribers, wholesalers and manufacturers banned from ownership.
Spain	Pharmacists or partnerships of pharmacists must own at least 75% of each pharmacy.
Switzerland	No specific regulations
UK	No specific regulations

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### ANNEX 2: PATIENTS' FINANCIAL CONTRIBUTION TO TREATMENT COSTS

In marked contrast to the US, the statutory systems account for about three-quarters of total health expenditure in most EU countries (Netherlands is the main exception). Out-of-pocket payments come next, followed by private health insurance.

Similarly with pharmaceutical costs, even when including OTCs in the total, the statutory system is the main single payer across the EU:

*Share of public expenses of total expenditure on medicines, 2003*

Country	%
Denmark	49.2
France	67.2
Germany	74.8
Italy	49.1
Netherlands	57.4
Spain	73.5
Sweden	69.3
US	21.2

Source: OECD Health Data 2005

To raise funds directly and as a deterrent to unnecessary medication, most countries have introduced a form of cost-sharing for partly-subsidised outpatient medicines.

Direct forms of cost sharing include:

- co-payment (the patient pays a fixed amount for each prescribed item irrespective of its cost and the third party payer pays the balance of the cost);
- co-insurance (the patient pays a certain proportion of the cost with the third party payer paying the remaining proportion); and
- deductible (the patient pays all of the cost up to a certain ceiling amount over a certain time period, with the third party payer paying all of any excess).

Unless the payment made is flat rate it is based on the public price of the product, which includes distribution margins as well as VAT (if applicable).

All countries exempt at least some patient types from a co-payment liability on age, socio-economic or medical grounds. Most countries also make provision for an annual cap on out-of-pocket expenditure, thus offering protection against catastrophic risk

There is no tradition in most European countries of patients paying the full cost of prescription medicines themselves. Indeed, as they have contributed already, through payroll deductions or income taxes, this would be tantamount to paying twice, which is naturally resisted. Patients would ask if there is a full or part-reimbursed alternative, and doctors and pharmacists willingly oblige. As a consequence, with just a handful

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of exceptions (mainly treatments for erectile dysfunction, baldness and weight loss, collectively termed 'lifestyle drugs') getting public reimbursement status has always been a virtual prerequisite for a new product's commercial success in Europe.

Italy is the main exception among the EU-15. Despite the total absence of co-payment under the Italian NHS at national level (the regions may levy token charges for some products), many Italians show a willingness to pay in cash for products on the non-reimbursable category C list as long as they believe they are receiving a superior product in this way. There are more non-reimbursed prescription drugs in Italy than in other west European countries. Pharmacies have the option of offering patients a maximum 20% discount on the list price of category C lines and also have to substitute a prescribed category C brand with a cheaper equivalent version (same active ingredient, dose and form) if one is available on the AIFA list. Manufacturers offer heavy discounts to pharmacies to encourage use of their category C brands, both prescription-only and especially OTC medicines.

In central and eastern Europe co-payments are higher as less reimbursement is offered and on fewer products. At 40% (excluding OTC purchases), patients' average contribution to the cost of medicines in Poland is especially high.

Reference pricing is a form of indirect cost sharing applied in several EU countries, including France, Germany and the Netherlands. Groups of interchangeable products are formed with the payer only reimbursing a fixed price below the maximum price of members in the group. Patients therefore have to pay themselves any excess above this reference price ceiling.

Hospitalised patients across the EU receive all drug treatment without payment, though some countries levy a small, flat rate 'hotel charge' on inpatients.

While evidence shows that cost-sharing policies do have some impact on the utilisation of prescription drugs, demand is relatively insensitive to price, at least for non-vulnerable groups of people. Price sensitivity is higher for heavy users of medicines and people with low incomes.

### ANNEX 3: DISTRIBUTION CHANGES ELSEWHERE BY PFIZER

#### Spain

From May 2001, Pfizer became the second manufacturer in Spain after Glaxo Wellcome (GW; now GSK) to introduce devise a form of dual pricing there. That it announced a scheme apparently similar to GW's just 13 days after the European Commission's unequivocal decision against the latter was seen as especially provocative by wholesalers. (This decision was later largely revoked by the European Court of First Instance and is currently pending before the full European Court of Justice.) Pfizer was the leading pharmaceutical company on the Spanish market, with a 9.7% market share at the time.

Unlike GW, no attempt was made to seek wholesalers' agreement of Pfizer's new terms. Instead, Pfizer initially said it would seek confirmation after a sale was made to a wholesaler that goods automatically supplied at a 'provisional discount' to Pfizer's 'freely fixed' prices were dispensed in Spain. If this confirmation – in the form of pharmacy invoices – was not forthcoming within six months of supply, another invoice to recover from the wholesaler the difference between the 'freely fixed' prices in annex 1 of its sales terms and the 'regulated price' in annex 2 would be raised by Pfizer.

Compliance with Article 100 (2) of the Spanish Medicines Law was stated as justification for the change by Pfizer. This Article – which was only enacted at the end of 1999 and therefore was not available to GW to use in its initial defence – had its origins in the Spanish Constitution, which gives enterprises a right to commercial freedom. Furthermore, while the EU price transparency Directive (89/105 EC) does allow member states to set pharmaceutical prices, this was only justified under Spanish national law if:

- there is a need to protect public health (e.g. to ensure patients have adequate access to medicines), and
- there is a need to control public healthcare expenditure
- 

Neither is applicable to medicines outside the Spanish healthcare system, and Article 100(2) confirmed that companies are free to determine prices, except when the conditions for government interference are met:

- the product is sold in the national territory, and
- is financed by the social security budgets or by public funds belonging to the national Health Service.

Article 100(2) became Article 90(2) of the new Medicines Law 29/2006.

A number of changes to Pfizer policy in Spain have taken place since 2004 and a mixed system now operates.

Direct sales to pharmacies are made using LSPs. The principal logistics provider is Logista (part of a tobacco company, the leading wholesaler Cofares pointed out). Direct distribution was apparently Pfizer's preferred approach but in response to

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protests from wholesalers and 'serious doubts' expressed by the Ministry of Health that service levels to all 20,000 pharmacies could be maintained with direct distribution alone, Pfizer also signed supply contracts with 16 of the larger wholesalers. Some, like EDIFA, act as purchasing centres for several wholesalers, so in reality Pfizer could route its products through about 40 wholesalers and achieve nationwide coverage. (Spain only has one wholesaler with national reach, Cofares.) Some smaller wholesalers, however, were cut out by Pfizer. The logistics provider Aitena is used as prewholesaler to supply the selected wholesalers with Pfizer products.

The manufacturer first invoices a 'European' price until the wholesalers prove that the products have exclusively been sold to pharmacies in Spain. Once this proof is provided, the first invoice gets replaced by a second one showing the 'Spanish' price. Differences between the two price levels are reportedly often large; several in 2005 were over 100% and some (e.g. with Zarator [atorvastatin] 80mg) were more than 200%. On the other hand, annex 1/annex 2 price differences with 40% of Pfizer's Spanish portfolio were zero.

Pfizer's changes to its scheme followed publication of Spanish Royal Decree 725/2003. Enforcement of Article 100 (now Article 90) only became possible because the Royal Decree introduced requirements for manufacturers and wholesalers to track product movement, and for pharmacies to provide sales data.

By simple subtraction of domestic resale figures from total sales in Spain, it is possible for manufacturers to know which wholesalers export, how much and when. In fact, the batch tracking method described in the Royal Decree was initially unworkable for technical reasons but Pfizer devised and implemented its own traceability scheme in conjunction with the Spanish Council of Pharmacists. The Ministry of Health has also signed an agreement with the Council to allow pharmacists to provide the data required by Pfizer, and to certify the sales inside and outside Spain.

Only Pfizer will know for sure what share of its business in Spain now goes direct and what goes via wholesalers. Cofares estimates the current split is 5% direct and 95% indirect. Despite the critics who said that Pfizer would face a backlash from wholesalers and pharmacies, after making allowance for patent expiries, the company has maintained its Spanish market share.

The apparent success of Pfizer's dual pricing scheme has spurred other manufacturers (Lilly, MSD, Janssen-Cilag) to develop and introduce variants of their own, with Sanofi-Aventis and Novartis set to follow from 2008. GW's original scheme was suspended after an injunction was brought in 1998. According to Cofares, no other manufacturer in Spain has followed Pfizer into DTP in the same way. Other Spanish manufacturers do distribute direct, but only for generics and OTCs. Cofares comments: 'The real problem with direct distribution is that it is uninteresting in rural areas where pharmacies do not have the purchase capacity their colleagues in cities have. However, all citizens have equal right to treatment under the Spanish Constitution, so for equity you need full-line wholesalers'.

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Some observers believe that the combination of Article 90 and the Royal Decree (both unique to Spain) effectively underwrites the legality of dual pricing there (at least until the ECJ decision with GSK). The Royal Decree in particular provides manufacturers with the necessary data to check on the final destination of their products supplied to wholesalers without the need for a potentially illegal (Article 82 EC) agreement with them.

### Germany

Pfizer was reported to have sent all the leading German wholesalers a 40-page prospectus entitled *Modell zur Apothekendirectbelieferung* (Model for Pharmacy Direct Distribution) in 2005. This document invited each wholesaler to become a partner with Pfizer in the manufacturer's proposed new DTP system in Germany. The distributor eventually selected by Pfizer would handle approximately 30 million packs of Pfizer's 750 prescription products. Pfizer would retain stock ownership until delivery to pharmacies, and would determine any discounts or rebates offered to pharmacies. The partner's role was to be limited to supplying and invoicing pharmacies.

In an effort to generate support for its plan, Pfizer telephoned German pharmacists and placed advertisements in newspapers. However, staunch resistance from both PHAGRO and ABDA (and their members) led to Pfizer's DTP plans being abandoned in November 2005. According to PHAGRO, Pfizer restarted discussions with wholesalers in 2007.

### Australia

Through its 'Pfizer Direct' scheme, the company has reportedly been supplying pharmacies direct since mid-September 2007. DHL Exel Supply Chain has been appointed LSP by Pfizer for an initial term of five years. Pfizer is quoted in the trade press as claiming DTP is only an additional service offered to pharmacies, designed to supplement the use of wholesalers not replace them.