



# Competition challenges in the pharmacy/pharmaceutical sector



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Executive summary of report from  
the Nordic Competition authorities

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# Executive Summary

## Preface

In consultation among the competition authorities of Denmark, Finland, Iceland, Norway and Sweden in autumn 2007, it was decided that the theme of the next Nordic cooperation project should be the competition challenges in the pharmacy/pharmaceutical sector. The following report is the result of this project.

The objective of the report is to draw together the experience of various approaches to the regulation of structure and price, and various competition-related issues and experience in the pharmacy and pharmaceutical sector in the Nordic countries. This will provide a better knowledge base for the respective competition authorities in their assessments of proposed changes in framework conditions for the sector, as well as a better basis for choosing where to direct their own initiatives. The report shall also provide a better basis for handling cases related to the sector, including with respect to the assessment of mergers.

The report aims at presenting, in a systematic way, approaches from a competition perspective and experiences in the Nordic countries. In this connection, it is important to point out that the Swedish pharmacy market will be radically changed during 2009 with the expected abolishment of the state pharmacy monopoly. This means that many of the descriptions, assessments and experiences that are presented in the report that relate to the Swedish market, will be of limited relevance to the situation after the pharmacy monopoly has been abolished.

The report is primarily aimed at describing retail and wholesale trade on the respective Nordic markets, thus information about and descriptions of the pharmaceutical producers are limited.

## Characteristics of the pharmacy/pharmaceutical market

There are some fundamental characteristics of the pharmaceutical market that also hold true for most European countries. For the most part, doctors make the choices regarding the use of pharmaceuticals, and the authorities insure the citizenry against large drug expenses due to illness by paying the costs of drugs prescribed by doctors. A large part of the individual consumer's costs for pharmaceuticals is financed by the public sector. The state pays most of the cost of pharmaceuticals, either directly via hospitals or indirectly via patients who receive reimbursement. De Laat, et al., (2002) contains the following saying:

*"Who consumes, neither chooses nor pays; who pays, neither consumes nor chooses; who chooses, neither pays nor consumes"*

The demand for prescription pharmaceuticals is, in other words, very price inelastic. This means that the price for individual pharmaceuticals, for example, a life-prolonging drug, can be greatly increased without any substantial effect on quantity demanded. That the demand is very price inelastic is a consequence of there being no direct relationship between consumption and the person who decides what shall be consumed (the doctor) and the person who shall finance the consumption (generally, this is the state).

That the authorities in most countries, including each of the Nordic countries, impose a maximum on the price that pharmacies may charge consumers for pharmaceuticals that are reimbursed, should be seen against that background. Further, it is usual for the authorities to regulate the price that pharmacies may pay to producers or wholesalers. The reason for this is to ensure that the pharmacy makes a certain profit margin from the activity.

Further, under the health policy in most countries, the authorities consider it important that all of the country's inhabitants have good access to pharmaceuticals, regardless of where they live or their physical condition. Drug production and pharmacies play an important role in healthcare. In most countries, therefore, an explicitly expressed political objective is tied to the pharmacy and pharmaceutical sector.

There are further strict limits on marketing and trading of prescription drugs. In addition, various and comprehensive safety requirements apply to the various actors in the sector. That implies, again, that a large variety of government bodies are involved in various ways.

From the point of view of health authorities, pharmacies have a central role to play for rational pharmaceutical use. WHO defines this as, "The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community," Rational pharmaceutical use comprises, according to the WHO definition:

1. Safe and proper dispensing of drugs
2. Correct use of drugs
3. Cost effective use of drugs

Retail trade in pharmaceuticals is not harmonized in EC law. Member States are thus free to legislate in the area, provided that they follow the European Union primary, secondary and supplementary law. In Directive 2006/123/EC on services in the internal market, healthcare and pharmaceu-

tical services provided by health professionals to patients to assess, maintain or restore their state of health, are excluded from coverage of the Directive where those activities are reserved to a regulated health profession in the Member State in which the services are provided.

The area of pharmaceuticals, as a whole, is subject to a high degree of harmonisation, with considerable community legislation, for example through Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as well as Directive 2001/82/EC on the Community Code relating to veterinary medicinal products.

It is well known from economic theory that various forms of market failure can justify various forms of market regulation. Examples of market failures would be externalities, collective goods, natural monopolies and imperfect competition. And as we have seen in the preface, the pharmaceutical market has several characteristics that can lead to market failure. This is also a sector subject to price and structural regulation of a wide variety of types and of various levels of the distribution chain.

It appears that this market structure is susceptible to price competition to only a limited degree. It is also a sector that is subject to a comprehensive degree of price regulation applied to various links in the value chain. Nevertheless, competition has played an important role in the sector, for example in facilitating

- competition among generics,
- competition among non-prescription pharmaceuticals,
- competition on the basis of quality and availability among retailers and
- competition among wholesalers.

The aim, within the framework established for the sector, is for competition to contribute to a more effective use of resources, services of higher quality and a broader choice of as well as cheaper pharmaceuticals.

### **Main features concerning the regulation of market behaviour as well as a summary description of market actors**

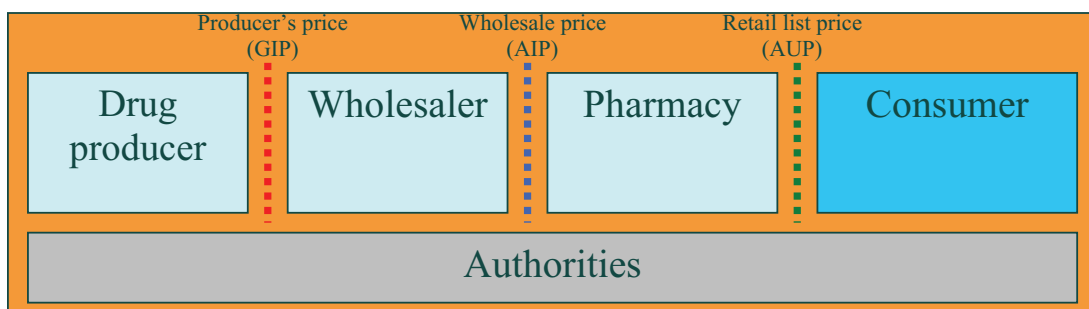
As a consequence of the distinctive elements of the pharmacy/pharmaceutical market as described above, the pharmacy and pharmaceutical sector in the Nordic countries, as in most other countries, is heavily regulated. This is the case both with respect to the structure of the market, not least ownership and establishment, and how the actors can operate in the market. The table below provides an overview description of the main features of the law on the regulation of the structure and market behaviour in the respective Nordic countries. The table also provides a general description of the market actors in the different levels in the pharmacy and pharmaceutical arena.

|   | Denmark  | Finland  | Iceland  | Norway   | Sweden   |
|---|--|--|--|--|--|
| Retail level                              | <p><b>Regulation.</b> Restricted entry as a consequence of the licensing system. Pharmacy qualification required to obtain a license.</p> <p>Licenses for shops other than pharmacies to sell non-prescription drugs.</p> <p><b>Participants.</b> 246 single proprietor pharmacies. 322 pharmacy sales points with, and 1043 without, prescription drug dispensing. About 1400 shops for non-prescription drugs. Possibility for e-commerce for pharmacy products.</p> | <p><b>Regulation.</b> Restricted entry, proof of need is required to establish a pharmacy. Only pharmacists can own pharmacies. The exception is the university pharmacy chain.</p> <p><b>Participants.</b> Sole proprietor pharmacies, 804 pharmacies with prescription drug dispensing, of these 196 are subsidiary pharmacies. Nicotine replacement therapy (NRT) can be sold in grocery stores, kiosks, and petrol stations.</p> | <p><b>Regulation.</b> Free entry. Licensing system. Pharmacy qualification required. The sale of NRT and fluoride preparations is permitted in shops.</p> <p>Free ownership. Doctors cannot own pharmacies.</p> <p><b>Participants.</b> Two pharmacy chains and 12 independent pharmacies.</p>   | <p><b>Regulation.</b> Free entry, but license required. Entities under the supervision of the Norwegian Food Safety Authority can sell certain non-prescription drugs.</p> <p>Doctors and the pharmaceutical industry cannot own pharmacies.</p> <p><b>Participants.</b> Three large pharmacy chains. Few independent pharmacies.</p>  | <p><b>Regulation.</b> Statutory state monopoly on the retail sales of prescription drugs and most non-prescription drugs.</p> <p>Retail sales of animal- or mineral-based substances as well as non-prescribed NRT permitted at retailers other than pharmacies.</p> <p><b>Participants.</b> The state owned National Corporation of Swedish Pharmacies (Apoteket AB) with approximately 880 traditional pharmacies.</p> |
| Wholesaler                                | <p><b>Regulation.</b> Free entry, but license from the Danish Medicines Agency for wholesale trading is required.</p> <p><b>Participants.</b> Very concentrated market, where almost the entire supply of products is by only two full-range wholesalers.</p>  | <p><b>Regulation.</b> Free entry, but approved pharmacy qualification required.</p> <p>System with single channel distribution implies that in practice there are high barriers to entry.</p> <p><b>Participants.</b> Two dominant wholesalers. Pharmacies have agreements with both participants.</p>   | <p><b>Regulation.</b> Free entry, but license and pharmacy qualification are required, and cannot have a licence to operate a pharmacy.</p> <p><b>Participants.</b> Two levels of wholesaling, partly for import and intermediate sales, partly wholesale distribution. Two dominant distributors. One small distributor.</p>                                  | <p><b>Regulation.</b> Free entry, but license for wholesale activities required.</p> <p>Wholesalers that sell pharmaceuticals to pharmacies must have a full product range. Wholesalers that sell pharmaceuticals to sales points other than pharmacies must have a minimum product range.</p> <p>Producers can, under their production licenses, engage in wholesale activities in their own products.</p> <p><b>Participants.</b> Three recognized full-range wholesalers.</p> | <p><b>Regulation.</b> Free entry, but wholesale trade licence required.</p> <p>System with single channel distribution implies that in practice there are high barriers to entry.</p> <p><b>Participants.</b> Two dominant wholesale trade companies account for almost all distribution to Apoteket AB's pharmacies.</p>  |
| Production and import                     | <p><b>Production/import.</b> Free, but approval from the Danish Medicines Agency required.</p> <p><b>Participants.</b> Approximately 170 producers/ importers with marketing licenses.</p>   | <p><b>Production.</b> Free, but only recognized pharmaceutical plants with pharmaceutical manufacturing license.</p> <p><b>Import.</b> Free, but commercial importer qualification required.</p> <p><b>Participants.</b> About ten manufacturers, of whom three are significant. In addition, about 130 pharmaceutical companies.</p>  | <p><b>Production/import.</b> Free entry and ownership in practice. Licence and pharmacy qualification required and the owner shall not have a pharmacy licence.</p> <p><b>Participants.</b> One generics producer. Two large and one smaller importer of patented pharmaceuticals. Three small importers of generics or parallel imported pharmaceuticals.</p> | <p><b>Production.</b> Free entry, but license for the activity required.</p> <p><b>Import.</b> Free entry, but import license required. Private persons may import for own consumption.</p> <p><b>Participants.</b> 672 participants with marketing licenses. 10 companies with pharmaceutical production of products with marketing licenses.</p>   | <p><b>Production/import.</b> Free, but approval from the Medical Products Agency required.</p> <p><b>Participants.</b> Approximately 130 pharmaceutical companies with production licenses and 310 companies with wholesale licenses.</p>  |
| Vertical integration retail and wholesale | Not permitted.   | Not permitted.   | Permitted, but a licence holder can only have a licence on either retail or wholesale level. Nevertheless, it is possible to own companies on both levels.   | Permitted.   | Not relevant.  |

## Approaches to price regulation

As described above, demand for prescription drugs is very price inelastic. For this reason, these are also products subject to strict price regulation. The way in which the price is regulated varies among the different Nordic countries, and also depends upon whether the drug in question is a prescription drug under patent or a prescription drug subject to competition from generics, or a non-prescription drug.

In addition, it is not only the pharmaceutical's price for the final consumer that is subject to price regulation, but even the prices earlier in the distribution chain. The distribution chain, as well as the different prices, is shown in the following diagram.



**GIP.** Wholesalers' purchase price, price of the pharmaceutical charged by the producer/importer to the wholesaler.

**AIP.** Pharmacy's purchase price, price of the pharmaceutical charged by the wholesaler to the pharmacy/retailer.

**AUP.** Pharmacy sales price, price of the pharmaceutical charged by the pharmacy/retailer to the user. In certain countries, for example Denmark, the definition of AUP generally does not include taxes since these are applied in addition.

The table below provides a general description of the approaches to price regulation in the respective Nordic countries.

|   | Denmark   | Finland   | Iceland   | Norway  | Sweden  |
|---|---|---|---|---|---|
| Patented prescription drugs                 | <p>The Ministry of Health and Prevention enters into 2 year agreements with LIF (the Danish Association of the Pharmaceutical Industry) on the regulation of prices of reimbursed prescription drugs.</p> <p>Producers can, within the agreement's framework, freely set AIP and are obliged to notify changes in AIP to the Danish Medicines Agency every 14th day.</p> <p>The Danish Medicines Agency fixes AUP on pharmacy-only drugs.</p> | <p>Maximum AIP, "reasonable wholesale price," is negotiated and authorized by the Pharmaceuticals Pricing Board. Applies to all drugs for which reimbursement is paid.</p> <p>For pharmaceuticals that are not covered by reimbursement regulation, the AIP can be freely set. AUP identical for all.</p> | <p>The Icelandic Medicine Pricing and Reimbursement Committee sets the maximum AIP.</p> <p>Regulated profit and maximum AUP.</p> <p>Based on price comparison in the Nordic countries.</p> <p>Patented (average of DK, SE, NO)</p> <p>Discount from maximum AIP and AUP is possible. Though from 1st Oct. 2008: same price at the same company over the entire country (AUP from 1st Jan. 2009).</p>        | <p>Maximum AIP based on the three lowest prices in a sample of nine countries.</p> <p>Pharmacy profit is regulated, i.e., implicit regulation of AUP.</p> <p>Profit sharing model shares the profit between the pharmacy and customer if the actual AIP negotiated is lower than maximum AIP.</p> | <p>The Dental and Pharmaceutical Benefits Agency (TLV) fixes AIP.</p> <p>TLV calculates AUP by using AIP as an input into certain formulas. This implies that TLV regulates Apoteket AB's trading margin.</p>   |
| Prescription drugs with generic competition | <p>Generic producers and parallel importers are not subject to the price agreement.</p> <p>Producers and importers may freely set AIP, but they are obliged to notify changes in the AIP to the Danish Medicines Agency every 14th day.</p> <p>Danish Medicines Agency limits the AUP on pharmacy-only drugs and publicises consumer prices on medicinpriser.dk.</p>  | <p>For pharmaceuticals that are covered by reimbursement regulation: Approval of AIP is handled according to a simplified procedure.</p> <p>The pharmacy is obliged to substitute the lowest-priced available preparation within the price range.</p>   | <p>Based on price comparison in the Nordic countries.</p> <p>Generic (average of DK, SE, NO, FI)</p> <p>Discount from the maximum AIP and AUP is possible. From 1st Oct. 2008: same price within a single firm across entire country (AUP from 1st Jan. 2009).</p> <p>Planning to revise the reimbursement so that the maximum support equals the price of the cheapest competing, substitutable drugs.</p> | <p>"Trimpris" (prices reduced in steps) based on the maximum AUP at the date competition from generics begins.</p>  | <p>Generic manufacturers apply to the TLV to get AUP. TLV has an electronic "marketplace" where companies can change their prices on a monthly basis.</p> <p>Generic substitution. According to the law, Apoteket AB must substitute a prescription drug with the least expensive substitute drug that is available in the inventory of the pharmacy where the customer visits.</p> |
| Non-prescription drugs                      | No regulation.  | Free price setting, but the same AUP must be charged over the entire country.   | No regulation.  | No regulation.  | Free for Apoteket AB, but the same AUP must be charged over the entire country.   |

## Ongoing reforms and experiences

The pharmacy and pharmaceutical sector in the Nordic countries has experienced broad changes in its framework during the last fifteen years. These changes have led to dramatic changes in market structure and market operation. The table below gives a general description of the ongoing and future reforms in the pharmacy and pharmaceutical sector in the Nordic countries. The table also contains brief descriptions of the experiences of the ongoing reforms.

|                            | Denmark   | Finland   | Iceland   | Norway  | Sweden  |
|----------------------------|---|---|---|---|---|
| Retail                     | <p>2001: Abolition of the pharmacy monopoly as well as the fixed price system for non-prescription drugs. Experience: Total sales have not been affected, but liberalisation has lead to lower prices in the shops and easier access to non-prescription drugs.</p> | <p>2003: Generic substitution. Experience: Generic substitution has resulted in significant savings.</p> <p>2006: NRT in grocery stores. Experience: The price of NRT fell.</p> | <p>1994: Liberalisation under the Medicinal Products Act. The old license system abolished. Possible for non-pharmacists to own pharmacies, but a pharmacist must nevertheless take responsibility for the pharmacy. Possible for the same owner to possess several pharmacies. Experience: Development of chains, concentration. Limited vertical integration.</p> <p>1996: Development of chains.</p> <p>2008: Liberalisation of the sale of certain non-prescription drugs outside of pharmacies according to the Medicinal Products Act. Experience: Not evaluated.</p>   | <p>2001: Deregulation with respect to ownership through new pharmacy law and opening for generic substitution. Experience: Increased entry by pharmacies and accessibility. Building of chains and concentration. Little effect on price.</p> <p>2003: Permitted trade in certain non-prescription drugs outside of pharmacies. Experience: Increased availability and reduced price rises.</p> | <p>1971: Statutory state monopoly on the retail sale of prescription drugs and most non-prescription drugs. The only participant in the retail market is the state owned Apoteket AB.</p> <p>2002: Required generic substitution. Experience: Cost savings.</p> <p>2008: The sale of non-prescribed NRT possible in locations other than pharmacies. Experience: Large increase in the number of sales outlets.</p> <p>2008: The market for pharmaceuticals sold to hospitals opened to competition. Experience: Not evaluated.</p> |
| Wholesale/ Production      |   | <p>2006: The government decreed that the AIP be reduced by 5 pct. Experience: Producers withdrew 81 pharmaceuticals from the list of reimbursed drugs.</p>                      | <p>1994: Liberalisation. Experience: Concentration.</p>   | <p>1995: Termination of NMD's monopoly position. Experience: Two new wholesalers entered the market.</p>  |   |
| Veterinary pharmaceuticals | <p>2007: Removal of the pharmacies' monopoly as well as the fixed price system on veterinary drugs for farm animals. Experience: Not yet evaluated.</p>   |   |   | <p>2002: Free price setting of veterinary drugs. Experience: Not evaluated.</p> <p>2004: Termination of pharmacies' monopoly, professional final consumers begin to buy drugs for animals directly from the wholesaler. Experience: Not evaluated.</p>  |   |
| Future reforms             | <p>2009: The Ministry of Health and Prevention shall evaluate the liberalisation of the veterinary medicine.</p> <p>2009: The Ministry of Health and Prevention shall review the legal frameworks of the pharmacies.</p>  | <p>2009: Reference price system.</p>  | <p>2008: Mail order trade in pharmaceuticals allowed, sale of NRT and fluoride preparations in grocery stores allowed, etc.</p> <p>2008: Same price for prescription drugs in all pharmacies in the same chain over the entire country. Same AIP from wholesaler to all pharmacies, for the same product. Discounts on max. prices shall be reported to the Icelandic Medicine Pricing and Reimbursement Committee and made public in the medicine price catalogue. Changes to the regulation on support for drugs for treatment of peptic ulcer: The max. support equals the price of the cheapest of the competing and substitutable drugs.</p> |   | <p>2009: Abolition of the pharmacy monopoly is expected on 1st July. The market for trade in pharmaceuticals for animals is opened to competition in connection with the termination of the present pharmacy monopoly.</p> <p>2009: The sale of certain non-prescription drugs in locations other than pharmacies will become possible at some point after 1st July.</p>  |

## Approaches to competition issues and items for attention

Although the pharmacy and pharmaceutical sector in the Nordic countries has experienced broad changes in its framework with resulting changes in market structure and increased competition, there remain a number of competition issues and challenges. The table below provides an overview of these issues and challenges that have been identified by the respective Nordic competition authorities.

|            | Denmark   | Finland  | Iceland   | Norway   | Sweden   |
|------------|---|--|---|--|--|
| Retail     | <p>Competition among pharmacies is weak because of the restricted entry and the many behaviour rules, hereunder the fixed price system.</p>               | <p>So tightly regulated that competition among pharmacies is not possible.</p> <p>Pharmacy entry requires proof of need.</p> <p>Pharmacy ownership connected to pharmacist examinations.</p> <p>One pharmacy per owner plus at most 3 subsidiary pharmacies.</p> | <p>Oligopolistic market.</p> <p>Collective market dominance by two pharmacy chains.</p> <p>The pharmacy chains' occupancy of the most favourable sales locations is a barrier to entry.</p>   | <p>Concentrated market, few independent pharmacies remaining in the market.</p> <p>Possible collective market power.</p> <p>Age limit and self-service in the sale of certain non-prescription drugs outside of pharmacies.</p> <p>Call the attention of the HOD (Ministry of Health and Care Services) to possible competition distortions among pharmacies and sellers of nursing items.</p> | <p>The Swedish government has, as an argument for abolishing the pharmacy monopoly, stated that retail trade in pharmaceuticals in Sweden can be improved, above all with respect to the availability of pharmacies for consumers.</p> |
| Wholesale  | <p>Limited number of direct customers (pharmacies).</p> <p>Limited parameters on which to compete (service and, to a very limited extent, discounts).</p> | <p>Highly concentrated market; single channel distribution.</p> <p>The single channel system implies, in practice, high thresholds for establishing new wholesalers due to exclusive distribution rights which limit the product range of new participants.</p>  | <p>Single channel distribution leads to high barriers to entry. Oligopolistic market.</p> <p>One large generic producer with strong market power.</p> <p>Free entry, but not for pharmacists who have a license to operate a pharmacy.</p>  | <p>Concentrated market.</p> <p>Possible collective market power.</p> <p>The need for a full range of products is a possible entry barrier.</p>   | <p>Free entry, but single distribution channel system implies that in practice there are high barriers to entry.</p>   |
| Production | <p>3 types of producers/importers (original, copy and parallel) which are not competing simultaneously.</p>   |  | <p>Single channel distribution and oligopoly in the wholesale market can hinder the entry of new producers into the market.</p> <p>The position of Actavis (a major producer of generic pharmaceuticals) in the market limits the possible entry of new producers and importers of generic pharmaceuticals.</p> |  |  |



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