

Unclassified

DAF/COMP/GF/WD(2014)35

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

03-Feb-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Finland

-- Session III --

This contribution is submitted by Finland under Session III of the Global Forum on Competition to be held on 27-28 February 2014.

Ms Cristiana Vitale, Senior Competition Expert, OECD Competition Division
Tel: +33 1 45 24 85 30, Email: cristiana.vitale@oecd.org

JT03351835

Complete document available on OLIS in its original format

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

DAF/COMP/GF/WD(2014)35
Unclassified

English - Or. English

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Finland --

1. Supply conditions

1. The pharmaceutical sector is highly regulated in Finland. The aim is to ensure the supply of safe and affordable pharmaceuticals (also referred as medicines) to consumers, including the reimbursement of the costs of pharmaceuticals through a national health insurance system. Pharmaceuticals are distributed by manufacturers through a so-called single channel wholesale system to pharmacies which supply them to consumers. The systems have a number of advantages. The wholesale system may, for example, have prevented falsified medicines from entering the legal supply chain. The national health care system ensures that approximately half of the costs of pharmaceuticals are financed through public funds. However, a detailed and strict regulation may stiffen the market and prevent innovations as well as prevent efficiency.

2. Provisions concerning the pharmaceutical sector are mainly provided in the Medicines Act (395/1987 as amended by 904/2013)¹ which provides for the maintenance and the promotion of the safety of pharmaceuticals as well as the safe and proper use of pharmaceuticals. The Medicines Act also ensures the appropriate manufacture and availability of pharmaceuticals. The Medicines Decree (693/1987)² provides for the manufacture, import and wholesale of pharmaceuticals. The Health Insurance Act (1224/2004)³ provides for the health insurance system and the reimbursement of pharmaceuticals. The Council of State Decree on the price list for drugs (713/2013) determines the pharmacies' margin and hence the fixed retail price. In addition, separate acts and decrees cover areas such as pharmacy fee, electronic prescription (e-Prescription) and the obligatory storage of pharmaceuticals.

3. The pharmaceutical sector is also characterized by a number of different types of market players. The vertical value chain consists of pharmaceutical companies, wholesale companies and pharmacies. A number of different governmental organizations also act as authorization and monitoring authorities. The Ministry of Social Affairs and Health is responsible for the planning, guidance and implementation of social and health policy in Finland and, therewith, responsible, for example, for promoting welfare and health and providing social and health services as well as social insurance. The Finnish Medicines Agency (Fimea)⁴ is in charge of the market authorization of pharmaceuticals and the post-licensing monitoring. The Pharmaceuticals Pricing Board (Hila)⁵, subordinate to the Ministry of Social Affairs and Health, reviews the pricing and reimbursement applications of companies and makes the decisions about the

¹ The Medicines Act (amendments up to 1340/2010 included) is available in English at http://www.fimea.fi/national_laws.

² The Medicines Decree (amendments up to 69/2011 included) is available in English at http://www.fimea.fi/national_laws.

³ The Health Insurance Act is available in English at <http://www.finlex.fi/en/laki/kaannokset/2004/en20041224.pdf>.

⁴ More information about the Fimea is available at <http://www.fimea.fi/frontpage>.

⁵ More information about the Board is available at <http://www.stm.fi/en/ministry/boards/pharmaboard>.

reimbursement of medicines. The Social Insurance Institution (Kela)⁶ provides a National Health Insurance scheme which covers the part of the costs of health service including, for example, prescribed pharmaceuticals. In addition, the Association of Finnish Pharmacies⁷ is an active player in this sector.

4. The Finnish Competition and Consumer Authority (previously the Finnish Competition Authority, the FCA)⁸ has taken notice the structural barriers to competition laid down in above-mentioned regulations. In particular, the pharmacy license and the reimbursement of costs may encounter certain competition problems. The FCCA has received complaints regarding the pharmaceutical sector and it has also opened ex officio investigations in the sector. The FCCA's advocacy efforts in the pharmaceutical sector have concerned, for example, the price regulation system for pharmaceuticals. As a result, the FCCA has proposed that the system as a whole should be reformed. The fact the Medicines Act has been amended approximately 40 times since its entry into force in 1988 also speaks for the necessity of reform.

5. In August 2012, the FCCA published an extensive report on the provision of pharmaceuticals in which it proposes a regulatory reform to the regulation on the pharmacy system and the provision of pharmaceuticals.⁹ The report, for example, recommends the removal of a so-called needs testing in connection with the establishment of pharmacies and of the restrictions on the number of pharmacies. The freedom of pharmacists to apply different competition parameters is proposed to be increased so as that the company form of a pharmacy could be freely chosen in the future. The FCCA also proposes the pricing of pharmaceuticals to be amended: the price conforming to the pharmacy mark-up scheme could be a maximum price in the future, and pharmacies could freely determine the price of a product below that tariff. According to the FCCA, price competition would also be enhanced by including parallel imports in the reference price system, already when the patent of the original pharmaceutical is still effective. The market share of parallel imports is much lower (only one percent) in Finland than in comparable countries. The reasons for this are debated but the FCCA considers that a stricter legal regulation is needed to ensure that parallel imports - when they are cheaper – also get distributed by the pharmacies. As regards self-medication, by allowing the sale of self-medication - which is deemed safe - also outside the pharmacies could promote price decreases.

6. The FCCA considers that these amendments would aim at a major improvement in the effectiveness and productivity of the provision of pharmaceuticals and lowering of the costs caused to society from the distribution thereof. Consumers would benefit from these reforms as decreased prices and improved availability. The FCCA's proposals are based on its view regarding the ineffectiveness of the supply of pharmaceuticals in the retail sector. The wholesale prices in Finland are among the lowest in Europe whereas the retail prices are among the highest in Europe.

7. The FCCA's report was preceded by, for example, a joint Nordic study on the pharmaceutical sector including price regulation published by the Nordic Competition Authorities.¹⁰ In addition, detailed

⁶ More information about the Institution is available at <http://www.kela.fi/web/en/about-kela>.

⁷ More information about the Association of Finnish Pharmacies is available at <http://www.apteekkariliitto.fi/en/home.html>.

⁸ The Finnish Competition Authority and the Finnish Consumer Authority merged into a joint Finnish Competition and Consumer Authority on 1 January 2013.

⁹ Valliluoto, Sari (2012), "From the provision of pharmaceutical products to pharmaceutical markets - value chain and regulation", Finnish Competition Authority, Report 2/2012, available in Finnish at <http://www.kilpailuvirasto.fi/tiedostot/Selvityksia-2-2012-Laakemarkkinat.pdf>. See also the FCA Press Release: "Reform of pharmacy system would significantly lower costs of pharmaceutical sector", available at <http://www.kilpailuvirasto.fi/cgi-bin/english.cgi?luku=news-archive&sivu=news/n-2012-08-28>.

¹⁰ Executive summary of the Nordic study is available in English on pages 5-11 of the Report.

information about the health care system in Finland is provided in the report produced by ÖBIG for the European Commission (Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States).¹¹ It should be noted that certain information provided in the report is no longer valid. For example, the reference price system was introduced in Finland after the publication of the report.

8. Regulations, market players and the role of the governmental organizations in the pharmaceutical sector are discussed in more detailed below.

2. Manufacturing level

9. According to Article 8 of the Medicines Act, pharmaceuticals may only be manufactured industrially by pharmaceutical product manufacturers that have acceptable production facilities and equipment and a licence from Fimea. The licence may incorporate conditions. Most of the pharmaceuticals manufactured by pharmaceutical companies are supplied to pharmacies and hospitals, for example in 2011 approximately 73% and 27 % respectively.

10. According to Article 20a of the Medicines Act, a medicinal product may be sold to the general public or otherwise released for consumption only if the Fimea has granted an authorization for the product or registered it under the Medicines Act or if it has a marketing authorization granted by an institution of the European Commission.

11. In principle, pharmaceuticals are freely priced but in practice the health insurance system regulates the prices. Pharmaceutical companies apply for the reimbursement status for their pharmaceuticals. The Pharmaceuticals Pricing Board reviews the pricing and reimbursement applications of companies and makes the decisions about the reimbursement of pharmaceuticals. Pharmaceutical shall have a maximum wholesale price approved by the Board before they enter the reimbursement system. According to Article 37a of the Medicines Act, the wholesale prices of pharmaceuticals must be the same for all pharmacies. The wholesale price must take into account all discounts, rebates and other benefits to pharmacies.

3. Wholesale distribution

12. Finland applies a so-called single channel wholesale system where only one wholesale company mainly distributes the products of each pharmaceutical manufacturer, i.e. wholesale companies have exclusive distribution contracts with an individual pharmaceutical company. The single channel system is not based on the provisions of law but is a practice established by the market players in 1970s. The system was reasoned on the basis that it would bring efficiencies.

13. According to Article 32(3) of the Medicines Act, the wholesaling of pharmaceuticals may only be carried out under a licence granted by the Fimea. However, compared to the manufacturing level and the retail distribution, the wholesale distribution is subject to fewer provisions of law. It should be noted that the wholesale companies do not own the pharmaceuticals. The wholesale distribution in Finland is based on the dealing and it is a logistic solution.

14. The wholesale market is dominated by Oriola and Tamro which have a combined market share of almost 100%. A third wholesale company, Magnum Medical Finland, entered the Finnish market in 2006 but did not gain any significant share in the market. Both Oriola and Tamro have a distribution system covering the whole geographic area of Finland. A majority of pharmaceutical companies active in Finland holds a wholesale permit but does not currently exploit the permit. However, the wholesale permit provides the pharmaceutical company with an opportunity to react to any changes in the market.

¹¹ The report is available at http://ec.europa.eu/comm/competition/mergers/studies_reports/oebig.pdf.

15. The FCCA has investigated the competitive effects of the single channel distribution of pharmaceuticals between 1997 and 2012 but did not take any measures to change the single channel distribution.¹²

16. At the wholesale level, pharmaceuticals are almost exclusively purchased by pharmacies. A certain number of pharmaceuticals are purchased, for example, by the 24 hospital pharmacies, which do not function as retailers, have a combined market share of 18%. A wholesale mark-up is unregulated. The Pharmaceuticals Pricing Board approves a maximum wholesale price in case where the pharmaceutical company applies for reimbursement status for its pharmaceuticals. The pharmacy purchase price includes the combined price of the pharmaceutical company plus the wholesale margin. The wholesale margin is freely negotiated between the wholesale company and the pharmaceutical company. Thus in practice the pharmaceutical company has to take into account when it negotiates the pharmacy purchase price with the Pharmaceuticals Pricing Board that it will afterwards have to give a certain amount of the price away to the wholesale companies as the latter's margin. Wholesale margins are generally small because wholesale companies have rather limited functions in the Finnish value chain as opposed to some other countries where wholesale companies engage in marketing etc.

4. Retail distribution

17. According to Article 38 of the Medicines Act, pharmaceuticals may be sold to the general public only from the pharmacies, pharmacy service points and online pharmacy services.¹³ Online pharmacy services may only be performed by regular pharmacies. Hence, pharmaceuticals are supplied to consumers mainly through pharmacists. However, according to Article 54 of the Medicines Act nicotine products may also be sold by tobacco-selling retail stores, kiosks and service stations as well as bars and restaurants on the basis of the authorization granted by the municipality where the sales outlet is located. In addition, physicians may supply a small amount of pharmaceuticals to patients in order to immediately start medication.

18. According to Article 40 of the Medicines Act, the operation of a pharmacy requires a licence (i.e. a pharmacy licence) from the Fimea. The party awarded the licence is referred to as a licenced pharmacist. A pharmacy licence is granted for operating a specific pharmacy business in a municipality or part thereof. Pharmacies are mainly privately owned. There are approximately 800 private pharmacies in Finland which makes one pharmacy for approximately 6580 inhabitants. Each pharmacist may own maximum one pharmacy and three subsidiary pharmacies. Article 42 of the Medicines Act provides also for the University of Helsinki and the University of Eastern Finland each to maintain one pharmacy. In addition, the University of Helsinki is entitled to maintain 16 subsidiary pharmacies.¹⁴ Besides selling pharmaceuticals, the function of pharmacies maintained by the universities is to provide practical training in connection with pharmacy teaching and to conduct research. In Finland, there are no pharmacy chains as the pharmacy licence is granted, as stated in Article 44 of the Medicines Act, to a named individual. However, some of the pharmacies carry out, for example, marketing cooperation.

¹² See, for example, the FCA Press Release: "The FCA re-examines single channel distribution of pharmaceuticals", available at <http://www.kilpailuvirasto.fi/cgi-bin/english.cgi?luku=news-archive&sivu=news/n-2000-02-07>.

¹³ Pharmacies can locate in shopping centres but not inside supermarkets. However, a pharmacy service point can be located in groceries.

¹⁴ See also the judgment of the Court of Justice in Case C-84/11 concerning the interpretation of Article 49 TFEU and the application of the Medicines Act with respect to the conditions set for the University of Helsinki to establish subsidiary pharmacies. The judgment is available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=124184&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=548115>.

19. Article 44 of the Medicines Act has also been interpreted to prohibit the ownership by pharmaceutical companies and wholesale companies of pharmacies. Hence, there is no vertical integration between pharmaceutical companies and wholesale companies and pharmacies.

20. With regard to the demographic criteria for establishing a pharmacy, Article 41(2) of the Medicines Act states that the Fimea makes decisions on the establishment of new pharmacies in municipalities or parts of municipalities if the availability of medicinal products so requires, i.e. the needs testing.¹⁵ Decisions are made on the initiative of the Fimea or the municipality concerned. In assessing the availability of medicinal products, the number of inhabitants, existing pharmacy services in the area and the location of other health care services must be taken into account. The Fimea may also decide to change the pharmacy location area and transfer a pharmacy from one part of a municipality to another if it is necessary in order to safeguard pharmacy services. The aim of the needs testing is to ensure that pharmacy services can be obtained without difficulty also in remote districts. At the same time the Medicines Act provides for the number of pharmacies to be established as well as their locations. As regards providing pharmacy services, there are no restrictions regarding opening hours of pharmacies. However, according to Article 40 of the Medicines Act the pharmacy licence may incorporate conditions pertaining to the opening hours in order to safeguard the availability of pharmaceuticals.

21. Article 41(2) of the Medicines Act states further that the Fimea may decide to close a pharmacy if the availability of medicinal products no longer calls for a pharmacy in relation to the number of inhabitants, existing pharmacy services in the area and the location of other health care services concerned. Closure decisions may not be enforced before the pharmacy licence has become available unless the licensed pharmacist concerned has announced willingness to submit to the decision. Pharmacies in Finland have experienced high profitability in populated areas.¹⁶

22. In addition, Article 41(3) of the Medicine Act states that the Fimea must consult the municipality concerned before making decisions referred to Article 41.

23. With regard to the retail prices, there are special provisions. The Council of State Decree on the price list for drugs determines the pharmacies' margin and hence the fixed retail price. According to Article 3 of the Decree when the prescription medicines are sold from the pharmacies, the price is to be determined according to the table below. The Decree has been interpreted as meaning that pharmacists may not give any rebates to their customers and thus deviate from the regulated price.

Pharmacy purchase price (PPP)	Retail price
EUR 0-9,25	1,45 x PPP
EUR 9,26-46,25	1,35 x PPP + EUR 0,92
EUR 46,26-100,91	1,25 x PPP + EUR 5,54
EUR 100,92-420,47	1,15 x PPP + EUR 15,63
over EUR 420,47	1,1 x PPP + EUR 36,65

24. The costs of pharmaceuticals for the treatment of an illness can be reimbursed. The reimbursement depends on the severity of the patient's condition. The basic reimbursement for most conditions is currently 35% of the cost of prescription medicine. For certain more severe chronic conditions the reimbursement is 65% of the costs and in some even more severe cases 100% of the costs (here a co-payment of EUR 3 is charged for each medicine purchased at one time). Also, it is regulated that new pharmaceuticals during an introduction period of two years all are reimbursed in the 35% category

¹⁵ The establishment of an on-line pharmacy also requires a licence from the Fimea but it is not subject to a needs testing.

¹⁶ Report by the Fimea was published (available only in Finnish) on 6 November 2013.

until enough evidence is gathered about their efficiency. There is also a ceiling for patients' costs of the pharmaceuticals. The ceiling is currently at EUR 610. If a patient has yearly costs above EUR 610, only a service charge of EUR 1.50 per delivery is charged.¹⁷

25. As a complement to the reimbursement of pharmaceuticals Finland introduced the reference price system to the pharmaceutical market in April 2009.¹⁸ The aim of the reference price system was to reduce prices and it is applied when there are generic pharmaceuticals available on the market. An ex-ante report published by the Ministry of Social Affairs and Health in July 2009 estimated that the reference pricing system would decrease prices by 10%.¹⁹ In order to save public funds the sale of generic pharmaceuticals are promoted. Hence, the reference price system is a vehicle to achieve maximum price competition. Generic pharmaceuticals are usually much cheaper but their sale would not expand if the patient was reimbursed regardless of the price. With the reference price system only the cheapest pharmaceutical, i.e. the cheapest form a so-called price tube from which the pharmacy may select the product, is reimbursed. The price tube is discussed below in point 7. If the patient insists on ordering another product, the patient has to pay the price difference himself. In practice generally the cheapest product will be chosen.

5. International donors

26. International donors of medicines do not play a role in Finland.

6. Public and private insurers

27. The Finnish health care system is organized through a National Social Health Service system. The system covers all Finnish residents and is mainly financed from tax revenues. The municipal health expenditure is financed from municipal tax revenues and the state subsidy to the municipalities. In addition, the Social Insurance Institution provides a National Health Insurance scheme which covers part of the costs of health service, such as prescribed pharmaceuticals, private medical and dental consultations and private diagnostic tests and treatments. The Ministry of Social Affairs and Health is responsible for the health care subsidies to municipalities as well as for the National Health Insurance regulation. Voluntary health insurance is, with the exception of complementary insurance, of minor relevance in Finland.

7. Generics competition

28. The system where pharmaceuticals are exchanged to the cheapest products by pharmacies as well as the reference price system have led to the emergence of generic products and have also decreased prices. The sales of generic products account approximately 50% of the sales of pharmaceuticals.

29. According to Article 57b of the Medicines Act, when supplying a medicinal product on the basis of a prescription by a physician, pharmacies must exchange it to the comparable publicly available medicinal product on the list of mutual comparable pharmaceuticals whose price is the lowest or the price of which differs from the lowest price:

¹⁷ More information about the reimbursements for medicine expenses is available at <http://www.kela.fi/web/en/reimbursements-for-medicine-expences>.

¹⁸ More information about the reference price system is available at <http://www.kela.fi/web/en/reimbursements-for-medicine-expences>.

¹⁹ The report published by the Ministry is available at http://www.stm.fi/c/document_library/get_file?folderId=39503&name=DLFE-9829.pdf. See also the Ministry's Press Release: "Reference pricing in Finnish pharmaceutical markets: pre-policy evaluation", available at http://www.stm.fi/en/publications/publication/-/_julkaisu/1420890#en.

- by no more than EUR 1.50 when the product costs less than EUR 40; or
- by no more than EUR 2.00 when the product costs EUR 40 or more.

30. This is called as a price tube. The lowest-cost price among mutually comparable medicinal products is defined as the retail price inclusive of value added tax of the lowest-cost product on the first day of each quarter-year period or, when reference price groups are in effect, of the lowest-cost reimbursable product in the reference price group. No exchange must be made, however, if the prescriber of the medicinal product has forbidden exchange on medical or treatment grounds by making an entry to that effect in the prescription, or if the purchaser of the medicinal product refuses the exchange.

31. As regards cases, competition concerns in the pharmaceutical sector have derived, for example, from the rebates which were given by pharmaceutical companies to pharmacies from the wholesale prices of pharmaceuticals. The rebates primarily related to pharmaceuticals which could be substituted by generic products. An individual pharmacy was tied to the products of a pharmaceutical company in a manner of which limited the possibilities of competing pharmaceutical companies to obtain shelf space for their products from the pharmacies and hence to make the pharmaceuticals available to customers. Such agreement limited customer choices and had effects on competition between pharmaceutical companies. Since, due to regulation, the retail prices of medicines shall be the same for all customers, the discount prices did not extend to consumer prices. The FCA found the practice to be a breach of the Competition Act and Article 81(1) of the EC Treaty (currently Article 101 TFEU). In 2006, in the course of the FCA's proceedings, a law reform was passed according to which the manufacturer and importer is obligated to sell the medicinal product to all pharmacies at the same price. The case was closed by a decision taken on 20 March 2006, as the undertakings involved had abolished the discount systems under investigation and as the above-mentioned new special enactment with regard to pharmaceuticals which prohibits rebates unless the same rebate is given to all pharmacies had been adopted.²⁰

8. Concluding remarks

32. The FCCA has stated that there are structural barriers to competition in the pharmaceutical sector, in particular related to the establishment of pharmacies. The FCCA has therefore recommended the removal of needs testing in connection with the establishment. It has also recommended the removal of the restrictions on the number of pharmacies. In addition, the company form of a pharmacy should be freely chosen.

33. The FCCA also considers that price competition in the pharmaceutical sector could be enhanced in various ways. The price conforming to the pharmacy mark-up scheme could be a maximum price, and pharmacies could freely determine the price of a product below that tariff. Price competition would also be enhanced by including parallel imports in the reference price system, already when the patent of the original pharmaceutical is still effective. In addition, the sale of self-medication also outside the pharmacies could promote price decreases.

34. The actions which the FCCA has taken in the pharmaceutical sector have mainly consisted of advocacy efforts. The number of reforms the FCCA has proposed – and which have been opposed, for example, by the reason of the safety of pharmaceuticals - requires the reformation of the above-described system as a whole. The FCCA considers that the goals of the safety of pharmaceuticals and the efficiency of the system can be pursued simultaneously to the benefit of consumers. In the beginning of 2014, the FCCA was invited to the working group on the developing of pharmacy sector in Finland.

²⁰ See the FCA Press Release: "FCA finds rebates given by medical companies to pharmacies unlawful", available at <http://www.kilpailuvirasto.fi/cgi-bin/english.cgi?luku=news-archive&sivu=news/n-2005-12-07>.