

Unclassified

DAF/COMP/GF/WD(2014)18

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

16-Jan-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 Hungary

-- Session III --

This contribution is submitted by Hungary 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

JT03351169

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)18
Unclassified

English - Or. English

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Hungary --

1. Supply conditions

1.1 Do you consider that in your country there is an adequate and reliable supply of affordable drugs of an acceptable quality?

1. In general the supply of medicinal products in Hungary is adequate and reliable; drugs of an acceptable quality are available at affordable prices.

2. The rules concerning the marketing of medicinal products are compatible with European Union law; the pharmaceutical authority (GYEMSZI, National Institute for Quality- and Organisational Development in Healthcare and Medicines) is responsible for authorising the distribution of medicinal products and for ensuring their safety.

3. In Hungary only drugs which have been authorised for distribution can be marketed.

4. The admission of drugs into the health insurance system occurs via the administrative procedure of the National Health Insurance Fund. The aim of the system is to guarantee that drugs are available at affordable prices, in the proper time and through a transparent procedure. Over the counter (OTC) drugs are typically not subsidised by the health insurance system.

5. In the case of hospital drugs the rules on public procurement prescribe that certain groups of active substances may only be procured in a special joint procurement procedure which covers all public health institutions in the country.

1.2 If not, can you describe the extent of the problem and possibly quantify it?

6. It may be difficult to obtain certain non-subsidised prescription drugs intended for special patient populations. Drugs for certain rare diseases and conditions can be expensive and patients may not be able to afford them.

7. Furthermore, it may be difficult to obtain more expensive drugs if their use is only allowed with the collaboration and supervision of a health institution (i.e. if they cannot be prescribed and bought in a pharmacy). As a general rule, hospitals operating in the framework of the compulsory health insurance system are responsible for supplying medicinal products (i.e. they should provide inpatients with drugs), but there is generally not enough money in the budgets of the hospitals for this. Therefore, in the case of those drugs which may also be bought by patients on prescription, the procurement and financing of medicinal products by hospitals is not a realistic alternative to patients buying the drugs themselves, especially in the case of more expensive drugs.

8. In Hungary, hospitals are typically state-owned and operate in the framework of the compulsory health insurance system. The majority of hospitals are obliged by law to conduct centralised procurement

procedures regarding certain drugs. Consequently, in the case of certain subsidised drugs it is not on the market of the drug itself where there is competition but on the market of the affected active substance, and this typically lasts for one year. In comparison to the situation that existed in the past where undertakings competed to supply single hospitals, or in the case of joint procurement to supply several hospitals, undertakings now compete for a substantially larger market. The higher stakes may incite tenderers to make cartel agreements.

1.3 What are the main reasons for these problems? What solutions have you attempted?

9. One of the main reasons why certain drugs cannot be afforded is that social security funding is limited; this flows partly from the low Hungarian GDP. The state as institution-owner and as financing entity applies various methods – including competition – to try to keep the prices of drugs down in order to be able to provide a wide range of drugs and better access to them.

1.4 What role can competition policy play to improve the situation (both through competition law enforcement and competition advocacy)?

10. The GVH can take action when there is evidence of collusive behaviour between competitors or of other prohibited practices. For example, in 2000 the GVH initiated proceedings against three associations in the pharmaceutical sector, the members of which were producers and distributors. The associations had agreed to provide recommendations to their members that they apply a 8,5% price increase vis-à-vis their customers. As a consequence more than half of the members notified the Ministry of Health, the National Health Insurance Fund, the wholesalers as well as the administrators of the IT systems of the pharmacies of a price increase the extent of which in the great majority of the cases was an identical 8,5%. The GVH ordered the suspension of the practice by an interim measure and later in its final decision the GVH found that the recommendation of the associations constituted indirect price fixing and imposed fines on the associations.

11. Having regard to the fact that in Hungary the conditions governing how drugs can be marketed (for example which group of drugs will be subsidised under which system or what the extent of the subsidy will be in percentage terms) are determined in the procedures of state authorities, the competition authority – especially since EU-accession – plays no direct role in this process.

12. When the system of subsidies was reformed in 2004 the GVH pursued competition advocacy work in order to improve the transparency and predictability of the proceedings concerning the admission of medical products for subsidisation into the social security system as well as to enhance the ability of the admission procedure to make use of the potential competition (for example concerning the generic markets the GVH recommended solutions which could generate, utilise and strengthen price competition).

2. Manufacturing level

2.1 What kind of regulation, if any, exists on ex-factory prices of originator drugs?

13. Ex-factory prices are not directly regulated; it is only the retail prices of the drugs that are determined when they are being admitted into the social security subsidy system. However, considering that in the case of subsidised drugs there are fixed (maximum) wholesale and retail margins, in practice this means that ex-factory prices will also be determined during the admission procedure.

14. The regulation of retail prices enables price-competition to emerge among the drugs (on the level of the active substances as well as among drugs that are competitors on the therapy level) when they are being admitted into the social security subsidy system; however, this affects generic drugs to a larger extent than originator drugs. In respect of originator drugs, lower prices may be negotiated due to the so

called subsidy volume agreement between the National Health Insurance Fund and the manufacturer by which the market of a given product volume is guaranteed for the manufacturer in return for accordingly lower prices.

2.2 *What kind of regulation, if any, exists on ex-factory prices of generic drugs?*

15. The ex-factory prices of generic drugs are also determined when the drugs are being admitted into the social security subsidy system. The rules governing the admission of drugs into the social security subsidy system has a further impact on the ex-factory prices of the generic drugs: according to the legal rules, in order to obtain admission into the social security subsidy system the distributor must offer lower prices than the prices of the drugs that had been previously admitted into the system. In the case of the majority of the drugs that are already in the subsidy system the National Health Insurance Fund can achieve lower prices by applying price-bids (so called blind bids relating to single groups of active substances).

2.3 *Are you concerned that this regulation may be stifling price competition or innovation?*

16. Theoretically, in the case of generic drugs it cannot be precluded that the prices get so depressed under the current system that on certain markets only one market player remains. However, considering that generic drugs can get back into the subsidy system through a relatively simple procedure, this concern is rather hypothetical.

17. Due to the small size of the Hungarian market it is unable to exercise considerable influence on innovation, as even those companies which pursue manufacturing in Hungary only sell an insignificant amount of their production in Hungary. As a general rule, the geographic market of the pharmaceutical products is worldwide.

2.4 *Have you ever performed a market study that has looked at this regulation?*

18. The GVH has not conducted market study or sector inquiry either on the regulation of the ex-factory prices of generic drugs and it is not aware of any other study dealing with this issue.

2.5 *Do you rely mostly on local manufacturers of drugs or on foreign ones?*

19. Although a significant percentage of the generic drugs that are used in Hungary are also manufactured in Hungary, there is basically no discrimination between Hungarian and foreign manufacturers. The manner in which the authorities regulate this area is generally neutral from a competition point of view.

2.6 *Are there barriers to trade and import that constraint the availability of drugs in your country?*

20. We are not aware of any significant barriers to trade and imports. The availability of certain drugs may be limited by financial circumstances. Due to budget-constraints expensive drugs may not be put on the list of subsidised drugs for a long period of time even if they are deemed as eligible for admission in the admission procedure or as available for a limited group of patients in a limited number of locations (i.e. certain specialised institutions). Such drugs are typically imported and are originator drugs.

3. Wholesale distribution

3.1 *How is wholesale distribution organised in your country? Are wholesalers buying drugs from manufacturers and selling them downstream or are they simply distribute of manufacturers? Is this changing and if so in what ways?*

21. The system is of a mixed nature: according to the legal rules the biggest wholesalers are obliged to distribute the full line of pharmaceutical products (except the manufacturers refuse to provide them with the necessary amounts and types of products). However, it must also be mentioned that certain wholesalers owned by manufacturers are permitted to only trade with their own branded drugs. Both pharmacy units and hospitals are supplied with the majority of the drugs they need by pharmaceutical full-line wholesalers.

3.2 *How many players are involved in wholesale distribution? Is it a very concentrated sector? Are there many layers (e.g. large national wholesalers who supply smaller local wholesalers)? Do retailers usually stock themselves from one wholesaler or do they rely on more than one?*

22. The wholesale market is highly concentrated (it tends to be tightly oligopolistic¹). However, due to the size of the country, in the case of certain drugs there may be no multilevel wholesale supply chains or independent local wholesalers.

23. The pharmacy units generally acquire 80-90% of the drugs they need from those wholesalers which are considered to be the main suppliers and only buy drugs from other wholesalers if their main suppliers cannot provide the products they require. The two biggest wholesaler undertakings – with almost the same ratio of market share – differ from each other in terms of their ownership: the first one is owned by foreign investors, while the second one is a joint venture of Hungary seated manufacturers and retailers with mixed or majority foreign ownership.

3.3 *Are there vertical agreements in place between wholesalers and manufacturers (e.g. exclusive distribution, and exclusive territories)? What are the main characteristics of these agreements? Do you have concern that these agreements may reduce inter and intra brand competition?*

24. There are currently no cases under the scrutiny of the GVH concerning the above-mentioned agreements and the GVH has not been made aware of the existence of such agreements from any source.

25. Interbrand competition takes place in the course of the admission procedure dedicated to the subsidisation of drugs by the National Health Insurance Fund. During this procedure the final consumer price is determined that serves as the basis for the subsidisation in the social security system.

26. In the market of non-subsidised drugs no effective price regulation is present for the price and the mark-up, both interbrand and intrabrand competition are about to take place therefore. However, the intensity of such competition is considered to be low and this can be traced back to fact that consumers are not provided with easy access to either drugs or information on prices. The ban on self-handling, off the shelf access to drugs may be one of the reasons for such shortcomings.

3.4 *Are wholesalers vertically integrated with retailers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?*

27. Vertical integration is not characteristic of the Hungarian market except in the case of the already mentioned Hungary seated pharmaceutical wholesaler and a few pharmacy units. However, vertical

¹ In the supply system of pharmacy units the two biggest wholesalers' market share exceeds 80%, while the market share of the biggest three exceeds 90%.

networks based on contractual relations are of more significance than integration as far as ownership is concerned. The GVH estimates that participants of the complete retailer market (almost 40% ,ca. 6-700 retailers and 4-5000 pharmacy units) are tied to the two biggest pharmaceutical wholesalers by such kind of contractual relations.

3.5 *Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?*

28. The GVH has had no cases in the last 10 years concerning abuse of dominance and has only had a few cases dealing with a restriction of competition²:

- VJ/112/2004., Ten pharmacy wholesaler undertakings had narrowed the scope of their services due to an expected rise in the price of drugs, however, the GVH did not establish any abusive conduct.
- VJ/57/2008., Hungaropharma Zrt.; creation and operation of the “Gyöngy” strategic partnership in which small pharmacies entered into cooperation agreements with Hungaropharma, a wholesaler of pharmaceuticals. The GVH found that the pharmacies had violated both Article 101 TFEU and the relevant provision of the Hungarian Competition Act by agreeing to maintain promotional prices and by undertaking to submit all individual promotions to the approval of the council of the members of the network. The GVH prohibited the continuation of the infringement but did not impose a fine.
- VJ/28/2013., EUROMEDIC-PHARMA Zrt., HUNGAROPHARMA Zrt., TEVA Magyarország Zrt.: Budapest Egészségközpont Zrt. invited tenderers for an accelerated procedure for the award of the public supply of infusion solution and drugs under a framework agreement with a net value of 5 million HUF. The tenderers engaged in bid-rigging, influencing the terms of the tender and sharing the market of the products concerned in the procurement procedure.

29. While the above cases cannot be interpreted as resulting from the then-existing market climate, there was a cartel case in 2000 which was a direct result of the regulation of this area.

3.6 *Are there special provisions or regulation in place to ensure that rural and sparsely populated areas are served by wholesalers?*

30. There are no legal rules in place to ensure that rural and sparsely populated areas are served by wholesalers.

3.7 *Are wholesalers subject to regulation on prices, profits or margins?*

31. The ministerial decree³ only determined the amount of the wholesale mark-up of the subsidised drugs.

3.8 *Are they subject to any other type of regulation that may affect the prices paid by final consumers or the availability of drugs to final consumers?*

32. The prices that may be charged for subsidised drugs are limited at both the manufacturer and wholesale levels due to the regulation of the amount of the mark-up that may be applied, and at the retailer

² VJ/93/2004., VJ/112/2004., VJ/60/2006., VJ/33/2007., VJ/57/2008.

³ 5/2007 (I.24.) EÜM rendelet

level by the admission procedure dedicated to the subsidisation of drugs by the National Health Insurance Fund.

33. There are certain legal obligations placed on pharmacies. For example, pharmacies are obliged to stock the cheaper preferred drugs of the National Health Insurance Fund and are obliged to inform consumers about the cheapest available drug if the active substance is the same for several drugs. Additionally, pharmacies are under an obligation to confirm that a consumer has been informed of the cheaper alternative if a consumer still purchases the more expensive drug. There are also certain measures in place aimed at boosting the sales of generic drugs (for example if the cheaper generic drugs are sold the insurer provides a separate refund).

3.9 *Does the existing regulation of wholesalers cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?*

34. The GVH is not aware of any such effects.

3.10 *Have you ever performed a market study that has looked at this regulation?*

35. The GVH has not prepared any market study or sector inquiry either looking at this regulation.

3.11 *Do wholesalers/importers source drugs in countries that have lower prices (often referred to as parallel imports)?*

36. The GVH assumes that parallel imports are rare as the prices of drugs in Hungary are relatively low in international comparative terms.⁴

37. In order to guarantee a sufficient supply of drugs, there is a legal provision limiting the amount of parallel exports. According to the legal provision in question, since the summer of 2013 the licensee (manufacturer) is obliged to offer for sale its own distributed drugs to wholesalers authorised to pursue activity in the territory of Hungary if the given wholesaler individually guarantees that the drugs concerned will be used to meet Hungarian demand.⁵ The wholesaler must only sell the abovementioned drugs to healthcare services organisations in Hungary and is not allowed to export them. The wholesaler is also obliged to keep a separate record for these drugs. It is now also the case that if the National Institute for Quality and Organisational Development in Healthcare and Medicines (GYEMSZI) establishes that the potential export of a drug may affect the supply of that drug, then it may impose a ban on the wholesale export of the given drug for no longer than one year.

⁴ Ex. According to the database of the Directorate General of National Institute of Pharmacy (OGYI), as of 13 October 2013 only one undertaking had a licence for the production of 12 drugs.

⁵ Article 16 of Act XCV of 2005 reads as follows: (5) The marketing authorisation holder shall ensure that any medicinal product wholesaler authorised in Hungary shall be given adequate opportunity to distribute the marketing authorisation holder's medicinal products on the wholesale market, if the wholesaler specifically indicates that there is solid demand in Hungary for the medicinal product requested. The medicinal products purchased under this Subsection may only be sold to Hungarian healthcare service providers, and may not be exported within the framework of wholesale trading activities. The wholesaler shall keep records of the medicinal products purchased under this Subsection separately, as decreed by the minister in charge of the healthcare system.

4. Retail distribution

4.1 How is retail distribution organised in your country?

38. Pharmacies are considered to be health care service organisations. The current regulation of pharmacies places limits on the number of possible pharmacy units on the basis of geographical criteria (especially number of population and distances) and also on the ownership structure (by 2018 pharmacists shall gain majority control in those pharmacy units that are currently owned or controlled by foreign investors). The regulation of pharmacies also prohibits a pharmacist from owning more than 4 pharmacy units at the same time (the pharmacy network that has been operative since 1994 shall be terminated), and also contains restrictive rules concerning the professional management, number of staff serving in the unit, conduction of standby services and the hours of operation of pharmacies.

4.2 Who can sell prescription drugs and who can sell over-the-counter drugs?

39. As a general rule, drugs may only be sold by public pharmacies which have been granted a licence. Only certain OTC drugs which are packaged in a specific manner and which have been approved for this purpose may also be sold by traders with a special licence under strict conditions (e.g. they have to be stored in closed storages).

4.3 Are there separate retail outlets for paying out of their pocket patients and for reimbursed/non-paying patients?

40. This kind of separation does not exist in Hungary. Patients whose drugs are subsidised by the health insurance system pay a reduced price, while those patients whose drugs are not subsidised are required to pay the full price. In the case of both categories of patients, the patients' drugs are distributed by the same pharmacy.

4.4 Are there publicly owned pharmacies and what is their role?

41. Currently there are no publicly owned pharmacies in Hungary. Pharmacies located in some publicly owned hospitals are allowed to sell drugs to out-patients.

4.5 Are doctors allowed to sell the medicines they prescribe?

42. This is only possible on settlements where no pharmacies are available.. In any community without a public pharmacy or a branch pharmacy, upon the request of a general practitioner the opening and operation of a dispensing pharmacy may be authorised⁶.

4.6 Can hospital pharmacies also sell to external patients?

43. To the operation of the pharmacies special licences are required. The licence accurately determines the type of operation of the pharmacy (public-, branch-, institutional- and mobile pharmacy). Two separate types of permits can be ensured to institutional pharmacies (hospitals). The first allows the supply of medical products only to patients of the hospital. The second provides an opportunity for purchasing drugs also for outpatients and external patients. According to the above mentioned facts, institutional pharmacies are allowed to sell drugs to patients if the licence for operation makes it possible.

⁶ At the beginning of 2013 260 of such pharmacies were in operation.

4.7 *Are on-line pharmacies allowed?*

44. Community based pharmacies may also sell non-prescription drugs online if they are specifically authorised to do so. If there are no pharmacies in a particular community, then it is not possible to sell drugs online. In other words, without having a pharmacy, no on-line sale is possible. Only a very small number of pharmacies are authorised to sell drugs online.⁷

4.8 *Is it possible to locate pharmacies in supermarkets?*

45. It is only possible to locate pharmacies in supermarkets if the pharmacies constitute separate shops within the supermarkets. It is not possible to have both a pharmacy and supermarket operating in one sales area as one company.

4.9 *Are chains allowed? What percentage of all existing pharmacies are chains?*

46. The regulatory system that was in place before 2010 did not directly prohibit the establishment of chains. Nevertheless, only a small percentage of all existing pharmacies are chains⁸.

47. According to the currently effective regulation the operation of these chains has to be ceased and the external owners have to sell their majority ownership by the end of 2017, or pass over the controlling rights to pharmacists⁹.

4.10 *Are their restrictions imposed on opening hours of pharmacies?*

48. The new rules in force indirectly restrict the opening hours of pharmacies by connecting the number of the pharmacists who can be employed to the opening hours. Based on press estimations, because of the new rules around 25% of the pharmacies were forced to reduce their opening hours, or employ additional staff.

4.11 *Are their restrictions on the number and locations of pharmacies? And other retail outlets of drugs?*

49. The new legal rules in force concerning community pharmacies stipulate that they can only be established after special tenders have been conducted, in settlements (or parts of settlements) without pharmacies and the number of supplied inhabitants by a pharmacy must be at least 4000-4500, the distance between pharmacies must be at least 300 meters in settlements of up to 50,000 inhabitants, and everywhere else 250 meters.

50. There are no such rules in force for other types of drug stores and the overly strict conditions that are applied to the operation of these shops has resulted in the number of these shops being below 600, with a decreasing tendency.

⁷ 30 pharmacies out of the total 2334 in November 2013.

⁸ Out of the 2500 pharmacies existing in 2010, one chain was in operation with around 110-120 pharmacies and a further 2-3 chains with 40-50 pharmacies each. There were a few more even smaller chains, but around 60-70 percent of the market was held by independent pharmacies.

⁹ According to press rumours there are around 680 pharmacies (around 30% of the total) which are owned by non-pharmacists.

4.12 *How is it ensured that a sufficient number of retailers are located rural and sparsely populated areas?*

51. Pharmacies operating in rural areas are entitled to financial support provided that their turnover level is low and there are no further pharmacies on the same settlement.

4.13 *Do NGOs run retail outlets in your country? What impact does it have on affordability and availability? Does their presence spur price competition?*

52. No such retail outlets operate in Hungary.

4.14 *Are retail outlets vertically integrated with wholesalers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?*

53. In the retail sector vertical integration is at a very low level and producers do not have any direct influence. The number of pharmacies in franchise relationships with wholesalers is relatively low and this means that there is not an appreciable effect on competition. No, since one of the sources of the vertical integration was the liberalisation of the pharmacy market in 2007, signs of intensification of competition could be observed at the beginning of the process in the form of discounts, more dynamic advertisements, etc. Since this process was stopped from the middle of 2010 and rules became even more restrictive than those prevailing before 2007, the adverse effects of vertical integration on inter and intra brand competition could not unfold in the long run.

4.15 *Have retailers tried to obtain some buyer power through the creation of chains or by creating buyers groups?*

54. Buyer power could not develop. The strengthening of the vertical relationship between wholesalers and retailers was originally initiated at the wholesale level because the market opening on the retail level and the dynamics of the changes interfered with the stable former relations and forced increased competition on the wholesalers.

4.16 *Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?*

55. Competition cases on the pharmaceutical markets during the last 10 years:

- VJ/93/2004., Hungarian Chamber of Pharmacists; request for exemption of the ethical rules – the GVH gave the individual exemption;
- VJ/60/2006., Hungarian Chamber of Pharmacists; broadened interpretation of the Code of Conduct having anticompetitive effects, the case was closed with the acceptance of commitments;
- VJ/33/2007., the Hungarian Chamber of Pharmacists, Association of Pharmaceutical Producers in Hungary, Association of Pharmaceutical Manufactures in Hungary, Association of Innovative Pharmaceutical Manufacturers, and the Hungarian Association of Generic Manufacturers and Distributors regularly exchanged information on drug prices thereby restricting competition. Additionally, the Chamber intended to hinder the distribution of drugs outside the network of pharmacies, but the case was terminated because there was not sufficient evidence to prove the infringement;

- VJ/57/2008., Hungaropharma Zrt.; through the “Gyöngy” strategic partnership small pharmacies entered into cooperation agreements with Hungaropharma, a wholesaler of pharmaceuticals. The GVH found that the pharmacies had violated both Article 101 TFEU and the relevant provision of the Hungarian Competition Act by agreeing to maintain promotional prices and by undertaking to submit all individual promotions to the approval of the council of the members of the network. The GVH prohibited the continuation of the infringement.

4.17 *Are retailers subject to regulation on prices, profits or margins?*

56. The ministerial decree determines a maximum margin regarding subsidised products in the retail sector. According to the Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products, the prices that are charged for the subsidised medicines are determined through the processes in which they are accepted into the social insurance system, and these prices should – as fixed prices – also be applied during the sale of the products.

57. Non-subsidised products fall under the free price system regardless of whether they are OTC or prescription drugs, and there is no regulation of the prices or margins that are applied to them (they are not subject to any form of price control). Different prices may be charged by different pharmacies.

4.18 *If so does this type of regulation cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?*

58. The type of the regulation of retail margin is gradually degressive, furthermore it operates with a fixed margin on the highest level. As a result of this, the stocking of expensive subsidised medicines typically leads to a loss. This does not affect the price of subsidised medicines, but it makes it more difficult for patients to gain access to the medicines. Pharmacies have no interest in stocking all types of medicines (they are not required to do so by law), so patients sometimes have to order the medicines they want and return to the pharmacies they placed their orders in, or find alternative pharmacies that stock the medicines.

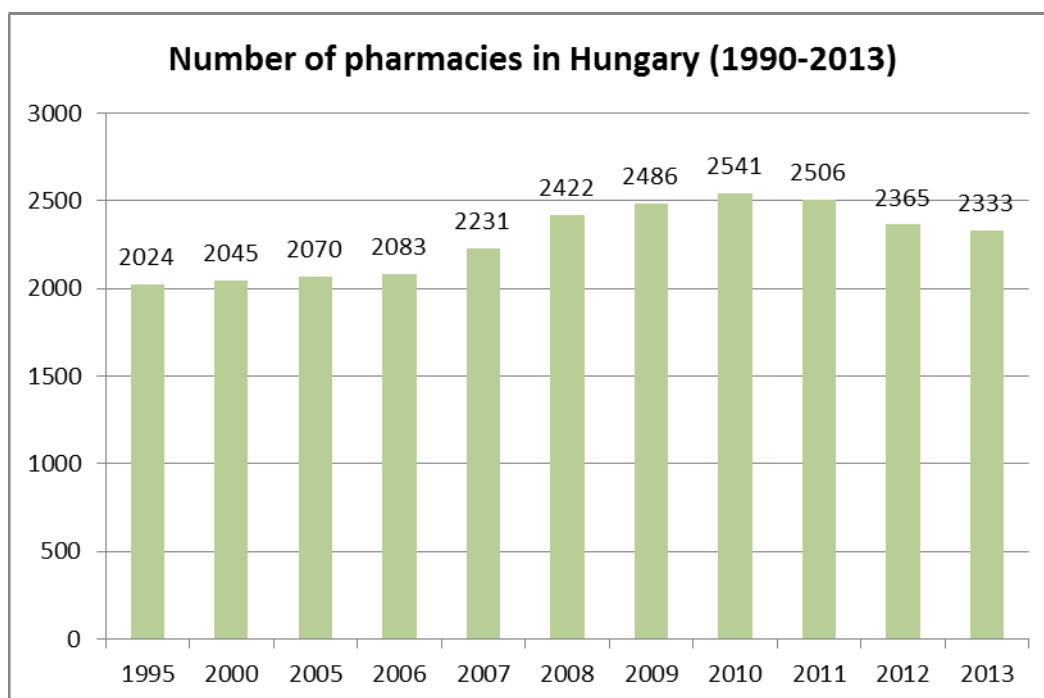
4.19 *Have you ever performed a market study that has looked at this regulation?*

59. The last piece of research that was done that looked at the effects of the liberalisation of the pharmaceutical market on consumers took place after the liberalisation of the retail market of non-prescription drugs in the Spring and Summer of 2010. No new research has been undertaken since 2011.

4.20 *Is there price competition between retail outlets? And service competition?*

60. In the pharmacies – where most of the drugs are sold – the level of price competition is very low and this is also the case as regards competition in services. Following the new legal rules governing the operation of pharmacies, the number of pharmacies has decreased and their opening hours have also shortened. Since the liberalisation of the market no significant delivery service has evolved and the number of pharmacies engaged in online sales has remained low.

61. The following diagram¹⁰ shows the changing number of pharmacies operating in Hungary.



5. International Donors

62. The GVH does not have any information on international donors, this solution is probably not typical or is only of marginal importance.

6. Public and private insurers

6.1 *Do public insurers try to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?*

63. While the decisions made by the National Health Insurance Fund influence the prices of the subsidised products, it generally does not have competence to influence the supply chain.

6.2 *Do private insurers, if present, play a role in trying to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?*

64. According to the information at our disposal, private insurers do not play a role in this issue. Private health insurance typically assists the patient to pay the required fee (according to information obtained from the press, private health insurance may cover 30-35 % of the whole fee) which the patient is required to pay.

¹⁰ <http://www.pharmindex-online.hu/hirek/a-gyogyszertarak-szama-magyarorszagon-1828.html>.

7. Generics competition

7.1 *How extensively are generics used in your country? Has their usage increased in the last few years? Do you think it has had an effect on prices of originators?*

65. According to the information at our disposal, generic drugs accounted for 45% of the drugs used in Hungary in 2010. In case of originators, the appearance of competition in the form of generic drugs among drugs which are no longer patent protected, typically leads to a margin, because one of the conditions of the acceptance of drugs into the social insurance system is that the price of the drugs being accepted should be reduced (to a certain extent) so that they are comparable to the already admitted products.

66. The National Health Insurance Fund endeavours to increase the use of generic drugs. We do not have any information as to whether this has actually occurred due to the introduction of various incentives.

7.2 *Are generics subject to the same quality and safety controls as originator drugs?*

67. In compliance with EU standards, the simplified procedure may be used to establish that a generic drug is equivalent to an originator drug.

7.3 *Does price or margin regulation at manufacturing, at wholesale and at retail level encourage the production and sale of generics? If so how? Could it be improved?*

68. The regulation of the margins that may be applied by Hungarian pharmacies does not make a distinction between drugs listed according to the above mentioned criteria.

7.4 *To what extent you consider that manufacturers affect the above incentives by providing wholesalers and retailers with financial incentives when they sell originators rather than generics?*

69. Since ex-factory prices are not fixed, it is acceptable as regards fixed retail prices for manufacturers to encourage pharmacies and wholesalers to sell their expensive products with higher margins.

7.5 *Does any other type of regulation favour/foster the sale and use of generics? For example are doctors required or incentivised to prescribe generics? Do doctors have maximum dispensing budgets? Are pharmacists required to substitute originators with generics whenever possible? Are there other types of financial incentives for doctors or pharmacists aimed at favouring the prescription and dispensation of generic drugs?*

70. There are legal rules supporting the sale and use of generics. According to pharmacies, however, these rules are not enough to eliminate the counter-incentives that derive from the difference between the absolute margin and the manufacturers' incentives. Doctors who are authorised to prescribe medication only receive information from a piece of computer software about the substitutability, subsidisation and price differences of subsidised drugs.

7.6 *Are there financial incentives on consumers to request generics rather originator drugs?*

71. The subsidisation of medical products under the social security system is based on the price of the certain reference drug within its respective group. The more expensive a particular drug is within its

respective group, the more a patient has to pay for the drug as the amount of the subsidy paid by the National Health Insurance Fund (OEP) is the same for every drug within a certain group. According to the applicable legal rules, patients should be informed about the substitutability of products in pharmacies. However, as the majority of patients are unaware of the legal rules, they are not applied properly.

72. It seems that pharmacies are not interested in generic substitution, presumably because of the bonus systems employed by wholesalers.

7.7 *To what extent you consider that manufacturers affect the above incentives by providing doctors with financial incentives when they sell originators rather than generics?*

73. Since 2007, in addition to prohibition of manufacturers pressuring doctors, various other legal rules have been introduced. For example,; an additional tax must be paid by pharmaceutical sales representatives and a detailed report has to be made on marketing expenditure. However, when a stringent punitive system was going to be implemented in order to ensure the use of less expensive drugs, it was met with resistance by doctors. According to reports which were based on the monitoring of doctors' drug prescription habits, it was found that high profile doctors have the tendency to prescribe more expensive medications. Up until this point, all attempted amendments to the legal rules concerning doctors, for example the procurement of medications based on their active substance content, have been unsuccessful.

7.8 *Do consumers perceive generics as safe and effective drugs, or does the suspicion that these drugs may be sub-standard or counterfeit encourage consumers to require/buy originators? How aware are they of the price difference between generics and originators?*

74. In order to maintain the common use of originator products, pharmaceutical companies use reinforcing promotional practices to form brand loyalty. Consumers are not properly informed about the subsidisation of medical products under the social security system and in general about the possibility of active substance content based drug substitution. In the press, information is usually contradictory and the dangers of substituting originator drugs with generic drugs are often overemphasised by doctors and pharmacists. Consequently, patients feel very uncertain about this matter. As it has been previously mentioned, patients should be informed about the price differences in pharmacies and if the more expensive drug is chosen, the decision should be confirmed by signature, although in practice this is hardly observed. While there is a Hungarian site which informs patients about the possibility of cheaper alternatives, it is barely known or used.