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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Turkey

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Turkey --

1. Introduction

1. Today, in parallel with the increase in population and health care expenditure, the pharmaceutical industry is growing each passing year. Having a different structure of demand from other sectors and specific dynamics, the pharmaceutical industry is subject to various regulations, mainly for the protection of public health and ensuring the sustainability of drug spending.

2. Similar to the growth and developments which is experienced in the world pharmaceutical sector, the regulative activities directed to the pharmaceutical sector in Turkey increased as well. The relevant statutory regulations and administrative practices largely give direction to the functioning of market and market players' behavior. In this context, regulation in the sector plays an important role in the activities of suppliers (pharmaceutical manufacturers) and distributors (pharmaceutical wholesalers and pharmacies) and affects the conditions of competition.

3. In order to examine the supply-level competition and to analyze the whole results of competitive conditions in the pharmaceutical sector, a pharmaceutical market research was conducted by Turkish Competition Authority (TCA). In preparing TCA Pharmaceutical Sector Inquiry which is published on 27.03.2013, information has been requested from organizations such as supply-level associations of undertakings (Pharmaceutical Manufacturers Association of Turkey/IEIS and Association of Research Based Pharmaceutical Companies/AIFD), pharmaceutical manufacturers (original and generic manufacturers) and Ministry of Health, Social Security Institution (SGK) and Turkish Pharmacists' Association (TEB), which executes the legal arrangements in the pharma sector. Additional detailed information was also obtained through a questionnaire distributed among suppliers in Turkey and from IMS research company.

4. Based on the information obtained from IMS, a comprehensive data set of active ingredient and drugs is gathered, as well as the size of pharmaceutical market and market shares of hospitals in the period between 2001-2011. Lastly, the information gathering process was concluded with a survey aimed at the 50 top-ranking pharmaceutical companies according to the IMS TL sales data. The survey requested information-including the information for other pharmaceutical companies in the same group-from the participants under many headings such as their operations and products; their turnovers, R&D expenditures and promotion expenditures; patents they hold and patent suits they are involved in. The survey was completed in the first half of the year 2012.

5. The TCA pharmaceutical sector inquiry is fundamentally concerned with the analysis of the structure and operation of the market at the supplier level. In addition, suppliers' activities at the retail pharmacy market and their relations with pharmaceutical wholesalers have been scrutinized.

6. Within this contribution, some main features of the basic structure of Turkish pharmaceutical market, suppliers in the market, legal regulations related with supply and distribution conditions and the

competitive environment shaped by these regulations are intended to be addressed with the assist of the final sector inquiry report.

2. Structure and Basic Characteristics of the Pharmaceutical Sector in Turkey¹

7. Alike with the global pharmaceutical market structure, the Turkish pharmaceutical sector is subject to intense public regulation and also the structure of demand is shaped by doctors, rather than consumer choice. Regarding drug manufacturers, it can be seen that the majority of the original pharmaceutical companies are operating on a global level. On the other hand, the generic drug companies are seen to be mainly local scale.

8. With reference to the size and growth of the industry, per capita health expenditure and total health expenditure share in Gross Domestic Product (GDP) in the Ministry of Health data is shown in the following table.

Table 1: Per Capita Expenditure on Health / Health Spending Share of GDP (US Dollar/%)

	1993	2002	2012
Turkey	124/ %1,8	330/ %3,8	789/ %4,4
OECD	984/ %5,5	1.565 / %5,9	2.386/ %6,9

Source: Ministry of Health 2013
Fiscal Budget Presentation

9. On the other hand, healthcare and pharmaceutical expenditure per capita of the country, the state's share of GDP and health expenditure are given in the following table.

Table 2: Health and Drug Expenditures in 2010 (US Dollar)

Countries	Drug Expenditure Per Capita	GDP Per Capita	Health Expenditure Per Capita	Drug Expenditure Per Capita	Per State's health spending /Health (%)	share in spending (%)
ABD	1.054	47.184	7.557	13,95		48
Japan	858	43.137	3.550	24,17		80
France	634	39.460	4.836	13,11		80
Germany	623	40.509	4.387	14,20		77
England	469	36.100	3.633	12,91		78
Spain	463	30.542	2.970	15,59		71
South Korea	234	20.757	1.387	16,87		56
Turkey	154	9.732	659	23,37		76
Singapore	122	43.867	1.417	8,61		37
Brazil	108	10.710	918	11,76		46
China	39	4.393	186	20,97		48
India	11	1.477	48	22,92		30

Source: AİFD, August 2012, Turkey Pharmaceutical Sector Report, Vision 2023

10. Analyzing the data, the first two countries that has the world's largest pharmaceutical market is seen as U.S. and Japan. Turkey's World ranking is approximately 14-16, and the share of the global market is about 1%.

¹ The data contained in this section, is quoted from Pharmaceutical Sector Inquiry Report.

11. The recent growth in the pharmaceutical market of Turkey is based on two decisions: assigning hospitals of Social Security Administration (SSK, now SGK) to the Ministry of Health and leaving distribution of drugs solely to pharmacies.

12. Considering the turnover of the top 50 manufacturers in various categories, the data regarding the size of the pharmaceutical industry are given below.

Table 3: Turnover of the Survey Participant Companies between 2006-2010

	2006		2007		2008		2009		2010	
	Distribution (TL)	Share (%)	Distribution (TL)	Share (%)	Distribution (TL)	Share (%)	Distribution (TL)	Share (%)	Distribution (TL)	Share (%)
Pharmacy	7.949.133.414	93,2	9.142.031.762	93,7	10.252.753.130	93,2	11.470.344.203	93,6	11.551.882.362	92,9
Hospital	530.568.707	6,22	570.158.128	5,84	700.236.586	6,36	706.052.736	5,76	790.589.140	6,36
Other	45.743.704	0,54	49.567.463	0,51	48.943.472	0,44	79.004.162	0,64	88.352.489	0,71
TOPLAM	8.525.445.825	100	9.761.757.353	100	11.001.933.188	100	12.255.401.101	100	12.430.823.991	100
Prescription	8.283.419.880	97,2	9.524.416.657	97,6	10.727.516.480	97,5	11.937.339.328	97,4	12.094.253.920	97,3
Non-prescription	194.787.042	2,28	184.368.120	1,89	207.818.140	1,89	250.062.730	2,04	258.291.066	2,08
Other	47.238.903	0,55	52.972.576	0,54	66.598.568	0,61	67.999.043	0,55	78.279.005	0,63
TOTAL	8.525.445.825	100	9.761.757.353	100	11.001.933.188	100	12.255.401.101	100	12.430.823.991	100
With Reimbursement	8.001.448.006	93,9	9.269.651.208	95	10.508.398.820	95,5	11.766.146.810	96	11.940.185.702	96,1
Without Reimbursement	476.141.770	5,58	435.111.255	4,46	422.627.984	3,84	421.404.180	3,44	417.094.956	3,36
Other	47.856.049	0,56	56.994.890	0,58	70.906.384	0,64	67.850.111	0,55	73.543.333	0,59
TOTAL	8.525.445.825	100	9.761.757.353	100	11.001.933.188	100	12.255.401.101	100	12.430.823.991	100
Original	6.157.593.207	72,2	7.071.814.124	72,4	7.788.113.528	70,8	8.608.265.966	70,2	8.541.475.026	68,7
Generics	2.299.758.917	27	2.575.924.211	26,4	3.074.302.324	27,9	3.436.321.152	28	3.716.487.895	29,9
Other	68.093.701	0,8	114.019.018	1,17	139.517.336	1,27	210.813.983	1,72	172.861.070	1,39
TOTAL	8.525.445.825	100	9.761.757.353	100	11.001.933.188	100	12.255.401.101	100	12.430.823.991	100

Source: Survey for Drug Suppliers

13. The turnover distribution of top 50 pharmaceutical manufacturer companies in pharmacy and hospital market remained stable between 2006-2010. The majority of the market (%92-93) consists of sales to pharmacies. On the other hand, in the pharmaceutical sales, share of prescription drugs is %97-98 and non-prescription drugs share is %2. The share of drugs which are in the list of reimbursement have increased steadily. In terms of original and generic drugs, it is seen that the share of original drugs which is about %72 in 2006 and 2007, decreased to %69 in 2010. Generics share rise to %30 at the same period.

2.1 Supply Conditions and Competition Between Manufacturers in Pharmaceutical Market

14. Manufacturers of branded and generic medicines are on the supply side of the pharmaceutical industry. Original drug is defined as “under patent protection when released to the market, new/original drug”. These types of companies producing original medicines are specialized in R&D, manufacturing and marketing of patented drugs.

15. Research of these companies across the globe is focused on finding new active substances (new chemical entity / NCA or developing the drugs which are already on the market and that have been

presented previously². Generic drug is defined as “a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product”.

16. If the equivalence is proved, the generic medicine is exempted from safety and efficacy phase such as pre-clinical and clinical testing stages. This kind of product is considered to have safety and efficacy as the reference product.³

17. On the supply side of the pharmaceutical industry, there are basically two types of competition. The first is competition between multiple original drug manufacturers under the same goal of innovation, the other is competition which rises from production and sale of generics. Both can serve to benefit consumers.

18. With the market entry of generic medicines, there is a motivation reducing risk for original manufacturers to develop new drugs. But at the same time, entry of generics is vital for price competition in pharmaceutical market.

19. Today, in many countries, the entry of generic medicines reduced drug prices significantly. In the United States, the first generic drug is priced %20-30 lower compared to the original drug. According to the EU Pharmaceutical Sector Report, within one year after entry of the first generic drug, 20% annual savings achieved in total. With promotion the use of generic drugs, it is known that the average market share of these drugs reaches %44-80 within one year.

20. On the other hand, the impact of price competition in generic entry depends on the extent of original and generic price regulation. The regulations limit the pricing policies of pharmaceutical manufacturers. Price regulation that determines production and supply conditions in Turkey is given in the following section.

2.2 Supply Level Price Regulation and Competition

21. In the Turkish pharmaceutical industry, state is the legislator and the largest drug buyer at the same time. Duties such as licensing and pricing are conducted by Pharmaceuticals and Medical Devices Agency (TİTCK), which is within the Ministry of Health of Turkey, while drug reimbursement is carried out by SGK.

22. Ministry of Health will determine maximum price for human medicine, according to Article 1 of “Council of Ministers Decision on Pricing of Pharmaceuticals for Human Use”⁴.

23. According to Article 2,

- Every year, 5-10 countries (from EU member states) will be determined as “reference country”.
- The lowest price for each original product in the reference country will be the reference price.

² EU Commission Pharmaceutical Sector Inquiry, p. 23.

³ EU Commission Pharmaceutical Sector Inquiry, p. 7.

⁴ Official Journal dated 30.06.2007 and numbered 26568 numbered.

- Until generic enters to the market, the original drug price shall not exceed the reference price. Once the generic granted licence, original product price may not exceed %60 of the reference price⁵. This price cap will be valid for further generics.
- Prices of generic products which have no original in Turkey, would be maximum %60 of the reference price.
- Until reference price falls below the 60% limit, it will not be reflected in the sale price to wholesalers. When the price falls below this limit, the new price can be taken up to %100 of new reference price.
- For over 20 years original products' which have more than 6,79 sale price to wholesalers, the price may be up to 80% of the reference price. And the generic prices may not exceed that price.

24. According to Article 3 of the Decision,

- in coordination with Ministry of Health and with the participation of the Ministry of Finance, Treasury and State Planning Organization and representatives of SSI, "Price Evaluation Commission" will be created. Commission shall meet quarterly as ordinary or extraordinary upon the invitation of one of the intuitions referred to. The Commission will be able to decide to increase or decrease of prices.
- Commission shall make an extraordinary meeting in case of euro exceeding upper and lower limits more than %5.
- Increase in price can be made only at rates to be determined by the Commission. Price changes will be implemented after 5 working days of publication. There is no waiting period for price decreases voluntarily made.

25. On the other hand, according to the "Notification on the Pricing of Pharmaceuticals for Human Use"⁶ article 5/1 (c), reference price will not be charged for non-prescription and without reimbursement drugs. For this kind of drugs, the maximum price is the highest sales price to wholesalers in the reference country.

26. According to the Notification article 6/1(d); "Co-marketed product may be the same price with the original product." In the same article, there is a provision aimed at protection of competition and dynamics of market. Hereunder, "to get a price which is %50 lower than the products available in the market or new to be released, this price will be evaluated by the Commission, with the aim of protecting competition and market balances, and availability of products."

27. In article 8/2 of Notification, it is said that the price of generic drugs will not be affected by changes in the price of the original product. The reference price reductions will not be reflected in the prices until exceeding the %60 limit.

⁵ According to the previous regulation, generic products prices can be up to 80% of the reference price and the market entry of generics did not affect the price of the original product. After these amendments, with the generic product entering the market, original drugs and generic drugs to all who may enter the market in the future can be given up to 60% of the reference price.

⁶ Official Journal date 22.09.2007, number 26651 (Herein after Notification)

28. When price increase decision is taken, it will apply to all products and firms' demand not to increase or making discounts will be taken into account, according to article 9/7 of the Notification.

29. In order to evaluate the effects of pricing regulations on competition, some survey questions were directed to the drug manufacturers within the preparation of TCA Pharmaceutical Sector Inquiry.

30. Seven of commenting manufacturers stated that pricing and reimbursement policies has put pressure especially on the original drug manufacturer companies, the reference price and the reimbursement terms are very strict, and these conditions reduce investments/jeopardizes the pharma sector.

31. Five of commenting manufacturers stated that, due to the fixing of euro rate of exchange which is used in determination of reference price, prices remain at low levels.

32. In TCA Sector Report, it is determined that suppression of drug prices by price regulation may affect R&D negatively. Similarly, it stated that R&D investment is much lower in Turkey, compared with global trend, and there is no foreseen development in this area

33. On the other hand, it is stated that the most effective way to enter a market is to apply low prices in pharmaceutical sector. Therefore, drug pricing system has to be designed as to reward low-cost drugs. However, in Turkey price control is provided by indexing generic drug prices to original drugs. Generic drug price is calculated as a percentage of the original drug price. The price level determined for generics is offering a point of reference and solidify prices down. This situation brings out two consequences for generic drugs. First, generic drug companies act as the original firms and make high promotional spending. Possible second result is restriction of generic entry to the market.

34. Evaluation of the information gathered during TCA Sector Inquiry, parallel with the possible consequences above, it is seen that generic drug companies uses an important portion of resources to promotional spending.

35. On the other hand, in TCA Sector Inquiry, it is expressed that the present drug pricing system in Turkey may have a promoting effect on anti-competitive agreements, between original and generic pharmaceutical companies. Under normal conditions, it is expected that generic drug entry to create competitive pressure on the original drug, get market share and reduce the average price of the relevant active ingredient. In Turkey, according to the current regulation, generic entry lowers the original drug price to %60 of reference price. In the TCA Sector Inquiry, it is stated that, due to this regulation, generic entry shrink the market nearly at the rate of %27.

36. In addition, it is said that coordination risk is existing in terms of co-marketing agreements. As said above, products that are co-marketed with the original products can be given the same price with the original product. In this case, making a co-marketing agreement instead of entry with generic, will enable the manufacturers to keep the price keep at %100 level, without the %60 drop. Such an agreement has the potential to create a loss both to the state and to the consumers. Evaluating the above mentioned regulations and comments received from manufacturers about the impact of these regulations on the market, following objectives are proposed in the sector inquiry report:

- Promoting and accelerating generic entry: In terms of authorization, for rewarding the first generic, a certain period of exclusivity can be ensured. Considering that it is the entry of first generic that lowers the price ceiling to %60 of reference price, encouraging the first generic is thus very important.

- By accepting license applications of other generic drugs or concluding the ongoing investigation, entrance of new generic drugs will not be prevented. In this context, a certain period of exclusivity can be given to the first generic drug. As an alternative or complement to this solution, there may be price premium.
- The market entry of original products which help reducing the costs can be facilitated or encouraged.
- Concerning the application of public prices can be more transparent, objective and stable.
- Resources can be encouraged to be routed to price competition.

2.3 *Wholesale and Retail Level Regulation and Competition in Pharmaceuticals*

37. Distribution activity in the pharmaceutical sector is carried out at two levels: wholesale level-pharmaceutical wholesalers and retail level-pharmacies. Wholesalers provide the product stream between suppliers and retailers and doctors /hospitals. Wholesalers fulfill the function of the stocking, together with distributing.

38. Pharmaceutical wholesalers, whose activities specified in the relevant legislation are divided into two according to the distribution type as “tenderer pharmaceutical wholesalers” and “pharmacy selling wholesalers”.

39. One of the most important features observed in the pharmacy sale segment of the wholesale drug market is, the high level of concentration. Large-scale wholesalers are able to achieve higher market shares by transferring the reductions they get to retail level and making sales in more favorable conditions. There is the “buyers’ high level of price sensitivity” behind the intensive competition in this segment.

40. In Turkey, two -national level- pharmaceutical wholesalers in the wholesale distribution and pharmacists cooperatives, come to the forefront with their share in total sales and their large distribution networks. On the other hand, there are also local level pharmaceutical wholesalers operating at small scale.

41. On the retail distribution level of the market, thousands of pharmacy operates. Pharmacies are subject to individual ownership. Their opening hours, and places according to population density is subject to regulation.

42. In terms of pricing, similar to the regulation for manufacturers above terms are implemented in the distribution segment. Basically, the price control which affects the ex-factory price, include the determination of the profit margin of pharmaceutical wholesalers and pharmacies. In the decision of the Council of Ministers article 7, the profit margin of pharmaceutical wholesalers and pharmacies while determining retail price of products is as follows:

Table 4: Pharmaceutical Wholesaler and Pharmacy Rate Of Profit

Of sale price to pharmaceutical wholesalers;	Pharmaceutical wholesalers Profit (%)	Pharmacy Profit (%)
Up to 10 Turkish Lira (including 10 TL)	9	25
Between 10 - 50 Turkish Lira (including 50 TL)	8	25
Between 50 – 100 Turkish Lira (including 100 TL)	7	25
Between 100 - 200 Turkish Lira (including 200 TL)	4	16
Over 200 TL	2	12

Source: Council of Ministers Decision

43. In TCA Sector Inquiry, it is expressed that pharmacists have no motivation for providing cheaper drugs under present pricing policy. It is seen that, for the majority of the drugs (10-100 TL), pharmacy profit is the same. As a competitive solution to this practice, it is mentioned in TCA Pharma Inquiry that all price ranges need to be re-made gradual, so a competitive measure will be taken in terms of demand.

44. On the other hand, there is “ordered distribution” enforcement for some prescriptive drugs. In this context, some prescriptions are distributed exclusively and shared between pharmacies within the defined sequence. This type of distribution is implemented for a limited number of group of drugs. According to Turkish Pharmacists’ Association (TEB) Law Article 39, it’s among the duties of TEB Central Committee to make agreements with health care institutions and organizations in this regard.

45. Based on this legislative provision, TEB Central Committee operate protocols with official institutions and organizations on behalf of pharmacies. Among them, there are protocols signed with the Ministry of Finance and SGK.

46. There has been numerous complaints to TCA about ordered drug distribution. TCA decided to send a written opinion to related public bodies that ordered drug distribution which is signed with TEB on the basis of the protocols be re-evaluated in the context of competition law⁷.

47. In general, at the distribution and retail level, following objectives are proposed in the inquiry report:

- As stated above, demand-side measures can be taken to reduce the incentive of pharmacy stores and pharmacies on selling more expensive drugs. In this context, segmented profit margin in all price ranges can be a solution.
- On Turkey, consumers are not adequately supported in buying the cheapest drugs. Yet, the pharmacists who are on the demand side tend to give the most appropriate one (due date, discount) instead of the cheapest drug.
- On the other hand, the doctors as the most important actor of demand side, are not sensitive to price. Therefore, demand-side measures need to be strengthened to prefer the cheapest drug.
- Writing drug name to prescriptions is one of the factors that limits the effect of equivalent (generic) drug. In this case, the patient tends to prefer the prescribed drug. Original drug has an advantage of being the first product on relevant active ingredient, and having brand awareness as a result of intense promotions. At this point, writing active ingredient to the prescription instead of drug name can affect the demand and equivalent drug enforcement.
- In order to make consumers more active on the demand side, the current system needs to be developed. In this context, firstly, it is necessary to raise the level of awareness of consumers about their participation to drug spending. For this, informing should be made about patient share and equivalent drug enforcement. In every drug supply by pharmacies, consumers should be informed about how they are going to pay for each equivalent drug segment. Also informing should be performed on rational drug use as a general information.

⁷ Turkish Competition Board decision dated 05.04.2007 and numbered 7-30/291-108.