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THE CURRENT CONDITION OF THE OTC MARKET IN TURKEY, AND SOLUTION PROPOSALS FOR DEBATES ON ITS DIRECT INTRODUCTION TO CONSUMERS

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Abstract

Today, the Turkish Over-the-Counter (OTC) market ranks 3rd among developing markets in terms of expectations for the annual growth rate, and this parallels the increase in the general consciousness and awareness about health care in Turkey. Pharmaceutical companies, whose profit margins have decreased due to legislation impacting the sector, have turned towards OTC and this has led to growth in the field. There is currently a lack of OTC regulations and classifications in Turkey, although a regulation does exist for prescription drug and over-the-counter drug classifications intended to be in accord with the European Union. Due to the differences among various EU countries on this issue and the chaotic situation that has subsequently arisen, however, there have been varying degrees of negative impacts on the prescription drug and OTC drug market in Turkey for doctors, patients, pharmacists, public funding and the economy. This study assesses the current status of the OTC market in Turkey through a consideration of the criteria needed for its reconstruction, EU legislation, data on health care, and national priorities. Furthermore, the study critically discusses the legality and potential benefits of direct advertising to consumers, which is a key point in supporting rational drug use and self-medication.

Keywords: Over-the-Counter (OTC) market; Pharmaceutical industry; Direct introduction to consumer

INTRODUCTION

The concept of OTC, in other words 'Over-the-Counter' is defined as non-prescription drugs, or drugs sold over the Counter. Non-prescription drugs are the drugs that can be sold without a prescription written by a physician, which are used in the treatment of minor ailments. Non-prescription drugs constitute about 15% of the total drug market in the world, with a sales figure of over $ 100 billion dollar. (Deloitte Report, 2010) This figure is about one sixth of the total drug market. In many countries, development of non-prescription drug market is determined by socio-economic conditions and the structure of the country's health sector. This leads to specific

applications differing in each country. For example, patient safety is the main criteria for discerning between prescription and non-prescription drugs in European Union (EU) member states. Drugs not included in the criteria of prescription drugs can be sold over the counter. However, this classification has been left to member states. Member States are free to make this classification, by taking considering the characteristics of their own communities. Therefore, a drug can be sold with prescription in a member state, and without prescription in another member state. Today, this concept is divided into two:

- Products with drug status, which are excluded from reimbursement
- Products, drug status of which have been canceled, which are not reimbursed, and prices of which are freed.

In addition, these products are classified in two categories, as the ones from the Ministry of Food, Agriculture and Livestock, and the ones from the Ministry of Health. Intermediate products, C/E certificated products, medical baby foods, and permitted products in cosmetic status. Since there are many definitions, documents and permits on this topic, the situation has became chaotic for both the manufacturer and consumer.

Global OTC market showed a growth of 6% in the last 4 years, and this rate of growth can be observed as low in developed markets, and high in smaller markets. OTC market can be assessed in its sub-groups. The wide range of situations stated above is reflected on the indication as well. For example, flu and allergy, vitamin-mineral, gastrointestinal supports, derma-cosmetic products, and products that can be called 'others' cover 22%, %17, %21, %14, %14 and 12 of the total, respectively.

The most developed over-the-counter drug market is in the United States of America. The relevant legislation and practices in the United States date back to the year 1951. The United States is known for its liberal policies intended for over-the-counter drugs. In other words, both pricing and direct promotion towards consumer can be made freely. There is no restriction on the sale of over-the-counter drugs, and such drugs can be sold in supermarkets, as well. Despite this sense of freedom, the obligation to ensure the availability of enlightening and clear information on the labels of drugs, in a format that can be easily read and understood by patients, is an important dimension of the non-prescription drugs regulations in the United States, intended for consumers. One of the important consequences of the liberal approach to non-prescription drugs is the decrease in the prices of non-prescription drugs, which is caused by the competition. For example, the 30-day usage cost of the drug named Claritin that has transited from prescription status to 'over the counter' status, fell from $ 96.30 to $ 22.37, after that transition. And the prices of generic versions of the drug in question fell below $ 2. **(**OTC Pazarı, 2012)

OTC MARKET IN TURKEY

The share of Turkey's health expenditures in Gross Domestic Product (GDP) has been growing rapidly in recent years. This rate raised from 3.6% (in 1990) to 7.7% (in 2004). The share of drug in total health expenditures followed a fluctuating course. The lack of data in this area does not allow for a considerably detailed evaluation. Nevertheless, a significant increase in drug expenditures has not been realized in total. In OECD's most current data, the drug expenditure per capita in Turkey in 2000 is declared to be 110 dollars (PPP). This figure constitutes a high total in a population of 70 million, but in fact; Turkey comes bottom of the list in OECD, with respect to drug expenditure per capita. The main issue in terms of public finance is that such a big amount of drug spending as 80% is reimbursed by public institutions. Social security deficits reaching high percentages as well as debt payment obligations urge governments to make retrenchments in this area.

Turkey is one of the first 15 largest countries in the pharmaceutical sector in the world. The Turkish pharmaceutical market is considered to be the 6th and 14th largest pharmaceutical market in Europe and the world respectively. Today, there are approximately 300 domestic pharmaceutical companies and 49 pharmaceutical manufacturing facilities in Turkey. Cough, Catarrh and Allergy drugs rank first, while Vitamins rank second with 26% in Turkey, according to the distribution in OTC pharmaceutical market in 2008. They are followed by analgesics with 19%. (Türkiye'de OTC Pazarı, 2012)

Institutional Framework in Turkey

Classification

The Regulation on Classification of Human Medicinal Products No. 25730 published in the Official Gazette dated 17 February 2005 has been prepared in accordance with the relevant EU Directive 2001/83/EC. In the regulation, the segregation between prescription and non-prescription drugs is determined with an understanding that prioritizes effective and correct use of drugs, i.e. patient safety. In Turkey, there is not any clause intended for the definition of non-prescription product, as in the EU; but instead, conditions for being a prescribed product are specified.

Pricing and Reimbursement

The Ministry of Health controls the prices of all drugs including over-the-counter drugs, as per the Pharmaceuticals And Medical Preparations Law No. 1262, and the Health Services Fundamental Law no 3359. In addition, regarding the pricing of the products called OTC products in the reference countries, there are the following statements in the Communiqué on

Prices of Human Medicinal Products published in the Official Gazette No. 25391 dated 3 March 2004:

Article 7 – New prices of products classified as OTC in all the reference countries are determined by applying new profitability ratios to their current factory selling prices.

The difference between the products called OTC in the reference countries and the products that are not subjected to prescription mentioned in the Regulation on Classification of Human Medicinal Products No. 25730 being enforced in Turkey; and the reason of such a separation in naming are unclear.

The reviews related to the determination of the drugs, which will be included in or excluded from the list of the drugs to be reimbursed in Turkey, will be made by the "Reimbursement Commission" formed by the Cabinet Decree No. 2004/6781 dated 06.02.2004. Some of non-prescription drugs are included while some others are not included in the reimbursement list. However, the reason of segregation between over-the-counter drugs remain unclear due to the fact that the criteria taken as a basis for the list of the drugs to be reimbursed, which will be prepared by the Reimbursement Commission, and that in line with what criteria the drugs to be included in or dropped from the list will be determined is unknown.

With the Transparency Directive, the European Union (EU) defines the basic principles required to be followed by the member states for pricing and reimbursement issues, and decontrols them regarding the both issues, on condition that they comply with these principles. The main approach taken as a basis by the EU is based on the ground of that the decisions are taken in accordance with the pre-determined transparent criteria. In other words, the member states are free to define their own criteria but they are obliged to clearly declare their criteria in advance, and to be transparent in their policies. In this context, considerable differences may exist in pricing and reimbursement policies of the member states, intended for over-the-counter drugs.

Labeling

In Article 3 of the “Regulation on Packing and Labeling of Human Medicinal Products” published in the Official Gazette on August 12, 2005, it is stated that the regulation has been prepared to ensure the accordance with the European Union Directive 2001/83/EC, which is related to human medicinal products. In articles of the regulation, the expression of OTC or non-prescription drug is not used but products used for self-medication are mentioned.

It is stated that if the product is a product used for self-medication, the instructions intended for the user should be available on the outer packaging of the product; and if the product has no outer packaging, the instructions should be written on the inner packaging. In addition, in the fourth part of the regulation, it is stated that the Ministry of Health will publish the

general principles intended for users, in the form of a guide, when it deems required or when the product is intended to be used for self-medication in particular.

Sales

In Turkey all prescription / non-prescription drugs are sold only in pharmacies. The EU legislation does not contain any restriction on selling spaces of over-the-counter drugs. However, in many EU member states, such drugs are not allowed to be sold in any places other than pharmacies.

Advertising Directly Towards Consumer

Applications intended for the promotion of drugs have been regulated by the Pharmaceuticals and Medical Preparations Law No. 1262 that has been in force since 1928. Article 13 of the law determines the boundaries for the promotion of prescription and non-prescription drugs. Accordingly, "making advertisements by motionless images or motion picture films, bills with or without light, radio or any other means of advertisement intended for praising preparations and attributing them healing effects that they have not, or exaggerating their healing effects are forbidden".

The "Regulation on Promotion Activities for Human Medicinal Products" dated 23 October 2003, prepared in a way compatible with the EU acquirements contains the following statement:

"Article 7—It is allowed to publicize products licensed/ permitted by the Ministry and produced in such a way as to be used with information and advice of a pharmacist, in case they do not require diagnosis, prescription writing or treatment monitoring by a physician or dentist, in terms of their contents or purposes. Reimbursed medicinal products are not allowed to be publicized". However, the State Council found this last provision to be against the Pharmaceuticals and Medical Preparations Law No. 1262, and consequently, this provision lost its validity by the decision on suspension of execution. Therefore, today promotion of any non-prescription drug to the public is not possible in Turkey.

In the EU, promotion of prescription drugs are not allowed to be made directly to consumers. However, promotion of non-prescription drugs are allowed. The member states have the right to restrict promotion of non-prescription drugs included in the scope of reimbursement.

Health and Drug Expenditures in Turkey:

According to OECD data, the share of total health expenditure in the gross domestic product increased in recent years. Total health expenditure constituted 3.6% of GDP in 1990, and that

ratio rose to 7.7% in 2004. The health expenditure per capita followed a similar course. In 1990, the health expenditure per capita in Turkey was 168 dollars (PPP), and that figure rose to $ 580 (PPP) in 2004 (OECD, 2006).

The public share of total health expenditure is increasing with each passing day. The public share of total health expenditure was 61% in 1990, and rose to 72.1% in 2004. In OECD sources, the most actual data showing the share of drug expenditure in total health expenditure in Turkey belongs to year 2000, and it shows the rate as 24.8%. If is taken into consideration that the total health expenditure per capita in 2000 was 446 USD (PPP), the drug expenditure per capita in the same year is calculated to be 110 USD (PPP) (OECD, 2006).

It is difficult to comment on how a course is followed by the share of drug in the total health expenditure per capita in Turkey. According to OECD data, the average share of drug in the total health expenditure is 12% between 1981 and 1987, 20.4% in 1990, 31.6% in 1994, 24.3% in 1999, and 24.8% in 2000. Therefore, there quite fluctuating and irregular course. Since in Turkey the national health accounts have yet to be prepared on a regular basis, the share of drug in the total health expenditure in recent years can be calculated by only indirect studies. According to the 1996 data released by the Ministry of Health, 88% of the total drug expenditure in Turkey is covered by the government (Tokat, 2001). In more recent studies, approximately 80% of the total drug expenditure in Turkey is estimated to be covered by the state (Kanavos, 2005).

OTC Market's Contributions to Economy:

According to 2005 IMS data, the total value of drugs sold in 1.2 billion boxes in Turkey is 6.6 billion dollar. AESGP known for his works on self-medication and over-the-counter drugs, gives the separation of prescription and nonprescription drugs in the categories formed according to active ingredients, by use of ATC (Anatomical Therapeutic Classification) classification system in its pharmaceutical market research in the EU15. AESGP lists can be taken as a basis for the definition of the total pharmaceutical market in Turkey ans the determination of the drugs that can be included in over the counter status. In this context, if a calculation is made by using AESGP lists, the possible volume of the over-the-counter pharmaceutical market in Turkey would be 503 million units of boxes with the total ex-factory price of 1.49 billion dollars, according to 2005 data. This figure constitutes 22% and 41% of the total pharmaceutical market, as a price and number of boxes respectively. When compared to that of the United Kingdom (57%) and Germany (56%), the rate on the basis of number of boxes seems to be quite low. When considered in terms of price, the ratio of the expenditure of over-the counter drugs (22%) in Turkey to the total market is higher than that of Germany (21%) and the UK (16%). 58% of the payments made for the drugs that may be included in the scope of over-the counter drugs in Turkey is calculated to be covered by the public sector (Kanavos, 2005).

Therefore, according to 2005 data, 58% of the total 503 million boxes, i.e. 292 million boxes that can be included in the over-the-counter market are deemed to be reimbursed by the public sector.

Based on the figures given above, the amount of the saving that will be created by excluding some drugs from reimbursement list, which are currently in the reimbursement list in Turkey but are not reimbursed by the social security institutions in the EU, is estimated to reach up to $ 1 billion. Therefore, a gradual and extended policy can be adopted in the transition of drugs from prescription to over-the-counter status.

One of the risks alleged to be encountered by the public funds in consequence of the transition of drugs used in minor ailments from prescription to over-the-counter status, i.e. their exclusion from reimbursement list, is that physicians may began to prefer more expensive alternatives within the scope of reimbursement, instead of drugs excluded from reimbursement, as a consequence that can be called 'prescription shift'. Regarding this issue, a report prepared by the World Health Organization contains the following statement: "If the doctors in the countries, where drugs are excluded from the scope of reimbursement upon their transition to OTC status, do not prefer more expensive alternatives within the scope of reimbursement, instead of drugs excluded from reimbursement, the public funds are expected to make saving. Such shifts have been identified in the past but there are limited number of evidence for their occurrence. More recent studies show that the transition to the implementation of non-reimbursement of OTC drugs succeeded in reducing the public funds and insurance expenditures."(Noyce, 2003)

When calculating the economic benefits of the proliferation of self-medication, there are also economic acquisition in addition to the saving created as a result of exclusion of over-the-counter drugs from reimbursement list.

In terms of Doctors

Proliferation of the self-medication understanding, and exclusion of over-the-counter drugs intended for treatment of minor ailments from the scope of reimbursement will reduce the visits to doctors for such ailments. It will enable doctors to make saving on the time they allocate for such ailments, and to devote more time for more severe diseases, and it will also shorten the waiting times of patients, spent in queues for examination.

As a result, it will have a positive effect on the quality of the health care system. The financial impact resulting from the decrease in the role of doctors in the treatment of minor ailments may vary, depending on the health system of the country being examined. In some countries, a fee is paid by patients to doctors for each visit, and in such cases, a decrease might be observed in the revenues of doctors, as a result of self-medication preferred by patients. In

some countries, doctors are paid by public funds, according to the number of patients they treat, and a decrease might be observed in the revenues of doctors in such cases as well. In some other countries, revenues of doctors do not depend on the number of patients, and only public funds are affected by self-medication.

In state hospitals of Turkey, where the patient density is high, doctors are paid a fixed fee and a fee from the circulating capital. A reduction in the number of patients will theoretically have a negative effect on the doctor fees. However, the effects of a decrease in the number of patients on the incomes of doctors can be deemed marginal, in a country like Turkey, where the population of patients per doctor is high, and where the number of patients that doctors have to examine in a day have been a matter for complaint for years.

In terms of Public Funds

Public funds would be utilized more efficiently, with the saving that will be resulted from non-reimbursement of the drugs used in the treatment of minor ailments. For example, those savings can be transferred to the reimbursement of the drugs used in the treatment of serious diseases. By this way, the drugs used in the treatment of the diseases having the first priority for human life can be provided more easily, and the problems regarding the reimbursement of expensive drugs, some of which are vital, can be lessened.

In terms of Patients

As a result of exclusion of over-the-counter drugs from reimbursement list, patients will pay the whole price of a product, instead of a certain percentage of it (10% - 20%). In consequence of this change, the payments made by patients from their own pockets is expected to increase. However, the fact that the prices of non-reimbursed drugs reduce within the framework of competition appears as a main finding in the U.S. and EU markets. The report includes the cases of Claritin and Prilosec. Therefore, in case of formation of the required competition conditions, the prices will show a falling tendency in Turkey, as well.

The amount of the costs encountered by patients as a result of non-reimbursement of over-the-counter drugs is important in terms of the principle of social state. For example, in Portugal the monthly OTC drug consumption per capita is 1.9 Euro, i.e. approximately 3.5 YTL. Nevertheless, reimbursement of such amounts that are not more than that of a pack of cigarettes can be maintained in some applications such as green card applications and for patients with chronic diseases, in order not to leave low-income patients in a difficult situation.

In terms of Pharmacists

There are important roles for pharmacists, in the formation of the over-the-counter market, and in terms of enabling the understanding of self-medication to be effective. Pharmacists should

lead patients to the correct and effective use of drugs. In addition, today both deductions in drugs reimbursed by the public institutions, and delays and troubles in payments to pharmacies are being experienced. If patients buy these drugs by themselves, pharmacists will collect the amount in cash, and since any deduction will not be applied, they will also gain a financial advantage.

In terms of National Economy

Formation of an over-the counter drug market will make positive contributions to the national economy. As a result of decrease in doctor visits for minor ailments, the current losses in working hours will be reduced. Patients will be led to pharmacies instead of doctor visits, and by this way, losses in working hours will be reduced. Secondly, doctors will be able to more focus on the treatments of patients with serious ailments.

SUGGESTIONS

Points to take into consideration when creating Over-The-Counter (OTC) Market in Turkey, and When Advertising Directly to Consumers

- Transition of prescription drugs from prescription to over-the-counter status should be definitely made transparently, by use of predetermined scientific criteria, and in consultation with some actors such as doctors, pharmacists and drug manufacturers. AESGP's experiences should be utilized on this subject. IMC components (advertising, personal selling, direct marketing, etc.) should be applied for promoting the drug to consumer, in line with the categories of prescription drugs and over-the-counter drugs determined by this way.

- The over-the-counter drug list to be prepared will be based on active ingredients or indications, depending on the decision that must be made in this regard. In conclusion, if some of the drugs having the same active ingredients or used in the treatment of the same indications are included in over-the-counter status while some others are excluded, some question marks about the process will appear, and such a situation will create difficulties in the formation of over-the-counter market and advertising directly to consumers in line with that.

- When preparing over-the-counter lists, the health-related national data should be be taken into account, in particular. The diseases widely encountered in Turkey and their effect on the health care economy should be considered. For example, in Germany and France anti-obesity drugs, which are within the scope of the identification of drugs

intended for improving the quality of life, are not reimbursed by public funds. However, the 5 molecules used in anti-obesity treatment are in the scope of reimbursement in the UK having an OTC market larger than that of Germany and France, where more drugs are non-reimbursed. The reason of why anti-obesity drugs are included in the scope of reimbursement in the UK while they are excluded in Germany and France is that the 22% of the total population in the UK are facing the risk of obesity, while the ratio is 13% and 10% in Germany and France respectively (Luc. 2005). Cough, Catarrh and Allergy drugs rank first, while Vitamins rank second with 26% in Turkey, according to the distribution in OTC pharmaceutical market in 2008. They are followed by analgesics with 19%. When these percentiles are considered, it is seen that the over-the-counter products launched to the market with the permission of the Ministry of Food, Agriculture and Livestock are advertised through the traditional media tools such as TV, newspaper, magazine, radio, billboard. For example, in the recent period we frequently see the advertisements of Roche's product Bepanthol in the printed media and outdoor advertising tools. We also recently see the ads of the catarrh drugs and vitamins released by Ministry of Health, on TV, radio, and printed media in Turkey.

- Advertising directly to consumer is the key point in supporting rational drug use and self-medication. For the over-the-counter policies encouraging self-medication with drugs, first physicians, patients and pharmacists must be trained in this regard. In order to form an over-the-counter product class for the drugs that can be sold with the help of a pharmacist, such products should be able to be used safely by the patients; and the safety criteria can be realized only by providing patients with self-medication training and raising the awareness of the people about rational drug use. For that purpose, social responsibility ads play a crucial role.

- Providing training to physicians and giving them detailed information about the use of both prescription drugs and over-the-counter drugs are important. In this way, treatments with drugs within the scope of reimbursement, instead of over-the-counter drugs can be prevented. Otherwise, the situation called 'prescription shift' is encountered, and that might lead to an increase in the public costs, instead of a decrease.

- Besides its direct economic benefits, exclusion of over-the-counter drugs from the scope of reimbursement will also be helpful for reducing the workloads of doctors, by reducing the doctor visits for minor ailments. It will enable doctors to be able to allocate much time

for patients with more serious ailments, by saving on the time that they devote to such ailments; and it will also lead to positive effect on the quality of the health care system.

- If transition of a drug from prescription status to 'over the counter' status excludes that drug from reimbursement list, citizens with a limited ability to pay might be adversely affected by it. The point to take into consideration here is that the regulations intended for reimbursement of over-the-counter-drugs should be maintained for chronic diseases and long-term treatments, by considering the principle of social state.

- Pricing of drugs should be considered separate from the subject of reimbursement. A different policy should be followed for pricing over-the-counter products. In the world, the prices of the over-the-counter products, which are not included in the reimbursement list and not purchased in big quantities by health insurance funds, are generally determined freely by manufacturer companies, and consequently, the intense competition in this market is allowed to be reflected on the drug prices. A similar pricing policy might be helpful for generating a competition that may reduce the prices of over-the-counter drugs in Turkey. And the prices of the drugs remained in reimbursement lists may continue to be subject to control.

- Drugs in reimbursement list should be distributed only through pharmacies, and the role of pharmacists in the application should be expanded because of the fact that pharmacists are one of the most important actors in the over-the-counter market. The role to be played by pharmacists as consultants in enabling patients to use such drugs without need for medical examination, and in enabling the understanding of self-medication to become healthy functional.

- The "Regulation on Promotion Activities for Human Medicinal Products" intended for the promotion of over-the-counter drugs directly to consumers, execution of which has been stopped by the State Council, should gain functionality. Especially if the prices of over-the-counter drugs will be freely determined by manufacturers, those products should be allowed to be promoted to consumers, in order to ensure the price competition for those products to be healthier. For doing so, it is necessary to make an amendment to the Pharmaceuticals and Medical Preparations Law.

- Manufacturer companies have important duties in the over-the-counter drug market that will be created as a result of exclusion of over-the-counter drugs from reimbursement

list, and their promotion directly to consumers. In order to be able to improve the understanding of self-medication, and enable patients to keep their health conditions under control, the promotions to be made by companies are required to have a structure that can enlighten consumers, as an obligation. Besides promotions, also training activities to be organized by companies should be made obligatory for making contribution to the awareness of patients.

CONCLUSION AND RECOMMENDATIONS

In Turkey, there is a regulation on over-the-counter drug classification designed to be compatible with the European Union. On the other hand, there are various differences in the applications in the EU member states. The number of over-the-counter drugs in Turkey is more limited when compared to that in the European countries. Based on AESGP data, it is possible to increase the number of over-the-counter drugs. In other words, transition of some drugs that are currently available in Turkey from prescription to over-the-counter status is possible.

The reimbursement status of the drug is one of the point to be considered during the transition between prescription and over-the-counter statuses. Currently there is not a uniform application related to reimbursement of the over-the-counter drugs in Turkey. Some of the over-the-counter drugs are included in the scope of reimbursement, while some others are excluded. Since the criteria that are the basis of reimbursement decisions have not a transparent framework, i.e., they are not known by the public, the reasons of this segregation cannot be understood.

Turkey is passing through a period, in which the health and drug costs of the public institution are increasingly rising, and on the other hand, the part that can be allocated from the budget for these items is being restricted. The demographic curve formed by the growing population of Turkey indicates that these expenses will increase more. Therefore, a transition to a structure is needed, which will not disrupt the continuation of the fight against diseases threatening the lives of people, on the contrary, will allocate a source for battling with them. Redetermination of over-the-counter drug policies provides various opportunities for being able to transfer source to this area.

It is observed that the Turkish people's access to vital medicines are being more difficult with each passing day. On the other hand, some the drugs used for the treatment of catarrh or indigestion, which are deemed to be minor ailments or used as dietary supplement, are continued to be reimbursed by the public institution. This situation does not match up with the health-related trends in the world. Developing the concept of self-medication and reducing the doctor visits by this way is the approach that increasingly become widespread both in the United States and EU. A fundamental part of this approach is the reimbursement of the drugs that can be used within the framework of self-medication, by health care systems. This understanding is

based on the ground of the effort to enable patients to access more expensive and essential drugs used for the treatment of life-threatening diseases, rather than the mentioned cheaper over-the-counter drugs.

Studies performed in European countries put forth the fact that the over-the-counter drug expenditures per capita are not as high as thought. For example in Portugal as a country considered as a reference by also Turkey, the monthly over-the-counter drug expenditure per capita is 1.9 Euro, and it is 2.1 Euro in Greece. This figure is an amount that can be compared to that of a pack of cigarettes.

On the other hand, the price of a drug supporting the immune system, which is required to be used for the treatment of many cancer diseases, can be hundreds or even thousands of Euros. (For example: The price of Octagam immunglobuli 200 ml 1 Falkon is 1.205 YTL - The price of Neupogen roche 48 miu/0,5 ml 5 in ready-to-use syringe is 1.136,35 YTL). Purchase of a drug of this type by patients without the support of health care funds is extremely difficult, or even impossible for most citizens (http://www.istanbul-ekonomi.com/tr/yayinlar/Recetesiz%20ilac%20raporu.pdf Access on: November 2012). Transfer of the savings obtained from the reimbursement of over-the-counter drugs to vital drugs should be assessed as a serious option. If such a method is adopted, it is required to redetermine firstly which drugs can be sold over-the-counter in Turkey. In order to ensure the study to succeed, is important to take the opinions of all the actors involved in the sector, particularly that of the doctors and pharmacists. Afterwards, the new classification should be based on detailed-defined and transparent criteria.

The most noticeable element of the Turkish legislation differing from that of the EU legislation is that it allows over-the-counter drugs to be promoted directly to consumers. Today a draft law on allowing for the promotion of over-the-counter drugs is on the agenda. In case of adoption of the draft, also consumers besides the advertising and media sector will benefit from that. Consumer awareness will reduce the misuse of drugs, and also prevent the consequences of misuse.

In Turkey, a flexibility was provided for the advertisements of over-the-counter drugs in the 1990s; and their advertising was accepted by the declaration of a regulation. However, upon the request of the Pharmacists' Association, the State Council annulled the regulation, and prohibited their advertising again. The issue of drug advertising ban became a current issue again, with the "Draft Law on Transition in Drugs, and Drug Administration", which is still waited to be enacted. With the arrangement, it is expected to pave the way for drug advertisements. In addition, if the draft becomes a law, simple analgesics, vitamins, catarrh drugs and antacids, which are sold without prescription in pharmacies and are called OTC (over-the-counter) drugs will begin to be sold in a unit separate from pharmacies. The draft that will also raise the

awareness of consumers will give an acceleration and vitality to the Turkish advertising and media sector.

Promotion of drugs to the public should be free, in such a way as to utilize all the communication channels (visual and written press, radio, TV, etc). The principles to be applied in the promotion of drugs to the public should be created on the basis of the directives of the European Union, WHO promotion rules, as well as the rules of the Association of the European Self-Medication Industry (AESGP). However, the audit to be applied to the promotion intended for the public should be carried out by also an independent and private committee consisting of people who are experts in their fields, in addition to the self-control of the companies. In promotions to be made through radio, television and printed media, the audit should be carried out before the broadcast/ publication, and the promotion should be allowed only if it has not encountered an objection.

The legal regulation on the advertising bans in the pharmaceutical sector seems to be designed with intent to protect consumers. However, unconscious use of drugs is highly widespread in Turkey, and moreover, people can recommend drugs to each other. This triggers the misuse of drugs and the consequential disabilities or even deaths. The Ministry of Health does not keep any statistics based on the misuse of drugs. The public can be given awareness and all the risks can be avoided by allowing the drug advertising intended for protecting the consumers in the pharmaceutical sector.

It would be a right approach if the manufacturer company makes an explanation to the consumer about the OTCs, use of which is not required to be determined by the physician. Any misleading communication will be prevented, since this formation will be controlled by also the Ministry of Health, Advertising Self-Regulatory Board, competitor companies, health care personnel, and consumers. What is required to be discussed here is not the subject of allowing advertisements but the way of its audit.

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Abbreviations Used

EU European Union

AESGP The Association of the European Self-Medication Industry

ATC The Anatomical Therapeutic Class

CDER Center for Drug Evaluation and Research

CHPA Consumer Healthcare Products Association

EFPIA The European Federation of Pharmaceutical Industries

FDA Food and Drug Administration

NDA New Drug Application

OECD Organisation for Economic Cooperation and Development

OTC Over-the Counter

TTB Turkish Medical Association

WSMI World Self –Medication Industry