

OTC Drug Regulations in Turkey: The Opinions of Community Pharmacists and Drug Industry

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Over the Counter (OTC) drugs are the drugs that are easily accessible from pharmacies without any prescription from a physician. These drugs are safe for short term use and effective for minor common diseases. The advice of a pharmacist is sufficient to use OTC drugs or as directed on the label. Food and Drug Administration (FDA) defines OTC drugs as safe and effective when used according to the label instructions and without a prescription, also when used in compliance with a health professional advice if necessary.

This study aims to enlighten possible OTC drug regulations in Turkey during the harmonization period with European Union. Also the regulations in some European countries are investigated. It is aimed to determine attitude, behaviors and opinions of senior executives and mid-level managers and community pharmacists on OTC regulations.

The design of this study is a voluntary survey. To collect the data for this study, a cross-sectional survey was carried out. Two different questionnaires were conducted to the community pharmacists in Ankara and pharmaceutical companies in Turkey.

According to the results, the employees of the pharmaceutical companies in Turkey have a more positive approach to the OTC regulations than the community pharmacists. International companies are inclined to that view than national companies.

Key words: OTC, Community pharmacist, Pharmaceutical industry, Non-prescription medicine

Türkiye’de OTC İlaç Düzenlemeleri: Serbest Eczacılar ve İlaç Firmalarının Görüşleri

Reçetesiz ilaç, günlük hayatta sıkça rastlanan basit rahatsızlıkların giderilmesi için, sağlık personeli müdahalesi olmaksızın, gerektiğinde sadece eczacının tavsiyesi ile kullanılmasında tıbbi herhangi bir sakınca olmayan, kısa bir süre kullanılmak üzere güvenli ve belirtilen endikasyonlar için etkili oldukları kanıtlanmış ilaçlardır. ABD Gıda ve İlaç Kurumu (FDA) reçetesiz ilacı, hekim reçetesi olmaksızın üzerindeki etiket yönlendirmelerine ve gerekirse sağlık profesyonelinin görüşüne uygun kullanıldığında güvenli ve etkili ilaç olarak tanımlanmaktadır.

Bu çalışma, Türkiye’de Avrupa Birliği ile uyumlaştırma sürecinde olası reçetesiz ilaç ile ilgili düzenlemelere ışık tutmak amacıyla tasarlanmış bir çalışmadır. Bazı Avrupa ülkelerinde var olan uygulamalar incelenmiştir. Türkiye’de reçetesiz ilaç mevzuatı ve uygulamaları olduğu takdirde, ilaç sanayinde çalışan üst ve orta düzey yöneticilerin ve serbest eczacıların tutum/davranış ve düşüncelerinin tespit edilmesi amaçlanmıştır.

Bu çalışmanın verilerini toplamak için gönüllülüğe dayalı anket yöntemi kullanılmıştır. Veriler kesitsel çalışma biçiminde toplanmıştır. Çalışmanın materyalini Ankara’da bulunan serbest eczacılar ve Türkiye genelinde faaliyet gösteren ilaç firmalarına uygulanan iki farklı anket formu oluşturmaktadır.

Araştırma sonucuna göre Türkiye’de faaliyet gösteren ilaç firmaları çalışanları, serbest eczane eczacılarına göre reçetesiz ilaçlar ile ilgili olası mevzuat düzenlemelerine daha pozitif bakmaktadır. Yabancı ilaç firmalarının, bu görüşü benimsemelerinde istatistiksel anlamlılık bulunmuştur.

Anahtar kelimeler: OTC, Serbest eczacı, İlaç endüstrisi, Reçetesiz ilaç

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INTRODUCTION

OTC drugs are drugs which are easily accessible from pharmacies without a prescription from a health professional. These drugs are safe for short term use and effective for minor common diseases. The advice of a pharmacist is sufficient as directed on the label. Food and Drug Administration (FDA) in USA defines OTC drugs as safe and effective when used according to the label without a prescription or when used according to a health professional's advice, if necessary (1). Self - medication is defined as medication taken by patients who take their own responsibility to treat their own minor illnesses (2). In Turkey the legislation defines prescription drugs as the products that can be dispensed with a prescription and OTC are the drugs that don't require a prescription (3).

OTC drugs don't require a prescription by a health professional. Therefore, they may be perceived as harmless however, OTC drugs also contain active substances like prescription drugs and some side effects can be seen when they are used.

Turkey adopts France, Italy, Portugal, Greece and Spain as reference countries in its drug pricing system. According to the OTC drug regulations in these countries it can be seen that OTC drug lists has been made. In France, drugs are divided into two groups; prescription and non-prescription (OTC) drugs. Patient information leaflets that are published on internet were prepared about OTC drugs. OTC drugs that have no reimbursement can be advertised. OTC drugs are more expensive than prescription drugs in France. OTC drugs can be dispensed only in pharmacies (4). In Italy similar to France drugs are classified into prescription-only drugs and OTC drugs. When deciding on the classification of a drug as "non-prescription" a general criteria is listed. All packs must carry a patient leaflet unless the information can be printed on the package label. Some OTC drugs in Italy are advertised to the public and some are not. The sale of all OTC drugs is allowed in non-pharmacy outlets. The retail price of all OTC drugs has been totally free since 2008 (4). In Portugal the classification system was thoroughly changed since 2005.

The distribution of OTC drugs was allowed outside pharmacies. The drugs whose distribution may take place outside pharmacies were moved to a regime of free pricing. However, a large number of OTC drugs remain on the reimbursement list. All packs have to carry patient information leaflets. OTC drugs may be publicly advertised in all media (4).

The Regulation on the Classification of Human Medicinal Products, dated 2005, presents the provisions of classifications for the drugs. The drugs effective usage and rational identifies the class of it. Accordingly patient safety becomes important while deciding on which drugs should be placed in the class of prescription or OTC. There is no certain definition of OTC drugs, besides the conditions set for prescription drugs (3).

According to the Regulation on Human Medicinal Products Licensing, dated 2005, during the approval process drugs are defined as prescription or OTC (3).

In accordance with the Pharmaceuticals and Medical Preparations Law, dated 1928, drug distribution was made only in community pharmacies in Turkey (5). Trade bodies also disapproved of drug sales out of pharmacies (6).

Drug advertising was regulated by the Law on Pharmaceuticals and Medical Preparations, dated 1928 (5). OTC drug advertisements are strictly forbidden in the country (7).

The Ministry of Health of the Republic of Turkey made a regulation about the promotion of human medicinal products taking into account the advices of the World Health Organization. The Regulation on Promotional Activities of Medicinal Products for Human Use, dated 2011, includes the provisions about prescription or OTC drug promotions. The provisions mention that advertisements are forbidden to society, they can be made only to the professional medicine community (8).

Radio and Television Law entered into force in 2011. The Law includes the statement "you do not connect commercially about prescription drugs. OTC drug advertisements can be done honestly and in a sort of verifiable way" (9). Although OTC drug advertising became free after the enforcement of Radio and Television Law, the arguments on this are still going on.

This study is planned to shed a light on the OTC drug regulations during the harmonization period with European Union in Turkey. The regulation in some European Union countries have been investigated and been dwelled upon their applicability. Some recommendations tried to be put forward as long as an OTC regulation is made in Turkey. It is aimed to determine attitude, behaviors and opinions of drug companies and community pharmacists about OTC regulations.

MATERIAL AND METHODS

The design of this study is a voluntary survey. The do to those were collected from pharmacists are evaluated according to pharmacy location and years of work in the community pharmacy. In our study pharmacy location has been described as large scale pharmacy and district pharmacy. The pharmacies which describe themselves as large scale are the pharmacies near a hospital or crowded places which have many patients bringing in prescriptions and who buy a lot of products. Hence, they have a high cash inflow and OTC sales are a lot more compared to district pharmacies. On the contrary, district pharmacies are a small group of pharmacies that have fewer patient potential compared to larger scale pharmacies (10). For this reason their endorsement is lower. The results of questionnaire that was conducted to pharmaceutical companies were evaluated according to the origin of the company and number of OTC products on the market. Some companies' are members of Association Research-Based Pharmaceutical Companies (AIFD) and some of them are the members of Employers Association of Pharmaceutical Industries (IEIS) in Turkey. AIFD was established in 2003, by research-based pharmaceutical companies operating in Turkey, with the objective of enabling Turkish people to access new and original drugs, and providing effective solutions to the health conditions in our country. While IEIS represented national pharmaceutical industry 10 years ago, it has now become a foundation consisting of national and international companies (11).

To collect data for this study a cross-sectional survey was carried out. The first questionnaire conducted to pharmacists consisted of two parts. First part was created to collect demographic data and the second part of questionnaire involved 16 statements (3 item likert scale). The second questionnaire was conducted to the senior executives and mid-level managers of pharmaceutical companies and had two parts likewise. The first part was for demographic data collection. The second part included 30 statements (3 Likert scale). The statements were collected under 4 topics (legislation, policy, price/reimbursement, advertisement). 1 statement was related to legislation, 7 statements related to policy, 3 statements were created to learn what community pharmacists think about pricing and reimbursement and finally 5 of the statements were related to OTC advertisement. For the second part of the questionnaire 2 statements were prepared to understand what the managers think about OTC legislation, 17 statements were related to policy, 4 of them were related to pricing and reimbursement and 7 statements were related to advertisement.

The statements were designed by researchers together with the opinions of community pharmacists and senior executives and mid-level managers of pharmaceutical companies. Intelligibility, validity and the coherence with the research issue of the statements were tested.

This study was conducted between May, 2012 and September, 2013. A pilot study was carried out with 10 pharmaceutical company employees and 25 community pharmacists.

The questionnaires prepared for community pharmacists were carried out by face to face interviews. The second questionnaire made for pharmaceutical companies were sent via e-mail periodically and responses were collected again via e-mail.

There have been 1397 community pharmacies in Ankara (N=1397). 300 community pharmacies were calculated to represent the whole population. 287 valid responses were included in the data analyses.

The questionnaires were sent all of the 78 pharmaceutical companies (N=78). 65 pharmaceutical companies were calculated to represent the whole population. 66

pharmaceutical companies were accepted to participate in survey. In our study the two representative associations of pharmaceutical companies mentioned above had been the main goal to reach the pharmaceutical companies' senior executives and mid-level managers.

A socio-economic data was obtained from questions about age, gender, pharmacy location, years of work in pharmacy, origin of the pharmaceutical company. Chi square test

was applied to compare the answers of statements related to regulations on OTC drugs in Turkey and demographic properties. Significance level has been defined as 0.05 and it has been accepted that if p is more than 0.05 there hasn't been any significant difference. Statistical Package for Social Science (SPSS) program (version 16; SPSS Inc., Chicago, IL, USA) was used for data analyses.

Table 1. Demographics of participants

Demographics of community pharmacists		
	Frequency (n)	Percentage (%)
Gender:		
Male	122	42
Female	165	58
Age:		
25-35	106	12
36-45	80	28
46-55	66	23
≥56	35	12
Years of work in community pharmacy:		
1-5	51	17.8
6-10	48	16.7
11-15	47	16.4
16-20	43	15.0
21-25	39	13.6
≥ 26	59	20.6
Location:		
Large scale pharmacy	49	17
District pharmacy	238	83
Demographics of pharmaceutical company representers		
	Frequency (n)	Percentage (%)
Origin of company:		
National	36	54.5
International	30	45.5
Year of activity on market		
1-10	17	25.8
11-20	11	16.7
21-30	10	15.2
31-40	2	3.0
41-50	4	6.1
≥ 51	19	28.8
Invalid	3	4.5
Number of OTC product in the market:		
None	18	27.3
1-10	17	25.8
11-30	21	31.8
≥ 31	10	15.2

RESULTS

According to the demographic data, 20.6% of the community pharmacists participating in the survey have been pharmacists for over 26 years (Table 1). 17% of community pharmacists reported their pharmacies as large scale pharmacy. 54.5% of pharmaceutical companies assumed themselves as national

origin. 48 representatives of pharmaceutical companies who participated in the survey have OTC products in the market and while 18 don't have them.

Answers to questionnaires were compared to demographic characters of pharmacists (location and years of work in pharmacy).

Table 2. Distribution of community pharmacists' answers given to the statements about OTC regulations

STATEMENTS	Agree n (%)	No idea n (%)	Disagree n (%)	p location of pharmacy	p years of work in pharmacy
I think that OTC regulations are arranged to decrease public expenditures.	162 (56.4)	113 (39.4)	12 (4.2)	p>0.05	p>0.05
I have a doubt on the decision about classification of OTC drugs and prescription drugs made on scientific base.	267 (93)	18 (6.3)	2 (0.7)	p>0.05	p>0.05
Conjunction with OTC regulations patients' demands for information from pharmacists may increase.	261 (90.9)	15 (5.2)	11 (3.8)	p>0.05	p>0.05
I think that OTC regulations are arranged for selling the OTC drugs out of pharmacies.	182 (63.4)	96 (33.4)	9 (3.1)	p>0.05	p>0.05
OTC products should be sold only in pharmacies.	283 (98.6)	4 (1.4)	0 (0)	p>0.05	p>0.05
I believe that the public cannot use drugs rationally when the OTC regulations are made.	252 (87.8)	29 (10.1)	6 (2.1)	p<0.05	p>0.05
OTC drugs should not be eliminated from the reimbursement lists which are prepared by Republic of Turkey Social Security Institution.	158 (55.1)	115 (40.1)	14 (4.9)	p>0.05	p<0.05
If OTC drugs are removed from reimbursement list, patients will not prefer to pay by cash.	124 (43.2)	98 (34.1)	65 (22.6)	p>0.05	p>0.05
Patients should ask for information concerning OTC drugs from pharmacists.	268 (93.4)	14 (4.9)	5 (1.7)	p>0.05	p>0.05
Paying OTC drugs by cash can provide a financial advantage to community pharmacists.	107 (37.3)	116 (40.4)	64 (22.3)	p>0.05	p<0.05

The answers of community pharmacists given to the statements about OTC regulations over the world have generally been negative. Significant difference was found at three of these statements above. District pharmacies

had more concerns about the problems originating from rational drug use ($\chi^2=6.7$, $df=2$, $p<0.05$). More than half of pharmacists (55.1%) expressed that OTC drugs should not be removed from the reimbursement list. It is

seen that there has been a significant difference about this statement according to the years of pharmacists working in the pharmacy ($\chi^2=19.3$, $df=10$, $p<0.05$). Some of the pharmacists (43.2%) had the opinion that if OTC drugs were removed from reimbursement list, patients would not be willing to pay. However; 37.3% of them defended paying drugs by cash provides some financial contribution to pharmacy ($\chi^2=19.9$, $df=10$, $p<0.05$).

The opinions of pharmacists about the regulations of OTC drug advertising in Turkey can be seen in Table 3.

Only 15% of pharmacists supported the direct-to-consumer advertising. Many of them (62.7%) were thinking that an adequate informing couldn't be done by OTC advertisements. On the other hand 63.4% indicated that direct-to-consumer advertising can lead to excessive drug use and increased drug consumption. In contrast the other part of pharmacists (49.1%) did not believe OTC advertisements cause irrational drug use.

The Survey conducted to pharmaceutical companies has been evaluated and the results can be seen in Table 4.

Table 3. The distribution of community pharmacists' answers given to the statements about OTC advertising

STATEMENTS	Agree n (%)	No idea n (%)	Disagree n (%)	p (location of pharmacy)	P (years of work in community pharmacy)
The public should be informed by direct-to-consumer advertising about OTC drugs.	43 (15)	80 (27.9)	164 (57.1)	$p>0.05$	$p>0.05$
Patients will want to take the advertised medicines immediately.	146 (50.9)	79 (27.5)	62 (21.6)	$p>0.05$	$p>0.05$
I believe that direct-to-consumer advertising can inform the patient adequately.	25 (8.7)	82 (28.6)	180 (62.7)	$p>0.05$	$p>0.05$
I believe that direct-to-consumer advertising can increase the consumption of that medicine and lead to overuse of OTC drugs.	182 (63.4)	75 (26.1)	30 (10.5)	$p>0.05$	$p>0.05$

Pharmaceutical companies' answers were evaluated. Thus, majority of them (71.2%) remarked the need for OTC regulations. Significant differences were found at six of the statements. They advised that OTC regulations have to be made as soon as possible. International pharmaceutical companies would like OTC regulations to be made more than national origins ($\chi^2=10.58$, $df=2$, $p<0.05$). International companies were requesting an OTC drug list more ($\chi^2=7.4$, $df=2$, $p<0.05$). Most of (60%) international companies were more likely to change the status of some prescription drugs to OTC in the market compared to nationals ($\chi^2=7.83$, $df=2$, $p<0.05$). However, companies did not

express a positive opinion to change the status of their companies' prescription drugs. It can be seen that they were unsettled. More than half of international companies (56.1%) were more willing to remove the controls on the prices of OTC drugs, compared to national ones ($\chi^2=5.6$, $df=2$, $p<0.05$). Willingness to OTC advertising was significantly associated with the origin of pharmaceutical companies ($\chi^2=7.9$, $df=2$, $p<0.05$). Most part of international companies (73.3%) were more willing to advertise OTC drugs. More than half of the companies (54.4%) promoted OTC drugs with a foresight that advertising increases the consumption, thus the sales.

Table 4. Distribution of pharmaceutical companies' answers given to the statements about OTC regulations

STATEMENTS	Agree n (%)	No idea n (%)	Disagree n (%)	p (drug company's origin)	p (drug company's OTC products in the market)
OTC drug regulations should be made.	47 (71.2)	12 (18.2)	7 (10.6)	p<0.05	p>0.05
A certain OTC drug list should be available.	40 (60.6)	19 (28.8)	7 (10.6)	p<0.05	p>0.05
Some of drugs' status should be changed from prescription to OTC in the market.	33 (50)	25 (37.9)	8 (12.1)	p<0.05	p>0.05
Some of drugs' status should be changed from prescription to OTC in our company.	12 (18.2)	24 (36.4)	30 (45.5)	p>0.05	p>0.05
If OTC regulations are made, we could increase the number of our OTC products.	24 (36.4)	27 (40.9)	15 (22.7)	p>0.05	p>0.05
Pharmaceutical companies should prepare drug labels for public to provide rational drug use.	56 (84.8)	5(7.6)	5 (7.6)	p>0.05	p>0.05
Responsibility of the side effects of OTCs belongs to the relevant company.	44 (66.7)	13 (19.7)	9 (13.6)	p>0.05	p>0.05
Pharmacovigilance studies on OTC products may not be done effectively after OTC regulations in our company.	-	11 (16.7)	55 (83.3)	p>0.05	p>0.05
Sales and marketing team for OTC products should be gathered within our company.	52 (78.8)	8 (12.1)	6 (9.1)	p>0.05	p>0.05
Marketing strategies of OTC drugs should be different from prescription drugs.	6 (9.9)	5 (7.6)	1 (1.5)	p>0.05	p>0.05
Direct-to-consumer OTC advertising should be set free and regulated.	38 (57.6)	14 (21.2)	14 (21.2)	p<0.05	p>0.05
More profit has been made from OTC drugs compared to prescription drugs.	15 (22.7)	23 (34.8)	28 (42.4)	p>0.05	p>0.05
Drug expenditures could get decreased by OTC drug regulations.	30 (45.5)	26 (39.4)	10 (15.2)	p<0.05	p>0.05
I do not want to get OTC drug approval. Because, OTCs are being taken out of reimbursement lists and physicians and patients wouldn't prefer them.	28 (42.4)	18 (27.3)	20 (30.3)	p>0.05	p>0.05
OTC drugs should be sold out of pharmacies.	16 (24.2)	19 (28.8)	31 (47)	p>0.05	p>0.05
Getting OTC drug approval should be easier than getting prescription drug approval.	32 (48.5)	16 (24.2)	18 (27.3)	p>0.05	p>0.05
Lots of patients could suffer due to some inadequacies (polypharmacy risks, drug-drug interactions, risk of excessive dose etc.) in rational drug use.	29 (43.9)	26 (39.4)	11 (16.7)	p<0.05	p>0.05

Table 5. The distribution of pharmaceutical companies' answers given to the statements about the policy of OTC prices

STATEMENTS	Agree n (%)	No idea n (%)	Disagree n (%)	p (drug company's origin)	p (drug company's OTC products in the market)
I think that physicians may most willing prescribe the drugs included in the reimbursement system, compared to the drugs not included in the reimbursement system.	33 (50)	19 (28.8)	14 (21.2)	p>0.05	p>0.05
OTC drugs should be removed from reimbursement list.	38 (57.6)	18 (27.3)	10 (15.2)	p>0.05	p>0.05
Controls on the prices of OTC drugs should be removed.	37 (56.1)	14 (21.2)	15 (22.7)	p<0.05	p>0.05
The prices of OTC drugs should be lower than prescription drugs.	15 (22.7)	15 (22.7)	36 (54.4)	p>0.05	p>0.05
The prices of prescription drugs decreases day by day, because of this the OTC drugs are more profitable than prescription drugs.	28 (42.4)	26 (39.4)	12 (18.2)	p>0.05	p>0.05

DISCUSSION

Community pharmacists and senior executives and mid-level managers' opinions about the OTC regulations were evaluated. According to 16 statements asked to community pharmacists, nearly half of the pharmacists had the opinion in favour of OTC regulations and so it being removed from the drug reimbursement lists, which can cause a decrease of drug expenditures. On the other hand, another study that was made in 2001 in Turkey shows that pharmacists did not agree with the idea that using OTC drugs could decrease the health expenditures (10). However, statistics on OTC use show some clinical-drug cost savings. When a drug is removed from reimbursement list, drug expenditures may decrease (12,13).

A great majority of pharmacists were willing to dispense drugs in pharmacies rather than in gross market or chain drug stores. More than half of the pharmacists think that OTC regulations made by the Government are being planned to sell the drugs out of pharmacies. In a similar study pharmacists

reported that they did not believe new working fields for pharmacists will be created together with selling OTC drugs out of pharmacies (10). As mentioned before prescription drugs and OTC drugs must be dispensed only in pharmacies (5). The most important reason for this is to provide a rational drug use by pharmacist consultation. Also a tendency to dispense drugs out of pharmacies can cause some risks like irrational drug use or misuse.

Almost all pharmacists had the opinion that pharmacist consultation will increase after OTC regulation. It can be understood that giving accurate advice to patients by pharmacists could be developed by OTC drugs according to Bond (14). OTC drugs have no inconvenience about using only upon the advice of a pharmacist. It was considered that pharmacists' responsibilities may increase. In another study it can be seen that most patients would prefer to take the drug counseled by a pharmacist (15).

Pharmacists believed that some problems can occur during OTC use because of inadequacy of rational drug use. It was seen in a study planned in England that patients did not have adequate information about the adverse effects of drugs. According to this study patients would prefer to ask physicians and pharmacists for information about drugs rather than reading the labels (16). Several researches have shown that there are a lot of patients faced with some problems (overdose, drug-drug or drug-food interactions) due to irrational OTC drug use (17, 18, 19). OTC drug dispensing should be done only by pharmacists and counseling is needed. Patient information leaflets should be carefully prepared and should be as simple as possible. Unless these precautions are taken, OTC drug regulations pose a threat to patients.

The more pharmacists spend years in pharmacy, the less they have the opinion that OTC drugs should be removed from the reimbursement list. The years in the profession can lead to adopt this idea.

Mostly pharmacists were unwilling to watch OTC advertisements. Similar results have obtained from a research conducted in Erciyes University. Thus, pharmacists did not approve direct-to-consumer advertising, they preferred advertisements in medical journals (20). Another study expressed advertisements promote excessive use of drugs. According to our study, advertisements misguided people and created a belief that the advertised drug can be useful in every condition (21). Researches show that balance of power between drug advertisements and health professionals has been changing (22). A group of pharmacists expressed few OTC advertisements conveys sufficient information to patients (23). On the other hand a lot of pharmaceutical companies consider that drug advertisements are ethically convenient and should be done. However, an unconscious consumer can be impressed from a drug advertisement and may use it in a wrong way due to an incentive feature of the advertisements. At that point a pharmacists counseling could correct all the misinformation from advertisements.

According to this study, some different views can be remarkable between international pharmaceutical companies and national companies. According to

pharmaceutical companies an OTC drug regulation should be made. Companies mostly were willing to prepare labels that patients can understand and they reported they can take the responsibility for side effects of OTC drugs. However studies shows that OTC drugs are not being used according to the instructions. Thus supervision of them would be needed (24).

More than half of pharmacists were of the opinion that price of OTC drugs should be higher than prescription drugs. However Hoy expressed that OTC prices should be lower than prescription drugs in 1994. Otherwise patients will spend more money (25). Undoubtedly, high price may cause a limited access to OTC drugs. OTC drug pricing should have to be done in an attentive way.

Willingness to OTC advertising was significantly associated with the origin of pharmaceutical company. International companies were more willing towards OTC advertising because of the great financial power compared to national companies. Therefore, it can be thought that they could afford advertising expenses. However, the information received by advertisements may not be accurate enough (23). Companies were willing to set prices themselves together with removing the price controls. International companies which have financial power may have an advantage using this way.

Preparing the list of OTC drugs and regulating them in compliance with laws can provide saving of drug expenditures. International companies were more willing to support this view. A study in Northwestern University demonstrated that OTC drugs used in upper respiratory system diseases had a saving potential of 5 billion dollar in a year (26). The Government should give priority to accessing the drugs rather than providing a saving from drug expenditures.

Companies were worried that physicians may mostly choose prescribing the reimbursed drugs, instead of non-reimbursable drugs. Turkish Employer Pharmacists Union (TEIS) had the opinion that the ratio of prescribing more expensive drugs with the same effect could increase and thus, it might be a burden to the Government (27).

The applicability of OTC regulations is not certain. In case of putting it into practice some uncertainty can be occurred. That is why companies are not willing to get OTC drug approval because of the uncertainty of the regulations. If OTC regulations were made properly, companies are willing to get OTC approval in a short time. They had the perception that the evaluation process of OTC drug approval should be easier in comparison to prescription drugs. However removing an OTC from reimbursement list doesn't mean it has no side effects. In case of differentiating the approving process, it should not be forgotten that OTC is a drug too. Therefore the process should be regulated in detail.

National companies were more worried about possible difficulties due to OTC drug misuse. An inappropriate OTC drug use and polypharmacy in elderly can increase the possibility to come across with adverse effects. As a result, financial burden may occur in the health system (28). At a platform in which the misuse of even prescription drugs is in discussion, the possibility to encounter an unwanted situation is possible.

CONCLUSION

In conclusion, the number of OTC drugs is increasing day by day in Turkey. The reason for this increase may arise due to an effort to provide a decrease of the public drug expenditures and to provide more profit from OTC drugs. Delegates of the Turkish pharmaceutical industry and the community pharmacists in Ankara have some concerns about OTC drug consumption. In Turkey OTC drug regulations are not enough and for this reason OTC regulations should be put into practice immediately. Pharmacists would not like OTC drugs to be sold out of pharmacies and OTC regulations to be put into practice. In contrast, pharmaceutical companies promote OTC drug regulations. It is possible to make some recommendations about OTC regulations in Turkey. Firstly an OTC drug list needs to be prepared. Then the Labels have to be made in such a way that everyone can easily understand. The rules of pricing, reimbursement, advertising and marketing of OTC drugs need to be set. If

OTC drugs are removed from reimbursement lists, precautions regarding low pricing of OTC drugs can be taken for affordability.

The study had a number of limitations. Firstly, it could not be possible to reach the whole community pharmacists in Turkey, and for this reason the generalizability of findings may be in question. Secondly, some of the pharmaceutical companies' managers were not willing to participate in the survey due to their privacy policy.

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