

A Study on Non-Prescription Drugs from the View of the Pharmacists and the Patients in Turkey

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Summary : In 1992, the European Union published the 92/26/EEC numbered directive about the classification of drugs in order to remove the differences between the laws of various countries and to ensure rational drug use. According to this directive, drugs are divided into two groups:

Prescription drugs

Non-prescription drugs

Non-prescription drugs have been defined as the drugs used without physicians advice. In Turkey, according to the law (number 1262) "Pharmaceutical and Medicinal Drugs Law", drugs are divided into two groups as those with prescription of a physician and those without prescription of a physician. But there is no non-prescription drug definition.

The aim of this study is to discover whether pharmacists advise drugs to patients without a physician's prescription and also determine the ratios of the patients who accept the advice.

In this study an inquiry has been carried out to 130 community pharmacists chosen randomly.

According to the answers given to the inquiry, 81% of the pharmacists advise patients drugs without prescription; 78% of the patients take these drugs; 12% do not want to take the drugs without prescription.

Key words: Non-Prescription Drugs, Laws, Community Pharmacists

Received : 15.10.1998

Revised : 26.11.1998

Accepted : 4.12.1998

Türkiye'de Eczacıların ve Hastaların Reçetesiz İlaç Satışı ile İlgili Görüşleri Üzerinde Bir Çalışma

Özet : Avrupa Birliği, ülkeler arasındaki mevzuat farklılıklarını gidermek ve ilaçların rasyonel kullanılmasını sağlamak amacıyla 1992 tarihinde, ilaçların sınıflandırılması ile ilgili (92/26/EEC) bir direktif yayınlamıştır. Bu direktife göre ilaçlar iki gruba ayrılmıştır:

1- Doktor reçetesine tabi ilaçlar

2- Doktor reçetesine tabi olmayan ilaçlar

Reçetesiz ilaçlar, hekimin önerisi olmaksızın kullanılan ilaçlar olarak tanımlanırlar. Türkiye'de 1262 sayılı "Tıbbi ve İspençiyari Müstahzarat Kanunu"na göre ilaçlar reçeteli ve reçetesiz olmak üzere ikiye ayrılmıştır. Ancak reçetesiz ilaç tanımı yapılmamıştır.

Bu çalışmanın amacı, eczacıların hekim reçetesi olmaksızın hastalara ilaç önerip önermediklerini ve hastaların bu önerilere ne oranda uyduklarını saptamaya çalışmaktır.

Bu çalışmada raslantısal olarak seçilmiş 130 eczane eczacısına bir anket uygulanmıştır.

Bu ankete verilen cevaplara göre, eczacıların %81'i hastalara hekim reçetesi olmadan ilaç önermekte; hastaların %71'i bu ilaçları almakta ve %12'si ise reçetesiz ilaç almak istememektedirler.

Anahtar kelimeler: Reçetesiz İlaç, Mevzuat, Eczane Eczacısı

INTRODUCTION & AIM

In recent years, marketing of OTC drugs -in other words non-prescription drugs- is one of the most discussed subjects in Turkey.

According to the 7th article of the 1262nd Law About the Pharmaceutical and Medicinal Drugs, the marketing of drugs with or without a physician's prescription is assigned by the Ministry of Health and this subject is determined on the licence¹.

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In this manner, marketing of the licensed drugs are defined in a law which has been brought out in 1928. On the other hand, drugs which are sold without a physician's prescription i.e. non-prescription drugs are not defined.

The researches show that 90 % of the patients use drugs without the prescription of a physician².

In this study, an attempt was made to determine whether the community pharmacists advise patients on drugs without a prescription of a physician, and the ratio of the patients accepting the pharmacists' advice.

MATERIAL & METHOD

This study is a descriptive research. The material of the study has been collected by questionnaires carried out with 130 pharmacists who are randomly chosen among 1376 community pharmacists. Sampling range has been planned to be 10 % of the 1376 pharmacists but we could contact only 130 of them. The questionnaires are carried out by direct interviews.

The data of the study has been evaluated with the SPSS (ver.5.0) software programme^{3,4}.

FINDINGS

Some of the findings of this study have been obtained according to the answers given by 130 pharmacists to the questions asked, and the findings have been listed with respect to the order of the questions on the questionnaires.

Table 1. Pharmacists' conception about the "sold with prescription" sentence written on the drugs' packages.

	Number	%
The sentence "sold with prescription" should be on the packages	56	43,1
The sentence "sold with prescription" should be removed	74	56,9
TOTAL	130	100

Table 2. Do pharmacists advise drugs to patients coming to the pharmacies?

	Number	%
Advise	107	82,3
Do not Advise	23	17,7
TOTAL	130	100

Table 3. Do patients buy the drugs advised by the pharmacists?

	Number	%
Buy	102	78,5
Do not Buy	15	11,5
Not Answered	13	10,0
TOTAL	130	100

Table 4. Do patients wish to consult someone else about the drugs advised by the pharmacists?

	Number	%
Yes	42	32,4
No	70	53,8
Not Answered	18	13,8
TOTAL	130	100

Table 5. Whom do the patients wish to consult about the non-prescription drugs advised by the pharmacists?

	Number	%
Physician	69	53,2
Relative	5	3,8
Other	2	1,5
Not answered	54	41,5
TOTAL	130	100

Table 6. Do the patients consult about the characteristics of the non-prescription drugs with the pharmacists while buying them?

	Number	%
Yes	121	93,1
No	9	6,9
TOTAL	130	100

Table 7. About which characteristics of the non-prescription drugs do the patients want to consult the pharmacists?

	Number	%
Indications	116	89,2
Adverse Reactions	4	3,1
Contraindications	1	0,8
Drug Interactions	9	6,9
TOTAL	130	100

Table 8. Pharmacists' conceptions about the narcotics and psychotropics.

	Number	%
Must be given with prescription	91	70,0
Can be given without prescription	39	30,0
TOTAL	130	100

CONCLUSION & DISCUSSION

In 1992, the European Union published the 92/26/EEC numbered directive on the classification of drugs in order to remove the differences between the laws of the member countries and to ensure rational drug use⁵. According to this directive, drugs are divided into two groups:

1. Prescription drugs
2. Non-prescription drugs

According to the same directive, groups of drugs have to be defined during authorization.

OTC, in other words non-prescription drugs are generally regarded as effective for some simple diseases and safe for the patients to use without a physician's supervision but with the advice of a pharmacist alone⁶.

The market share of the non-prescription drugs such as those for cold and cough, analgesics, laxatives, digestive, anti-acids, vitamins and minerals in the total market in European Countries is given in Table 9.

According to this data, the highest rate of the market share of non-prescription drugs in the total market are 36.0% in Switzerland, 35 % in Germany, 34% in France.

Table 9. The Market Share of Non-Prescription Drugs in the Total Market

COUNTRY	1993	1994	1995
	Total Non Prescription Market (%)	Total Non-Prescription Market (%)	Total Non-Prescription Market (%)
Austria	11.5	11.6	11.2
Belgium	23.1	22.9	22.3
Finland	19.0	18.0	18.0
France	35.0	35.0	34.0
Germany	32.0	35.0	35.0
Hungary	8.5	10.9	14.6
Ireland	22.0	22.0	22.0
Italy	11.0	15.7	17.8
Netherlands	13.0	13.0	13.0
Norway	11.5	11.1	11.4
Portugal	5.0	12.0	15.0
Spain	14.0	15.0	15.0
Sweden	13.7	11.2	10.5
Switzerland	39.0	38.0	36.0
United Kingdom	29.0	29.0	28.0

Reference: Economic and Legal Framework for Non-Prescription Medicines in Europe June 1996 AESGP.

Some samples from different European Countries about the application of OTC drugs have been given below:

FRANCE

Non-Prescription drugs, which are subdivided into:
 - Reimbursable products: these drugs are included in the list of products which can be reimbursed to persons with social security insurance coverage. They are only reimbursed when prescribed by a physician. They are not allowed to be advertised to the general public.

- Self-medication products (products grand public): These non-prescription drugs can be advertised after a licence has been obtained from the Health authority.

ITALY

Within the non-prescription drugs class, a special group is known as "farmaci di automedicazione" (self-medication drugs). These products are not

reimbursed and can be advertised to the general public. A non-prescription drug can be qualified as a "farmaco di automedicazione" or OTC product when it meets the criteria listed in the Board of Health circular letter n. 115 of 1975:

- Composition: active principles or combinations largely used in therapy for at least five years.
- Indications: minor ailments that patients can recognize themselves; typical products offering symptomatic relief.
- Route of administration : Injections and aerosols excluded.
- Dosage: within safety limits, per dose and pack.
- Pack size : small and suitable for short-time therapies only.
- No reimbursement.
- OTC Drugs cannot use the same trademark as prescription drugs.

SPAIN

Non-prescription drugs are classified into two groups:

- Non-prescription drugs, which can be either prescribed by a medicinal medical physician doctor or sold without a prescription in pharmacies. They cannot be advertised to the consumer. They are never reimbursed except under some special conditions by the Social Security System.
- Non-prescription drugs, EFP (Especialidades Farmaceuticas Publicitarias), are exclusively used for self- medication and can be advertised in all media. They are never reimbursed.

In Turkey, most of the drugs have to be sold with prescription. On the packages of these drugs "sold with prescription" is written. But in practice almost all these drugs are sold without prescription except psychotropics and narcotics.

57 % of the pharmacists wish the sentence "sold with prescription" to be removed from the drugs' packages (Table 1).

83 % of the pharmacists advise drugs to the patients come to the pharmacies without a prescription (Table 2).

78.4 % of the patients buy the drugs which pharmacists advise (Table 3), but 32.3 % of the patients wish to consult someone else about the drugs advised by the pharmacists (Table 4). 53.1 % of the patients wish to consult a physician; 3.8 % of them wish to consult a friend or a relative about the drugs advised by the pharmacists (Table 5). 93.1 % of the patients consult a pharmacist about the non-prescription drugs they buy (Table 6).

89.2 % of the patients consult pharmacists about the indications, 6.9 % of them consult about drugs interactions, 3.1 % consult about adverse reactions, and 0.08% consult about contraindications (Table 7).

70 % of the pharmacists stated that narcotics and psychotropics have to be sold with prescription (Table 8).

In conclusion, although most of the drugs have to be sold with prescription, the percentage of drugs sold without prescription is very high in Turkey. Patients ask for drugs without prescription from the pharmacists, and the pharmacists advise drugs for the patients according to their wishes and needs. Patients generally consult the pharmacists about the drugs they buy from the pharmacies without prescription.

In order to attain harmony between the pharmaceutical services and the changing conditions of the practice, The International Pharmaceutical Federation (FIP) adopted GPP Principles (Good Pharmacy Practice i.e. the principles of pharmacy practice of good quality). The aim of the GPP is to supply drugs and medicinal products to the community and to provide information to help patients take their drugs appropriately.

GPP requires that a pharmacist's first concern in all settings is the welfare of patients and the objective of each element of pharmacy service is relevant to the patient. GPP also requires that the core of the pharmacy activity is the supply of medication and other health care products of assured quality with appropriate information and advice for the patients, and the monitoring of the effects of use⁷.

In order to apply these requirements, the practice must become widespread. Primarily, drugs sold without prescription should be classified during authorization as in some of the European Countries. Due to buying drugs either with the advice of a pharmacist or without the supervision of a physician, the community should be taught about the prescription concept.

Pharmacists should be trained during their education, and the education should be sufficient in their professional life. Pharmacists should win patients' confidence. All subjects about pharmacy practice should be defined briefly and announced to all related sectors. From this perspective, universities and professional associations should be well organized.

Furthermore pharmacists should obey the rules of professional ethics, while advising non-prescription drugs.

In addition, drug manufacturers should re-label and re-package the drugs according to the packaging and labelling directive of the European Union (92/27/EEC) in order to make the warnings easily understood by the patients.

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