PHARMACY LAW

Regulations on Medications: Dispensing

OBJECTIVES

- Discuss the criteria by which a drug is determined to be prescritio or non-prescription.
- Describe the role of MEDULA system in drug dispensing.
- Recognize the general principles on dispensing controlled substances.
- Describe the places of wholesalers in drug distribution system in Turkey.
- Identify the pharmacy cooparatives and their importance.

REGULATIONS ON MEDICATIONS: DISPENSING

In contemporary pharmacy practice, dispensing includes more than order processing. Dispensing is a comprehensive activity that incorporates drug therapy monitoring and patient education, as well as drug distribution. However in Turkey pharmacists only distribute drugs, they cannot take place in patient counseling precisely.

The previous lectures provided an overview of regulatory aspects of drug development, production, and marketing. From now on, we are going to discuss regulatory activities which are directly involved in dispensing function.

THE CLASSIFICATION OF MEDICINES

Under Article 5 of the '***By-Law on the Classification of Medicinal Products for Human Use'*** (*Official Gazette No. 25730 of February 17, 2005*) drugs are categorized during the marketing authorization procedure. Drugs classified into two categories:

1. Prescrition medicines
2. Non-prescription medicines

What Are The Criteria To Be a Prescription Medicine?

1. Unsafe for health when used except under the supervision of a practitionar even if used correctly.
2. Frequent and widespread misuse and, as a result, direct or indirect danger to human health.
3. Requires further investigation of activity and/or adverse effects in terms of preparation of the substance or formulation.

Products that do not meet these criteria and are not classified according to these criteria can be classified as non-prescription medicinal products for human use.

Unfortunately, there are some misunderstandings because, we do not have any OTC regulation/laws yet that describes which active substances are suitable for self medication.

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.

DISPENSING

Dispensing process begins with the manufacturer. Pharmaceutical manufacturers sell their drugs to communtiy pharmacies, through pharmacy co-operatives and through wholesalers.

Chain pharmacies are not allowed in Turkey. In Turkey all prescription/non-prescription drugs are distributed to patients only in community pharmacies.

Internet/mail order pharmacies are not allowed, neither is the sale of non-prescription drugs in drug stores or supermarkets. Hospitals have their own pharmacies for the inpatient supplies.

DISPENSING

A system of **green** and **red** prescriptions is used to control the sale of certain medicines, including psychotropic medicines **(green prescriptions)** and narcotic substances **(red prescriptions).** Such drugs are usually not available without a prescription.

Pharmacists are authorized to substitute (branded) generics for original products or other branded generics prescribed by the physician, as long as the substitute is pharmaceutically equivalent and cheaper than the prescribed brand.

The generic for substitution should be listed officially to be one of the equivalent drug products. Since 2001, a nationwide information system allows pharmacists to obtain information on the equivalency profile of generic drugs for substitution for all drug reimbursement schemes.

DISPENSING

HOW ARE THE PHARMACISTS GET PAID?

Pharmacies receive their income from ***Social Security Institution (SSI)*** (reimbursement for patients that come with a covered prescription) and from ***private out-of-pocket*** payments.

Community pharmacists have to pay for drugs they buy usually within 90 days, unless the wholesaler offers more generous payment terms as an incentive.

Payment from SSI is received usually only after 90 days.

DISPENSING and REIMBURSEMENT

Prescription drugs are generally reimbursed by SSI.

The system called **MEDULA ECZANE** that community pharmacies use to process dispensing of reimbursed products is based on an online connection to a server at SSI that checks every entry and clears or rejects it.

The sections to be filled by practitioner on prescription

- Name and Surname of the patient
- Turkish Republic ID no/ passport no
- Gender of the patient
- Date and protocol no
- Name of the practitioner and registration number
- Diagnosis
- Drugs

All written prescriptions must be signed in ink with his own name by the practitioner.
All written prescriptions must be included registration number of the practitioner.

E- prescriptions

The implementation of e-prescribing enables all procedures to be carried out in a digital environment that can verify a patient's identity while eliminating the need for health record books and referral papers. By means of electronic prescriptions, the SSI can check all of the information within an electronic environment and classify the data statistically.

Electronic prescriptions have not been implemented in certain institutions that lack the necessary infrastructure, including institutional clinics, and in some health institutions. In these units, prescriptions are still written manually.

Pharmacists cannot, in any way, make open or confidential cooperation with a third party (physicians, health centers) to send them a prescription.

Physicians cannot refer a patient to a specific community pharmacy.

Pharmacists connot accept prescriptions with this way.

This way is forbidden by rules and additionaly it was considered as unethical.

ANTİHİPERLİPİDEMİK İLAÇLARIN ÖDENME KOŞULLARI

STATİNLER İÇİN;

<table>
<tr><td colspan="2">Raporu düzenleyecek sağlık kurumu</td><td colspan="2">Tüm sağlık kuruluşları</td></tr>
<tr><td colspan="2">Raporu düzenleyecek hekim</td><td colspan="2">Uzman hekim</td></tr>
<tr><td colspan="2">Rapora istinaden reçete yazabilecek hekim</td><td colspan="2">Tüm hekimler</td></tr>
<tr><td colspan="2">Maksimum rapor süresi</td><td colspan="2">2 yıl</td></tr>
<tr><td rowspan="5">Ödeme koşulları</td><td rowspan="4">Daha önce ilaç kullanmayan hastalarda;</td><td></td><td>LDL düzeyinin 190 mg/dl'nin üstünde olduğu durumlarda (son 6 ay içerisinde yapılmış 2 ölçümün de 190'ın üzerinde olması gerekir)</td></tr>
<tr><td>Ek Risk Faktörleri;
a) Hipertansiyon
b) Ailede erken kardiyobasküler hastalık öyküsü
c) 65 yaş ve üstü hastalar</td><td>LDL düzeyinin 160 mg/dl'nin üstünde olduğu durumlarda; (son 6 ay içerisinde yapılmış 2 ölçümün de 160'ın üzerinde olması gerekir) en az 2 risk faktörü gereklidir.</td></tr>
<tr><td></td><td>LDL düzeyinin 130 mg/dl'nin üstünde olduğu durumlarda; (son 6 ay içerisinde yapılmış 2 ölçümün de 130'ın üzerinde olması gerekir) 3 risk faktörü gereklidir.</td></tr>
<tr><td>DIABETES MELLITUS,
AKUT KORONER SENDROM,
GEÇİRİLMİŞ MI,
GEÇİRİLMİŞ İNME,
KORONER ARTER HASTALIĞI,
PERİFERİK ARTER HASTALIĞI,
ABDOMİNAL AORT ANEVRİZMASI
KAROTİD ARTER HASTALIĞI
OLANLARDA</td><td>LDL düzeyinin 70 mg/dl'nin üstünde olduğu durumlarda; (Tek ölçüm yeterlidir)</td></tr>
<tr><td colspan="2">Raporlu hastalarda raporun yenilenmesi</td><td>a) Raporlu hastalarda, raporun yenilenmesi durumunda; yapılan tetkik sonucu dikkate alınmaksızın daha önce alınmış ilacın teminine esas olan bir önceki raporun düzenlenme tarihi veya tedaviye başlama tarihi ve başlama değerlerinin raporda belirtilmesi yeterlidir.
b) Yeni yapılan tetkik sonuçları başlama değerleri uygunsa önceki rapor bilgilerine gerek olmaksızın yeni rapor düzenlenir.</td></tr>
<tr><td colspan="3">Atorvastatin, Simvastatin ve Pravastatin'in 40 mg ve üzeri formların ve rosuvastatinin 20 mg ve üzeri formları için kardiyoloji kalp damar cerrahi endokrinoloji uzmanı tarafınca rapor çıkarılıp reçete edilmesi gerekmektedir.</td></tr>
</table>

**** Hiperkolesterolemi, Hiperlipidemi (endikasyon uyumu aranır), koroner arter hastalığı (endikasyon uyumu aranır), katılım payından muaf olduğu raporlardır.***

Dispensing Magistral Medicines

- In magistral prescriptions, a maximum of ***10 days*** of treatment plan can be reimbursed.
- It should be stated by the physician that the ***daily use dose***, ***the duration of the treatment*** on the prescription. Additionaly the physician should point out that the prescirption is for the purpose of treatment.
- If the magistral presciription is prescribed by a report (daily use dose and majistral formula should be clearly stated in the report), the treatment period of ***3 months*** should be calculated.
- If there is a medicine in magistral prescription, these medicines should be recorded to MEDULA manually. If there is no data matrix on drugs, price clippings and barcodes should be added to the prescription.
- Registration should be made in accordance with the preparation of the magistral prescription and the choice of packaging.
  - For example; because of the fact that eu borique is prepared with hot water it must be entered into the system as a solution prepared in the heat.

REIMBURSEMENT SYSTEM IN TURKEY?

The manufacturers apply to SSI (Social Security Instutition) for their drugs they want to be covered by the reimbursement.

As a result of the evaluations by SSI, it is decided whether the drug should be taken into the scope of reimbursement.

Controlled Substances

Law on Control of Narcotic Drugs- Law no. 2313 controls concerned with dangerous and harmful drugs. It covers the import, export, production, supply, and possession of controlled drugs.

Which substances considered as Controlled Substances?

Preparations made from ***opium***,

Morphine and their derivatives,

All medicines containing more than 0.20% ***morphine and its salts***, and/or more than 0.10% ***cocaine and its salts***,

All substances similar to chemical structures of above.

Their import, export, production, supply, and possession is controlled by Ministry of Health.

Controlled Substances

Cultivating **Cannabis *(Cannabis sativa)*** plant is prohibited in Turkey. Because it may be used for marijuana production. Additionally, illegal production, import, export and sale of marijuana are prohibited in any way.

Dispensing Controlled Drugs

Retail sales of narcotics are made only by ***community pharmacies***.

Wholesales and cooperatives can only sell narcotics to community pharmacies and official institutions and laboratories.

The duty of importing, exporting, storing and distributing narcotic substances was given to ***the General Directorate of the Soil Products Office (TMO)***. TMO detects the need for this kind of material in the country and informs the Ministry of Health about bringing which substances, from where and what amount.

Drug manufacturers must obtain permission from the Ministry of Health every time for the controlled substances they receive directly from TMO.

Dispensing Controlled Drugs From Community Pharmacies

Normal Prescription

Red Prescription (for narcotic drugs)

Green Prescription (for psychotropic drugs such as barbiturates and benzodiazepines)

Purple Prescription (for blood components and products)

Orange Prescription (for hemophilia patients)

WHAT IS WHOLESALING?

According to '***By-Law on Pharmaceutical Wholesalers and The Products Stored in Pharmaceutical Wholesalers***'

Distribution by way of wholesale means '***selling or supplying it or procuring, holding or exporting it to a person who receives it for the purposes of selling or supplying it to one or more human beings in the course of business***'.

'***business***' includes a professional practice that of a medical practitionar.

*So, sales to a medical practitionar '**for use in his practice**' will be wholesale sale in health system.*

PHARMACEUTICAL WHOLESALERS

contribute an essantial link between
the ***pharmaceutical industry***
and
community pharmacies.

Retail sales from pharmaceutical wholesalers are prohibited.

Who may wholesale medicinal products?

Wholesaling of medicinal products may be carried out by:

1. Every pharmacist who has a right to open a pharmacy according to law on pharmacists and pharmacies-law no 6197.
2. Persons who are not pharmacists together with a responsible person (mesul müdür).
3. The companies.

Who may buy from wholesalers?

1. Pharmacies of public institutions and organizations.
2. Community pharmacies.
3. Other licensed wholesalers.
4. Public hospitals.
5. Public institutions and organizations that may receive wholesale medicines according to their special laws.
6. Health centers (sağlık ocakları).
7. Drug manufacturers.
8. Persons who are abroad and who are authorized to export drugs.
9. Certain health facilities that was established in line with special law (Regulation on Private Health Institutions for Outpatient Diagnosis and Treatment).
10. Veterinary clinics authorized to sell veterinary medicines, policlinics and animal hospitals.
11. Only for vaccines, private diagnostic and treatment centers.

Whıch products are prohibited to sell and distribute by wholesalers?

- Unauthorized medicines,
- Products containing prospectuses and promoted by medicinal impression as if a medicinal product,
- Counterfeit drugs,
- Medicines that are found to be improperly manufactured or contaminated,
- Expired drugs.

REQUIREMENTS FOR WHOLESALERS

By-Law on Pharmaceutical Wholesalers and The Products Stored in Pharmaceutical Wholesalers sets out the requirements for getting a licene:

- The wholesaler must display that the chemicals are registered in the codex.
- The wholesaler must maintain suitable staff, premises and facilities (should have a financial power enough for at least five pharmacies).
- The wholesaler must keep records of controlled substances properly.
- ***The Good Distribution Practices Guidelines of the Pharmaceuticals and Products Stored in Wholesalers.***
- A quality assurance system is required to guarantee the quality of the products stored in the pharmaceutical store throughout the shelf life.
- The wholesaler must control the storage conditions; check the safety of stocks and ready-to-ship products; determine the procedures to be applied for the returned products; organize emergency recall plan etc.

PHARMACIST COOPERATIVES

Pharmacist Cooperatives are organizations which;

- supply and distribute the requirements of the pharmacist partners,
- protect the rights and interests of the partners (pharmacists) by contributing in the healthy development of pharmacies and the pharmaceutical industry,
- aim at growth and improvement only with the power they receive by their partners and making the pharmacist have a voice in the industry.

COMMON PROPERTIES OF PHARMACIST COOPERATIVES

Equal Participation: Each member/partner has a single vote and equal rights to elect and be elected.

Transparency and Independent Audit: Pharmacist cooperatives are audited every year by independent audit companies.

Dividend: The cooperatives distribute the difference of income-expenditure they incur in a year to the partners on the proportion of their purchases (as per the Cooperation Law and the Articles of Association) as dividend.

Cooperatives do not consider the supply of medicines which is the primary requirement of their partners as a commercial activity. ***Sharing and equality*** is the main idea of pharmacist cooperatives.

Why the pharmacy cooperatives are more better than wholesalers?

- First of all, it should be known that cooperatives are not a special institutional structure, and that each member of the pharmacists who are the partners according to their capital is one of the stakeholders of the cooperative.
- The cooperative is not a private sector, but the pharmacist's own warehouse and power association.
- All rights obtained from the cooperative shall be distributed equally to the partners of the cooperative.
- The biggest difference from all the other pharmacy wholesalers is the pharmacists who are members of the cooperative determine all the developable and improvable projects.

- **Thank you for this week…**