PHARMACY LAW

Objectives

1. Describe the legal requirements of drug advertising and promotion in Turkey.
2. Identify the pricing system in Turkey.

Advertising and Promotion

Why is it important to regulate medicinal products' advertising?

Because medicinal products are more dangerous than most products, if a misunderstanding is occured the consequences may be more serious.

It is the responsibility and obligation of the pharmaceutical industry to provide training and accurate information to healthcare professionals about their products and ensure that they clearly understand exactly how to use medicines.

The advertising of medicinal products is controlled according to:

1. *Pharmaceutical and Medical Preparation Law No. 1262- Law No. 1262*
2. *'By-Law on Promotional Activities of Medicinal Products for Human Use'*

Advertisement to the public

Article 13 of the '*Pharmaceutical and Medical Preparations Law- Law No. 1262*' and Article 5 of the '*By-Law on Promotional Activities of Medicinal Products for Human Use*' prohibits advertising of medicinal products to the general public.

Advertisement to the public

How are the advertisements controlled?

The Supreme Council of Radio and Television (RTUK) is autorized to conduct examinations for radio and television broadcasts regarding the determination of advertisements that breach the principles set out in the '*Law on Establishment and Broadcasting of Radio and Television Institutions- Law No. 6112*'.

Advertisement to the public

According to Article 11 of the '*Law on Establishment and Broadcasting of Radio and Television Institutions- Law No. 6112*' :

- *No advertisements for prescription medicinal products or treatments can be broadcasted.*
- *Advertisements for non prescription medicinal products and medical treatments shall be prepared under the principle of integrity, and in such manner that they will comprise elements that reflect the truth and can be verified.*
- *Tele-shopping may not be permitted for pharmaceuticals and medical treatments.*

Advertisement to health professionals (Promotion)

Advertising to general public is prohibited, however promotion to health professionals within certain rules and limitations is allowed in Turkey.

What is promotion?

All informative activities organized by marketing authorization holders.

What are these activities?

The activities of product promotion representatives,

Advertisements published in medical or professional books or journals,

Announcements made through direct mailing or the press,

Scientific educational activities, meetings, and similar events.

Promotion Standards

The promotion of a product should provide members of the health profession with informative and evidence based information about the features of the product that will help them form their own opinions about the product's therapeutic value.

Promotion Standards

Promotion cannot be done using misleading, exaggerated information or information that has not been proven to be accurate, which may lead to the use of the human medical product being used unnecessarily or risky situations.

Promotion Standards

No cash or in kind advantage can be provided to physicians, dentists or pharmacists while introducing a human medical product to them and no such proposal or promise may be made. The said members of the health profession may not accept or request any kind of incentive during promotion activities.

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The Quality of Information and Scientific Proofs

1. The promotion of the medicine should be informative, accurate, realistic, complete based on the context, verifiable, reliable, and understandable enough for the physician to decide on the drug's therapeutic, diagnostic or other medical value, and pharmacist to make an opinion on the use of the drug and its features.,
2. Information on promotion materials must be based on the updated assessment of the scientific evidence available and comply with SPC (Summary of Product Characteristics)/ package insert information approved by the health authorities.
3. Scientific information must be available if requested by a healthcare professional.

Safety Data

Basic information on the safety of medicines; such as contraindications, situations that warrant caution, warnings, adverse effects and precautions that need to be taken should be provided in an appropriate and consistent manner in accordance with the information of product characteristics.

Free samples

Free samples may only be supplied to physicians, dentists, and pharmacists.

There are a number of conditions laid down:

- Samples may only be supplied in limited numbers,
- There must be a system of control and accountability,
- Only small size packs are allowed,
- Each pack must be marked ‘promotion sample- not for resale’
- Each sample must b e accompanied by

a copy of the SPC and package insert.

The Drug Pricing System in Turkey

Medicinal product prices in Turkey are regulated and controlled by TMMDA.

Drug prices are controlled under the supervision of the Ministry of Health.

Turkey uses a reference pricing system for originator products (‘*Decree on the Pricing of Medicinal Products for Human Use*’ which was published on the *Official Gazette* No. 30195 on 29 September 2017).

What is reference pricing system?

The reference pricing system is a system in which the payment to be made for a drug is determined based on the price of one or more alternative of the reference product. Reference price is the lowest sale price to wholesaler.

What are the other types of pricing?

1. Free Pricing

- In some countries, there is no centralized approach for pricing and reimbursement of drugs.
- The vast majority of drugs are listed automatically for reimbursement under national or social health insurance and prices are determined by the manufacturer.
  - In Germany, the prices of all drugs are freely determined by the manufacturers.
  - Companies are free to change the prices of the products. Germany applies the negative list system in reimbursement.
  - A drug that is marketed is automatically qualified as a reimbursed drug unless it is explicitly excluded.

What are the other types of pricing?

2. Direct Price Controls

Aims at fixing the maximum drug prices. What is the reasonable maximum price varies from country to country and depends on many factors, including budget limits, prescribing behavior, use patterns and the importance of the pharmaceutical industry in the national economy.

With the exception of Germany, where patented new drugs are freely priced when marketed, all European Union countries have direct price controls on patented drugs.

What are the other types of pricing?

2. Direct Price Controls

The price determination can be carried out by mutual acceptance as a result of the negotiations with the company as in France and Spain or by a unilateral decision of the price authority.

What are the other types of pricing?

2. Direct Price Controls

While the price is determined according to the mutual acceptance method, some criteria are taken as basis. These can be such as producer's costs, therapeutic efficiencies, R & D expenditures, prices of similar products, international prices, sales amount, advertising expenditures and contribution to national economy etc.

The most common of these criteria is to compare the prices of drugs in the same category within the country or other countries.

What are the other types of pricing?

3. Profit Controls

Profit controls are a system in which prices are not directly determined by the regulatory authority and can be considered as indirect price control.

In this system, the profits of pharmaceutical manufacturers is controlled rather than price.

This system, implemented by a small number of countries, first it was appeared in the UK. Currently, Spain, Korea, Czech Republic, Mexico and Turkey are applied this system.

What are the other types of pricing?

3. Profit Controls

Profit control system is divided into two as product profit control and manufacturer profit control.

1. In the profit control on product basis, a common profit rate is determined for each product by considering the costs related to the production of the product. The prices are determined within this framework. Thus, cost increases can be reflected directly to drug prices. (Spain and Turkey)
2. In the profit control on producer basis, producers can offer the products at any price in accordance with the profit margin of the firm. This margin is determined within a certain upper limit as a result of negotiations between the manufacturer and the regulatory authority. (UK)

The basic elements of the reference pricing system are:

1. Grouping drugs according to similar therapeutic or pharmaceutical effects,
2. Being free when product prices are determined by manufacturers,
3. The reference price is determined based on a certain point (minimum or average) within the prices in the group,
4. Setting the reference price as the maximum reimbursement price for the group created,
5. Manufacturars are free to put the price above the reference price, in that case, the difference is compensated by the consumer.

Why reference pricing?

Behind this widespread application of reference pricing;

- Contributes competition,
- The reimbursement can be made at an effective price level,
- Allowing consumers to pay for the drug they desire at a higher price if they would like to.

Reference Pricing

- Reference pricing identifies fixed reimbursement limits for the products in the same group.
- The purpose is to limit the increase in drug expenditures by demanding from patients to pay surplus if there is any surplus in the price of the prescribed drug according to the reference price.
- Even when reference pricing system has led to some savings in drug expenditure, this effect has generally been short-term. An explanation of this is that the increase in the consumption and price of drugs except the reference price system eliminates the drug savings usually achieved with this system.

The Pricing System in Turkey

In February 2004 a new pharmaceutical pricing system, namely the external reference pricing system, was launched.

The price for an originator product is determined according to the lowest ex-factory price among five EU countries (France, Spain, Italy, Portugal and Greece).

Some Definitions

Sales Price to Wholesaler (ex-factory price), is the sales price of the reference product, excluding VAT (Value-added taxt-KDV) and discount in the country/countries where the sale is offered.

Sales Price of Wholesaler, is the sales price of the product to the pharmacy excluding VAT.

Pharmacy Retail Price, is the sales price of the product to the public including VAT and mark-ups for wholesalers and pharmacies.

The Pricing System in Turkey

Once the ex-factory price of the drug is determined, the price is converted into ₺ by using the fixated euro value (2,6934 ₺); this price constitutes the sales price to wholesalers.

The fixated euro value is updated based on the fluctuations in the euro-₺ exchange rate. Even though 1 euro is currently exchanged for around 6.71₺ in the market.

The decree of pricing envisages an update in case of a change in the foreign exchange rate, government avoids using this current rate to hold ₺ prices of drugs lower.

The Pricing of Original and Generic Drugs

For original products, reference price is 100% of the price of the lowest ex-factory price.

For generics, prices are determined as 60% of the price of the original product.

The prices of generics cannot be higher than the originators' reference prices and the highest price of the equivalent generic in the market. If the originator lowers the price, the generics have to lower prices as well.

See you next week…