

Cost containment in the Pharmaceutical Sector

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1. Legal framework in the Netherlands

This chapter describes the main issues of the legal framework in the Netherlands:

- Law on Pharmaceutical Prices;
- Reimbursement system;
- Healthcare Market Regulation Act;
- Regulation on expensive drugs and orphan drugs;
- Top Institute Pharma.

1.1 Law on Pharmaceutical Prices (WGP)

A maximum wholesale price (or pharmacy purchase price) was introduced in 1996. The maximum wholesale price of all prescription-only medicines (POM) are calculated as the average wholesale price of comparable pharmaceuticals in four European countries, Belgium, France, Germany and the UK. Maximum list-prices are revised every six months. Pharmaceuticals are considered comparable when they contain the same active ingredient, strength and pharmaceutical form. The prices are divided by pack size to get the price per unit and for each country an average price per unit is calculated. The mean of these averages becomes the maximum price per unit of the comparable pharmaceutical in the Netherlands. A maximum price can be determined if a comparable pharmaceutical is on the market in at least two of the four reference countries. Both, patented pharmaceuticals and generics are treated in this way.

Wholesale margins are not fixed, but are based on individual agreements between the manufacturer or importer and the wholesaler, and vary from pharmaceutical to pharmaceutical.

1.2 Reimbursement system (GVS)

Reimbursable pharmaceuticals are listed on a positive list, which is divided into the following three categories:

- Annex 1A: Therapeutically interchangeable pharmaceuticals (including parallel imported pharmaceuticals) reimbursed according to a reference price system.
- Annex 1B: Unique pharmaceuticals (not reimbursed according to the reference price system, no reimbursement limit exists).

- Annex 2: Pharmaceuticals only reimbursed under specific circumstances, for example if prescribed by a specialist, if administered within a specialised health care centre (e.g. for cancer treatment), or after approval of the health insurance.

1.3 Healthcare Market Regulation Act

On the basis of the Healthcare Market Regulation Act the NZa sets maximum rates a pharmacy may charge a patient i.e. his health insurer. As of 1st of July 2008 self-dispensing doctors will receive the same dispensing fee as pharmacists.

This rate consists of two fees: a fixed amount for services provided by the pharmacy (€ 6.10 for each prescription dispensed) covering the costs of his pharmacy and his income and a fee to cover the costs of the purchase of the pharmaceutical supplied to the patient.

Both fees are maximum fees which are subject to negotiation with health insurers. The fixed fee is an amount that the pharmacy may charge per dispensed prescription.

The maximum purchase fee is in fact the list-price of the medicine as listed in the "tax" minus a clawback. Pharmacists are reimbursed these costs albeit with some restrictions. For generics, however reimbursement is based on the lowest priced generic that could theoretically supply the whole market. Pharmacists are generally reimbursed at the full list price (i.e. price according to the tax) minus the clawback because few manufacturers say they are able to supply the entire market. For parallel imports, reimbursement is based on the cheapest price per country of origin.

In practice, pharmacies agree discounts for these list prices from their suppliers. These purchase benefits are periodically the subject of public debate. Preferential policy is reducing the list-prices and therefore the amount of discounts pharmacists can obtain.

1.4 Regulation expensive and orphan drugs

Most of these drugs are only dispensed in hospitals. Dutch hospitals have a budget also covering the costs of pharmaceuticals. 80% of the costs of the expensive drugs admitted in this regulation are reimbursed to hospitals. 100% of the costs of orphan drugs are reimbursed to the hospitals because of the impact they have on the hospital budgets.

1.5 Top Institute Pharma

Top Institute Pharma is a public private partnership between the industry, the universities and the government. The goal of this institute is to improve the efficiency of the process of the development of pharmaceuticals.

2. Questions that are raised and debated in our country

The main issues of debate in our country are:

- Which innovation do we wish?
- How can this innovation be stimulated?
- Can we afford these innovative pharmaceuticals?

2.1 Which innovation do we wish?

Each year there are a lot of new pharmaceuticals on the market. However, most of the time these new pharmaceuticals are so-called me-too's. How can be stimulated the research to pharmaceuticals for diseases like Alzheimer or other diseases?

2.2 How can this innovation be stimulated?

The Netherlands try to stimulate this research by means of a public private partnership between the industry, the universities and the government (Top Institute Pharma). In Europe this is to be stimulated by the IMI. Furthermore, innovation is stimulated by the fact that innovative pharmaceuticals are fully reimbursed and not clustered (see 1.2).

2.3 Can we afford these innovative pharmaceuticals?

New pharmaceuticals are very expensive. Of course, the industry has to reward the stockholders. However, which price is reasonable? Why not lower the price, if more people are using the pharmaceuticals. For instance, pharmaceuticals like Imatinib, Adalimumab, Darbepoetine Alfa and Eterncept have nowadays a lot more users then in the beginning. If new pharmaceuticals become more and more expensive, and prices are not lowered if the number of users increases, it might become impossible to reimburse all pharmaceuticals. The price and volume arrangements made in France might be a solution.

3. Key issues and main questions proposed for debate

The main problem in our opinion is the transparency of the pharmaceutical market. Value-based pricing sounds theoretically very promising. However, at the moment there still is a lack of transparency of the revenues and costs of the pharmaceutical industry. Therefore, before value-based pricing can be introduced, it is necessary to have more insight in the revenues and costs of the pharmaceutical industry. How?

The second problem to our opinion is how to stimulate the wished innovation. In our opinion Top Institute Pharma and IMI are promising steps.

In these problems the EU might play a role, because these problems are EU-problems. All EU-Member States prefer to have knowledge about the revenues and costs of the pharmaceutical industry. Furthermore, an EU-research program might be helpful to all Member States.

However, each Member State has its own social system, its own welfare level. Therefore, it is impossible to decide at a European level which pharmaceuticals are reimbursed at which price. How reimbursement levels are determined etc. We are not sure that equity pricing is the solution to improve access of other Member States.