

# New government measures aim to keep medicines affordable

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The minister for medical care recently announced a set of measures to control the rising costs of pharmaceutical drugs, which – without action – are forecast to rise by at least 10% annually. The measures aim to guarantee patient accessibility to medicines and the affordability of care in the long term. The minister estimates that the measures – including those discussed below – will save the country €467 million per year by 2022.

## **Lower maximum prices for medicines**

The minister wants to amend the Medicine Prices Act to set lower maximum prices for medicines. When pharmacists buy medicines, they cannot pay more than these maximum prices. At present, the maximum allowable rates are set by comparing prices in four reference countries: Belgium, France, the United Kingdom and Germany.

Medicine prices in Germany are significantly higher than in the Netherlands. Therefore, the minister wants to replace Germany as a reference country with a country with lower rates. As a result, the Dutch maximum rates will drop. Because the Netherlands is a reference country for 15 other countries, this drop could also affect prices in other countries.

This measure will mostly affect manufacturers of patented medicines, as the majority of these medicines are sold at the maximum price. By contrast, patent free medicines are often priced lower than the maximum prices due to competition.

## **Price negotiations**

Further, the minister wants to undertake frequent negotiation regarding expensive medicines by using the so-called 'sluice' more often. The sluice is a mechanism where expensive drugs are removed from the open inflow into the insurance package. While the drug is in the sluice, government authorities can assess its effectiveness and the minister can negotiate the price with the manufacturer. The drug will become accessible as an insured form of care only:

- when there is a reasonable price and cost projection; and
- if there are sufficient guarantees for responsible use and good evidence of its efficacy.

In July 2018 the sluice criteria were lowered. Medicines that cost €50,000 per treatment per year or more than €40 million in total per year can be put into the sluice. In March 2018 the minister identified eight medicines that are expected to be registered in 2018 and will probably be put into the sluice. By comparison, the sluice has been used eight times since its introduction in 2015.

## **Compulsory licences**

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In addition, the minister wants to investigate the possibility of compulsory licences in order to lower the prices of expensive patented medicines.

A compulsory licence can be granted to a third party when it is required by means of general interests – for example, when price negotiations have failed. Due to the compulsory licence, the medicine can nonetheless be made accessible for patients.

However, under the Medicines Act, the licensee must prove that the medicine has demonstrated efficacy and is safe. This requirement can be a burden, because the patentee has an exclusive right to the research data for 10 years. When the patentee does not give permission to use such data, the licensee must conduct its own research or wait until the 10 years are over. When the drug is an orphan drug, others cannot register a drug with the same therapeutic value in any case during the 10 years.

This data and market exclusivity are a result of the EU Directive on Medical Products. The minister will explore the possibilities to terminate data and market exclusivity rights in the case of compulsory licences.

### **Preference policies**

Finally, the minister also wants to ensure that the so-called 'preference policy' remains possible.

In the Netherlands, most health insurers provide cover only for the cheapest version of a registered medicine. The cheaper medicines (ie, generic drugs) have the same active ingredient as the branded drug. By using cheaper versions, health insurers spend less money on medication.

Further, the minister wants to stimulate the use of biosimilars and recently granted a subsidy to stimulate awareness about their possibilities.

### **Comment**

Evidently, the minister of medical care is planning to use several different methods to control the rising costs of pharmaceutical drugs in the Netherlands.

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