



The Netherlands

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

Mitigating measure ERP

- Medicines in the Netherlands have a maximum price based on external reference pricing. This measure replaces a temporary measure taken by the COVID-19 crisis. This precautionary measure is intended to prevent medicine shortages as a result of the maximum prices. October 2023, tentatively, the measure will probably be replaced by a **more permanent mitigating measure**. This precautionary measure will increase the maximum prices of groups of pharmaceutically comparable medicines with relatively low sales (below 500k annually) by 15 percent.

CHANGES IN REIMBURSEMENT

Changes in access to hospital drugs

- There will be an update of the **additional conditions** in the Internal Reference Pricing (probably in May)
- The Dutch government will be tightening up the rules for reimbursement of the most expensive medicines as of July 1, 2023. To increase its control over the costs of medicines, the Dutch government introduced the **Coverage Lock (CL)** policy in 2015. The CL is a negative list which postpones decisions regarding reimbursement of expensive medicines until an HTA has been concluded by the National Health Care Institute. The threshold value for the application of the CL will be lowered, after which more medicine will be reviewed into detailed prior to price negotiation and reimbursement. The **threshold will be lowered** from € 40 million to € 20 million annual expenses.

OTHER CHANGES

- A comprehensive healthcare agreement has been reached in the Netherlands. The agreement covers a wide range of topics, including long-term care, mental health care, and expensive medicine. In the area of expensive medicine, the agreement includes an annual maximum acceptable expenditure growth of 5% to 7% between 2023 and 2027. The agreement was reached after extensive negotiations between government officials, healthcare providers, and patient organizations.
- Dutch horizon scanning is increasingly using the information generated by the international horizon scanning initiative.
- In 2023 a dashboard will be designed to improve insight into timelines throughout the reimbursement decision making procedure.
- Currently no inflation mitigating measures are taken
- In light of EU regulation the national debate focuses on undesired market behaviour of pharmaceutical companies e.g. evergreening, incremental indication extensions, budget impact of any give product, etc. A project is starting to look at the Value framework applied to medicines.
- There is a notification centre where MAH must report supply interruptions. These notifications are assessed on duration and availability of alternatives. If a shortage with no alternatives will occur, solutions will be investigated depending on the duration of the shortage. Solutions could include scaling up of other MAH, new registrations, import of a similar medicine, etc. There is a roadmap for this process that we are currently reviewing.

SPECIAL TOPIC:

Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

Medicine shortages

- During Covid we established a coordination centre for medicines, they currently still play a role in severe shortages, e.g., in mapping supply and demand, coordinating distribution of stock and working with medical specialists in prioritizing patients.
- Safety stock: Per 1 January 2023, the legal obligation of 'sufficient supply' is quantified to 6 weeks of safety stock for MAH and 4 weeks for wholesalers