



## **New regulation: the Netherlands lock system for new medicines**

The Netherlands Minister of Health recently tightened the regulation for reimbursement of new highly specialised inpatient medicines<sup>1</sup>. Usually, inpatient medicines are automatically included in the insurance benefits basket if they meet all quality standards.

The National Health Care Institute (“Zorginstituut”) is the reimbursement authority and draws up a horizon scan for new medicines; a horizon scan is an integral and public overview of all new medicines that are expected to enter the market soon and their (financial) impact. The National Health Care Institute advises the Minister about the financial risks of including the new medicines on the positive list.

The new medicines can be very expensive resulting in reduced cost effectiveness; the claim of new medicines on the health care budget is also substantial.

In 2015, the Minister introduced a lock system (“sluis”) for certain medicines before inclusion in the insurance benefits basket. Only included medicines are eligible for reimbursement.

During the process of admission into the lock, the Ministry negotiates for lower prices. The negotiated discount is not publicly disclosed for each individual medicine. When a price settlement is reached, the medicine is included in the positive list and reimbursed.

. The regulation on this matter has two criteria for admission to the lock:

- i. The annual total macro costs are more than € 40 million or
- ii. The annual costs of dispensing the medicines are more than € 50,000 and the annual total macro costs range between € 10 and € 40 million.

### **Defining a strategy**

The tightened regulation for admission of new medicines in the benefits basket poses challenges. Tagliente can help you define a strategy and provide expertise to the following questions:

- How affects the new regulation your business?
- Who are the stakeholders involved?
- What is their role and decision power?
- Which (negotiation) strategy is best needed prior to and in the lock?
- And after that, you still need to get the medicine to the patient!

Tagliente can offer you a concise advice and guide you through the entire process. We have partnerships with consulting firms for specific additional pharmaceutical knowledge.

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<sup>1</sup> These can also be existing highly specialised medicines in case of extensions of indications