The Netherlands

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING

Transfer of medicines from outpatient to inpatient (ongoing)
Goal: more market power in hospitals

As of 1 January 2019 VAT on medicines from 6% to 9%

Changes in the Dutch ERP basket (Germany out, Norway in) pending parliamentary approval implementation in 2020
Goal: price pressure

Changes to the (VT) Temporary and conditional access to medicines with a focus on orphan drugs and medicines with conditional approval by the EMA (effective mid 2019)
Goal: improve early access to medicines

CHANGES IN REIMBURSEMENT

Preparation to modernize the internal reference pricing (IRP) system: streamlining or an abolition of the IRP? (deadline 2022)

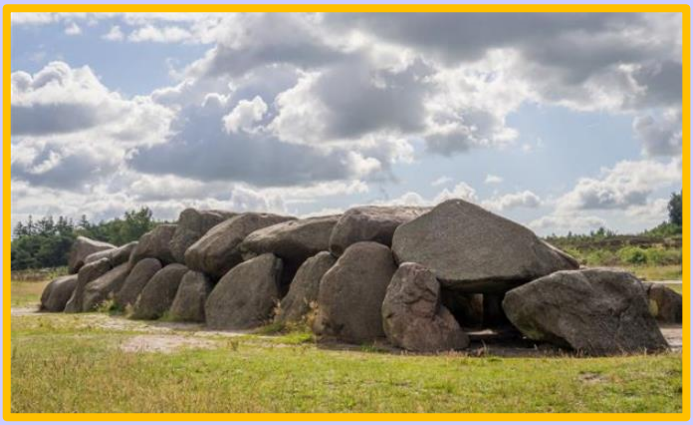
As from 1 January 2019 the patient's out-of-pocket payments on medicines will be maximized at € 250 per year per patient

National Park Duinen van Texel (10.625,4 acres)
It has had the status of National Park since 2002

National Park De Hoge Veluwe (13.590,6 acres)
It has had the status of National Park since 1935

OTHER CHANGES

- **IT projects**: rebuilding GENMID (IRP) and GENEUR (ERP)
- **Discussion** about pharmaceutical production in hospital pharmacies of registered products: CDCA (chenodeoxychol acid) case. In the Netherlands there was a registered product (Chenofalk) for the treatment of gallstones until 2009. After 2009 AMC (hospital pharmacy) have been preparing this medicine exclusively for their own patients but they have also used it for a rare disease. A new manufacturer has registered this product again for the rare disease and has drastically increased the price. Is this allowed and how are Health Insurers going to reimburse this price?



National Park Drentsche AA (24.710,2 acres)
It has had the status of National Park since 2002

National Park De Biesbosch (22.239,2 acres)
It has had the status of National Park since 1994

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

- No special incentives are provided to bring an orphan drug to market if it is authorised in the Netherlands. New CED Programme (to replace current VT): specific focus on inter alia bridging the gap between medicine approval and reimbursement of orphans.
- There are two specific programmes at ZonMw with regard to orphan medicines (correct use of medicines and translational research)
- Compassionate-use programmes are allowed in the Netherlands (financial responsibility of manufacturer)
- No specific limitations on access to orphan drugs. The medicines are reimbursed either through:

  1 IRP (Internal Reference Pricing) or
  2 direct coverage for in-patient or
  3 an MEA following lock procedure (see below)

- Place of treatment (Centre of Expertise)
- There are no special arrangements for setting a price for orphan medicines in the Netherlands
- There are no special funds to reimburse orphan medicines
- Reimbursement rates are not higher for orphan medicines
- Assessment of orphan medicines is done in the same way as regular assessments of medicines (National Health Care Institute). If the price is extremely high, the National Health Care Institute will advise negotiations with the manufacturer.

LOCK PROCEDURE

By default, in-patient drugs are reimbursed directly following MA (= Market Authorization).
If a drug meets criteria
1 total expenses of 1 medicine (with all indications) 40 million or more per year (whole population)
2 total expenses of a treatment per person (one indication) € 50.000 or more per year and the total expenses of this medicine (one indication) are 10 million or more per year

the product will be excluded from automatic reimbursement, awaiting obligatory MEA (=Managed Entry Agreements)