



# The Netherlands

## Ministry of Health, Welfare and Sport

### AUTHORIZATION/CLASSIFICATION

**EMA or Medicines Evaluation Board (CBG)**

- Decision on authorization and registration
- Quality, safety, efficacy (Directive 2004/27/EG or Medicines Act)

**Medicines Evaluation Board (CBG)**

- Decision on prescription and dispensing requirements
- Directive 92/26/EEG and Medicines Act

### PRICING

Out patient      In patient

**Pharmaceutical companies**

- Determine list price

**Ministry of Health**

- Calculation of maximum prices using external reference pricing (Medicines Pricing Act)
- Reference basket: UK, France, Belgium and Germany
- Option to negotiate price for selected medicines

**Wholesaler**

- Mark up not regulated

**Z-index**  
Publication price list (taxe)

**Pharmacies**

- remunerated according to tax-price (pharmacy purchase price)
- 6% VAT for all medicines

**Dutch Health Care Authority (NZa)**

- Determines tariff for healthcare providers
- Determines special tariff for high cost drug and orphan medicines (add-on)

**Hospital**

- Negotiate with pharmaceutical companies on prices
- In some cases using regional purchasing groups (tenders)
- Apply for special tariff

### REIMBURSEMENT

Out patient      In patient

**Ministry of Health**

- Final decision on reimbursement status based on formal appraisal and advice from the Health Care Institute (ZINL)
- Option to negotiate terms of reimbursement for selected medicines
- Option to conditionally reimburse medicines pending additional research on effectiveness / cost effectiveness

**National Health Care Institute (ZINL)**

- Advice on reimbursement for all out-patient medicines
- In some cases advice on reimbursement for in-patient products
- Appraisal criteria: necessity, efficacy, cost-effectiveness, feasibility.

**Reimbursement System (GVS)**

- Positive list for reimbursed medicines
- Internal reference pricing for therapeutic equivalent products (set limit)
- Co-payment: if price is higher than the maximum price or the group price (IRP)
- If registered for specific indication or sub-set of patients reimbursement can be limited
- No reimbursement: most OTC and small number of POM

**Health insurers**

- Reimbursement if medicine is on positive list
- Generics: therapeutic substitution, preference policy

**Reimbursement system:**

- Hospital budget
- Reimbursement using DRGs
- Additional compensation for high cost medicines
- No co-payments for patients
- Negotiation between health insurers and hospital on tariff for reimbursement

**Hospital**

- Individual decision on procurement of medicines

**Health insurers**

- Reimbursement if medicine is determined to be in line with the current established medical science and medical practice