



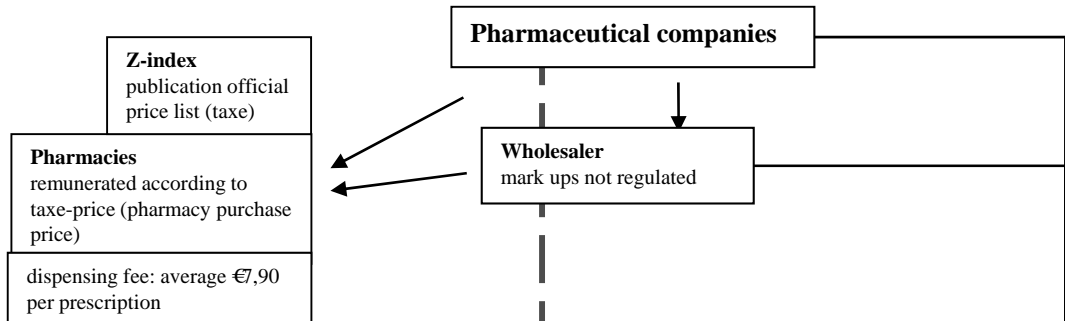
AUTHORIZATION/  
CLASSIFICATION

**EMA or Dutch Medicines Evaluation Board (CBG)**  
 Task: Decision on authorization and registration  
 Criteria: Quality, safety, efficacy (Directive 2004/27/EG or New Medicines Act)

**Dutch Medicines Evaluation Board (CBG)**  
 Task: Decision on prescription and dispensing requirements  
 Criteria: Directive 92/26/EEG and New Medicines Act

PRICING

**Ministry of Health**  
 Task: Calculation of maximum prices  
 Criteria: external price referencing; Medicines Pricing Act (WGP)



REIMBURSEMENT

**Health Care Insurance Board (CVZ)**  
 (College voor Zorgverzekeringen)  
 Task: decision on reimbursement  
 Criteria: medical therapeutic, pharmaco-economic

consulted by  
**Pharmaceutical Care Committee (CFH)**

**Dutch Health Care Authority (NZA)**  
 Task: set tariffs for DRG groups; maintain list of high-cost and orphan medicines for hospitals

**Reimbursement System (GVS)**  
 positive list for reimbursed medicines

<b>reimbursement limit</b> therapeutically interchangeable medicines	<b>fully reimbursed</b> unique medicines, proven clinical benefit and cost-effectiveness
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optional: conditions for reimbursement (only reimbursed when used for specified indications)

not reimbursed: most OTC's

**Hospital**  
 Task: decision on use of medicines  
 Criteria: clinical benefit, user-friendliness, costs

Pharmaceutical formulary per hospital

**Regional purchasing groups**  
 task: purchasing of medicines (tendering)

- most medicines paid for out of hospital budgets (via DRGs) - extra financial compensation from health insurer for medicines on NZa list of high-cost and orphan medicines

OUT- IN-  
PATIENT