Denmark

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Flowchart of the pharmaceutical system

AUTHORISATION / CLASSIFICATION

European Medicines Agency (EMA) or Danish Medicines Agency (DKMA).

Task: Decision on authorization and registration

Criteria: Quality, safety, efficacy etc. (Directive 2004/27/EC) and Danish Medicines Act, No. 1180 of 12 December 2005.

Danish Medicines Agency

Task: Categorises pharmaceuticals into POM, pharmacy-only OTC (Ha), OTC for limited free sale (Håndkøb, Hx) and OTC for general free sale (Frihandel, Hf)

Criteria: Safety, suitability for self-medication, etc. (Danish Medicines Act, No. 1180 of 12 December 2005 and Executive Order on Prescriptions, No. 155 of 20 February 2007)

Task: Decides if pharmaceuticals (generics) are substitutable or not substitutable

Criteria: Active ingredient (ATC-5 level), bioequivalence, strength, pack size (Section 61 of the Danish Medicines Act, No. 1180 of 12 December 2005 and Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98)

PRICING

Pricing is free. However, the DKMA has to be notified of the PPP.
No permanent price control. Prices are set freely.
DKMA publishes the consumer price and reimbursement price.

The companies can change prices every two weeks
Prices are subject to subsequent control by the Danish Competition Council.

OUTPATIENT SECTOR

INPATIENT SECTOR

DKMA advised by the Reimbursement Committee

Task: Decides on eligibility for general or conditional reimbursement

Main criteria: Therapeutic value and cost-effectiveness according to the Danish Health Act, No. 546 of 24 June 2005 and Executive Order, No. 180 of 17 March 2005 on Reimbursement

Reimbursement types

Reimbursable medicines

General reimbursement. Prescription-only pharmaceuticals eligible for reimbursement automatically

General conditional reimbursement. Prescription-only pharmaceuticals prescribed for specific diseases or groups of persons

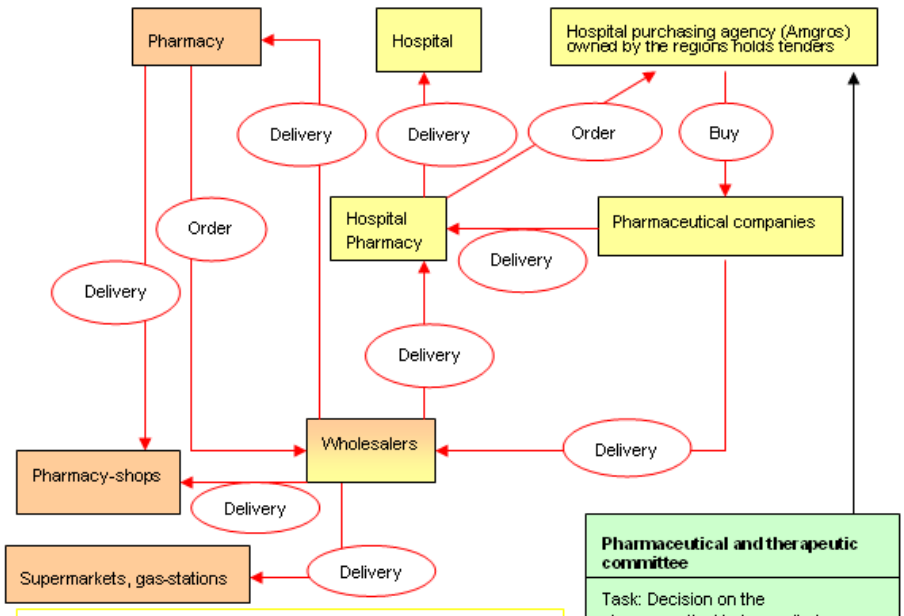
General conditional reimbursement. OTC pharmaceuticals prescribed for specific diseases or groups of persons

Non reimbursable medicines

Individual reimbursement on applikation from doctor.

The amount of reimbursement is calculated on the basis of the price of the cheapest pharmaceutical with the same active substance (ATC-level 5) (= reimbursement group).

Distribution



All hospital treatment in public hospitals, including pharmaceuticals, is provided free of charge to the patient.

Pharmaceutical and therapeutic committee

Task: Decision on the pharmaceutical to be applied in hospital pharmaceutical formulary