Denmark

Danish Medicines Agency

Flow chart – pharmaceutical system in Denmark in the in- and out-patient sector

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 pharmacy purchase price (PPP).
No permanent price control. Prices are set freely.
The Danish Medicines Agency must be notified of the pharmacy purchase price.

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

Price ceiling. From 2009 up to 31 December 2011, the price on medicinal products cannot be raised above the price applying to individual packages on 30 August 2006.

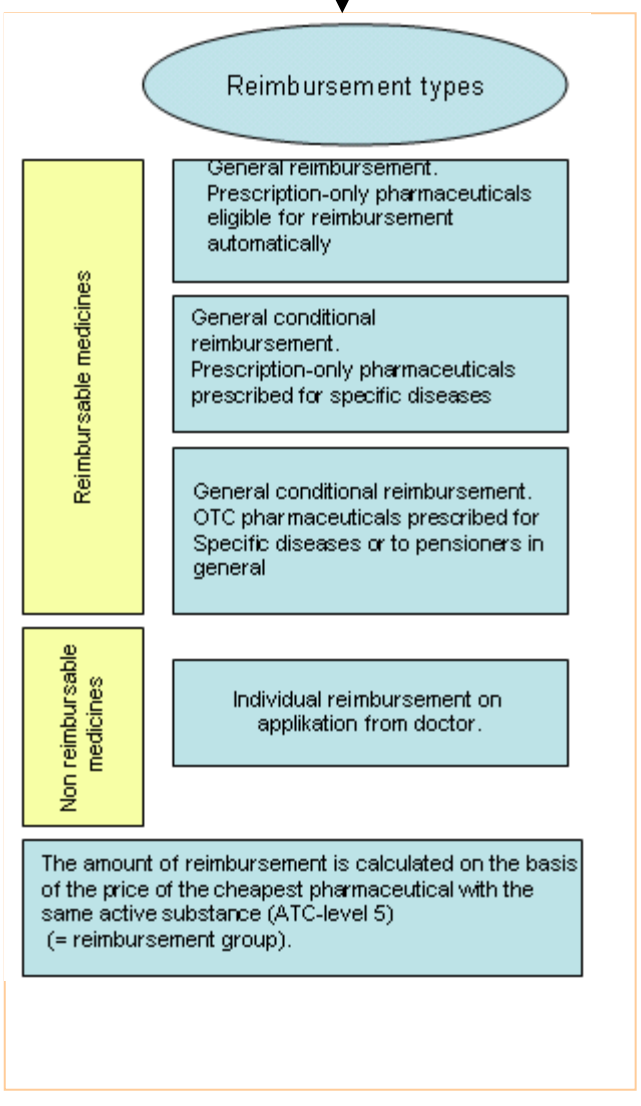
Prices are the same in all pharmacies

The pharmacy retail price is regulated by law. It is made up of the pharmacy purchase price plus a fixed amount and a percentage profit.

The wholesale margins are determined through negotiation between the individual manufacturer or importer and the wholesaler, and the profit level is determined by competition

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



INPATIENT SECTOR

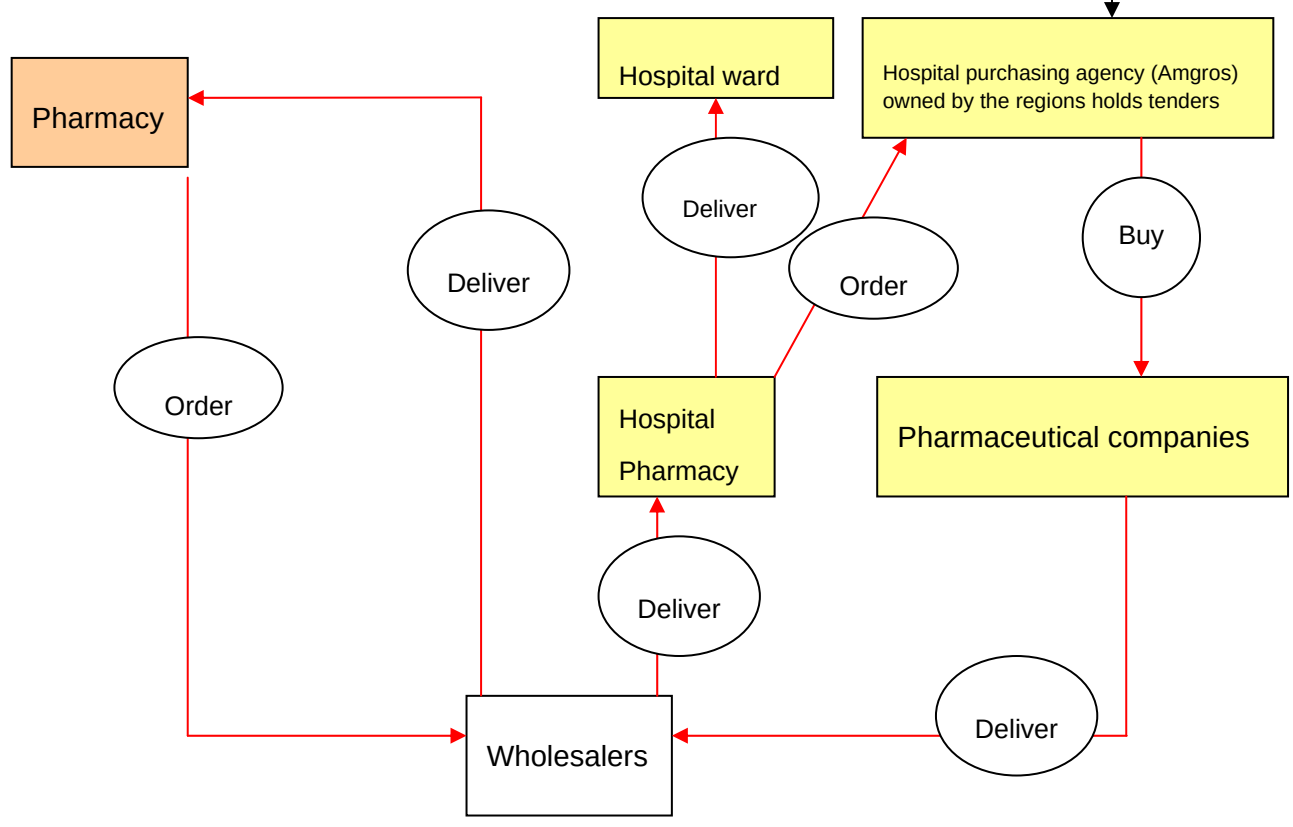
The regional council of each of the 5 regions.

Task: The Regions are responsible for running the hospitals and for financing pharmaceuticals

Pharmaceutical and therapeutic commitee

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

Distribution



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