

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.
PRICING	Danish Medicines Agency	
	Task:	Categorises pharmaceuticals into POM, pharmacy-only OTC, OTC for limited free sale and OTC for general free sale.
	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 is free. However, the DKMA has to be notified of the pharmacy purchase price (PPP). No permanent price control. Prices are set freely. Prices are subject to subsequent control by the Danish Competition Council	DKMA publishes the consumer price and reimbursement price. The companies can change prices every two weeks

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

