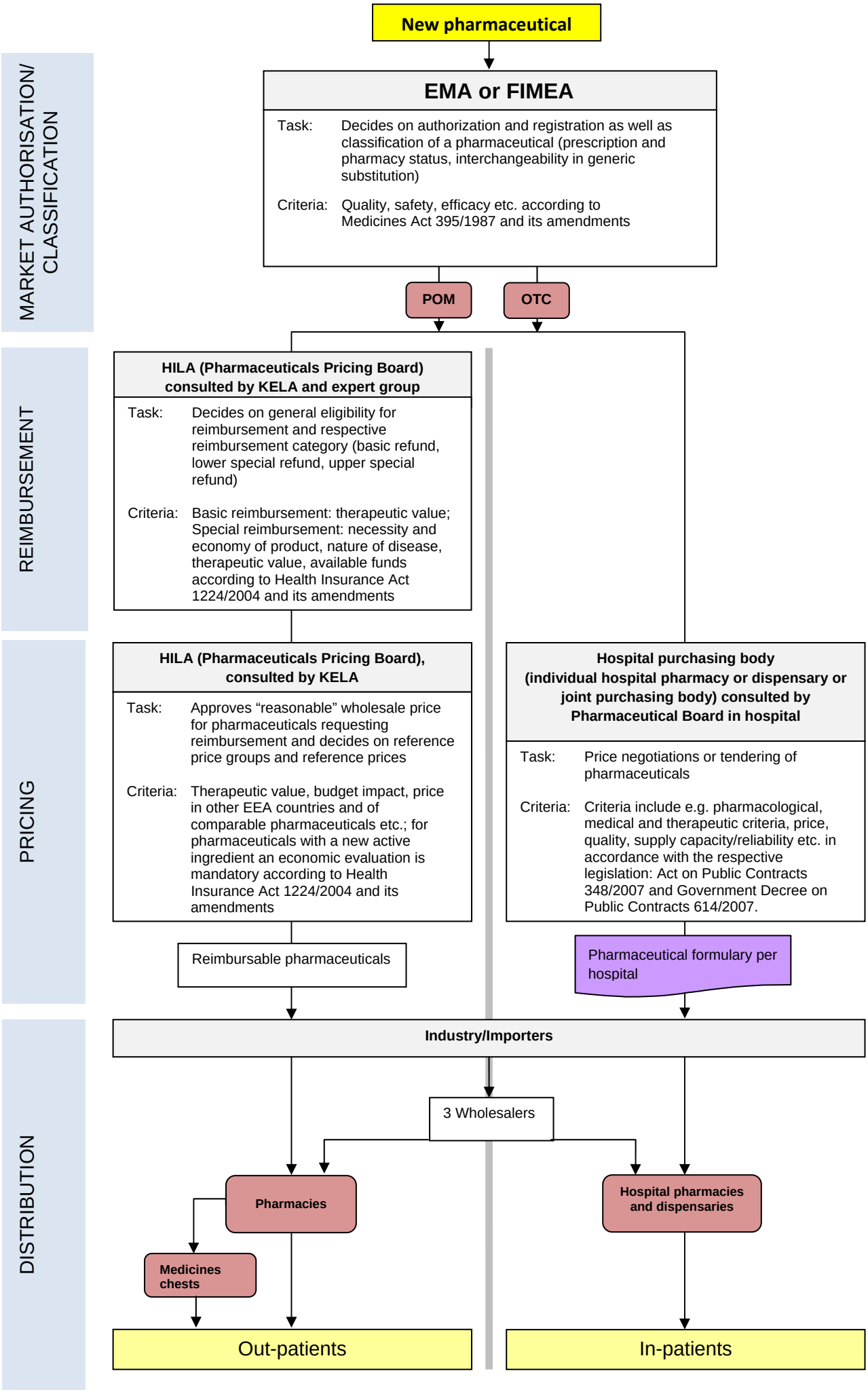
New pharmaceutical
MARKET AUTHORISATION/ CLASSIFICATION
EMA or FIMEA
Task: Decides on authorization and registration as well as classification of a pharmaceutical (prescription and pharmacy status, interchangeability in generic substitution)
Criteria: Quality, safety, efficacy etc. according to Medicines Act 395/1987 and its amendments
POM
OTC
REIMBURSEMENT
HILA (Pharmaceuticals Pricing Board) consulted by KELA and expert group
Task: Decides on general eligibility for reimbursement and respective reimbursement category (basic refund, lower special refund, upper special refund)
Criteria: Basic reimbursement: therapeutic value; Special reimbursement: necessity and economy of product, nature of disease, therapeutic value, available funds according to Health Insurance Act 1224/2004 and its amendments
PRICING
HILA (Pharmaceuticals Pricing Board), consulted by KELA
Task: Approves "reasonable" wholesale price for pharmaceuticals requesting reimbursement and decides on reference price groups and reference prices
Criteria: Therapeutic value, budget impact, price in other EEA countries and of comparable pharmaceuticals etc.; for pharmaceuticals with a new active ingredient an economic evaluation is mandatory according to Health Insurance Act 1224/2004 and its amendments
Hospital purchasing body (individual hospital pharmacy or dispensary or joint purchasing body) consulted by Pharmaceutical Board in hospital
Task: Price negotiations or tendering of pharmaceuticals
Criteria: Criteria include e.g. pharmacological, medical and therapeutic criteria, price, quality, supply capacity/reliability etc. in accordance with the respective legislation: Act on Public Contracts 348/2007 and Government Decree on Public Contracts 614/2007.
Reimbursable pharmaceuticals
Pharmaceutical formulary per hospital
DISTRIBUTION
Industry/Importers
3 Wholesalers
Pharmacies
Medicines chests
Hospital pharmacies and dispensaries
Out-patients
In-patients
OUT-PATIENT
IN-