

Denmark

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Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

OUT- PATIENT IN - PATIENT

PRICING

In the out-patient sector the Danish Medicines Agency (DMA) are the competent authorities for pricing and reimbursement.

- Free pricing on pharmaceuticals
- Pharma supplier companies can do biweekly pricing changes, with notification to DMA
- High competition by the system biweekly pricing have resulted in some of lowest priced generics at European level

In addition, a price cap agreement exists, between the Ministry of Health, Danish Regions and The Danish Association of the Pharmaceutical Industry. Result is a cut of 15 % on list price level for pharmaceuticals used in the in-patient sector. In out-patient prices can not be increased.

Pharmacy remuneration are 8.2% + 5,46 DKK of the pharmacy purchasing price ex. VAT (25 %)

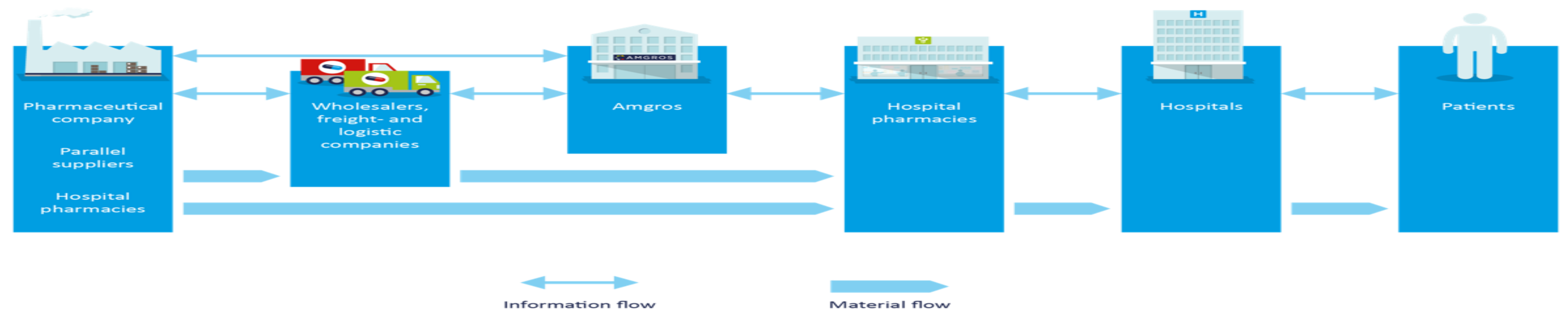
In the in-patient sector the national procurement organisation AMGROS I/S are the competent authority for procurement of pharmaceuticals to hospitals at national level

- The Danish hospitals procure medicines via EU legislated tenders, managed and owned by AMGROS I/S in a national centralized procurement setting
- Tenders are either with one or more winners, and criteria can both be qualitative in combination with price or price alone
- Prices are confidential retail prices to hospital pharmacies and within the EU tender legislation context
- Key focus is to secure supply to the hospitals in Denmark and to have fair competition on prices

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HTA process: The funding model is defined by a combination of the clinical added value and the health Economical analysis, followed by a negotiation with the supplier of the medicine, resulting in a contract. The contract can either be defined as a single supplier contract or performed as a procurement contract with bids.

Distribution chain at hospitals in Denmark:



REIMBURSEMENT

The Reimbursement Committee advises the DMA on which products that is reimbursed. The Danish Regions are the payer of the reimbursement. The regions are publicly funded. There are three types of reimbursement, which are listed below.

Annual personal expenditure on reimbursable medicine before deduction of reimbursement	Reimbursement for persons over the age of 18	Reimbursement for persons under the age of 18
0-131 €	0%	60%
131 – 218 €	50%	60%
218 – 471 €	75%	75%
In excess of 471 €	85%	85%
In excess of 2.554 € (Under the age of 18 3.137 €)	100%	100%

The Medicine Council evaluates- with armlength principle to AMGROS I/S – incoming applications for the reimbursement.

Reimbursement is based on the positive decision from Medicine Council in Denmark.

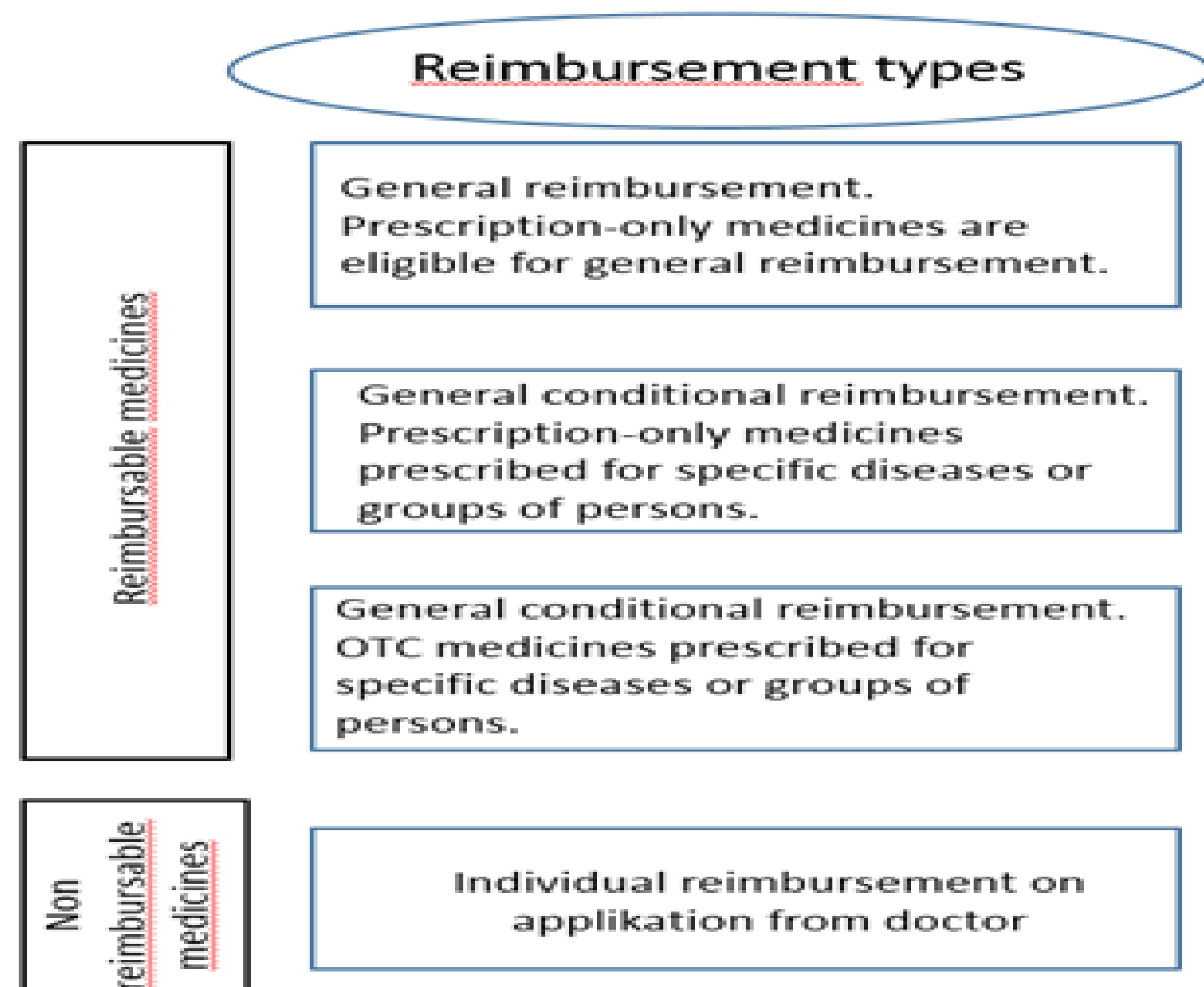
If a positive reimbursement is achieved, implementation in the hospitals will be taken place after a tender or contract agreement on national level through AMGROS I/S as procurement body.

In the formularies at hospital level, the decisions on which medicines to choose and use will be highlighted.

All hospital treatments are full reimbursed for the patients.

All new medicines and indications apply for a SoC decision through the medicine council, prior to contracting or procurement.

In-patient sector reimbursement types & in-patient sector pilot scheme for conditional reimbursement



Pilot scheme for conditional reimbursement on terms of risksharing

Pharmaceuticals with a risk of first-line use, even though it should not be the case, are not eligible for general or conditional reimbursement.

Only pharmaceuticals where the risk is economic could be a part of the pilot scheme.

Two products have been chosen to be a part of the pilot scheme. **Brilique 60 mg** for AMI and **Skilarence** for psoriasis.

DMA have estimated the patient population which fulfil the clause for the pharmaceuticals. The companies have to reimburse the expenses for the patient population which exceed the estimated population.



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