

Meeting between EUROPE and the Danish Medicines Council

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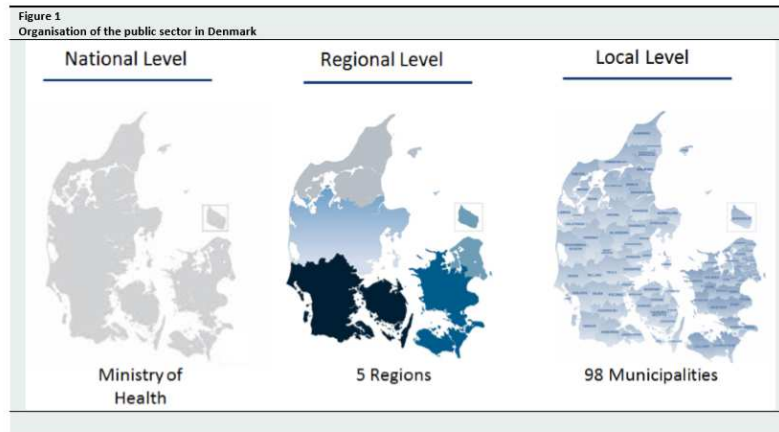


Agenda



- Brief introduction to DMC
- Brief introduction to AMGROS
- Questions

The organization of Health Care in Denmark



 Medicinrådet

Organizational structure of the Danish healthcare agencies related to medicines



Danish Medicines Agency

- Marketing authorization – Medicinal products
- Reimbursement – Primary Health Care
- Prices
- Groups of distribution

Danish Medicines Council

- Asses new medicine /new indication – hospital only
- Treatment guidelines

 Medicinrådet

Development of the Danish Medicines Council

1990: Amgros

2009: RADS, Danish Council for the Use of Expensive Hospital Medicines

2012: KRIS, Coordination Council for deployment of hospital medicines

2017: DMC, Danish Medicines Council

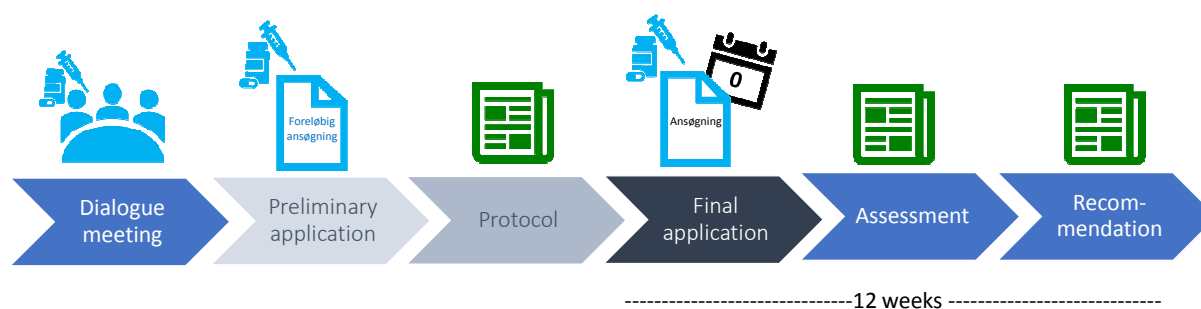


The Danish Medicines Council assesses:

- **New hospital medicine / new indication** – what is the added clinical value compared to medicines already in use and what are the expenses?
- **Several medicines within the same therapeutic area** (treatment guideline)



Application process



 Medicinrådet

What causes delays?

- Difficulties in establishing an expert committee

- Impartiality
- Few experts in the specific area

⇒ Day 0 starts later

- Delays in deliveries from applying company

- Meetings with the expert committee are postponed

- Incomplete final applications not fully answering the questions in the protocol

⇒ Deadlines for meetings in the Medicines Council can not be met

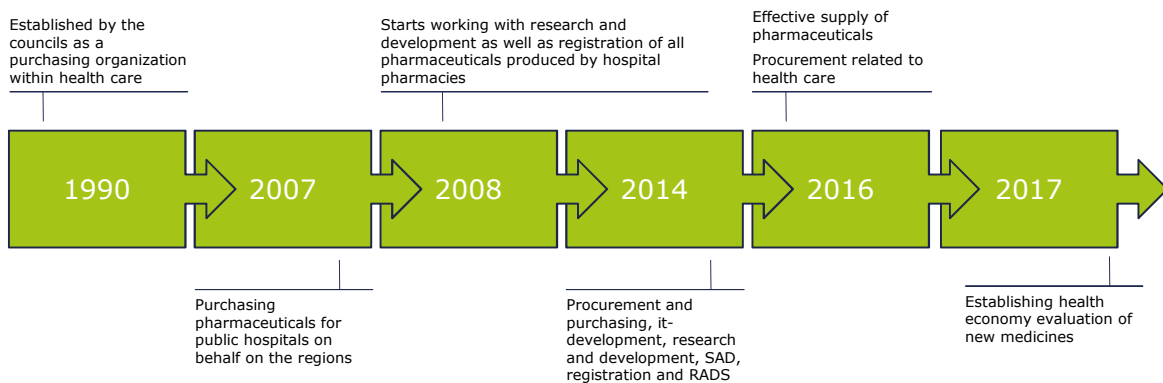
 Medicinrådet



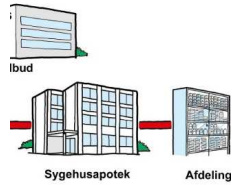
AMGROS



TRANSFORMATION FROM PURCHASING ORGANIZATION WITHIN THE PHARMACEUTICAL AREA TOWARDS MORE STRATEGIC BUSINESS DEVELOPMENT ORGANISATION



"THE PHARMACEUTICALS MARKET"

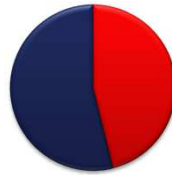


MARKET SHARE IN DENMARK

TOTAL MARKET 2017 – 2.6 BILLION EURO (PPP)

Market share 60%
Turnover 1.55 Billion EURO

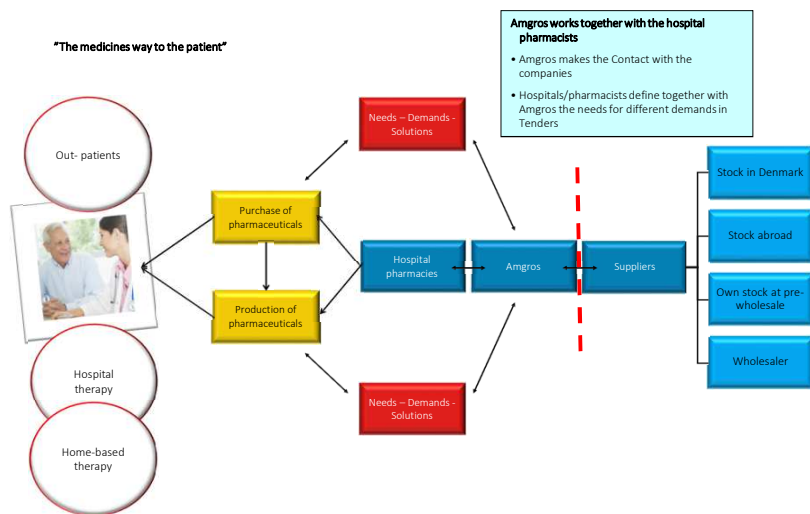
Market share 4%
Turnover 1.05 Billion EURO



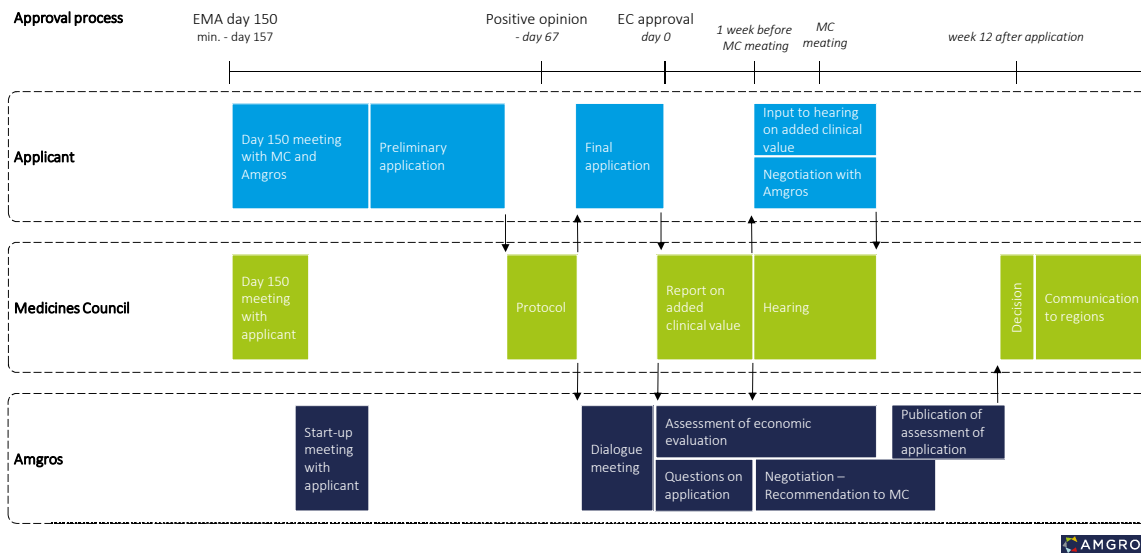
■ Primær sektor ■ Hospital sektor

Kilde DLI

SUPPLY AND COLLABORATION WITH THE HOSPITALS FOR PHARMACEUTICALS



PROCESS FROM EMA DAY 150 TO DECISION IN DANISH MEDICINES COUNCIL (MC)



THE APPLICATION

Economic analyses

When submitting an application to the Medicine Council, the applicant must also submit two types of economic analyses for Amgros' assessment.

Cost analyses

The purpose of the cost analysis is to estimate the total incremental cost to society per patient for the compared medicines.

Budget impact analysis

The purpose of the budget impact analysis is to estimate the total economic impact of using the medicine on a regional level.

Guidelines are available on www.Amgros.dk

ECONOMIC ANALYSES

Special attention points in the process

- Important that the economic analysis are based on the clinical protocol
- Important that the analyses complies with the defined guidelines
- Important that you are available to answer questions regarding the economic analysis 1-3 weeks after submitting the final application
- Important that you inform in the case of changes in timeline or content

NEGOTIATIONS

- Price negotiations will be based on the cost- and budget impact analysis in combination with the Medicine Council's evaluation of the added clinical value
- The negotiations will be based on the conclusions on the added clinical benefit from the Medicine Council and the conclusions on the added costs of using the medicine from Amgros
- The purpose of the negotiations is to reach a **reasonable relationship between the added clinical benefit of the medicine and the added costs** of using the medicine compared with the current standard treatment

PROCESS FROM EMA DAY 150 TO DECISION WITH SH MEDICINES COUNCIL (MC)

