



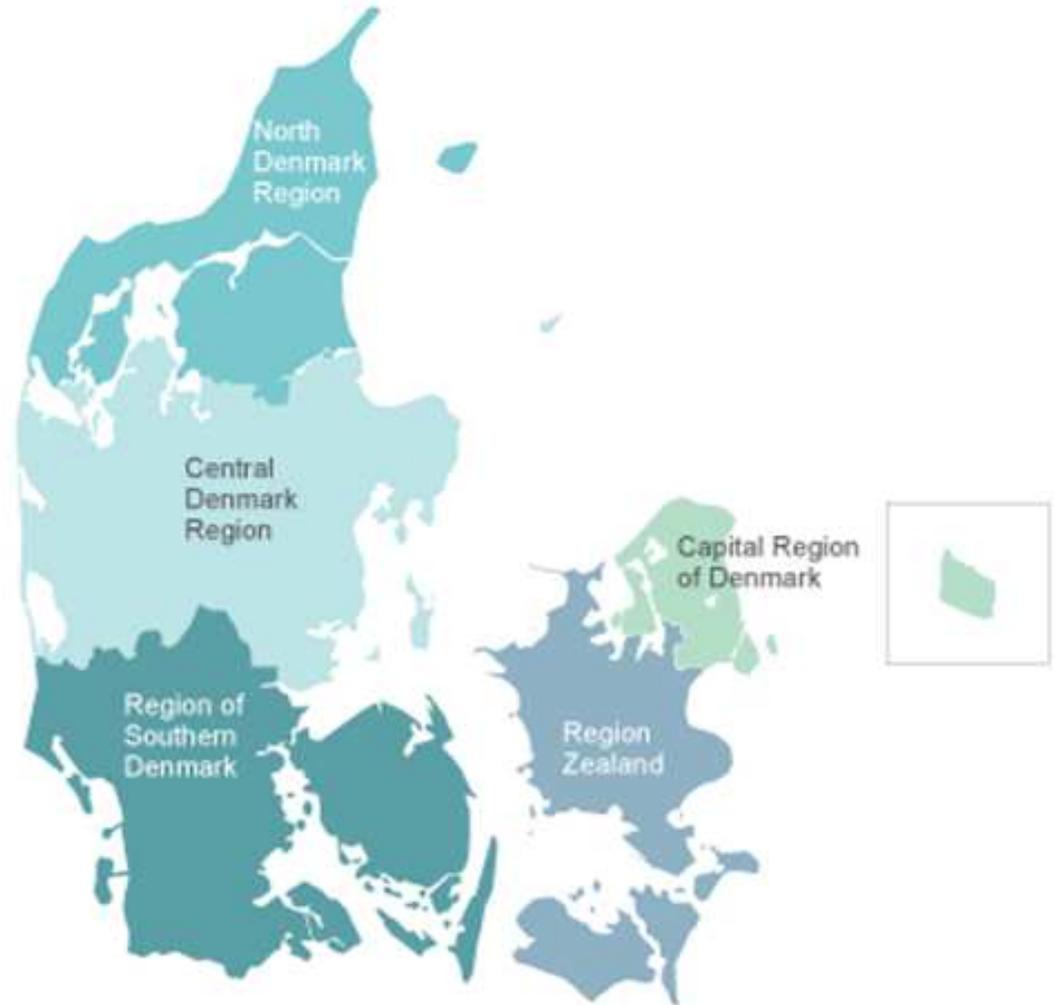
Update on the Danish Medicines Council and Nordic joint procurement

June 2018

The Danish Medicines Council

The Danish Medicines Council is to:

- + Ensure fast and homogeneous use of new and existing medicines across hospitals and regions
- + Impose stricter requirements for documentation to support that patients will benefit from new and existing medicines
- + Enhance the basis for Amgros' price negotiations and calls for tenders. Amgros is the joint procurement service for the Danish regions and is mostly concerned with procurement of medicines for hospital use.



Application overview

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

↑ Indicates transfer of document

Approval process

EMA day 150
min. - day 157

Positive opinion
- day 67

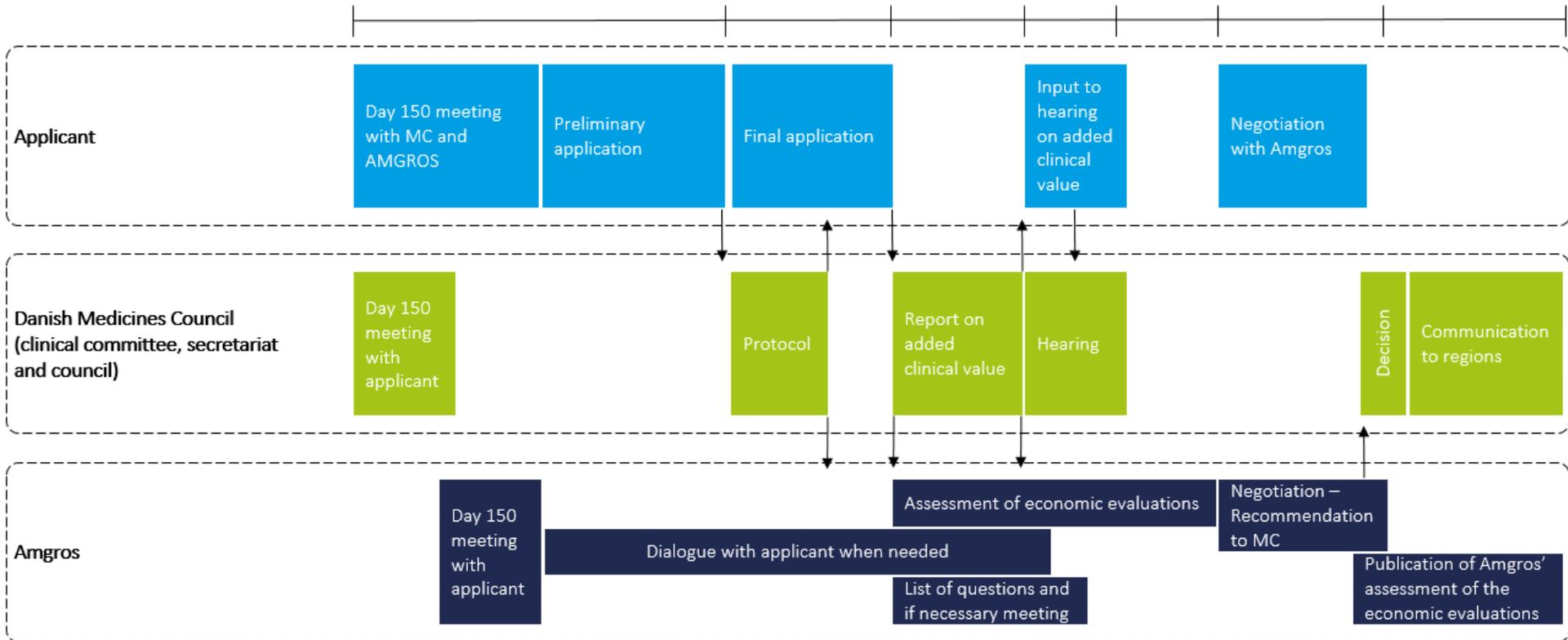
EC approval
day 0

week 2-5

week 6-8

week 10

week 12



Source: <http://www.amgros.dk/en/health-economics/new-medicines-and-new-indications/>



Danish Medicines Council – Status June 2018

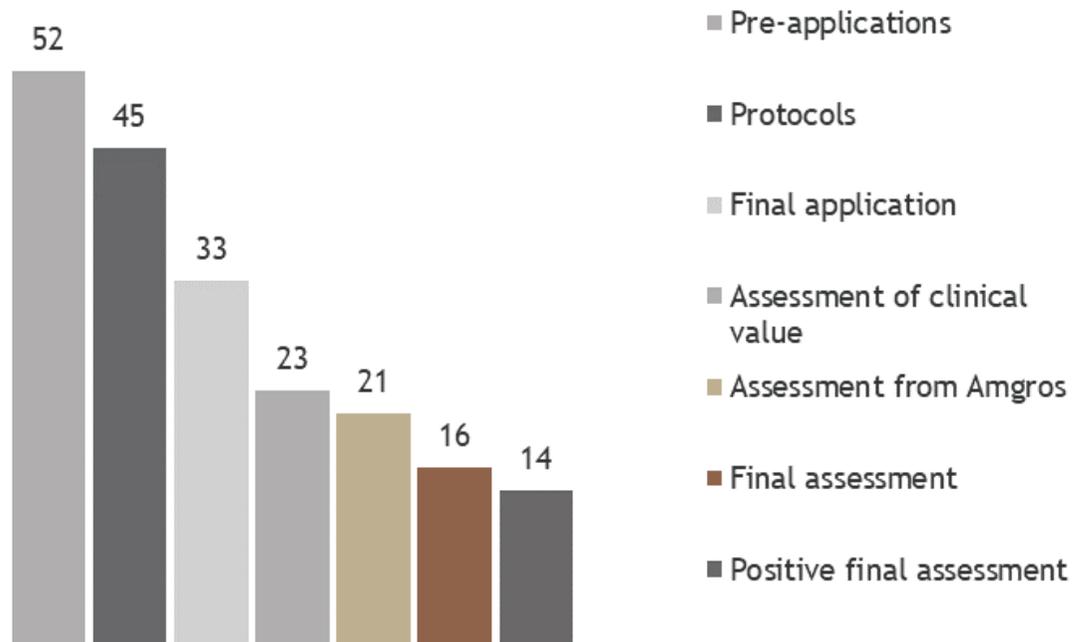


The current status of the Danish Medicines Council (DMC)

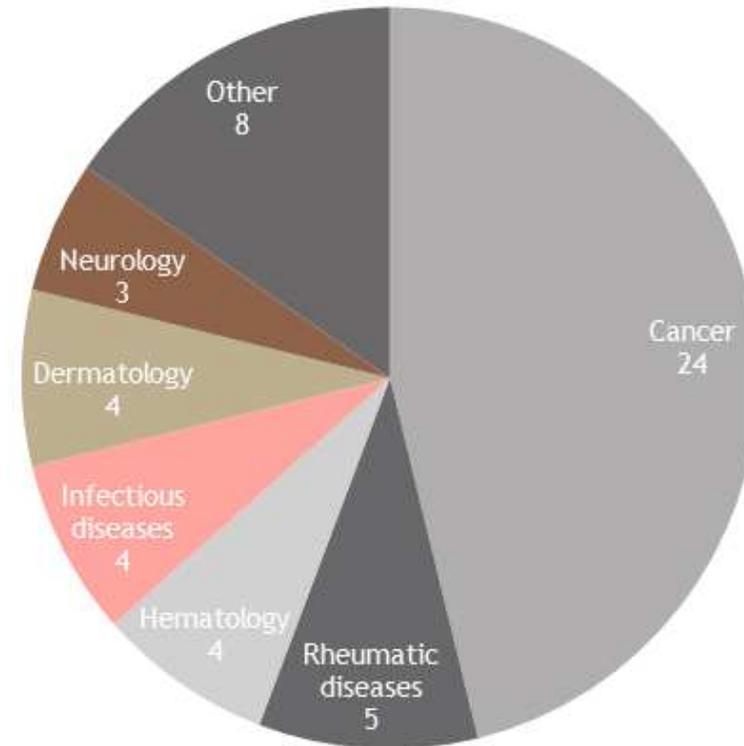
- + Price is increasing issue!
- + Official guide from DMC on HEOR as they see quality varies
- + The initial dialogue meeting is close to mandatory
- + Changes in current application vs. start a new application process
- + Few examples where a company successfully changed the comparator, but it is possible.
- + No “low border” set. I.e. the whole process has to be followed also for products with very few patients or little economic impact.
- + Recently an internal battle in DMC between the “Expert Committee” and the “DMA Deciding Committee”. The expert committee kept arguing for a higher rating.

DMC - applications

- + 52 pre-applications in the system end May 2018 and 14 of these have positive final assessment.

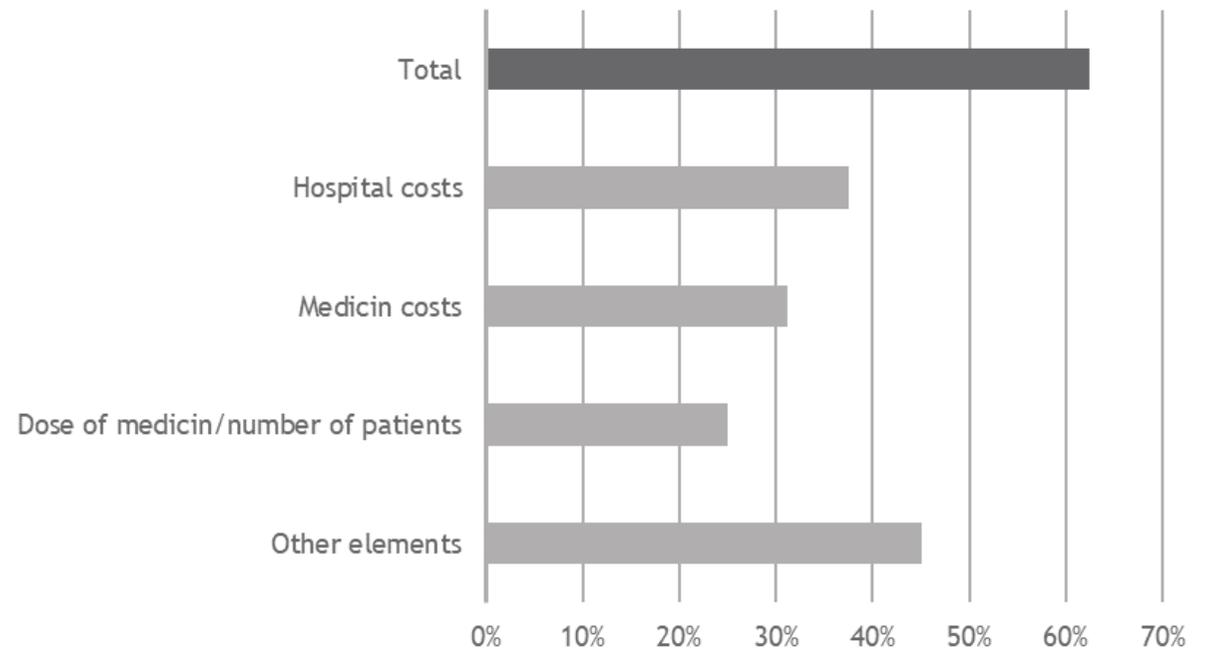


Application data on disease area. Cancer drugs lead the way.



Amgros changes assumptions in more than 60% of applications

- + Amgros is scrutinizing the economic application (cost per patient / budget impact analysis)
- + Amgros performs their own assessment and changes assumptions. Keep the models transparent and user friendly.
- + Amgros made changes in the assumptions for more than 60% of the applications



How do you increase chances of approval at a fair price level?



To increase chances of approval and obtain fair price:

- + Remember that Denmark is the country in the world with the highest level of trust among people. Be realistic from the beginning.
- + Present your product and its benefits in a clear, honest and balanced way without exaggeration or bias
- + Give the authorities what they ask for. If it is not possible, explain why. Several cases where an alternative solution was accepted.
- + Make sure doctors in the “Expert Committee” understand the data and can convey the message to the “DMC Deciding Committee”.
- + Keep the dialogue close to DMC to maintain current application and avoid to re-apply.

Keep up to date:

- + Join the linkedIn group “Market Acces in Denmark”
- + Sign up for quarterly updates on “MEMO” – focusing on DMC data and hot topics in the applications.

Contact details

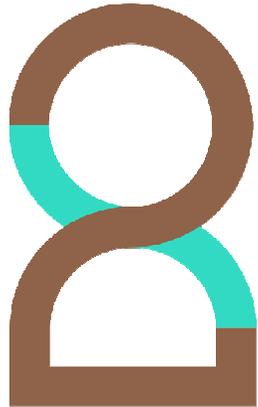


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