



LÆGEMIDDELSTYRELSEN

EU Joint Clinical Assessment – One for All and All for One?

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Agenda



Organisation of Danish HTA bodies

Multiple organisations are involved



Implementation of JCA in Denmark

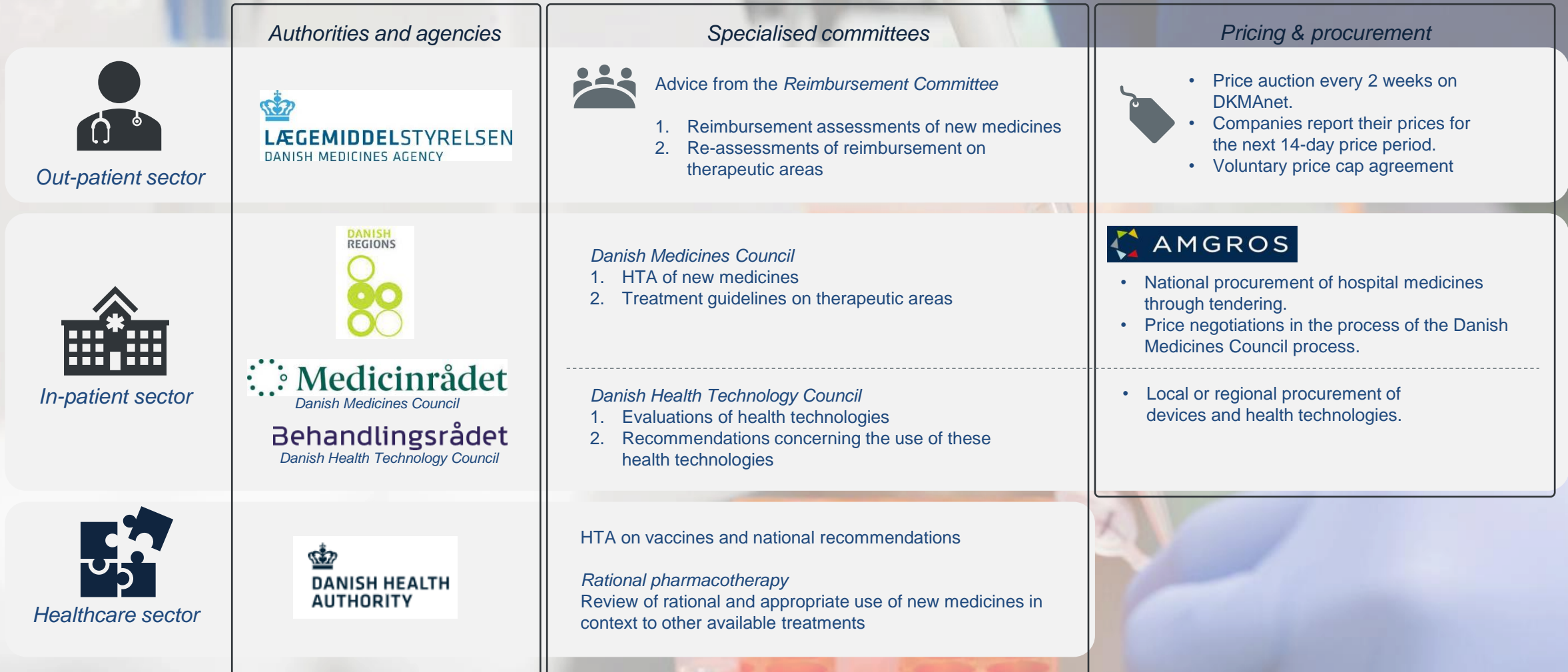
Cooperation and focus on Danish clinical practice



JCA in relation to the local scope

Short timelines from EU HTA application to national decision on reimbursement

Multiple HTA bodies are involved in HTA decisions





Implementation of JCA in Denmark

- All national HTA bodies cooperate on implementing the HTAR – in EU fora and nationally.
- Focus on the methodology and procedural guidance documents from the HTA Coordination Group.
- The scoping process guideline will be a key document in order to define PICO's that reflects clinical practice in Denmark.



Member States are obliged to use the JCA

1. When carrying out a national HTA on a health technology for which joint clinical assessment reports have been published or in respect of which a joint clinical assessment has been initiated, Member States shall:

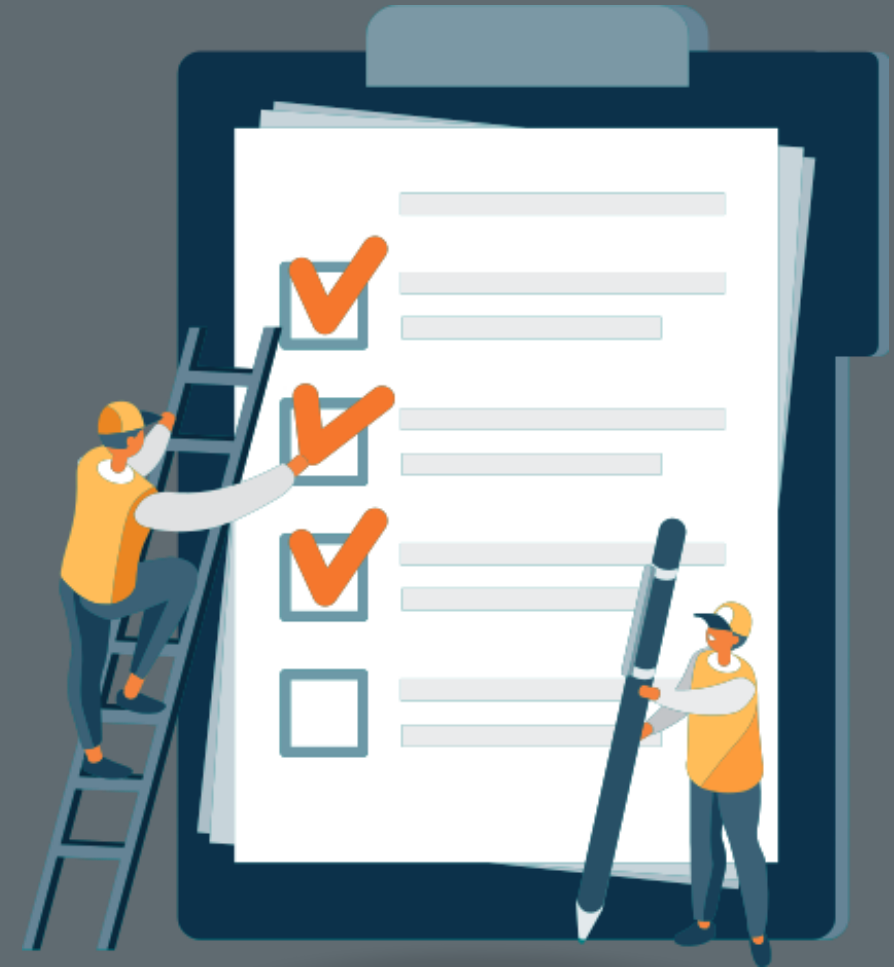
(d) not request at the national level information, data, analyses or other evidence that has been submitted by the health technology developer at Union level in accordance with Article 10(1) or (5);

- According to Article 13(d) in the regulation Member States can "not request at the national level information, data, analyses or other evidence that has been submitted by the health technology developer at Union level..."
- The scoping process will be essential to identify PICO's that reflect clinical practice in Denmark.
- A national assessment can be performed if the clinical scope used in the EU JCA do not reflect clinical practice in Denmark, e.g. if there is need for analyses based on other subgroups or other comparators.



JCA in relation to reimbursement in the primary healthcare sector

- The DKMA receives reimbursement applications without any predefined scope of the assessment.
- HTDs can reach out, if they have any questions regarding the assessment scope.
- The application is assessed according to the main criteria for reimbursement: is the price of the medicinal product is proportionate to the therapeutic value compared with other relevant treatments





JCA in relation to the local scope in the hospital sector

- The Danish Medicines Council (DMC) receives a request for assessment from the HTD which includes a suggestion regarding PICO.
- If the PICO does not correspond to the Danish PICO, the HTD will be informed about this prior to submission of their application.
- The DMC has the option of requesting additional information throughout the assessment process.
- Implementing the HTAR will require a formalised evaluation of the assessment scope and PICO's at an earlier timepoint.





The unknown

FUNDING

How will the Member States be funded for working as assessor or co-assessor on a EU JCA?

TIMELINES

Clarity of EU JCA timelines is needed to analyse the need for local adaptation of HTA processes.

INSIGHT

How can local HTA bodies follow the EU JCA work and prepare for the national assessments?

NATIONAL SETUP

How will we ensure a robust national setup and coordination between all four national HTA bodies?



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