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

### Authorities and agencies

**Out-patient sector**
- Danish Medicines Council
  1. HTA of new medicines
  2. Treatment guidelines on therapeutic areas

**In-patient sector**
- Danish Health Technology Council
  1. Evaluations of health technologies
  2. Recommendations concerning the use of these health technologies

**Healthcare sector**
- HTA on vaccines and national recommendations
  - *Rational pharmacotherapy*
  - Review of rational and appropriate use of new medicines in context to other available treatments

### Specialised committees

**Advice from the Reimbursement Committee**
1. Reimbursement assessments of new medicines
2. Re-assessments of reimbursement on therapeutic areas

**Danish Medicines Council**
1. HTA of new medicines
2. Treatment guidelines on therapeutic areas

**Danish Health Technology Council**
1. Evaluations of health technologies
2. Recommendations concerning the use of these health technologies

### Pricing & procurement

**AMGROS**
- Price auction every 2 weeks on DKMAnet.
- Companies report their prices for the next 14-day price period.
- Voluntary price cap agreement

- National procurement of hospital medicines through tendering.
- Price negotiations in the process of the Danish Medicines Council process.

- Local or regional procurement of devices and health technologies.
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

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.
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 proportionate to the therapeutic value compared with other relevant treatments.

JCA in relation to reimbursement in the primary healthcare sector
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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