



Could Early Dialogues in Medical Devices Accelerate Reimbursement?

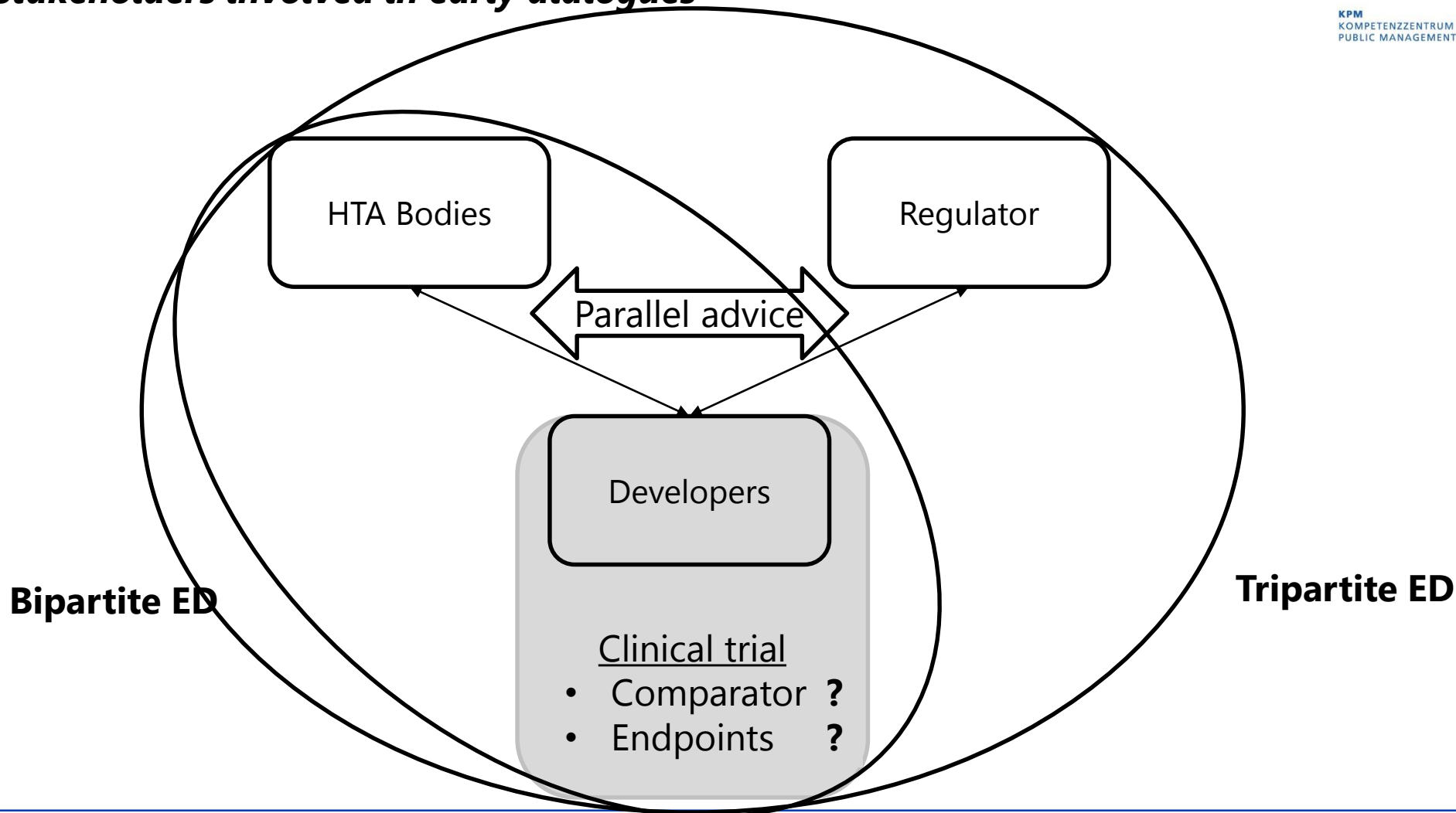
HTAi Session: Policy Issues: Market Access of Medical Devices

Cologne, June 17, 2019

Florian Dams

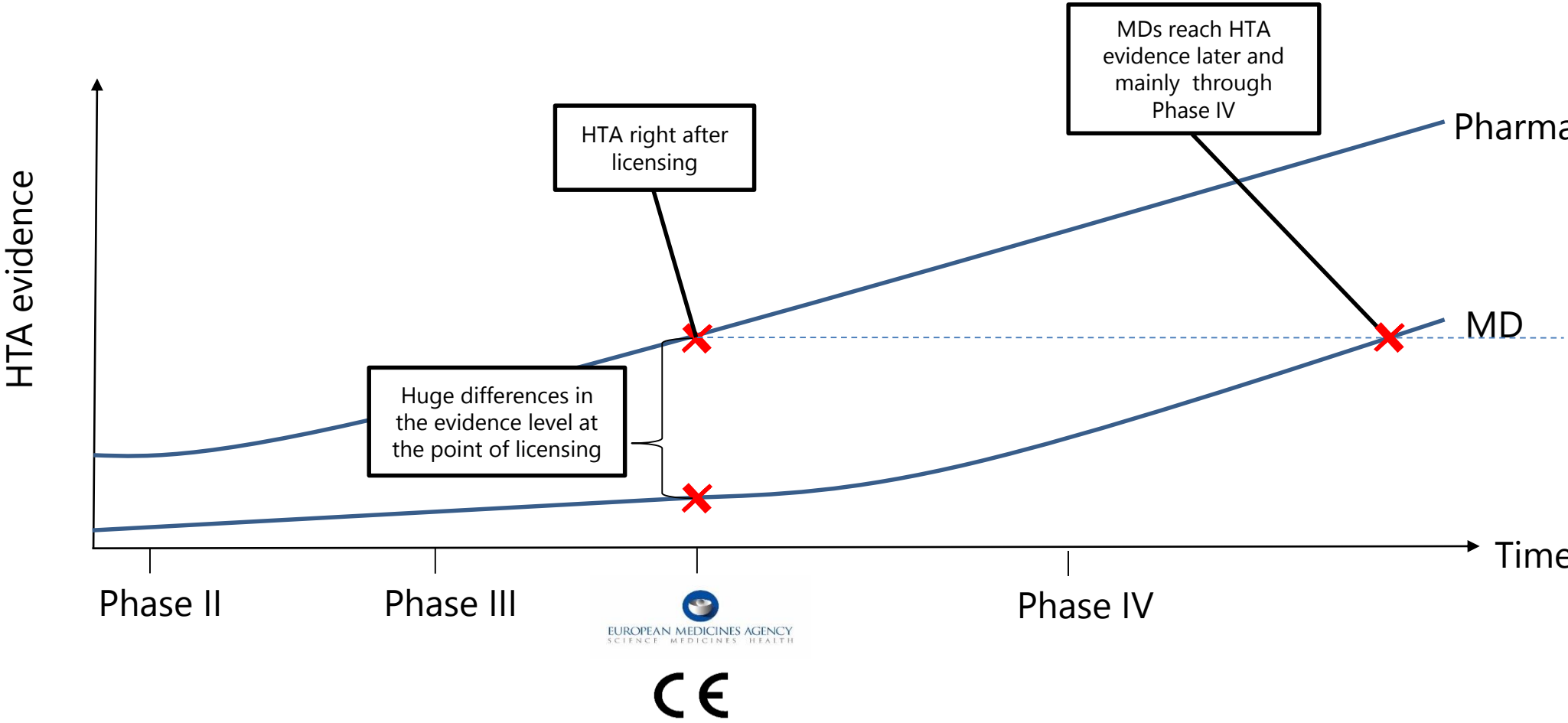
Early dialogues aim to improve the data produced by developers in view of future HTA assessments

Stakeholders involved in early dialogues



Medical devices lack HTA relevant evidence at market launch

Level of HTA evidence for medical devices and pharmaceuticals



Little is known about early dialogues in medical devices when compared to pharmaceuticals

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Reasons to investigate

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

- **Joint clinical assessments**
- **Joint scientific consultation**



- **multi-HTA Early Dialogues for MDs**
- **1 completed, 1 in progress, 1 withdrawn**
- **workshop Task force on HTA and MDs**

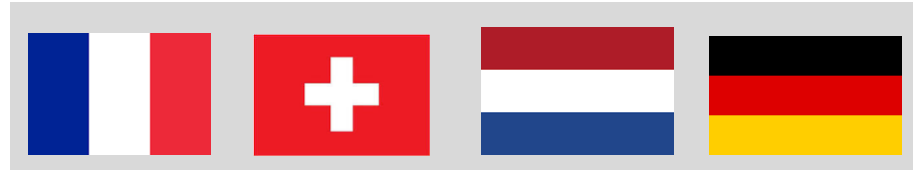
We survey Developers, Regulators (competent authorities) and HTA Bodies about their knowledge and preferences in Early Dialogues

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Focus countries

Social Health Insurance (SHI):



National Health Systems (NHS):



Central and Eastern Europe (CEE):

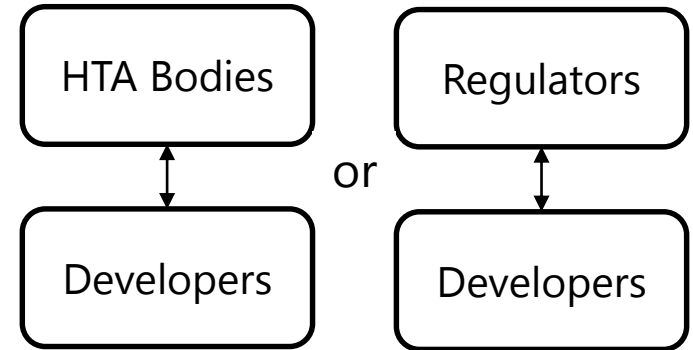


The first part of the survey asks stakeholders about bipartite EDs, whereas the second asks about tripartite EDs that involve regulators

Structure of the questionnaire

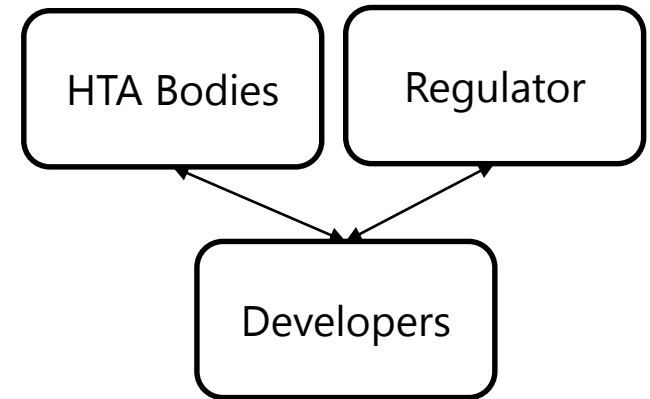
Bipartite (current situation)

- Do HTA bodies and Competent Authorities offer EDs?
- Are manufacturers aware of it?
- What are challenges and opportunities?



Tripartite (future scenario)

- Do HTA bodies and Competent Authorities cooperate?
- Do stakeholders see potential for tripartite EDs for MDs?
- What are challenges and opportunities?



The piloting revealed several challenges for bipartite but in particular for tripartite EDs involving regulators

Piloting feedback

Developers

- HTA does not seem to play a huge role yet
- Many SMEs, with fewer resources
- Currently challenged by MDR

Regulator

- Notified bodies are not allowed to consult
- HTA requirements should not interfere with the regulation

HTA Bodies

- HTA is most advanced and used in pharmaceuticals

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