



RECOMMENDATIONS FOR EFFECTIVE CROSS-COUNTRY COLLABORATION: STAKEHOLDER PERSPECTIVES ON THE BENELUXA INITIATIVE

Lammens Michiel¹⁺, Claessens Zilke^{1*+}, Huys Isabelle^{1#}, Barbier Liese^{1#}

¹KU Leuven, Department of Pharmaceutical and Pharmacological Sciences, Leuven, Belgium

*Contact: zilke.claessens@kuleuven.be, + joint first author, # joint senior author



PDF

BACKGROUND AND OBJECTIVES

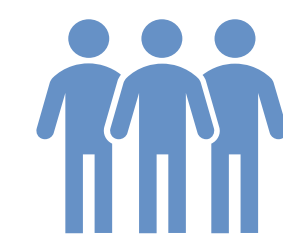
New technologies with increased technical complexity → Increased Budgetary & clinical uncertainties → Challenge for HTA and P&R decisions

Cross-country (CC) collaborations, such as the BeNeLuxA initiative, are built to pool resources and expertise to address uncertainties at the HTA and P&R level.

OBJECTIVES

1. Assess stakeholders' views about the **added value of CC collaborations** in general
2. Identify **recommendations** specifically for the BeNeLuxA initiative and **CC collaborative areas** in general

METHODS



Purposive sampling



Semi-structured interviews (n=17)



Framework analysis

Industry experts (n=10)

Pharmaceutical companies and/or pharmaceutical umbrella organizations

Policy makers/assessors (n=6)

HTA bodies, national payers and/or policy makers

RESULTS

Stakeholder perception of the value of CC collaborations

Gain in the efficiency of assessment by:

- | | |
|---------------------------------|---|
| Duplicate work reduction | <ul style="list-style-type: none"> • 1 submission dossier • Combined HTA and P&R negotiation |
| Streamlined requirements | <ul style="list-style-type: none"> • Early communication and advice • Alignment across involved member states |

Gain in the quality of assessment by:

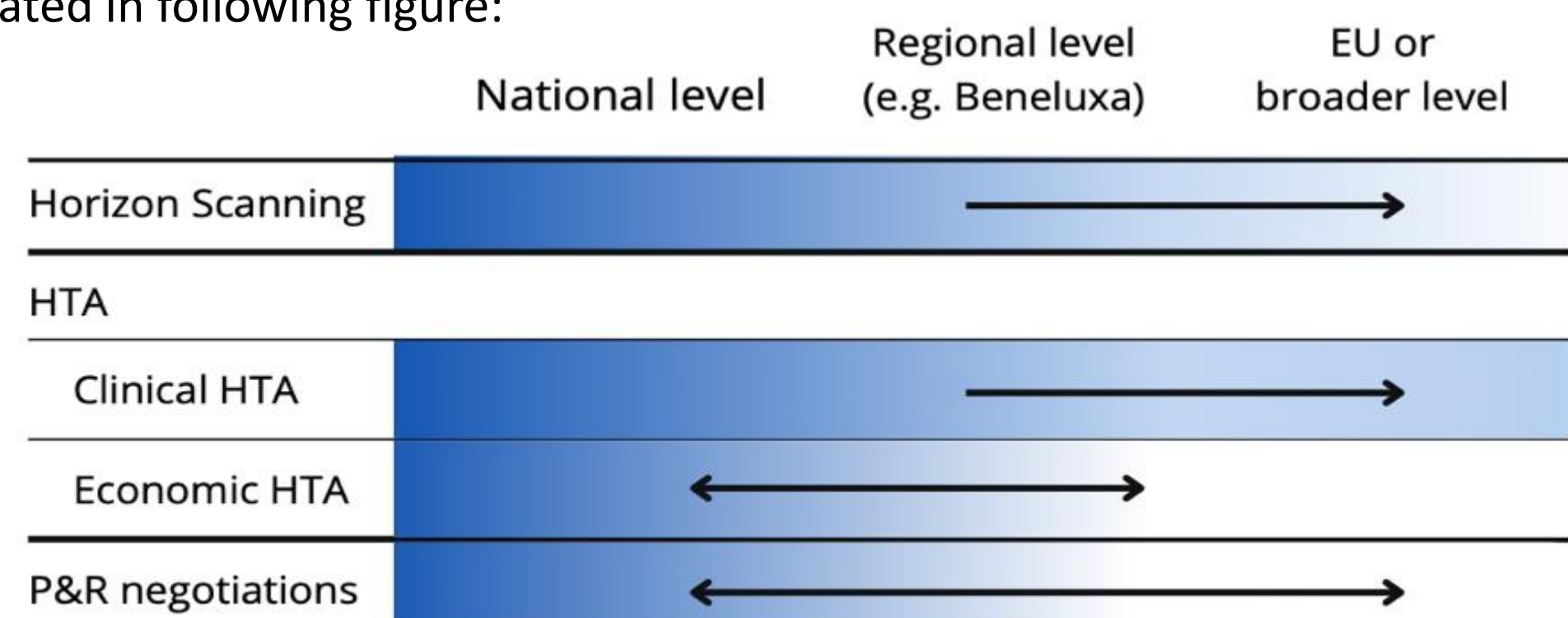
- | | |
|---------------------------|---|
| Expertise bundling | <ul style="list-style-type: none"> • Learning from each other's practices • Exchange on dossiers |
| Fair decisions | <ul style="list-style-type: none"> • More in-depth value assessment • Approach approved by involved member states |

Recommendations for the CC collaboration

- | | |
|---|--|
| Procedures & timelines | <ul style="list-style-type: none"> • Transparent communication and guidance on procedures to applicants • Sharing of experiences and lessons learned by applicants |
| Legislative framework | <ul style="list-style-type: none"> • Embedding of CC procedures in a legislative framework to create clarity • Embedding of CC procedures in national law to ensure implementation |
| Companies' internal organisation | <ul style="list-style-type: none"> • Guidance for pharmaceutical companies to adapt their affiliate structure to enable CC practices |

Collaborative areas and its CC collaboration potential

The collaboration potential depends on the area type and the existing CC framework, illustrated in following figure:



Colour-gradient: dark blue indicates the presence of the activity, and white indicates the absence

Arrow: direction of the arrow indicates the level of collaboration that was favoured by participants, two-direction arrows show diverging preferences

ABBREVIATIONS

CC = Cross-Country, P&R = Pricing and Reimbursement
HTA = Health Technology Assessment

ACKNOWLEDGEMENTS

This study is supported by the KU Leuven. We thank all study participants for their time and for sharing their views.

CONCLUSION

Participants see a clear added value of CC collaboration, particularly for horizon scanning and clinical HTA, and in specific cases, such as health emergencies, also for clinical HTA and P&R negotiations. Recommendations for effective CC collaboration are:



Providing clear procedures & timelines



Embedding of CC in a legislative framework



Adaptation of the company's organizational structure