



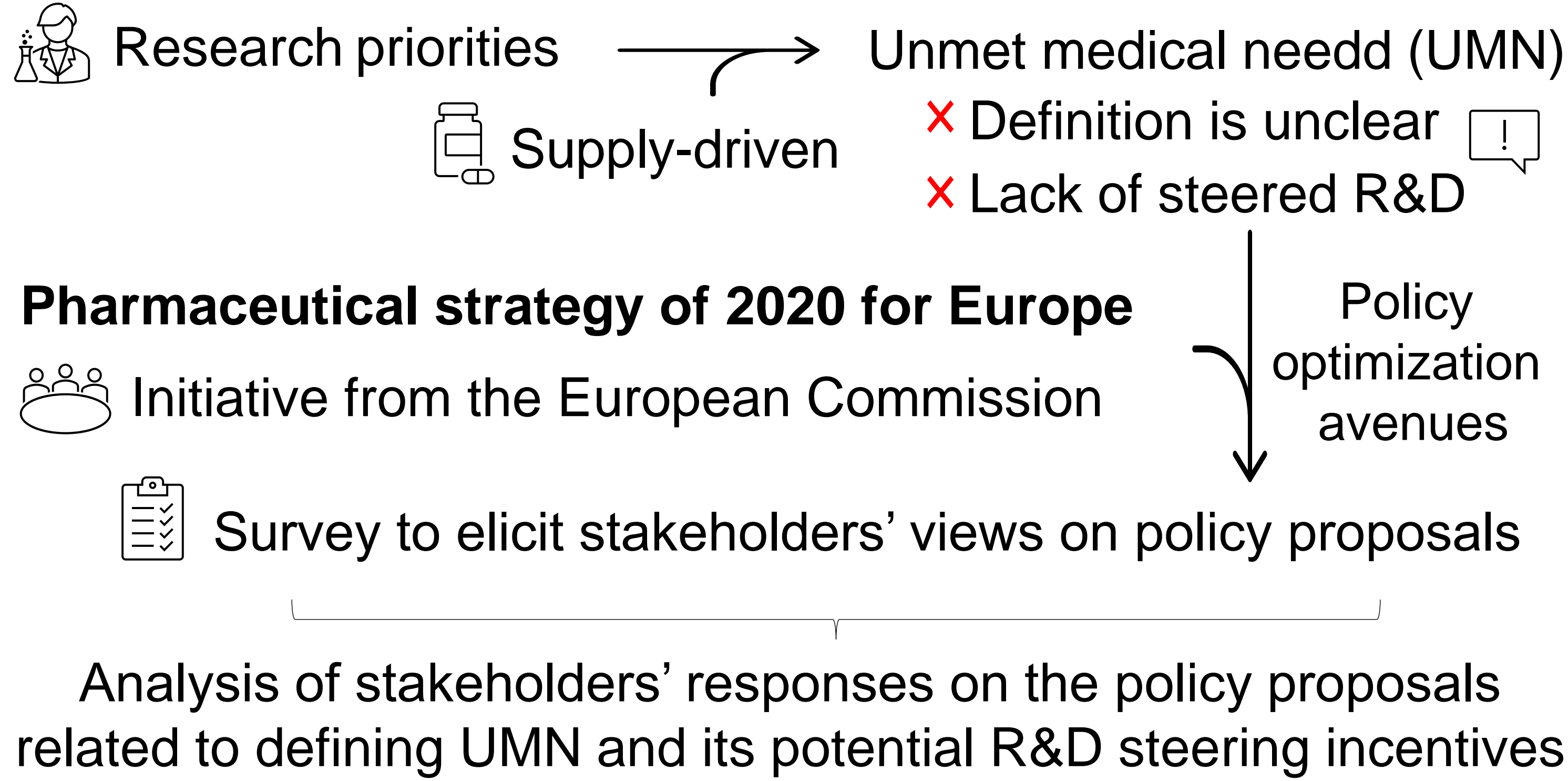
Stakeholders' Perspectives on the Unmet Medical Need Concept: An EU Pharmaceutical Strategy Survey Analysis

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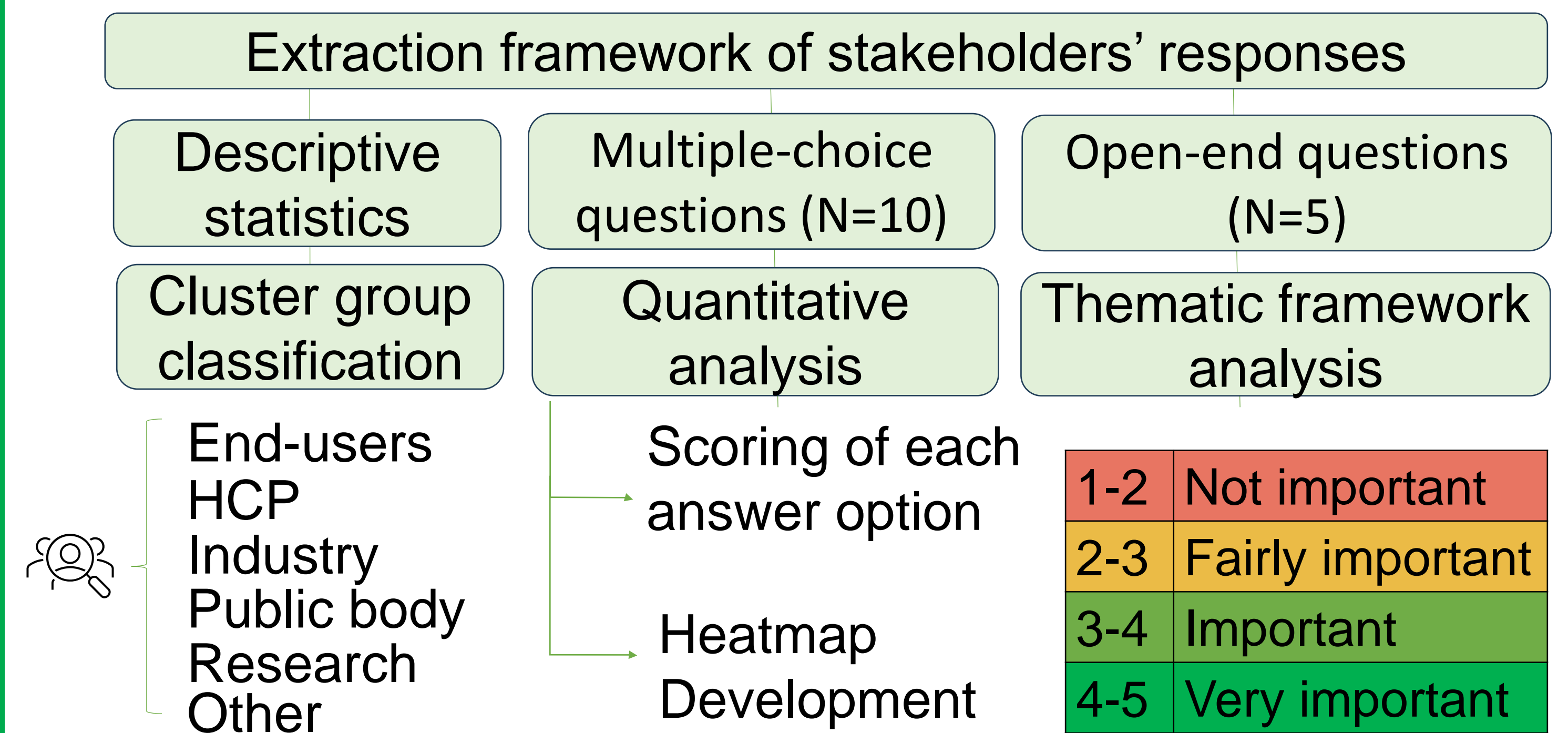
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Background and objectives



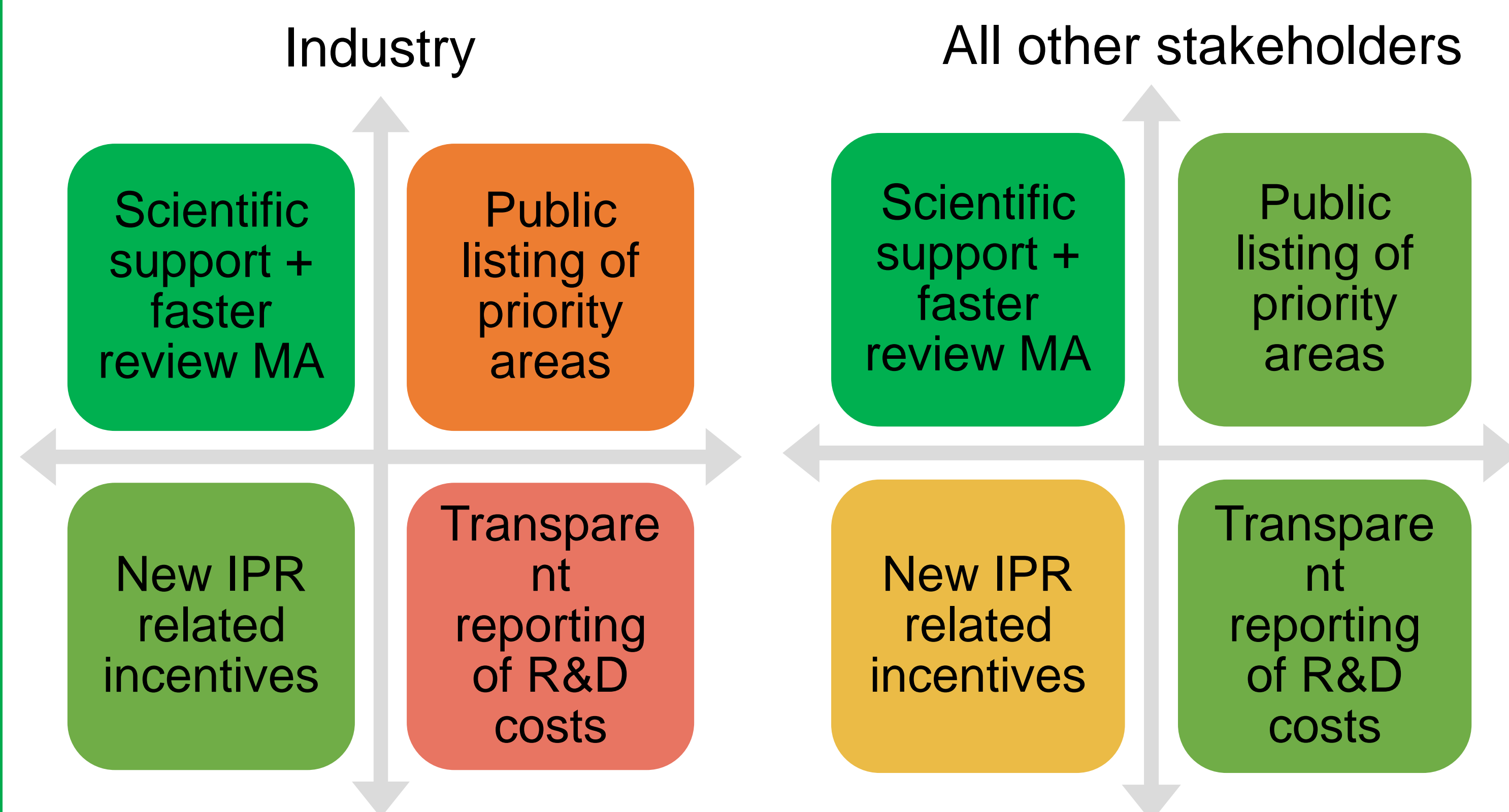
Methods



Descriptive statistics

Stakeholder group	N (%)
End-users	90 (19%)
HCP	82 (17%)
Industry	172 (36%)
Public body	36 (7,5%)
Research	33 (7%)
Other	66 (13,5%)
Total	478

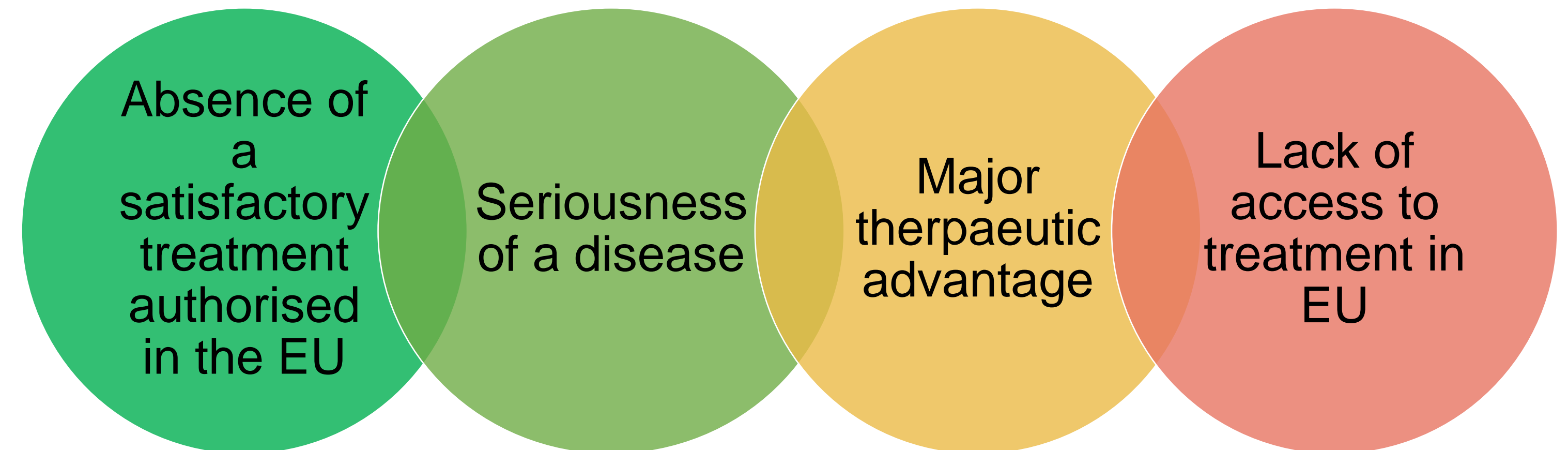
Proposals to support innovation in UMN-areas



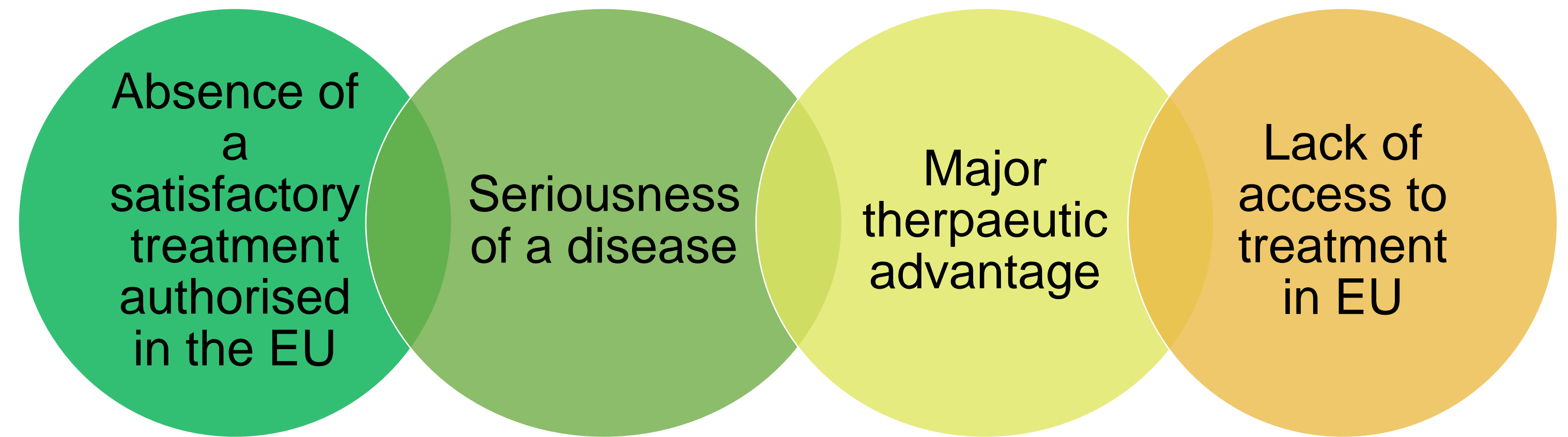
- All stakeholders agreed that faster MA of medicines should not jeopardize their value and efficacy
- Industry believed that if UMN-related incentives would be dependent on cost transparency → barrier for innovation
- All other stakeholders were not in favour of providing additional IPR incentive for industry → overcompensation

Defining the concept of UMN

Industry



All other stakeholders



- All stakeholder agreed that the current predefined criteria should be made quantifiable
- Industry believed that the definition for UMN should not be too strict → hampers innovation and development
- UMN is a dynamic concept → some stakeholders believe that criteria should be updated over time

Criteria to be added to the definition of UMN

- Disease incidence & prevalence
- Disease & current treatment burden
- Impact on QoL

List of abbreviations

UMN: unmet medical need, R&D: Research & Development, HCP: Healthcare Professional, HTA: Health technology assessment, MA: Marketing authorization, IPR: Intellectual property rights, QoL: Quality of Life

Acknowledgements

SB PhD fellow at FWO - 1S52123N

Conclusion

- Absence of authorised treatment and seriousness of disease are important criteria for defining UMN → made quantifiable
- Industry had conflicting opinions on the proposals to steer innovation in areas with UMN and was mostly in favour of receiving scientific support, and additional IPR incentives