



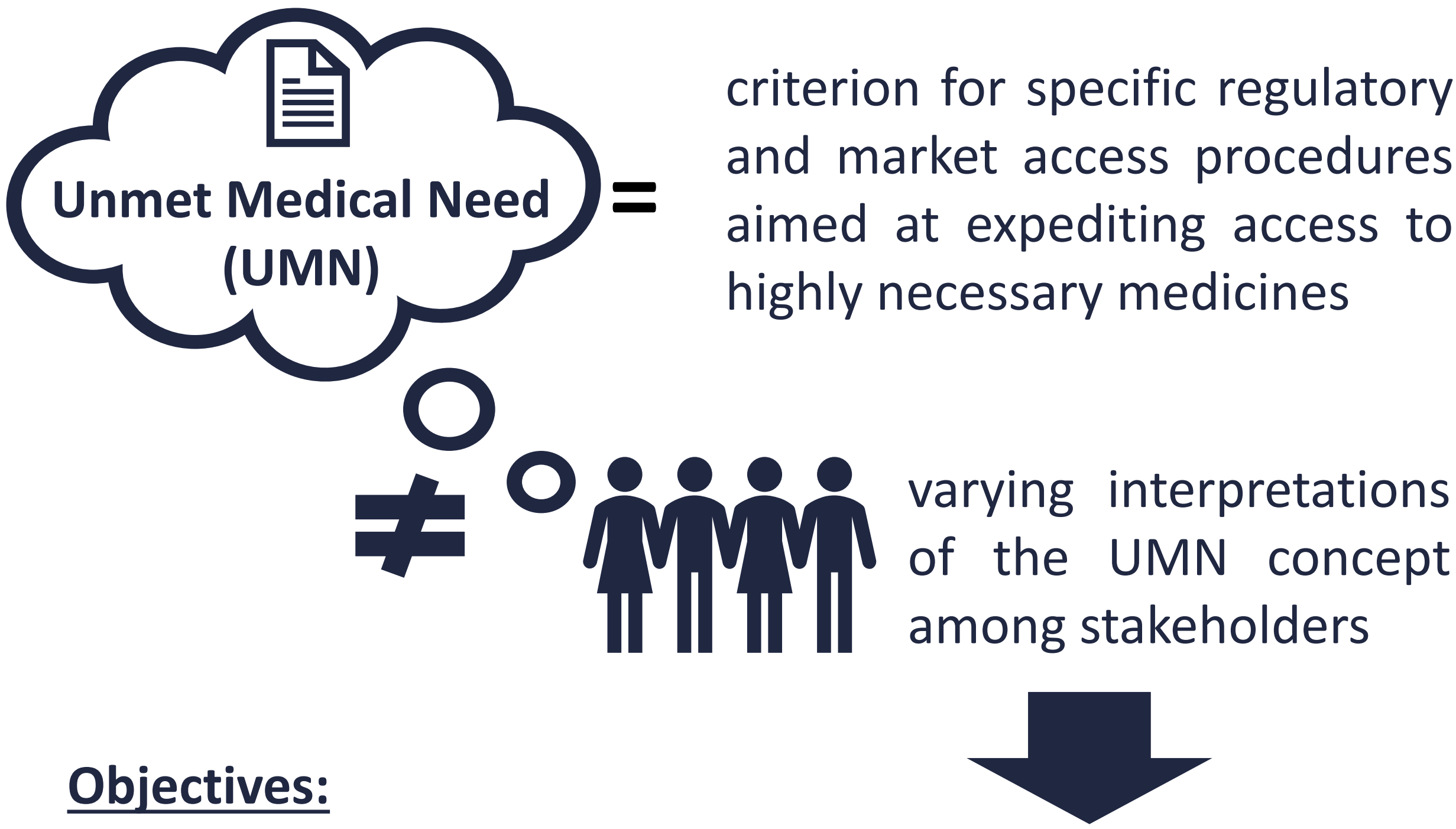
How is the Unmet Medical Need Concept Applied in Marketing Authorisation and P&R Assessments? A Structured Document Analysis

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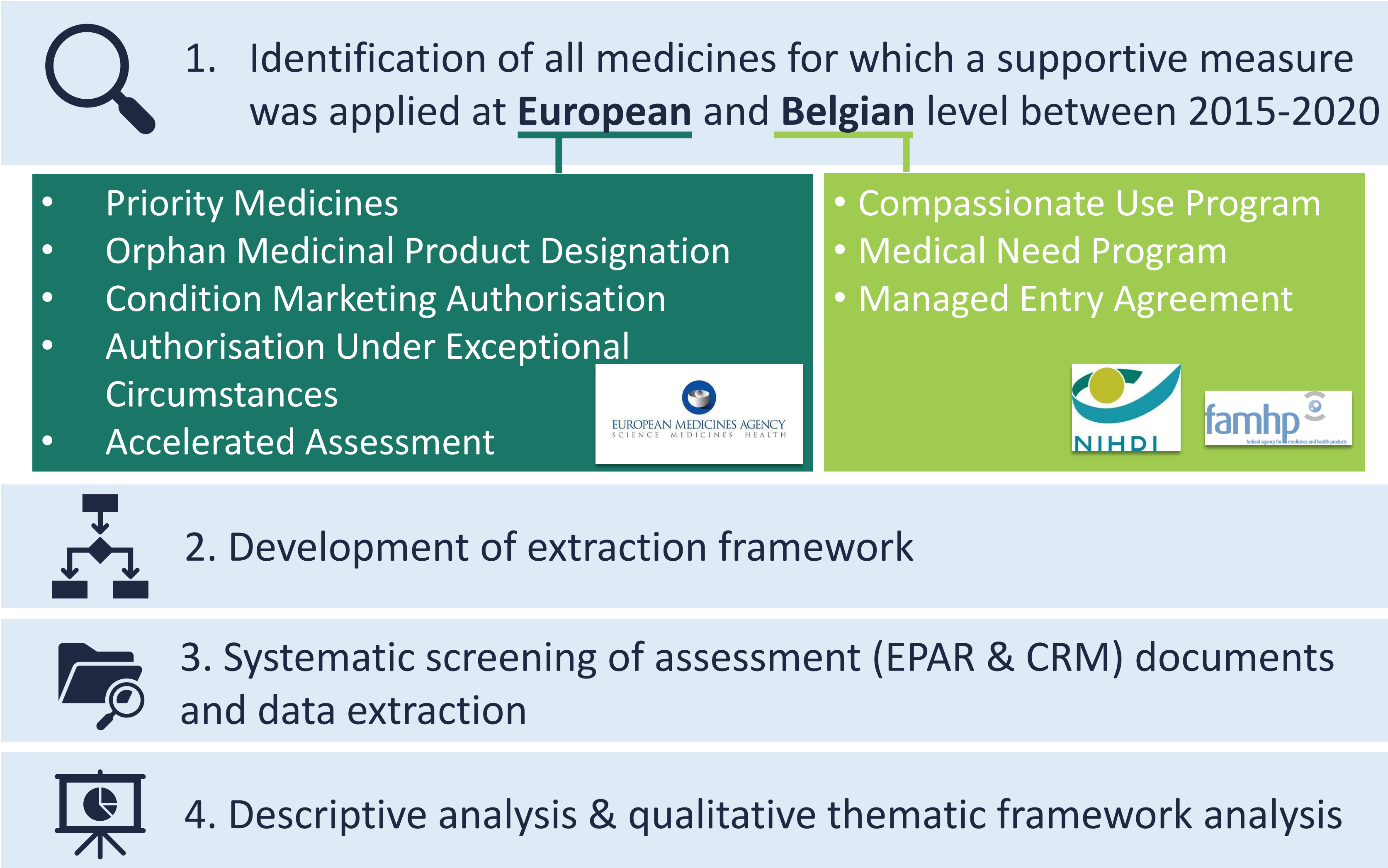
BACKGROUND AND OBJECTIVES



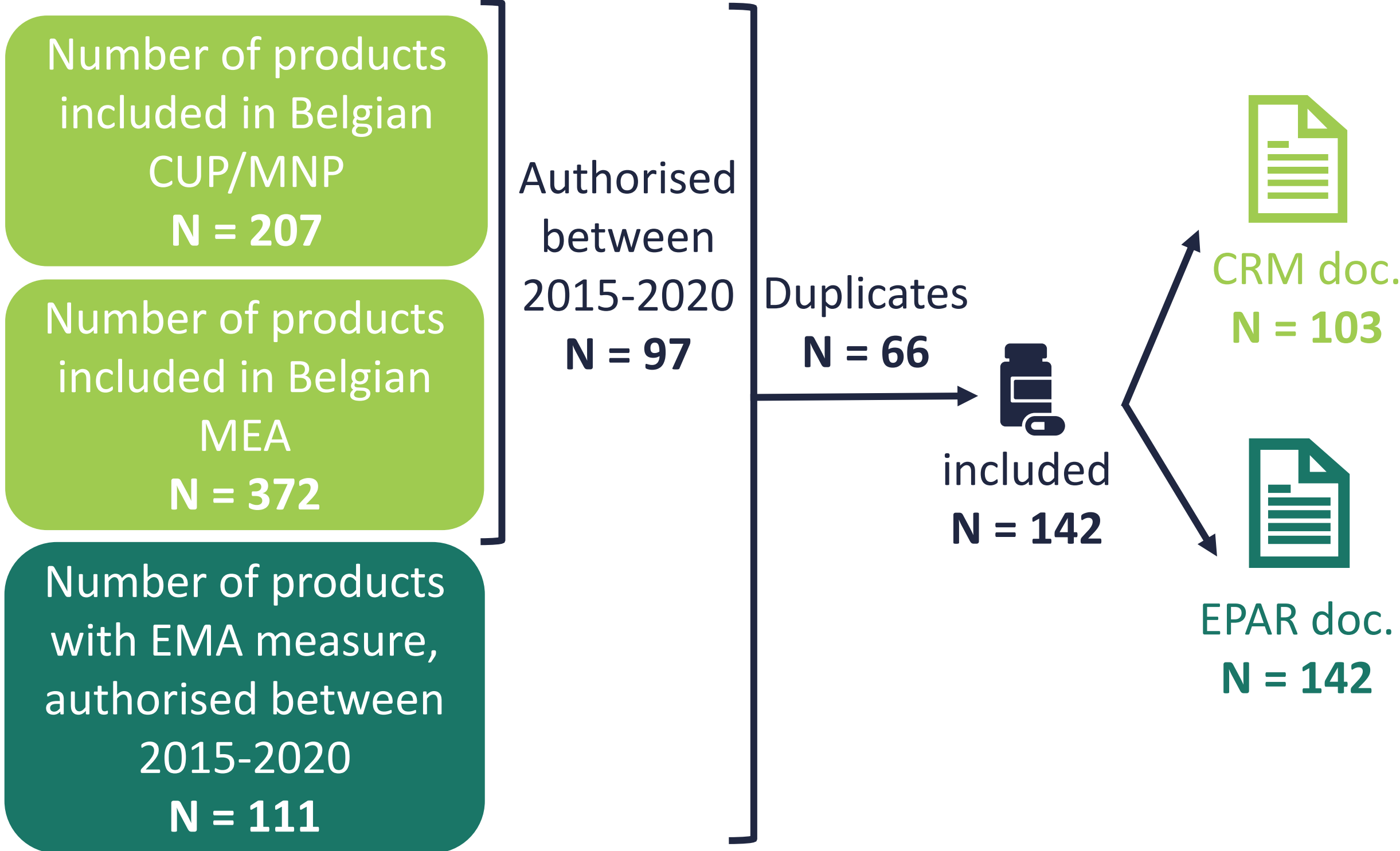
Objectives:

- (A) gain insights into the **frequency and consistency** in the application of the UMN concept in assessment documents, and
- (B) identify the **elements** used to substantiate the UMN in specific cases.

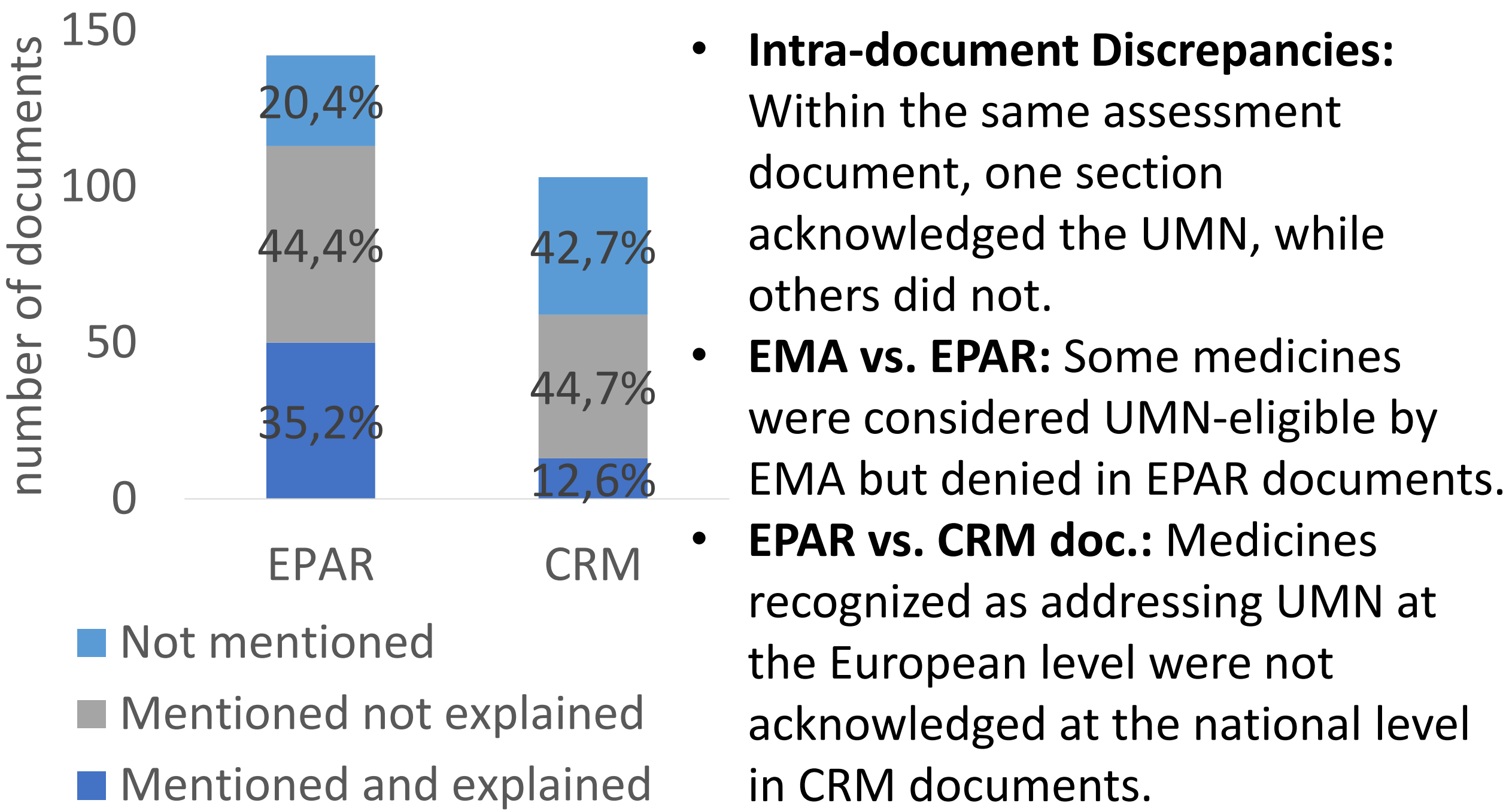
METHODS



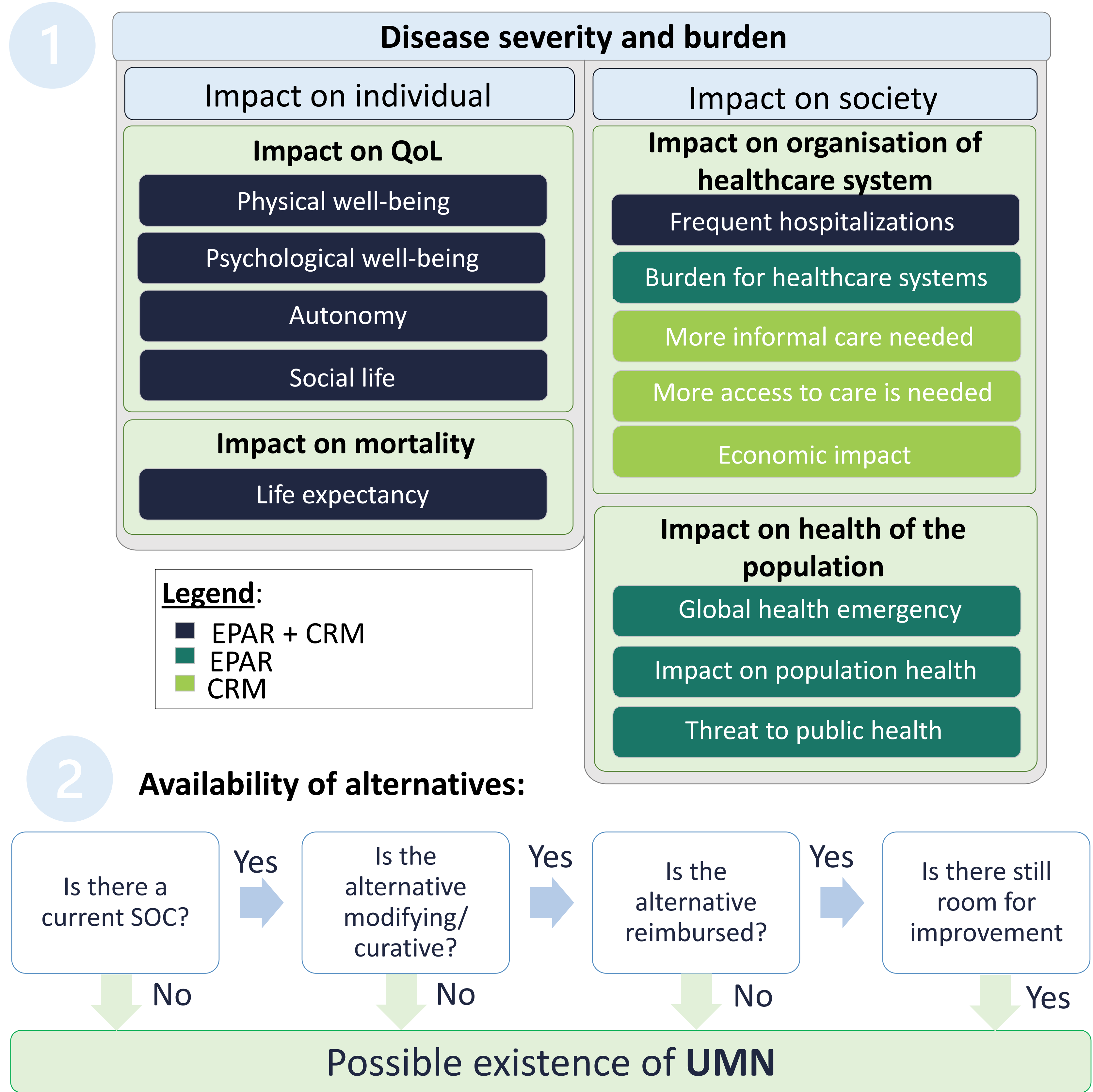
INCLUDED DOCUMENTS



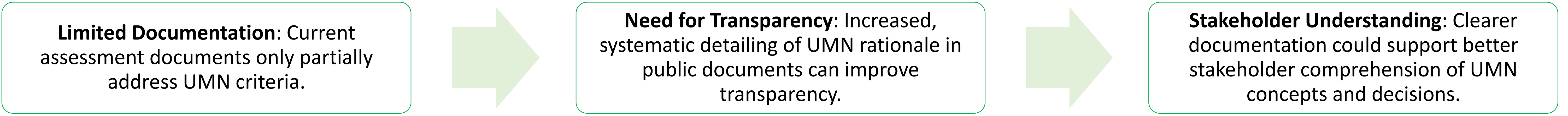
FREQUENCY AND CONSISTENCY OF APPLICATION OF THE UMN CONCEPT



UMN CRITERIA



CONCLUSION



ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

CRM: Commission Reimbursement Medicine, doc.: document, EMA: European Medicines Agency, EPAR: European Public Assessment Report, UMN: unmet medical need, QoL: Quality of Life, SOC: Standard of care.