HTA CG

MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Overview of HTA Regulation Principles (Methodology)

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5 October 2026

Guidance on Joint Work

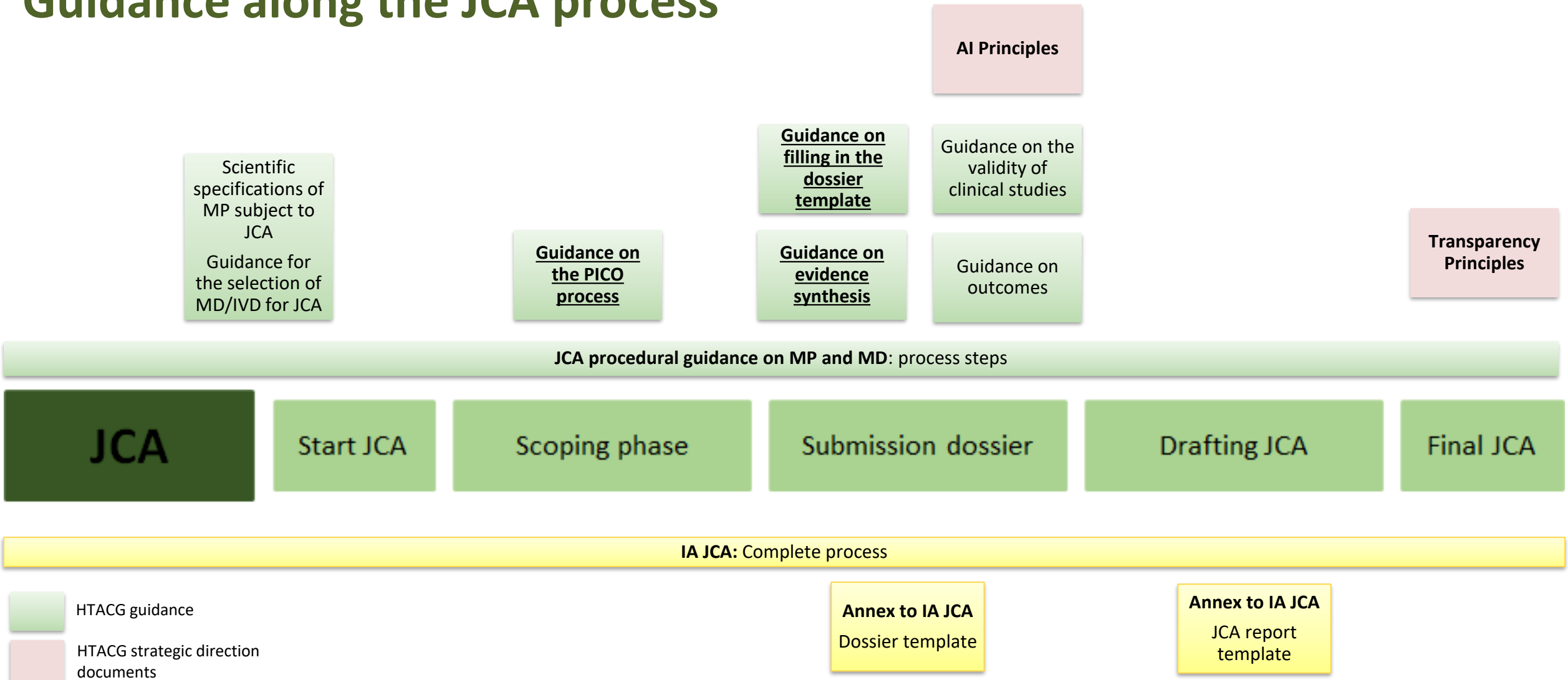
HTA Regulation	https://health.ec.europa.eu/publications/regulation-eu-20212282-health-technology-assessment_en
Implementing Regulation	https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic_topic%3A226
Guidance documents by the HTACG	https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic_topic%3A227
Q&A on methodological and procedural issues	https://health.ec.europa.eu/latest-updates/updated-questions-and-answers-general-methodological-and-procedural-issues-joint-clinical-2026-05-18_en

The content of a JCA according to the HTAR

- HTAR Article 9 (1) A joint clinical assessment …. a description of the scientific analysis:
  - (a) of the **relative effects** of the health technology as assessed on the health outcomes against the chosen parameters which are based on the assessment scope as set out pursuant to Article 8(6);
  - (b) of the **degree of certainty of the relative** effects, taking into account the strengths and limitations of the available evidence.

- The dossier and the JCA report shall present **relative effects of the new MP/MD/IVD *versus* the comparators** defined by the Member States (and laid down in the PICOs comprising the assessment scope)

Guidance along the JCA process

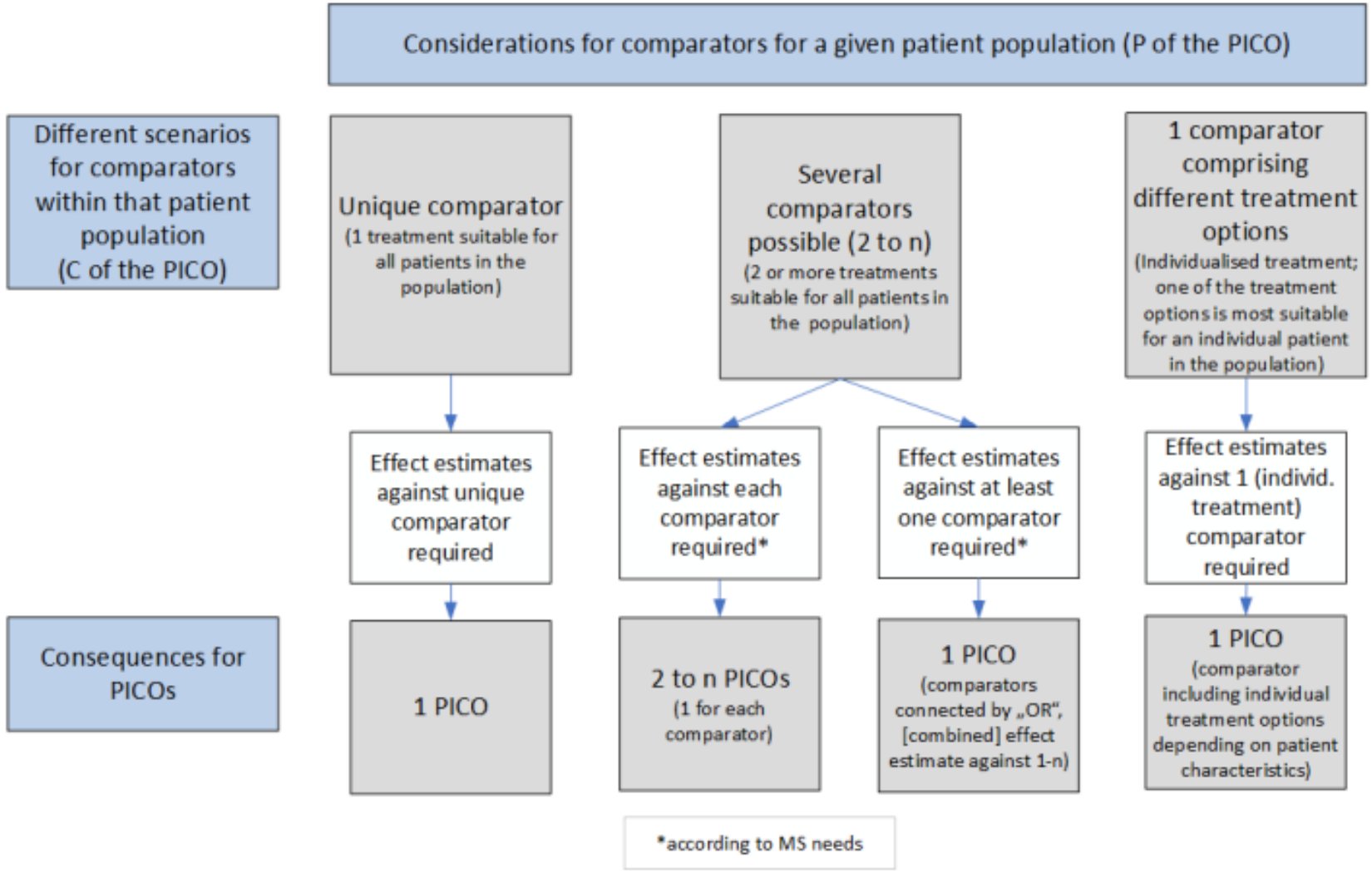


PICO process

- Reflect Member States' needs in terms of data and analyses to be submitted by the HTD to inform national HTA (policy questions)
- Input from patients/careers/clinical experts
- Consolidation as much as possible
- Communicate to HTD → 1st request → JCA Dossier Requirements

PICO process

- 3 different scenarios:
  - AND
  - OR
  - Individualised treatment



Evidence Synthesis

Direct comparisons

- The gold-standard evidence is from adequate RCTs with low RoB and adequate sample size
- Single study or
- Pairwise meta-analyses from 2 or more trials I vs C
    - Fulfil the assumptions of similarity and homogeneity

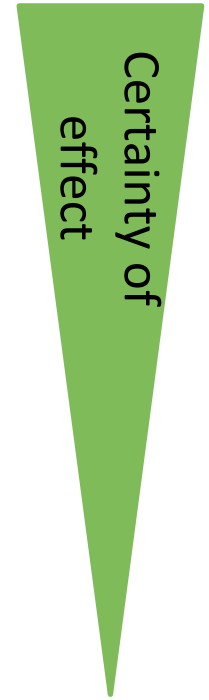
Evidence Synthesis

Indirect comparisons

- When indirect comparisons are performed, methods for anchored indirect comparisons with one or several common comparators should be used.
- Anchored indirect comparisons preserve randomisation and should always be used in preference to unanchored methods.
- Unanchored indirect comparisons compare treatments without a common comparator and therefore rely on stronger assumptions than anchored comparisons.

Evidence Synthesis

Available studies	Methodological option
RCTs comparing the new HT with the C from a PICO	Direct comparison (single study or meta-analysis)
Different RCTs with either the new HT or the C from a PICO	Anchored indirect comparison
Single arm trial with the new HT (or non-randomised comparison of the new HT with the C from a PICO)	Unanchored indirect comparison vs an external/non-randomised control



From PICO to a JCA Dossier

- A systematic and comprehensive literature searchs for each PICO is required
- Identification of relevant studies for each PICO
- Dossier complete with regard to the assessment scope
- For a complete dossier, data for all PICOs for which a systematic information retrieval identified relevant evidence need to be presented.
- Develop an a priori list of potential effect modifiers, informed by literature, clinical expertise and knowledge of the disease area
- Transparency and prespecification are essential

From PICO to a JCA Dossier

- If an analysis is not possible due to the unavailability of data, HTDs should provide relevant analyses that meet the requirements as closely as possible and explain and justify any deviation.

- Detailed descriptions should be provided where an indirect comparison was not conducted, although potential studies were identified in the systematic information retrieval.

Key take aways

- Carefully consider HTACG Methodological Guidance
- Prespecification and transparent reporting are integral parts of the method analysis
- All underlying documentation/reports need to be annexed to the dossier (eg. CSR, feasibility assessment report, ITC report)
- HTDs should familiarise earlier with the PICO landscape in Europe for better preparation for JCA
- Alignment is needed between the PICOs, the evidence generated, the analytical methods and the information provided in the dossier.

Thank you!