Can national Early Scientific Advice support JCA readiness in the absence of Joint Scientific Consultation?

HTA60

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INTRODUCTION

- A Joint Scientific Consultation (JSC) has been established to provide advice on evidence requirements for the Joint Clinical Assessment (JCA)[1]. However, due to the number of JSC slots being limited to a maximum of 17 per year (2026)[2] and the expected annual demand for JSC of ~50 products a year[3], some eligible products might not participate in the JSC. Indeed, in 2025, 10/17 products submitted to JSC were not accepted for consultation[4]
- Beyond the JSC, manufacturers planning for HTAs in Europe can also obtain scientific advice though national bodies such as the National Authority for Health (HAS) in France, Federal Joint Committee (G-BA) in Germany, and National Institute for Health and Care Excellence (NICE) in England

OBJECTIVE

To assess how the scope of national-level early scientific advice offered by key European HTA bodies compares to the JSC, and understand the extent to which they can support JCA readiness, in cases where a JSC cannot be secured

METHODS

A structured comparison of publicly available ESA guidance documents as of 24 September 2026 was conducted for JSC[1,2], HAS[5], G-BA[6], and NICE[7]. Guidance from each framework was qualitatively evaluated against JCA submission requirements[8,9] across three predefined domains:

1. Scope alignment with PICO requirements
2. Guidance on pivotal study design and statistical analysis
3. ESA eligibility and procedural feasibility

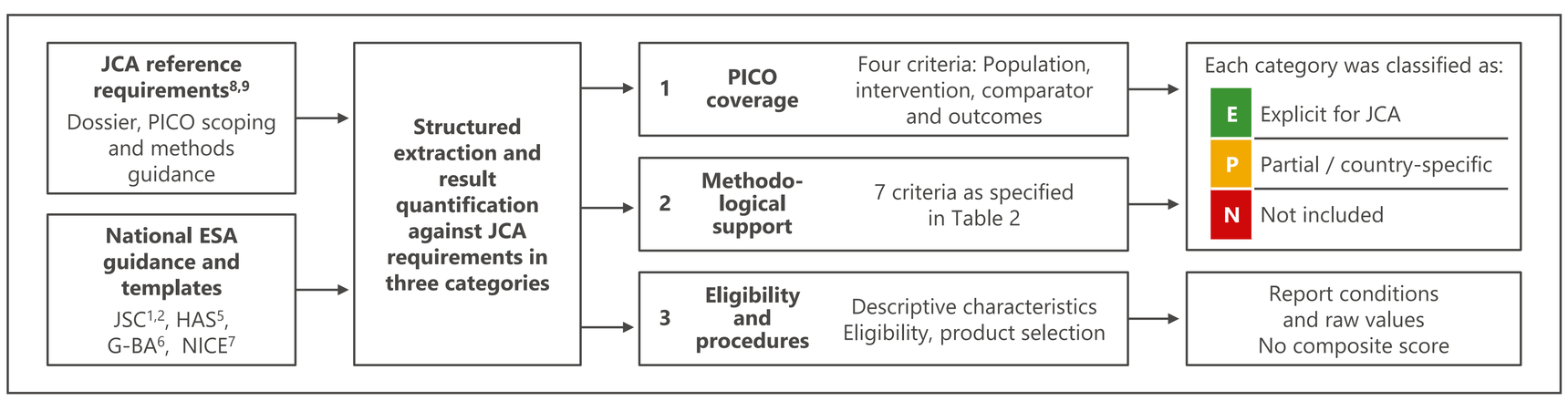


Figure 1: Research methodology

RESULTS

PICO: All three national ESA pathways could inform JCA-relevant PICO research questions. However, national advice reflects country-specific HTA requirements and therefore cannot reproduce the EU-wide, multi-Member-State scoping function of JSC (Table 1)

Methodological support: National ESAs also addressed several methodological considerations relevant to JCA readiness, although the breadth of documented support differed (Table 2). HAS provides the broadest documented support across the criteria assessed, including pivotal-trial design and additional evidence-generation advice. G-BA provides strong support for pivotal-trial planning, with minimal documented support for evidence generation beyond the pivotal programme. NICE addresses several trial-design considerations and provides advice on evidence generation, although it remains oriented towards English HTA requirements and cost-effectiveness modelling and therefore has limited applicability for JCA readiness

Table 1: Can national ESA address PICO readiness for the JCA?

	JSC[1]		HAS[5]	G-BA[6]	NICE[7]
Population	E	Explicitly advises about the European PICOs included in the future JCA	P	Can only inform about the PICO specific to the country	
Intervention	E		P		
Comparator	E		P		
Outcomes	E		P		
Support of JCA readiness		Explicit		Only on national level	

Table 2: Can national ESA address specific trial design questions supporting readiness for the JCA?

	JSC[1]		HAS[5]		G-BA[6]		NICE[7]	
Trial power and precision	E	Explicitly discussed	E	Explicitly discussed	P	Discussed at manufacturer's request	P	Discussed in context of economic model
Study duration	E	Advice whether trial duration is sufficient to show clinical benefit	E	Advice whether trial duration is sufficient to show clinical benefit	E	Advice whether trial duration is sufficient to show clinical benefit	P	Discussed only in the context of the economic model
Estimands of treatment effect	E	Advice whether treatment effect estimands are correct	E	Advice whether treatment effect estimands are correct	E	Advice whether treatment effect estimands are correct	P	Discussed only in the context of the economic model
Missing data generation	E	Advises on evidence generation activities beyond submitted trial	E	Advises on evidence generation activities beyond submitted trial	N	Consults only named pivotal trials	E	Advises on evidence generation activities beyond submitted trial
Sensitivity analyses	E	Advises on the trial sensitivity analyses	E	Advises on the trial sensitivity analyses	E	Advises on the trial sensitivity analyses	P	Discussed only in the context of the economic model
Post-launch evidence generation	E	Advises on evidence generation activities beyond submitted trial	E	Advises on evidence generation activities beyond submitted trial	N	Considers only named pivotal trials	E	Advises on evidence generation activities beyond submitted trial
Patient and clinician involvement	E	Both from patients and clinicians	P	HAS decides if patients and clinicians take part	N	Only clinical society opinion is given	E	Both from patients and clinicians
Support of JCA readiness		Explicit		High relevance for JCA readiness		Medium relevance for JCA readiness		High relevance for JCA readiness

Eligibility and procedures: Eligibility differed substantially between national institutions (Table 3). HAS applied restrictive product eligibility criteria, such as a novel MoA, high unmet need in the disease area and excludes products that are already pursuing the JSC route. G-BA and NICE had no formal eligibility criteria or capacity limits. In contrast, JSC requires products to meet formal eligibility requirements and, can reject an application based on capacity

Table 3: Product eligibility criteria and procedural information for national ESAs

	JSC[1,2,10]	HAS[5, 11, 12]	G-BA[6]	NICE[7]
Product eligibility	The product is likely to undergo JCA, prioritised if first-in-class and for a disease with high unmet need	A new mechanism of action of the product in the disease and an unmet or insufficiently covered need	No major eligibility criteria	No major eligibility criteria
Selection and capacity rules	Up to 17 slots per year (2026)	No specific ESA slot limit, 4 request period a year	Pre-specified request periods, slot limit specific to each period	Accepted on a rolling basis
Advice status and limitations	**High**: Deviation from JSC has to be explained in the JCA	**Low**: Advice does not influence the JCA	**Low**: Advice does not influence the JCA	**Low**: Advice does not influence the JCA
Restrictions	Only one JSC submission is allowed	Not eligible with previous or parallel JSC	No restrictions	No restrictions

CONCLUSIONS

Understanding how scope and accessibility compare is particularly relevant for manufacturers, given that the number of products expected to go through the JCA exceeds the JSC's available slots; manufacturers may have to rely solely on national-level ESA routes and national-level readiness. This analysis found that there is substantial alignment between ESA at the national level and JSC, but the level of alignment varies by country. The HAS is the most aligned with JCA needs; however eligibility restrictions apply. G-BA consultation can comprehensively cover the pivotal clinical trial, but advice on evidence generation beyond the trial are not possible. NICE ESA offer advice on most areas covered by JSC, but the advice is centred around cost-effectiveness, rather than focusing on the comparative clinical benefit assessment. G-BA and HAS advice are the most aligned with the scope of the JSC to support JCA submissions overall

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Abbreviations: ESA: Early scientific advice; EU: European Union; G-BA: Federal Joint Committee; HAS: National Authority for Health; HTA: Health technology assessment; JCA: Joint Clinical Assessment; JSC: Joint Scientific Consultation; MoA: Mechanism of action; NICE: National Institute for Health and Care Excellence; PICO: Population, intervention, comparator and outcomes

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