Conflict-of-interest management rules and implications for orphan medicinal product assessments: a comparative review of the EU Joint Clinical Assessment (JCA) and selected European national HTA approaches

WHITE PAPER

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Table of Contents

1. Executive summary

Rare diseases are clinically complex and heterogeneous, often involving highly variable genotypes and phenotypes, small, clinically distinct sub-populations, and non-linear and poorly documented disease progression. Clinical and patient experts are essential to interpret how trial populations reflect real-world patients, assess whether endpoints meaningfully capture disease severity and progression and distinguish clinically relevant differences that may appear statistically marginal.

The Commission Implementing Regulation (EU) 2024/2745 adopted under the European Union Health Technology Assessment (HTA) Regulation aims to promote transparency and consistency by applying uniform criteria and linking specific declared interests to defined restrictions, including threshold for expert compensation by health technology developer (HTD). While the Regulation appropriately prioritises impartiality, its features may create several critical problems for orphan medicinal products (OMPs) assessments. Given the limited pool of clinical and patient experts for each rare disease, those best placed to interpret and contextualise OMP evidence packages are often also involved in clinical trials, registries, advisory boards, and other essential activities that contribute to advancing the development of these therapies. At present, some of these activities fall within the conflict-of-interest (CoI) categories set out in the Implementing Regulation. As a consequence, participation restrictions may be triggered for the Joint Clinical Assessment (JCA) and other joint HTA work, leading to disqualification of leading experts with deep disease-specific expertise and limiting the voice of the people living with a rare disease. Although the regulation includes an "exceptional cases" provision to allow the involvement of indispensable experts where suitable conflict-free alternatives are not available, it does not fully define the conditions under which it should apply. This creates uncertainty for experts and HTDs around whether, and how, expert engagement during evidence generation and product development may affect later eligibility to contribute to JCA processes.

To explore potential solutions to the challenges of maintaining impartiality while preserving access to essential rare disease expertise, this paper compares the EU Joint Clinical Assessment conflict-of-interest framework (EU JCA CoI) with national HTA approaches in Austria, Belgium, France, Germany, Ireland, Italy, the Netherlands, Spain, and Sweden. Across these national systems, CoI is generally managed through individual assessments of interests, linked to proportionate measures, rather than default exclusion. Several countries use "managed involvement" models for indispensable experts - permitting participation under safeguards such as narrowly scoped input, advisory-only roles, or written contributions in place of in-person involvement. Others stratify interests into multiple tiers to enable tailored mitigations aligned to the level of risk. These national practices show how several EU Member States have addressed this CoI challenge, suggesting a need for a more pragmatic approach. The potential solutions emerging from this comparative analysis include:

1. Clearer operational criteria for applying the "exceptional cases" provision to support predictable access to essential clinical and patient expertise where suitably qualified conflict-free experts are scarce.
2. Managed participation mechanisms, drawing on proven national models, allowing experts to contribute under proportionate safeguards (e.g. scoped input, written contributions, or participation with disclosed CoI), to preserve both credibility and access to essential expertise.
3. A more pragmatic approach to better balance expertise, impartiality, and transparency in COI management, including greater transparency around expert selection, to strengthen confidence in the CoI management process and the credibility of JCA assessments.

These suggestions are not exhaustive and are intended to contribute to ongoing discussions, which should be guided by evolving expert insights and emerging experience.

Given the unique constraints of OMP assessments, an inclusive and fit-for-purpose expert selection framework is needed for rare diseases, ensuring that the right expertise can be included while potential CoI is managed through transparency, declarations of interest, and tailored safeguards rather than default exclusion. Access to high-quality clinical insight is fundamental to delivering robust, equitable assessments across the EU.

2. Introduction

The EU Health Technology Assessment (HTA) Regulation establishes the Joint Clinical Assessment (JCA) with the purpose of harmonising and streamlining the clinical evaluation of new health technologies across Member States. Clinical and patient expert engagement is embedded within the JCA process and is essential to ensuring that trial evidence is interpreted correctly, contextualised against lived experience and unmet need, and applicable across diverse health systems.

To protect the integrity and credibility of assessments, Commission Implementing Regulation (EU) 2024/2745[1] sets out rules for the declaration, review, and management of conflicts of interest (CoI) for participants contributing to joint HTA work under the EU HTA Regulation, including the JCA process.

In many therapeutic areas, these rules can be applied without materially constraining access to expertise. In rare diseases, low prevalence means that there are fewer patient experts able to contribute disease-specific lived experience, and fewer clinicians with direct experience of the condition. As a result, the pool of relevant experts is limited, and many are involved in research, advisory, or evidence-generation activities that fall within the scope of declared interests under CoI rules. Rare diseases often lack clinical consensus or established guidelines, leading to heterogeneous practice. This makes it essential to include as much relevant expertise as possible to ensure that assessments are clinically meaningful and well-informed. CoI management must therefore safeguard impartiality while still enabling access to the best available specialist insight.

This research aims to compare CoI management rules in the Implementing Regulation (EU) 2024/2745 and in the HTA frameworks of selected EU countries (Austria,[2,3] Belgium,[4,5] France,[6] Germany,[7-9] Ireland,[10-12] Italy,[13] the Netherlands,[14] Spain,[15] and Sweden[16-18]) with the purpose of highlighting opportunities to optimise orphan medicinal products (OMPs) clinical assessment by supporting proportionate, transparent, and feasible expert participation.

3. Conflict-of-Interest Rules and Management under the EU JCA Implementing Regulation (EU) 2024/2745

Under the Implementing Regulation (EU) 2024/2745, experts contributing to JCAs are required to submit a curriculum vitae and a signed declaration of interests (DoI). The declarations of interests are reviewed by the European Commission to identify potential conflicts of interest and determine whether participation is permissible.

Experts must declare a broad range of interests across seven categories (employment, consultancy, strategic advisory roles, financial interests of the expert or their immediate family members, involvement as principal investigator and lead membership in an organisation funded by a health technology developer (HTD)), both current and within the past three to five years.

The assessment of DoIs is conducted against a structured matrix set out in the Implementing Regulation (Annex II), which links categories and timing of interests to defined consequences summarised in Table 1. Depending on the timing and nature of the conflict, experts may be considered ineligible to participate in joint assessments, including assessments of the specific technology, competing products, therapies within the relevant therapeutic area, or any joint work. No restrictions other than full exclusion from participation in the assessment are proposed. For example, receiving expense reimbursements with a cumulative value exceeding €1,000 from one HTD within the past three years prevents the expert from participating in joint work related to that developer's products in the relevant therapeutic area or, where the therapeutic area cannot be identified, across all of its health technologies. Experts who currently hold consultancy or advisory roles with an HTD (e.g., serving on an advisory board) are excluded from participating in any joint work. Similarly, experts currently serving as investigators in HTD-sponsored clinical trials cannot participate in joint work related to that developer's products. If the expert's involvement with the HTD occurred in the past and was limited to acting as a consultant, advisor, or trial investigator for a single technology, the restriction applies only to assessments of that specific technology and its comparators. In addition, experts who oversee institutions receiving funding from an HTD are not permitted to participate in joint work related to technologies developed by that HTD.

TABLE 1: JCA CONFLICT-OF-INTEREST EXCLUSION RULES FOR INDIVIDUAL EXPERTS (COMMISSION IMPLEMENTING REGULATION (EU) 2024/2745 ANNEX I AND II SUMMARY)

Depending on the time frame and nature of the declared interest, experts may be excluded from participation in joint assessments, including any joint work (■), or from joint work within a defined scope (◆) relating to a therapeutic area,[1] a specific technology,[2] or the health technology developer.[4] For some interests, the scope depends on the circumstances, including study sponsorship[3] or the type of family-member financial interest declared.[5]

Declared interest		Time frame and related exclusion
Employment	Executive role	■ Current
		◆[1] Within the past 5 years
	Other horizontal responsibility	■ Current
		◆[1] Within the past 3 years
	Individual product responsibility or Employment in a consultancy or contract research organisation	■ Current
		◆[2] Within the past 3 years
Consultancy (Regardless of remuneration)	Individual product-related	■ Current
		◆[2] Within the past 3 years
	Horizontal	■ Current
		◆[1] Within the past 3 years
Strategic advisory role (Regardless of remuneration)	Individual product-related	■ Current
		◆[2] Within the past 3 years
	Horizontal	■ Current
		◆[1] Within the past 3 years
Financial interests	(Co)ownership, shares, etc., intellectual property rights	■ Current
	Payment/reimbursement of expenses (of a cumulative value above 1.000 EUR from one health technology developer over the past 3 years)	◆[1] Currently, Within the past 3 years
Principal investigator and investigator		◆[3] Current
		◆[2] Within the past 3 years
Lead member in an organisation/institution receiving funding from health technology developers		◆[4] Current financial year, Most recent financial year closed
Interests of immediate family members		◆[5] Current

CoI exclusion rules key: Interests constituting a CoI resulting in exclusion from:
- ■ Any participation in the joint work
- ◆ HTA in relation to the health technology developer, specific health technology, or therapeutic area

1. No involvement of the individual expert in joint work in relation to health technologies under assessment or comparator health technologies from the HTD, where the role, horizontal responsibility, presentation, training course, participation in a conference/seminar/event is/was related to a therapeutic area or several therapeutic areas, or if the therapeutic area cannot be identified, in relation to any health technologies from the HTD. **2**. No involvement of the individual expert in joint work in relation to specific health technologies under assessment or comparator health technologies, defined as a health technology identified in the assessment scope for the joint clinical assessment. **3.** If the clinical trial, observation study, clinical investigation or performance analysis is/was sponsored by an HTD, no involvement of the individual expert in joint work in relation to any health technologies from the HTD. If the trial or study is/was sponsored by other means except by HTDs, no involvement of the individual expert in joint work in relation to specific health technologies under assessment or comparator health technologies. **4.** No involvement of the individual expert in joint work in relation to health technologies under assessment or comparator health technologies from the health technology developer. **5.** In the case of intellectual property rights, no involvement of the individual expert in joint work in relation to specific health technologies under assessment or comparator health technologies. In all other instances, no involvement of the individual expert in joint work in relation to any health technologies from the HTD.
Abbreviations: CoI, conflict of interest; HTA, health technology assessment; HTD, health technology developer

The Implementing Regulation includes an "exceptional case" provision intended to address situations - such as rare diseases - where no suitably qualified experts are available who are free from conflicts of interest:

Article 7.3: *"By way of derogation from paragraph 1, where in exceptional cases, for example, for rare diseases, no individual experts free from conflicts of interests within the meaning of Annex II that have the relevant in-depth specialised expertise are available, the Commission may propose to the relevant subgroup the appropriate involvement of such individual experts in the joint work considering their conflicts of interest."*

However, the Regulation does not further specify what constitutes an "exceptional case," nor does it clarify how it would operationalise "appropriate involvement" (e.g., the conditions, safeguards, or practical examples).

4. Potential impact of the Implementing Regulation (EU) 2024/2745 conflict-of-interest rules for OMP assessments

The Implementing Regulation sets out a transparent, standardised approach to managing conflicts of interest in expert engagement. While this framework may support consistency and predictability across joint clinical assessments - particularly compared with some national processes where decision-making is less formalised or less transparent – its restrictive nature may also present specific challenges for OMP assessments. The inclusion of patient involvement within the JCA framework and the Implementing Regulation is an important development, helping to pave the way for more systematic patient participation in HTA across Member States; however, the Regulation's CoI rules may lead to the exclusion of irreplaceable rare disease expertise.

Rare diseases are characterised by very small patient populations, and the corresponding specialist communities are therefore limited. This issue is particularly acute in ultra-rare conditions (typically defined as affecting fewer than 1 in 50,000 people), and in smaller Member States, where the pool of clinical experts and expert patients may already be extremely limited. Many of these individuals are routinely involved in research, advisory activities, or patient engagement initiatives. Although such activities are essential to generating evidence and advancing clinical understanding, they may also be treated as potential conflicts of interest under the current framework. The inclusion of a relatively low cumulative reimbursement threshold over a three-year period, for example, may further restrict the pool of eligible experts in these small specialist communities. As a result, the clinicians and expert patients best placed to interpret limited and heterogeneous evidence, contextualise outcomes in clinical practice, and explain the lived experience of disease may be more likely to be deemed ineligible. Although the Implementing Regulation includes an "exceptional cases" provision, the lack of clear operational criteria, together with its discretionary, last-resort nature, may limit its practical utility. Without clearer guidance, patients and clinical experts may lack certainty around appropriate involvement, while companies may face difficult choices between engaging experts during product development and risking their exclusion from assessment, or limiting engagement.

This could lead to systematic exclusion of leading rare disease specialists from OMP assessments, leaving assessors more reliant on generalists less familiar with rare disease complexity and more likely to default to conservative, methodologically rigid interpretations of heterogeneous evidence. As a result, expert input critical to contextualising clinical outcomes, interpreting limited datasets, and ensuring clinically relevant assessments may be reduced, potentially compromising both assessment and development quality.

5. Identified national HTA approaches to CoI management

The JCA's prescriptive model contrasts with the reviewed Member States' national HTA approaches (Table 2), which rely on committee-led, case-by-case assessments to determine appropriate actions (e.g., exclusion, restricted involvement, or participation with disclosed CoI), without predefined financial interest thresholds or exclusion triggers. The national

HTA committees can apply a tailored assessment, distinguishing between lower-risk or unavoidable interests and those more likely to introduce undue influence, and thereby reducing the risk of unnecessary exclusion of suitable experts.

Table 2 summarises key differences in declaration of interest (DoI) requirements and how CoI is identified and managed across the JCA and selected national HTA systems.

TABLE 2: COMPARISON OF JCA VS NATIONAL HTA CONFLICT-OF-INTEREST RULES FOR INDIVIDUAL EXPERTS

	Declaration of Interest (DoI) Requirements		Conflict of Interest (CoI) Management	
	DoI form / guidance available?	DoI lookback period	How is CoI identified?	How is CoI managed?
JCA	✓	3-5 years (See Table 1)	● EC assesses CoI in accordance with the criteria set out in Annex II	Where a conflict is identified, measures are applied in line with the established rules (Table 1)
Austria	✓	3 years	✱	
Belgium	Limited	-	◆	✱
Germany	✓	3 years	◆	Only voting members may be excluded from participation; other participants' DoIs are shared with the advisory board, but do not lead to exclusion
France	✓	5 years[c]	◆ The published guide outlines interests that are "likely" to lead to exclusion	Outcomes in case of identified potential CoI include exclusion or participation with declared conflicts disclosed
Ireland	✓[a] / ✗[b]	2 years[d]	✱	
Italy	✓	3 years	◆	Declarations are classified into three levels: 1. Absent/irrelevant conflict – full participation allowed 2. Relevant conflict – participation in related procedures prohibited 3. High conflict – no participation
Netherlands	✓	Current[e]	◆ The published guide outlines interests that are "likely" to lead to exclusion	Measures are proportionate to CoI, based on risk of bias and damage to credibility. Outcomes are conditional participation or exclusion. Potential direct financial gain from the assessment always triggers full exclusion
Spain	*New Royal Decree (draft form as of 16/02/2026) on HTA evaluation aims to establish new CoI rules. The draft decree establishes the CoI management framework, but the practical instruments (declaration forms and guidelines for third-party participation in the HTA) have not yet been published*			
Sweden	✓	5 years	◆ Published guidance highlights "typical situations" that may indicate higher CoI risk	The assessment is made based on the intended assignment and the nature of the connection to the company or organization; if CoI is considered significant, the expert is not appointed. "Disqualification may be disregarded where impartiality is clearly not affected"

Key: ● Predefined CoI criteria
◆ Case-by-case evaluation of the DoI by the appointed body
✱ CoI management process details not available

a. Patient organisation; **b.** Clinical experts; **c.** For main activities (paid or unpaid activity, carried out as a freelancer or employee, and for which the person or organisation is likely to derive a tangible benefit or be significantly penalised by the work of the HAS for which they are requested.); **d.** Only reported for patient representatives, **e.** No lookback period stated
Abbreviations: CoI, conflict of interest; DoI, declaration of interest; EC, European Commission; HAS, Haute Autorité de Santé; HTA, health technology assessment; JCA, joint clinical assessment

Across the reviewed countries, national HTA conflict-of-interest frameworks vary in scope of assessed interests (Appendix A). However, several include mechanisms that can preserve access to scarce rare disease expertise while

protecting credibility. These approaches place primary emphasis on managing interests through transparency and tailored mitigation measures, rather than default exclusion:

- **Conflict of Interest stratification and proportionality-based approach**

In Italy, declared interests are classified by the assessor into different risk levels, which determine participation outcomes and enable a graded response: absent or irrelevant conflict - full participation allowed; relevant conflict - participation in related procedures prohibited; high conflict - no participation. This model enables proportionate management rather than binary inclusion or exclusion.

In Sweden, national CoI guidance similarly emphasises individual appraisal and proportionality, noting that "ultimately it is always the conditions of the individual case that are decisive in an evaluation." It provides illustrative lists of "typical situations" across broad categories, ordered to signal gradations of risk, but these are intended to prompt assessment rather than automatic exclusion. Disqualification may be disregarded where impartiality is clearly not affected, and conflicted experts may still participate where tasks cannot reasonably be performed by others "without significant delay."

- **Managed involvement of conflicted but indispensable experts**

As summarised in Table 3, this can take the form of allowing contribution under defined safeguards, such as limiting the role to advisory input, restricting the scope of contribution, or excluding the individual from drafting recommendations or decision-making.

TABLE 3: COMPARISON OF PROVISIONS REGARDING INVOLVEMENT OF CONFLICTED EXPERTS

	CoI management rules - provisions for conflicted expert involvement when the expertise is indispensable, and no equivalently competent conflict-free expert can be found
JCA	"The Commission may propose appropriate involvement considering their CoI"
France	The conflicted expert may be consulted or provide a written contribution but cannot participate in drafting conclusions/recommendations. Identified CoI must be disclosed to the commission before the contribution and reasons for requesting the expert and the modalities must be annexed to the work
Italy	An expert may contribute in a consultative, non-decision-making role
Netherlands	An expert may participate in a committee meeting (but not in decision-making on a conflicted dossier), or provide input through a hearing procedure only
Sweden	An expert may perform tasks nobody else can perform without a considerable delay

Abbreviations: CoI, conflict of interest; JCA, joint clinical assessment

6. Considerations for Supporting Expert Participation in OMP JCAs

OMP assessments require a balance between impartiality and access to scarce specialist expertise. An overly rigid application of CoI rules may undermine assessment quality. Maximising access to relevant clinical and patient expertise is particularly important, where evidence bases are limited, patient populations are small, and the standard of care is poorly defined and heterogeneous. In this context, expert input is not supplementary but essential to interpreting the relevance, credibility, and practical significance of the available evidence. Establishing concrete modalities for managed expert participation is key to guaranteeing the assessment quality.

The current Implementing Regulation provides a structured framework for managing conflicts of interest. However, in rare diseases, where the pool of suitably qualified experts often is limited, a predominantly exclusion-based approach may have unintended consequences for the quality and completeness of JCAs. The challenge is therefore not whether conflicts of interest should be managed, but how they can be managed proportionately while preserving access to indispensable expertise.

While national HTA systems vary, the experience of several Member States provides useful insights as the JCA framework enters into force for OMPs in 2028. There, conflicts are not treated solely as a basis for exclusion, but are assessed in light of their relevance, context, and the role the expert is expected to play. These approaches illustrate that transparency, credibility, and appropriate expert involvement are not mutually exclusive.

Drawing on the analysis of the current Implementing Regulation and experience of CoI management in the Member States reviewed, three considerations appear particularly important for the evaluation of OMPs:

1. First, **defining clear operational criteria for applying the "exceptional cases" provision** (Article 7.3).

   Ensuring greater clarity on when and how the exceptional cases provision may be applied (for example where there is demonstrable scarcity of suitably qualified conflict-free experts), would support a more predictable approach to expert involvement in rare disease JCAs. Such criteria would help clarify how expertise, impartiality, and transparency should be balanced in practice, bringing benefits across the JCA ecosystem.

2. Second, **enabling appropriate participation for experts** with concrete mechanisms in place, drawing from proven national models.

   This could include applying proportionality through structured stratification of interests linked to appropriate mitigations, as applied by the Italian Medicines Agency. It could also further allow for tailored safeguards proportionate to the potential CoI, as illustrated by the approaches taken in Germany, France, Sweden, and the Netherlands, including scoped input on specific questions, written contributions, or participation with disclosed CoI. Establishing defined participation mechanisms for managed expert participation, drawing on proven national models, could allow access to essential expertise while appropriately managing potential conflicts of interest.

3. Third, **adopting a more pragmatic and transparent approach to CoI management**

   A more pragmatic and transparent approach could help better balance expertise, impartiality, and transparency, while strengthening confidence in the CoI management process and the credibility of JCA assessments. This could include enhancing clarity of expert-selection process through documenting the justification for selecting a given expert from the pool of potential experts, as well as explaining what safeguards were applied to manage any identified CoI.

These considerations are intended to inform implementation rather than prescribe specific reforms. Nevertheless, the comparative analysis indicates that a more proportionate, pragmatic, and transparent approach to expert input may be especially relevant for rare disease assessments, where expertise is scarce, and overlaps are common. This matters because, in rare diseases and OMPs, clinical and patient expert input is essential to interpreting limited and heterogeneous evidence, supporting robust development, and ensuring that assessments reflect real-world clinical and patient experience. In this context, the credibility of the JCA depends not only on protecting against undue influence, but also on ensuring that rare diseases and OMPs are assessed through comprehensive, representative, and high-quality expert involvement.

A modified, more pragmatic JCA approach for rare diseases that better balances expertise, impartiality, and transparency in COI management, accompanied by clarification and guidance on how Article 7.3 will be implemented in practice, would bring several benefits to all stakeholders involved: for assessors, access to essential clinical expertise for comprehensive assessments; for industry, a predictable framework for R&D planning and expert engagement throughout development; and for patients, higher-quality assessments informed by the best available clinical knowledge. This clarity would also send a strong signal that the EU, through the JCA, is progressing towards an innovation-enabling and forward-looking HTA framework, rather than reverting to more restrictive and fragmented approaches.

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Appendix A

APPENDIX 1: COMPARISON OF DECLARATION OF INTEREST REQUIREMENTS

	Declaration of Interest (DoI) Requirements			
	Mandatory DoI for HTA participants?	**DoI form / guidance available?**	**Differences vs JCA scope**	**Lookback period**
JCA	✓	✓	See Table 1	
Austria	✓	✓ (standard ICMJE DoI form utilised)	🡻 Family, principal investigator, leader in HTD funded orgs not listed 🡻 Consulting only when with fee 🡹 Receipt of equipment, materials, drugs, medical writing, gifts and planned patents	3 years
Belgium	✓	Limited	No details of scope apart from "Any potential CoI, including direct and indirect relationships with the pharmaceutical industry is to be declared"	
Germany	✓	✓	🡻 Leader in orgs with HTD funding not listed 🡹 Potential CoI not only of immediate family but any relevant parties	3 years
France	✓	✓	🡹 Elected official functions (e.g. mayor, regional councillor) must be declared	5 years (for "main" activities)*
Ireland	✓	✗ (clinical experts) ✓ (patient organisation)	◆ Clinical experts: no scope detail 🡻 Patient organisation member: Only need to declare funding received from HTD within last 2 years & details of any individuals who have had a significant role in drawing up their submission and have interests to declare	
Italy	✓	✓	◆ Broadly aligned with JCA framework	3 years
Netherlands	✓	✓	🡹 Must declare interest of any close personal relationships, not just family	Not directly mentioned; likely only current
Spain	✓	*New Royal Decree (draft form as of 16/02/2026) on HTA evaluation aims to establish new CoI rules. The draft decree creates the CoI management framework, but the practical instruments (declaration forms, the guidelines for third-party participation in the HTA) are not yet published.*		
Sweden	✓	✓	🡻 Leadership in HTD-funded orgs not listed 🡹 Must declare relevant friendships /hostility	5 years

Key: 🡻 Lower disclosure requirements than JCA requirements
🡹 Higher disclosure requirements than JCA requirements
Not listed: Requirements aligned with JCA requirements

*paid or unpaid activity, carried out as a freelancer or employee, and for which the person or organization is likely to derive a tangible benefit or be significantly penalized by the work of the HAS for which they are requested.

Abbreviations: CoI, conflict of interest; DoI, declaration of interest; HAS, Haute Autorité de Santé; HTA, health technology assessment; HTD, health technology developer; ICMJE, International Committee of Medical Journal Editors; JCA, joint clinical assessment