

JSC & JCA – Legal Considerations

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Agenda



Obligation to take into account according to Art 11 EU-HTA-R and the effet utile according to Art 4 (3) TEU

Legal principles of the JSC

Legal protection

Theses

Fictive Example I „Comparator“

	JFC (Germany) 		JCA (EU HTA) 	
	<i>Comparator</i>		<i>Intervention</i>	
2024	Pipa [®]	<	Lupa [®]	
2025	Lupa [®]	<?>	Mopa [®]	PICO 1 C = Pipa [®]
				PICO 2 C = Lupa [®]
2026				Pipa [®] > Mopa [®]
				Mopa [®] > Lupa [®]

Pipa[®] > Mopa[®] > Lupa[®]?

Comparator regulation

Germany



Sect. 6 AM-NutzenV

- 1) The appropriate comparator therapy is to be determined as a rule according to standards resulting from the **international standards of evidence-based medicine**.
- 2) The appropriate comparator therapy must be an appropriate therapy in the area of application according to the **generally accepted state of medical knowledge** (§ 12 of the Fifth Book of the Social Code), preferably a therapy for which **endpoint studies are available** and which has proven itself in practical application, unless guidelines pursuant to § 92 (1) of the Fifth Book of the Social Code or the principle of economic efficiency speak against it. The **actual supply situation** as it would have been without the medicinal product to be assessed must be taken into account.

EU-HTA





Recital 9: in order to assess the added therapeutic value and relative effectiveness of health technologies compared with **the best available alternative**, that takes into account the level of innovation and benefit for patients.

Recital 28: “**Member States should remain responsible** for drawing conclusions at national level on the clinical added value of a health technology, as such conclusions depend on the specific healthcare context in any given Member State, and on the relevance of individual analyses included in the joint clinical assessment report (for example, several comparators could be included in the joint clinical assessment report, of which only a selection is relevant to a given Member State)... The joint clinical assessment report should be **factual** and should **not contain any value judgement**, ranking of health outcomes, conclusions on the overall benefit or clinical added value of the assessed health technology, any position on the target population in which the health technology should be used, or any position on the place the health technology should have in the therapeutic, diagnostic or preventive strategy.

→ **Comparator is what the national administration has considered as Comparator orientated on the national standard of care.**

No rules - no rights?

Fictive Example II „Patients“

	JFC (Germany) 		JCA (EU HTA) 	
	<i>Patients</i>	<i>Intervention</i>		
2024	All Patients with multiple myeloma	Lupa [®]	PICO 1 P = All Patients with multiple myeloma	PICO 2 P ¹ = female Patients with multiple myeloma P ² = male Patients with multiple myeloma
2025	Lupa [®]	<?>	Mopa [®]	
2026			Lupa [®] = Mopa [®]	P ¹ : Mopa [®] > Lupa [®] P ² : Mopa [®] < Lupa [®]

The obligation to take into account and the effet utile

The relevant case law of the CJEU on the effet utile (Art. 4 para. 3 TEU)

1999 · Rs. T-13/99

Pfizer

The scientific level of a deviating statement of reasons must be at least equal to that of the contradicted expert opinion.

2021 · Rs. C-83/19

Forumul Judecătorilor

"Obligations to take into account" are substantively binding — derogation only with verifiable justification.

1991 · Rs. C-6/90

Francovich

State liability for breaches of EU law

Core principle:

Interpretation that deprives Union law of practical effect is inadmissible.

Boundaries

Principle of effectiveness: do not make the scope and effectiveness of Union law impossible in practice or excessively difficult

Principle of equivalence: no distinction can be made compared to proceedings in which similar domestic situations are decided

Binding for national authorities

Direct binding: even without legal implementation, they have their own obligation to implement the regulatory objective of EU law

No commitment to national laws that contradict the regulatory objective.

→ national administrative body is obliged by Article 4(3) TEU to ensure complete, uniform and effective enforcement.

Art. 11 EU HTA Regulation

Obligation to take into account the JCA results · Effet Utile Effects



Reasons for Deviation

Good Reasons

- No availability in national context ✓
- New evidence ✓
- demonstrable errors ✓
- Result of JCA is due to different outcome-parameters or due to differences in PICO ✓

Bad Reasons

- ✗ „Decision was made“
 - No legal obligation to make a preliminary decision
 - divergent decision-making practice
- ✗ „JCA ist not binding“
 - Obligation to take into account Art. 11 EU HTA Regulation
 - Obligation to state reasons for deviation
- ✗ “We assess the evidence differently”
 - Violation of obligation to take into account?
 - scientific level of a deviating statement?

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Selection & Duty to State Reasons

- Scarce consultation slots → competitive procedure
- Strict transparency & equal treatment (Art. 296 TFEU)
- Clear, objective and verifiable criteria required
- **Detailed reasoning** for rejections necessary
- Lack of comparative transparency limits review

Art. 17 EU-HTA-R

NR. 3

- (a) unmet medical needs;
- (b) first in class
- (c) potential impact on patients, public health, or healthcare systems
- (d) significant cross-border dimension
- (e) major Union-wide added value
- (f) Union clinical research priorities

Mitigation Through Publication

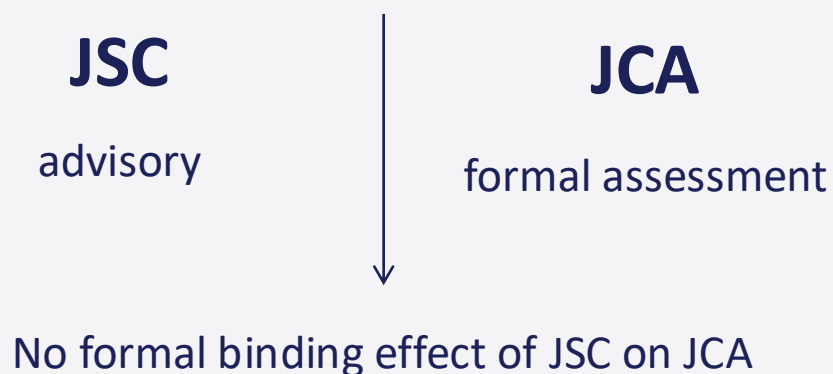


- Publication improves general transparency (Art. 8 HTA Reg.)
- Reduces informational asymmetry
- No access to comparative decision-making
- Confidentiality limits disclosure (C-450/06 Varec)
- Does not fully ensure equal treatment

JSC vs. JCA – Legal Relationship

Article 16 Principles of joint scientific consultations

3. The joint scientific consultation outcome document shall not give rise to any legal effects on Member States, the Coordination Group or the health technology developer. Joint scientific consultations shall not prejudice the joint clinical assessment which may be carried out on the same health technology.



Duty to state reasons for deviations
(Art. 296 TEU) ?

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Judicial Remedies & Limitations

JSC-Decision

- Actions under Art. 263 Par. 4 TEU (direct & individual concern)
- Challengeable: lack of reasoning, transparency, discrimination
- Comparative errors hard to review

JCA-Decisions

- National courts decide on the legally compliant implementation of EU law (Art. 19 para. 1 TEU)
- CJEU ensure that the law is observed in the interpretation and application of the Treaties.

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Legal robustness of JCA obligation

The JCA's factual basis on the obligation to take into account under Art. 11 EU-HTA-R and by the effet-utile case law on Art. 4 para. 3 TEU can only be shaken by the Member States by divergent facts (esp. new evidence, nationally divergent regulation and supply standards). A general appeal to the non-binding nature of the JCA is open to challenge.



Justification of budgetary decision

The budgetary decision to award JSC also requires a justification that – while maintaining confidentiality – makes the plausibility of the preference of other applicants verifiable.



Requirement of effective legal protection

Effective legal protection also requires the possibility at the European level of timely enforcement of claims against the CG for the implementation of a JSC and against the Member States' decision-makers (under national law) for sufficient consideration of the JCA.

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Thank you!

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