

JSC & JCA – Legal Considerations

Dominik Roters

Managing & Equity Partner at Dierks+Company

dominik.roters@dierks.company



The Regulation (EU) 2021/2282 on Health Technology Assessment (EU HTA Regulation) explicitly states that Member States may draw their own conclusions on the relative effectiveness of health technologies. However, this national decision-making prerogative regarding the substantive and formal consideration of the Joint Clinical Assessment (JCA) is subject to limits: since EU HTA reports consist essentially of scientific factual analyses, accurate findings — such as those on effect sizes and endpoints — are factually binding on national HTA institutions. Their formal right to deviate from the data-based scientific conclusions of the JCA report may only be exercised on the basis of demonstrable errors, more recent data, or binding national legal requirements; absent such justification, any deviation may constitute a justiciable violation of the obligation to take due account of the JCA report.

A duty of support can be derived from Art. 4(3) TEU, requiring Member States to actively promote the objectives of the European HTA framework. Member States are therefore obliged in particular to notify PICOs that enable them to adopt the findings of the JCA as comprehensively as possible. This raises,

among other things, the question of whether a Member State is bound by its PICO submission — and in particular by its chosen comparator therapy — or whether it may disregard these in national proceedings by invoking subsequent developments.

Furthermore, the provisions governing Joint Scientific Consultations (JSC) warrant critical scrutiny:

- Does the budgetary cap on consultation slots give rise to a heightened duty to state reasons for rejections, along with a transparent selection process based on the prescribed criteria?
- Can the undue disadvantage faced by companies that were not granted a consultation be mitigated through publication of consultation outcomes?
- Under what conditions may Member States depart from consultation outcomes?

Finally, the question is examined of which breaches of obligation are legally challengeable and thus capable of grounding judicially enforceable claims for the affected undertakings.