Negotiation positions

RED LINES

Scope and transitional period

Transition period of three years during which Member States could limit their participation and op-out from Joint Clinical Assessments

Accept gradual build-up but reserve position on exact length of roll-out period

Delegated acts would be more appropriate

Voting regime

Simple majority voting

Cannot accept unanimity as the process must ensure timely delivery of reports

Scope and transitional period

Main concern: Time frame considering Article 36 and deletion of transitional period in Council text

Too long to reach full scope (3+4 years from transitional period to reach full scope), and too early to start Medical Devices

Voting regime

Introduces Qualified Majority Voting

Will not accept unanimity, need safeguards to avoid 26 divergent positions

Scope and transitional period

Gradual build-up for pharmaceuticals over eight-year period, starting with cancer drugs in first three years then OMPs and ATMPs

Dates of interim steps to be set by Commission by implementing acts

Flexibility mechanism for individual products by implementing acts

Voting regime

Provides for unanimity to approve reports

Negotiation positions

RED LINES

Use of joint clinical assessment reports and non-duplication

Proposed mandatory uptake of reports and non-duplication

Regrettable but acceptable, will await reactions from Parliament. The wording more accurately reflects how HTA reports are used in national decision-making

Joint scientific consultation

Use of joint clinical assessment reports and non-duplication

Propose ‘to use’ the reports

View Council proposal as significant weakening of obligation to not carry out duplicate assessments

The non-duplication obligation concerns the joint clinical assessment and updates (risk of duplication of updates at national level).

Joint scientific consultation

Main issue is how to select developers when number of eligible requests exceeds number of planned JSC

Use of joint clinical assessment reports and non-duplication

Obligation to use the report has been softened, replaced with ‘give due consideration’.

Deleted obligation to not duplicate assessments at national level.

Obligation for developers to submit data at EU level and for Member States to not duplicate request for that data

Joint scientific consultation

Negotiation positions

RED LINES

Quality, timeliness and transparency

Details proposed to be developed in tertiary legislation

Accept changes in principle, introduction of timeframe will prevent delays at Member State level, however overall timeline must be flexible to cover all eventualities in assessment process, especially for medical devices

Updates of joint clinical assessments

Updates are necessary to accommodate new evidence, and Commission can show openness on Article 9

Quality, timeliness and transparency

Transparency is main concern, along with meaningful involvement of stakeholder networks in the process

Aligned with the changes introduced by Council

Updates of joint clinical assessments

Risk of duplication at national level

Quality, timeliness and transparency

Introduces Articles on quality assurance and transparency and conflicts of interest and timing, submission of data and end of assessment.

Introduces timelines for medical devices

Updates of joint clinical assessments

Updates is limited to assess new clinical evidence, at Member State level or jointly in Coordination Group when requested.