

Potential implications of EU Joint Clinical Assessment (JCA) for the UK affiliate of a global pharmaceutical company

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Study objectives

To understand the purpose and processes of the JCA, especially as they relate to the potential impact on UK Market Access.

To identify JCA-related risks and opportunities for UK Market Access, as well as to consider JCA-driven changes to the internal and external environment that could affect UK Market Access.

To align on strategies for minimising JCA-related risks and maximising opportunities, ensuring that the UK continues to be a key launch market in this evolving environment.

Overview of the JCA

Purpose?

JCAs aim to harmonise the evaluation of medicinal products across EU member states, and achieve efficiency by replacing separate national clinical assessments with one EU-level report.

What are JSCs?

Joint Scientific Consultations are an optional procedure that provide scientific advice from EU HTA bodies before a pivotal trial protocol is finalised.

What?

An EU JCA is a centralised assessment of relative clinical efficacy for new health technologies compared with available treatments.

Where?

JCAs apply to the 27 EU member states and will impact all centrally authorised medicines.

How?

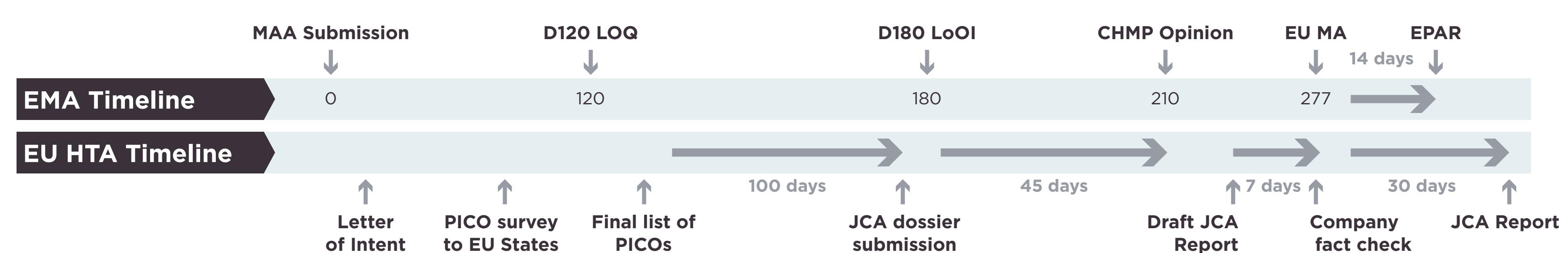
JCAs consider the Populations, Interventions, Comparators, and Outcomes (PICO) of every EU member state. JCA reports are published, but will not make evaluative statements. EU countries are expected to consider the JCA report during national HTA processes and cannot request data already submitted as part of the JCA.

When?

2025: Oncology products, ATMPs and medical devices

2028: Orphan designated products

2030: All centrally authorised medicinal products



Methods

Information gathering: 1

Desk-based JCA research

Distilling implications: 2

Core team evaluation of implications on UK market access

Validation: 3

Discussion with wider teams and above-country colleagues, especially those directly responsible for JCA internally

Tactical planning: 4

Core team information review to plan tactics for preventing/mitigating JCA risks, or maximising the opportunities it may bring about

Communication: 5

Sharing the findings with broader UK, EU and global colleagues internally and externally

Results

We identified that the introduction of the JCA and JSC creates four key areas of potential impact for the UK, and two separate aspects to keep track of:

Timelines

- The UK may face pressure to delay MHRA/ HTA submissions due to above country resource saturation from competing FDA, EMA, JCA timelines.
- Early mapping of UK launch timelines with an enterprise-wide optic regarding the overlap of key milestones will be required.

HTA scope & critique

- The published JCA report may raise additional clinical objections or subgroup data requests during UK HTA processes (or prove validating of UK HTA value messages); careful review of the JCA report and preparation of objection handling will be required.

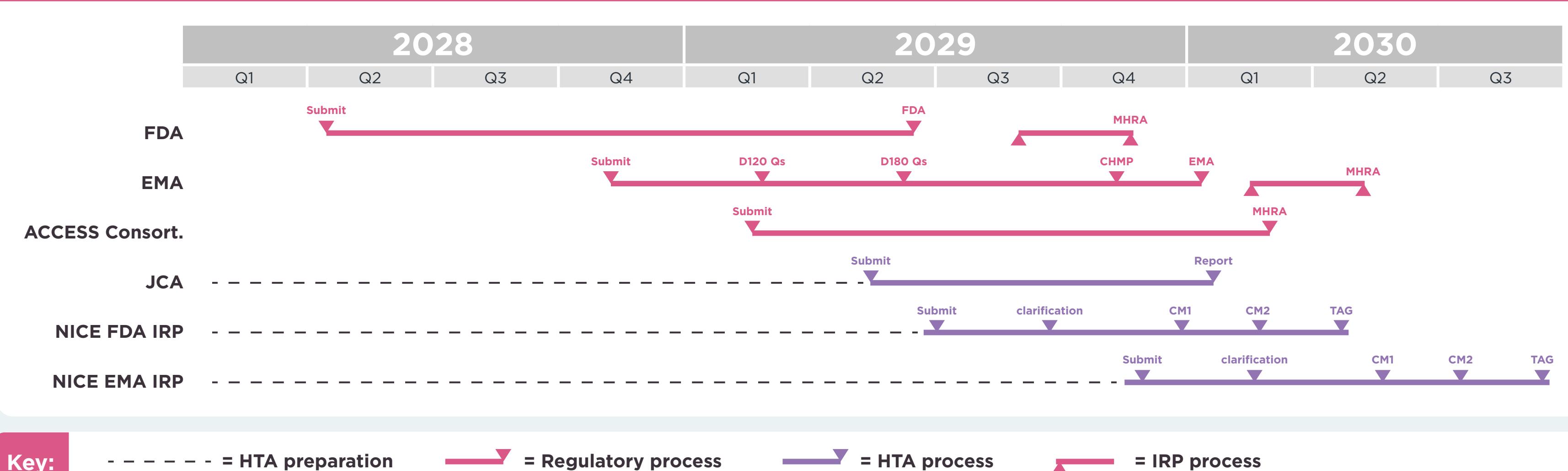
Support

- Global data teams (Biostatistics, Global Health Economics and Evidence Generation) are likely to experience additional pressure due to competing FDA, EMA, JCA data requests.
- The UK Market Access team will need to align on above-country data needs early or require additional budget and access to trial data to prevent disruption.

Early advice

- JSC may be prioritised over NICE early scientific advice, potentially reducing cost-effectiveness archetype feedback.
- We may require a clear narrative of the value of NICE scientific advice relative to JSC.

Estimated potential intersection between JCA, Regulators, and NICE



Two separate aspects to keep track of:

Internal UK influence

Recommend that the UK is part of early clinical evidence planning and contributes to the review of global PICOs as this information will be of use in a UK submission as well as the JCA.

NICE external influence

There is a risk that the global influence of NICE and its recommendations is diluted relative to the JCA report; however, this is unlikely as the JCA report will not make evaluative statements or assess value, but UK Market Access/HTA teams should continue to monitor this closely.

Strategic Implications

Start

- Sharing UK data needs early with global teams
- Informing and shaping the internal PICO process through participating in internal PICO exercises
- Reviewing early JCA reports to gain familiarity, targeting assets of interest for the company
- Identify ways to minimise need for local data analysis
- Integrating issues that emerge within the JCA report into the NICE submission or objection handler document (as appropriate)
- Monitoring the evolution of the JCA process

Continue

- Early mapping of UK launch timelines
- Being a valued partner to global, regional and country health economics and evidence generation teams
- Applying a strategic enterprise-wide mindset to determining the optimal UK regulatory, access and launch timeline
- Offering advice, critique and support to globally-led initiatives
- Advocating UK needs are integrated into Global plans
- Positioning the UK as the HTA reference country for cost-effectiveness archetypes and emphasising the global influence of NICE to global teams

Stakeholder tactics

Various UK company stakeholders are required to respond to the implementation of the JCA and collectively ensure the UK remains a priority launch market.

Senior UK Management:

- Highlight the influence of NICE globally
- Reinforce the UK as a key global launch market
- Leverage our fast track marketing authorisation routes

New Product Planning:

- Map UK launch timelines early, highlighting potential bottlenecks
- Communicate UK evidence and data needs within UK and to global teams

HTA Teams:

- Learn about the JCA experience from EU colleagues, including Ireland, that UK teams closely collaborate with
- Maintain a close strategic partnership with global health economics, evidence generation and internal JCA teams
- Review JCA dossiers and reports to anticipate issues that NICE may raise, updating objection handlers where timelines align.

Conclusion

The UK is expected to experience minimal direct impact, though above-country teams may face resource constraints in supporting multiple regulatory and HTA pathways

The introduction of the JCA will place additional demands on internal pharmaceutical company teams to deliver data analyses for simultaneous regulatory submissions, JCA assessments, and other submissions to HTA bodies. Given that the UK is not an EU member state, and therefore not explicitly involved in the JCA, maintaining the UK's position as a strategically important global launch market requires a continued commitment to ensuring timely and equitable patient access in the UK, through early alignment of evidence generation and access planning with global development timelines.



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