COULD THE EUROPEAN JOINT CLINICAL ASSESSMENT (EU JCA) DELAY ACCESS TO NEW MEDICINES IN FRANCE?

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BACKGROUND & OBJECTIVE

- Within the European Union (EU), Health Technology Assessment (HTA) methods and processes vary from country to country, leading to disparities in terms of access times. One of the main objectives of the European Joint Clinical Assessment (JCA) process, which will come into force next January, is to improve patient access to new medicines across the EU.
- In France in 2023, approximately 500 days on average separated centralized Marketing Authorization (MA) and market access [1].
- Acknowledging these important delays, the early access program (EAP) was created and implemented in France in 2021 to accelerate access to innovative medicines.

Whilst the centralized EU procedure aims to reduce duplication and improve the quality of local HTA processes, it will impact local HTA processes and consequently patient access.

This research aims to understand the impact of the EU JCA on access to innovative medicines in France.

METHODS

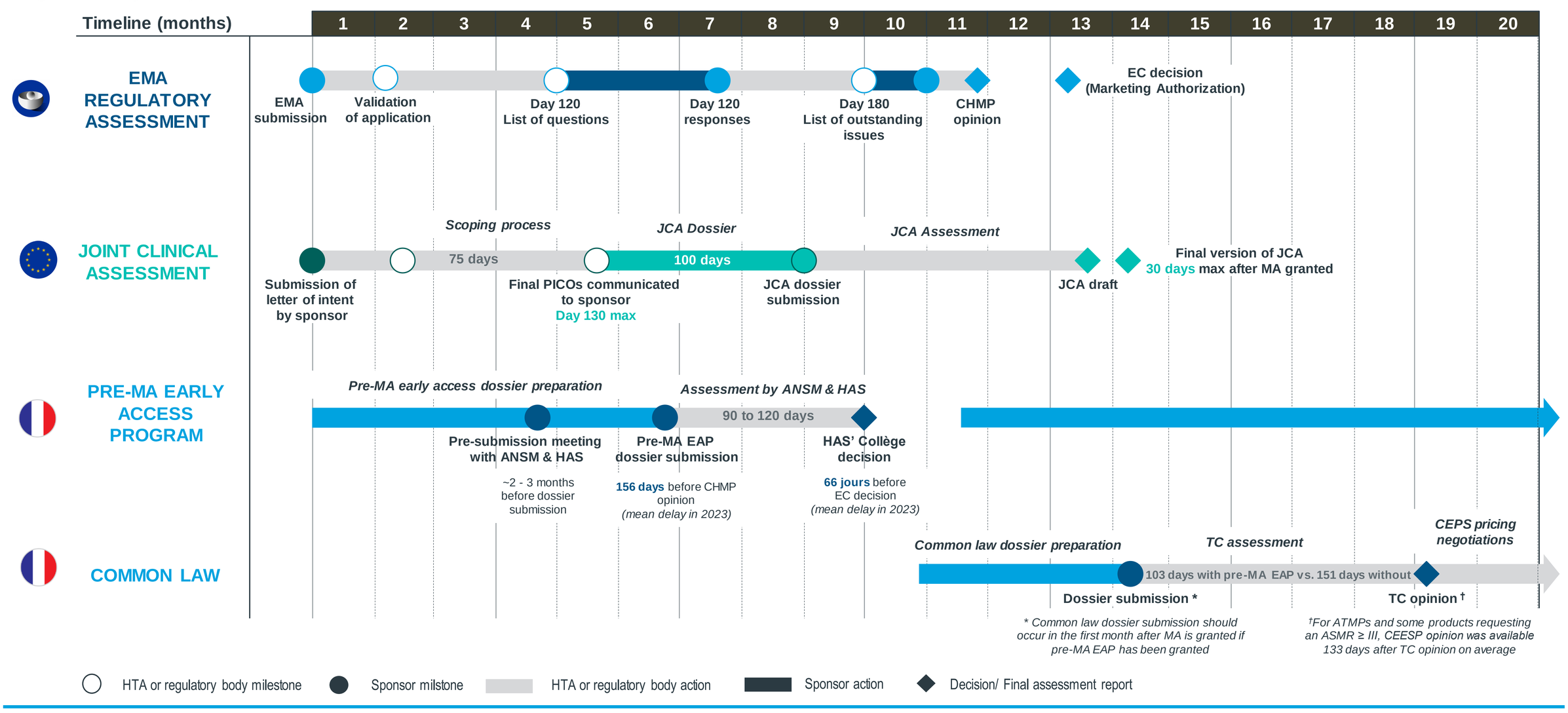
All documents published since 2021 by the European Commission (EC), as well as by Transparency Committee (TC) were reviewed. This included the EU HTA Regulation, JCA implementing acts (n=3), regulatory timelines and public communications by the HAS (including press releases, conferences etc.).

Using the Prismaccess® database, a comprehensive platform that covers regulatory, HTA, reimbursement and pricing assessments, we reviewed assessments completed by TC in 2023 to calculate HTA timelines. These timelines were then compared to expected timelines under JCA process.

RESULTS

- In 2023, TC assessed 125 indications under the standard reimbursement process (“common law”), 30 assessments under the pre-MA EAP and 28 as part of the post-MA EAP
- 30 products were made available under the pre-MA EAP, among which near 50% targeted solid tumors or hematological malignancies. Corresponding EAP decisions were published on average **66 days before** EC decision
- Pre-MA EAP dossiers were submitted on average **156 days before** the Committee for Medicinal Products for Human Use (CHMP) opinion and assessment took **103 days** in average. For products without EAP, the mean time between EC approval and TC submission was of **216 days**, and the mean TC assessment duration was **151 days** (with similar timelines between new products and indication extensions)
- TC and Economic and Public Health Evaluation Commission (CEESP) assessments are sequential: CEESP opinions were published on average **133 days after TC opinion**
- Price negotiations with Economic Committee on Health Products (CEPS) can only start when TC / CEESP opinions are available. This took on average **422 days for new products and 310 days for indication extensions**

Fig 1. JCA, regulatory and French HTA timelines overview [1]



KEY FINDINGS

- **The JCA report will be available 30 days after the EC decision. This coincides with the initiation of the TC assessment for products authorized through pre-MA EAP and for which a common law dossier submission should be submitted within the month following EC decision.**
- **HAS does not anticipate any change in common law assessment timelines for products granted pre-MA EAP. However, the lack of clarity on how processes will overlap may discourage pharmaceutical companies from pursuing EAP in France, thus delaying patient access to innovative medicines.**
- **Price negotiations are contingent to completion of the medico-economic assessment for all advanced therapy medicinal products (ATMPs) and for some products requesting an ASMR ≥ III. However, CEESP assessments are only available 133 days after TC opinion, and this should not change with the JCA.**
- **It is still uncertain if JCA will accomplish its goal of expediting access to innovative drugs considering that price negotiations are likely to remain the main driver for delay in France.**

1. IQVIA. Prismaccess® database.

ANSM: French National Agency for Medicines and Health Products; ATMPs: Advanced therapy medicinal products; CEESP: Economic and Public Health Evaluation Commission; CEPS: Economic Committee on Health Products; CHMP: Committee for Medicinal Products for Human Use; EAP: Early access program; EC: European Commission; EMA: European Medicines Agency; EU: European Union; MA: Marketing Authorization; HAS: French National Authority for Health; HTA: Health Technology Assessment; JCA: Joint Clinical Assessment; PICOs: Population, Intervention, Comparators,