

ANALYZING DELAYS IN ECONOMIC APPRAISAL IN FRANCE: A COMPARATIVE STUDY OF 2021 AND 2022

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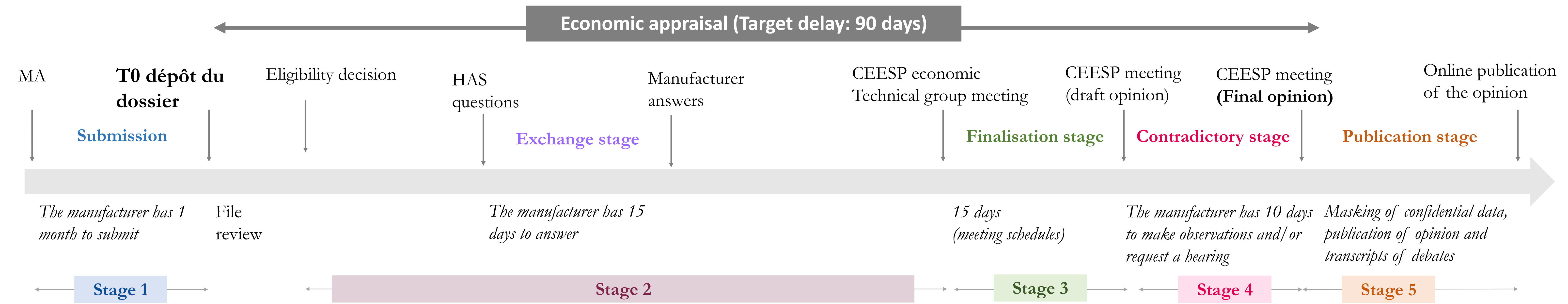
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Introduction

In French healthcare system, the timing and efficiency of market access for healthcare products play a pivotal role in ensuring patient access to innovative therapies. Regulatory guidelines in France prescribe a 180-day period for market access, encompassing the dual processes of Health Technology Assessment (HTA) by the French Health Authority (HAS) and price negotiations between manufacturers and the Economic Committee of Health Products (CEPS). This timeframe is theoretically divided into two equal phases of 90 days each.¹

This analysis will be centered on the economic evaluation phase, which is overseen by the Commission for Economic and Public Health Evaluation (CEESP). The activity reports of this committee for the year 2021 revealed notable delays, with the economic evaluation process taking an average of 139 days. Furthermore, data for the subsequent year, 2022, indicated a lengthened delay of 150 days.² This article is devoted to a comparative analysis of the data for 2021 and 2022, with the aim of shedding light on potential changes and improving our understanding of the complexities of economic appraisal s in the French healthcare system.

Figure 1 : overview of the economic evaluation process from submission of the marketing authorization to publication of the opinion



Results

25 eligibility decisions for the economic evaluation were granted in 2022, They relate only to drugs.

The mean delay for the economic evaluation was 133 days in 2022 (SD=34,6), with a decreasing trend compared to 2021 (mean= 144,3 days). This is explained by the average delay from eligibility decision to the first CEESP passage which was 116.5 days (SD=34), indicating a decreasing trend compared to 2021 (mean=136.4 days, SD=59.3). Despite a significant shortening of delays, they are still over the threshold of 90 days dedicated to the HTA process.

The average duration between eligibility decision and technical group review was 100.7 days (SD=33.4) for 24 cases (one dossier not examined). These delays were comparable to 2021 (mean=115.8 days, SD=56.6). For 48% (n=12) of the cases, an oral hearing led to a second CEESP passage within 14 to 63 days (mean=33.9, SD=19)in 2022. Delays between the last CEESP passage (appraisal adoption) and online publication averaged 82.5 days (SD=24.2).

Including the publication phase, in 2022, the average delays from eligibility decision to online appraisal publication were 215.6 days (SD=39.7) (n=25). This publication stage has not been calculated in 2021. To note, the publication phase is the second most time-consuming phase after the 1st examination phase.

Discussion

The French authority's activity reports for 2021 and 2022 indicate longer processing times, growing from 139 days in 2021 to 150 days in 2022. However, our study suggests a different trend. This difference can be attributed to the following factors:

- The starting point (T0) for calculating appraisal days, likely based on the date of dossier receipt, differs from the data we used in our study. This discrepancy leads to two important consequences: The list of dossiers used to assess delays varies due to the different T0 and delays appear underestimated if the eligibility decision is made later. Due to this T0 difference, the increased delays do not seem to result from the actual assessment time but rather from the time between application submission and the commencement of the review, which is challenging to assess with available public data.
- The reduction in phase 3 processing time can be attributed to an increased frequency of commissions (now two per month). Conversely, the extended duration in the contradictory phase may be due to a potential rise in requests for amendments to draft opinions from laboratories during this stage

Conclusion

Our analysis underscores the average delay of various stages in the medico-economic evaluation process by the French National Authority. In 2021, the delays taken for the economic evaluation was 133 days, while in 2022 it was 144,3 days, indicating a reduction in evaluation appraisal delays, although still above the initial target of 90 days. Notably, our findings highlight a decreasing trend in the average delay to the first CEESP passage. These outcomes inform the need for proactive planning by pharmaceutical companies to mitigate potential delays when introducing healthcare products to the market, thus optimizing patient access.

References

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Methods

Data collection: Relevant data were collected from the HAS website (eligibility decision³; CEESP meeting reports

Inclusion Criteria: Economic appraisal dossiers for healthcare products submitted in 2022 were included if the date of their eligibility decision (corresponding to the HAS college decision to review the submitted economic evaluation regarding criteria set by law.) was in 2022 . We also ensured that these dossiers had undergone evaluation, and their results had been published.

Time Variables: Key time variables were identified, including the date of eligibility decision, dates of CEESP meetings, the date of online publication of the appraisal, as well as other pertinent dates related to intermediate steps in the economic appraisal process.

Calculation of Delays: Delays between each stage of the economic appraisal process were calculated. These stages include the eligibility decision to the technical group meeting (stage 2), technical group meeting to draft opinion (Stage 3), draft opinion to final opinion (Stage 4- contradictory stage), and final opinion to online publication (Stage 5).These stages are represented in the figure below.

