

Comments on: Italian Medicines Agency's reform and time until pricing and reimbursement decisions: a time-to-event analysis

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We read with interest the study by Raspolini et al. (1), which assesses the impact on the timing of price and reimbursement (P&R) negotiations at the Italian Medicines Agency (AIFA) following the establishment of the new CSE (Commissione scientifica ed economica) in place of the previous CTS and CPR (Commissione tecnico-scientifica and Comitato prezzi e rimborso). In our view, the analysis presents important limitations that substantially undermine the validity of the conclusions.

Asymmetry in the start of observation between the two groups. In the main analysis (base case), the pre-reform group (hereafter PRE) begins to accumulate time from the date of European authorization, even before AIFA takes charge of the dossier. The post-reform group (hereafter POST), by contrast, starts observation on 1 March 2024, at which point many drugs had already progressed through part of the negotiation process. This structural asymmetry introduces a systematic advantage for the POST group that is independent of any actual improvement in AIFA's efficiency. The sensitivity analyses do not resolve this asymmetry, since in all analyses the POST group's observation "benefits" from the work already carried out during the PRE period.

Asymmetry in follow-up duration. Drugs reimbursed in the PRE group can be followed for more than three years from the European authorization, thus allowing the inclusion of very slow procedures. The POST group, by contrast, is followed for a maximum of approximately 15 months (March 2024 to May 2025). As a result, observations corresponding to the slowest procedures in the POST group are censored before the event can occur, with a selection effect whereby only the most rapidly concluded procedures are included in the POST group. This mechanically compresses the estimated median time in the POST group and inflates the apparent

advantage attributed to the new CSE. The authors mention the possibility of "informative censoring" in the Discussion section, but do not draw the implications regarding the direction and likely magnitude of the resulting bias.

A question on sensitivity analysis S3. We note that the third sensitivity analysis (S3), which uses the date of submission of the P&R dossier to AIFA as the start of observation, yields a reduction in POST-period times of 165 days—considerably greater than in the main analysis, where times appear reduced by 95 days (from 483 days in the PRE to 388 in the POST). The authors present this analysis as a more targeted assessment of AIFA's institutional efficiency, since the time elapsed before companies submit their application is excluded. We would ask the authors to clarify what, in their view, might explain such a markedly greater apparent improvement, when the only change introduced relative to the base case is precisely the exclusion of dossier submission times—a phase that lies outside AIFA's control and whose exclusion should, if anything, eliminate a source of noise.

Overall, the biases described share a common direction: they all tend to make the post-reform system appear faster than the pre-reform one, regardless of any genuine improvement. We do not rule out that the new CSE may have contributed to accelerating negotiations. However, on the basis of the analyses presented, it is not possible to conclude either for or against this hypothesis.

Disclosures

Conflict of interest: The authors declare no conflict of interest.

Financial support: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

References

1. Raspolini GM, Federico B, Nurchis MC, et al. Italian Medicines Agency's reform and time until pricing and reimbursement decisions: a time-to-event analysis. *Global and Regional Health Technology Assessment*, 2026;13(1):79–86. [CrossRef](#)

Received: April 16, 2026

Accepted: May 18, 2026

Published online: June 10, 2026

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