Analysis of factors impacting lead times in reimbursement processes

Abstract ID#:146830

ISPOR Improving healthcare decisions

Barcelona 2024

Van der Lelie LG, Yap EYS

LYSIAC institute for policy developments

objective

The objective is to get insight in the factors that may impact reimbursement process lead times to estimate and optimise time till patient access. Based on this insight, authorities and other stakeholders may contribute to an optimal flow of the reimbursement process. Better knowledge can help planning and increase efficiency and ultimately can improve processes.

This research concerns a snapshot of the current situation in the Netherlands. This can also be used as a baseline to compare with cases going through the EU-HTA process in the coming years.

methods

We investigated possible causal links between factors and lead times for a selection of recently HTA assessed products (finalized phase 2 from April '23 onwards ánd finalized phase 3 before November '24), based on the "CIBG Dashboard" from MoH (date of access: October 19th, 2024). Data is based on public information, where information from Zorginstituut complements the information from the Dashboard.

Only recent cases were included to minimize the impact of changing policies.

The lead times are divided in 3 phases:

1) submission: EMA approval → ZIN declaration of 'dossier complete'
2) assessment: dossier complete → publication ZIN advice
3) negotiation: ZIN advice → published MoH reimbursement decision

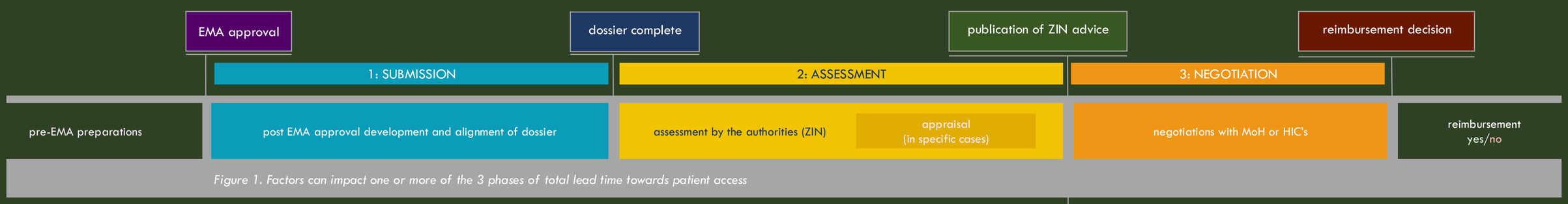


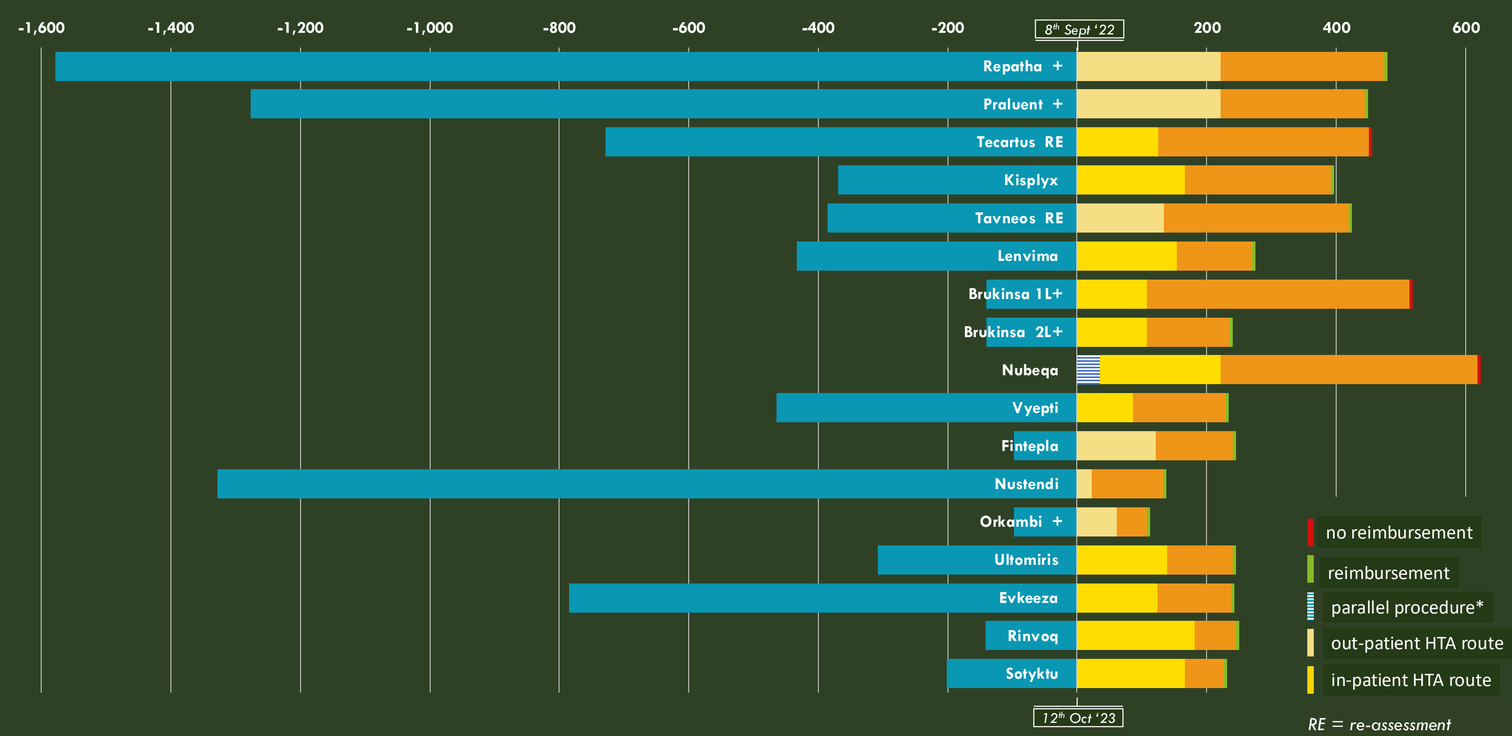
Figure 1. Factors can impact one or more of the 3 phases of total lead time towards patient access

results

Total lead times vary considerably (160-2.064 days), with the most variation in the submission phase 1 (97-1.584 days). Several factors contributing to variation in the submission phase are not publicly available, e.g. strategic considerations of a company or the informal processes prior to ZIN declaration of 'dossier complete'. Also, in case of negotiations, factors impacting the duration of phase 3 (64-410 days) are mostly confidential.

In relation to the total lead time, assessment phase 2 seems rather limited (23-221 days). However, factors in phase 2 that can be identified based on public information, may also have impact on phase 1 and 3. Identified factors in phase 2 include inclusion of pharmaco-economics in the dossier, added versus similar clinical value, magnitude of budget impact/ICER, HTA history, new policies, etc.
The number (n = 17) and heterogeneity of cases clearly do not allow statistical significance on causal relation between identified factors and lead times.

Graph 1: Total lead time and lead times per phase (1: submission, 2: assessment and 3: negotiation)



Cases are presented chronologically based on date of ZIN declaration 'dossier complete' (start phase 2)

**) Parallel procedure: regulatory EMA and HTA assessments run simultaneously.*

conclusions

Conclusions on meaningful quantitative impact of factors on lead time is not feasible, since changing policies limit the analysis period and hence the number of assessments. However, we identified a causal or at least plausible relation between a factor and lead time in some individual cases.

These and future qualitative results can give relevant and valuable information on factors impacting lead time for similar future cases.

measuring and monitoring are first steps towards estimation in individual cases and improvement overall

follow-up

Please let us know your experience with factors impacting HTA lead times or share your research on the subject. Also let us know if you will follow this up in your country or within the EU-HTA process.

Drop us an e-mail to stay in touch on the subject