

HTA and reimbursement timelines in the Republic of Ireland



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Objectives

To receive reimbursement in Ireland, all New Chemical Entities (NCE) must undergo a rapid review (RR) and, in some cases, a full health technology assessment (HTA) undertaken by the National Centre for Pharmacoeconomics (NCPE). Following an NCPE recommendation, the medicine is considered by the Health Service Executive (HSE) for reimbursement. The aim of this study was to evaluate trends in timelines to reimbursement for medicines that have been evaluated by the NCPE, and help pharmaceutical companies identify possibilities of shortening the market access (MA) timeline.

Methods

A retrospective data analysis from the NCPE website was conducted. 290 RRs and 108 full HTAs between 2017 and 2021 were identified, and appraisal outcomes, reimbursement status and dates were extracted. Timelines for each step were calculated as the average number of calendar days. The average timeline of RR was based on all RR submissions over all years that have been reimbursed; the average timeline of full HTAs was based on all full HTA submissions over all years that have been reimbursed.

Results

Of the 290 RRs and 108 full HTAs, only 70 and 66 were reimbursed respectively, as of February 2022. Where reimbursement was achieved after RR, regardless of the RR outcome, it took 39 days (average) for a medicine to complete RR plus 272 days to gain reimbursement. The time from RR submission to reimbursement decreased from 335 days in 2017, to 300 days in 2020 and 256 days in 2021 (Figure 1). Where reimbursement was achieved after a full HTA, regardless of the HTA outcome, it took 33 days for NCPE to complete RR, 107 days for preliminary assessment, 66 days for re-assessment after company's comments, and 19 days for finalising the appraisal; it took 119 days for a company to prepare for submission, 31 days for comments, and 11 days for factual check; and it took 88 days for a company and NCPE to schedule a pre-submission consultation meeting, and 384 days for the HSE and company negotiation and approval of reimbursement (Figure 2). The time between RR submission and reimbursement increased from 848 days in 2018 to 998 days in 2019 but decreased to 873 days in 2020 and 701 days in 2021 (Figure 3).

Figure 1: Reimbursement timeline in each year where reimbursement was achieved after RR

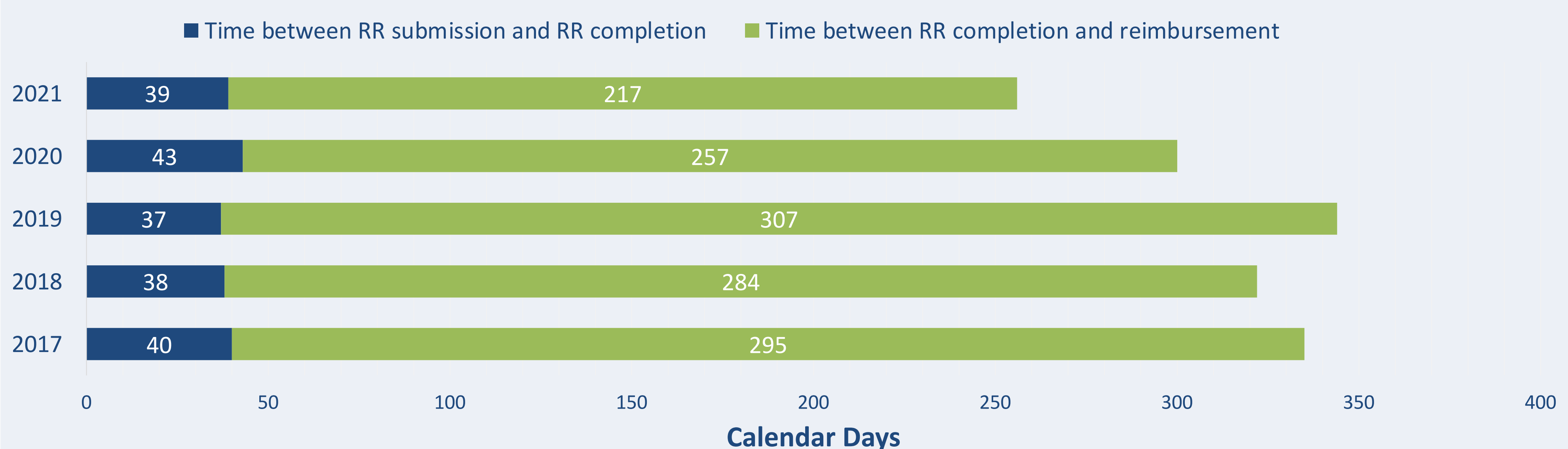


Figure 2: Detailed reimbursement timeline for all submissions over all years where reimbursement was achieved after full HTA

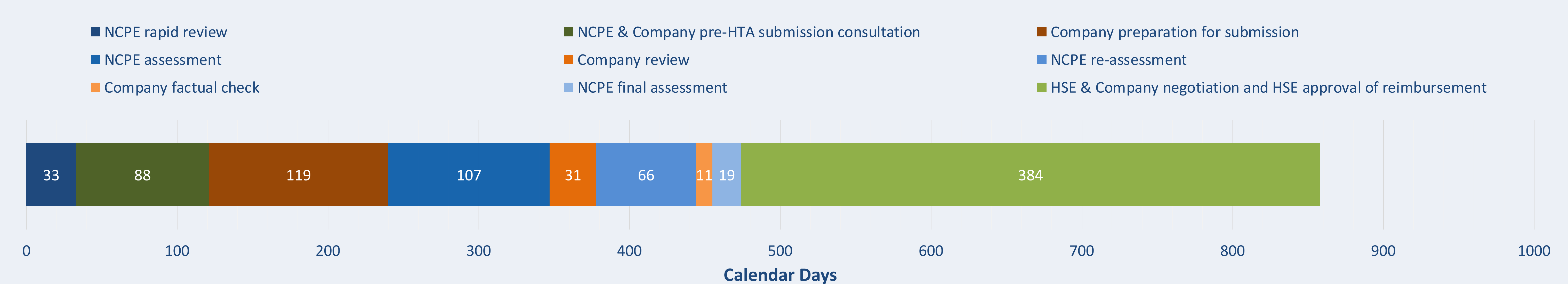
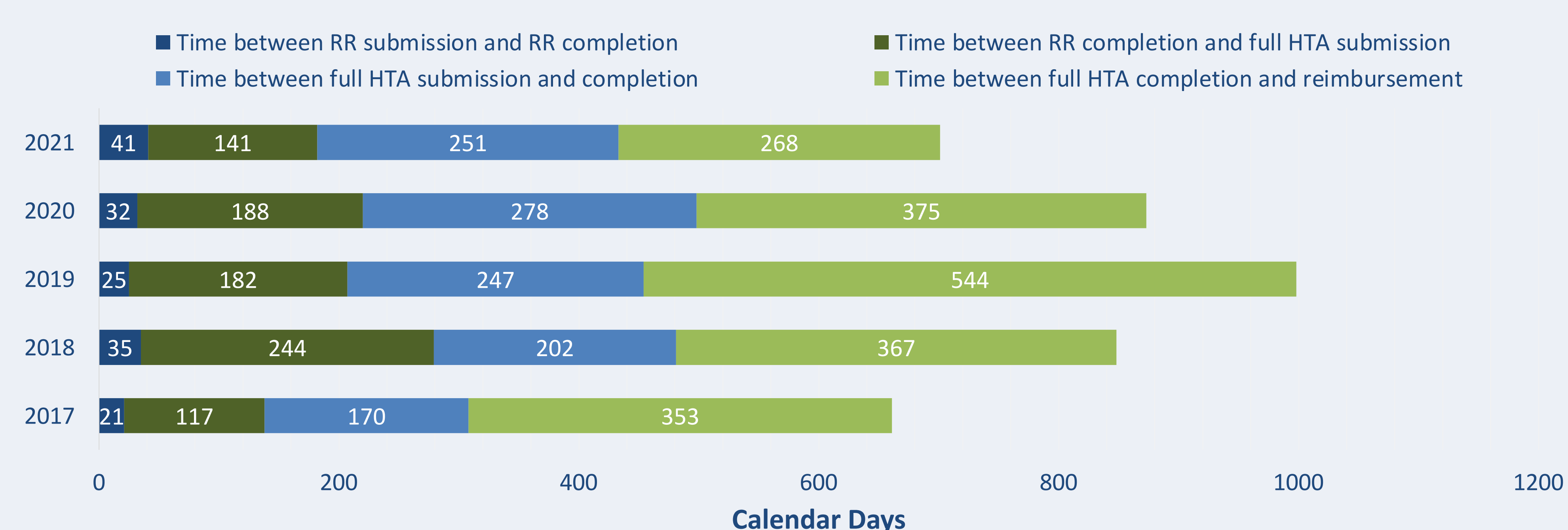


Figure 3: Reimbursement timeline in each year where reimbursement was achieved after full HTA



Conclusions

The NCPE's two-step assessment process provides an opportunity to maximise efficiency and minimise MA timeline. Where possible, companies should try to make a good RR submission to secure reimbursement and avoid the long full HTA process. Where a full HTA is unavoidable, companies could accelerate work on submission preparation, commenting and factual checks to shorten the MA timeline.

References:

1. MAP Patient Access HTA database and trends analysis. Selected charts available at: <https://www.mappatientaccess.com/maponline-ireland/>
2. Data on rapid reviews, full health technology assessments and reimbursement drawn from NCPE at: <https://www.ncpe.ie/pharmacoeconomic-evaluations/all-drug/>

