IN WHAT SEQUENCE DO COMPANIES SUBMIT HTA DOSSIERS IN THE UK AND IRELAND, AND IN WHAT SEQUENCE ARE THEY PUBLISHED?


Introduction

New medicines that offer patient benefit and value for money should be accessible through the UK health service as soon as possible. Therefore, patients and clinicians want the shortest time possible between licensing and patient access. In addition, manufacturers have a desire to shorten the time from licensing to sales, to recoup development costs and make returns on investment.

The health technology assessment (HTA) process for assessing whether a new medicine is clinically effective and cost-effective varies across the UK and Ireland. All new medicines for Scotland have to be assessed by the Scottish Medicines Consortium (SMC), either as a full or limited review. Approximately half of new drugs for England are assessed by the National Institute for Health and Care Excellence (NICE). New drugs may also meet the criteria for assessment by the All Wales Medicines Strategy Group (AWMSG) and National Centre for Pharmacoeconomics (NCPE) in Wales and the Republic of Ireland, respectively.

Methods

SMC published guidance from January 2017 to June 2017 were reviewed. The SMC publishes appraisals of all new medicines, so was used as the reference point. Resubmissions were excluded to avoid confounding timelines. The sequence of submission and publication of any corresponding NICE, AWMSG and NCPE guidance was calculated.

• Start dates for NCPE submissions were obtained directly from the NCPE website1.
• Start dates for NICE submissions were obtained from the company submission if available online, otherwise the start dates were calculated from the SMC website2 assuming start dates are 12 weeks before the 1st appraisal committee (AC) meeting, 15 weeks before publication of the AC document, 20 weeks before the 2nd AC meeting or 23 weeks before a multiple technology appraisal AC meeting.

• The time from SMC submission to guidance was assumed to take 18 weeks3.
• AWMSG submissions were assumed to occur 15 weeks before the new medicines group meeting4 (Figure 1).

Results

Ten of the SMC appraisals were resubmissions and were excluded. In the resulting sequences of submission and publication (Figure 2), NICE was the most common HTA alongside SMC, with 60% of SMC appraisals having a corresponding NICE appraisal. AWMSG and NCPE appraisals have thus far been the most infrequent, with only 3 AWMSG and 4 NCPE appraisals in the timeframe analysed, from January to June 2017.

The most frequent first submission was to NICE (55%), followed by SMC (35%) and AWMSG (10%). SMC guidance was published first in 65% of cases. NCPE submission and publication was consistently the last in the sequence. The modal submission sequence was NICE followed by the SMC (45%) but the modal publication sequence was SMC followed by NICE (30%).

For 12 of the 20 products, the submission and publication sequence were the same. For the 8 products that differed, in 7 cases NICE was submitted before SMC but publication was SMC followed by NICE.

Conclusions

Submissions are most often made to NICE first but the SMC is usually first to publish recommendations. This is likely due to the shorter timelines of the SMC process compared with the NICE process. Submissions to the NCPE were consistently after those to the UK, which may be due to international reference pricing strategy, or due to limited manufacturer resource since some companies are structured with one team covering the UK and Ireland. AWMSG completed few HTAs owing to the applicability of NICE decisions to England and Wales.

A limitation of this analysis is that we assessed SMC appraisals from earlier this year, indicating medicines licensed from late 2016 up to mid-2017. Four products had only been assessed by SMC but companies may plan to submit to other HTAs in the near future. This research may provide companies with insights into common sequencing of UK HTA submissions, highlighting the likelihood that submitting to NICE first will not necessarily result in guidance being published in England before Scotland.