This can be attributed to the TGA/PBAC parallel review process, which showed its benefit in reducing the overall time. A parallel review process is also available in Canada; however, it is not utilized as frequently by companies as in Australia.

OP172 Do Expedited Regulatory Pathways Affect Time To Health Technology Assessment Decision?

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INTRODUCTION:

In an effort to speed the assessment of new medicines while maintaining the quality of the regulatory review, facilitated regulatory pathways (FRPs) have been introduced in many countries. In this study, the effects of FRPs (expedited and conditional reviews) were investigated in terms of their influence on HTA outcomes and timing.

METHODS:

HTA recommendations issued between 2014 and 2016 were collected from CADTH (Canada), HAS (France), IQWIG (Germany), SMC (Scotland) and TLV (Sweden) for 90 internationalized medicines (new active substances approved between 2012 and 2016 by all regulatory agencies in the five jurisdictions). The HTA decisions were then classified into the following categories: positive, positive with restrictions, negative and multiple.

RESULTS:

Of this cohort of internationalized medicines that received an HTA recommendation, 31 percent in Canada and 28 percent in Europe were approved via a FRP. With the exception of Scotland, expedited medicines were more likely to be appraised within a year from regulatory approval and had a shorter median time between regulatory approval to HTA recommendation than standard medicines. The largest difference was seen in Sweden, where medicines were 66.5 days faster than standard pathways when it underwent the expedited pathways. Compared to standard pathways, there were generally a higher proportion of positive and positive with restrictions recommendations when expedited pathways were used. Germany reported the largest proportional difference (31 percent) between the two pathways.

CONCLUSIONS:

Medicines being designated for an expedited review pathway show a reduced time from regulatory approval to HTA decision. This finding suggests there is an alignment between regulators and HTA agencies on which medicines require expedited HTA pathways; however, from this data it cannot be assessed whether the reduced time from approval to HTA decision is attributed to the company strategy, HTA review time or both. Further investigation is required.

OP173 Eligibility Criteria For "Accelerated Access" Approval: A Global Survey

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INTRODUCTION:

Several early access schemes (EAS) exist, which aim to accelerate patient access to new, potentially life-saving therapies. While some information exists on key schemes and their modalities, the determinants that drive adoption of a new medicine under an EAS remain unclear. We aimed to map eligibility criteria for inclusion of new medicines into the different EAS available across countries.

METHODS:

Health technology assessment (HTA) stakeholders across 23 countries globally were invited via email to complete a web-survey with questions on (i) items that define product eligibility for EAS designation, (ii) standards for minimum level of evidence, monitoring, and additional evidence generation for early access products, and (iii) funding arrangements for these products across settings and types of schemes. Anonymized responses were analysed using descriptive statistics.

https://doi.org/10.1017/S0266462318001745 Published online by Cambridge University Press