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VP155 Synchronization Of Regulatory Approval And Health Technology Assessment Recommendation Timing

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INTRODUCTION:

Minimizing the delay between regulatory approval and Health Technology Assessment (HTA) recommendation is critical to ensure patients access to medicines of therapeutic value. The aim of this study was to evaluate the level of synchronization between the regulatory decision and HTA recommendation.

METHODS:

Data were collected from the public domain for new active substances that were first appraised by the HTA agency in Scotland (SMC - Scottish Medicines Consortium), France (HAS - Haute Autorité de Santé), Germany (IQWIG - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), Australia (PBAC - Pharmaceutical Benefits Advisory Committee) and Canada (CADTH - *Canadian* Agency for Drugs and Technologies), and that reached an outcome in 2014 and 2015. The year the product was approved by the European Medicines Agency (EMA), Australian Therapeutic Goods Administration (TGA) and Health Canada were also assessed.

RESULTS:

In 2014 and 2015, fifty-one products with HTA recommendations were identified for SMC and IQWIG, forty-two for HAS, forty for PBAC and thirty-eight for CADTH.

Of the HTA agencies studied, CADTH had the lowest percentage of HTA recommendations occurring the same year as jurisdictional regulatory approval. Of the products with CADTH recommendations in 2014, only 7 percent were approved by Health Canada in the same year. By comparison, all of the products with PBAC recommendations in 2015 were approved by TGA in the same year.

For 2014 and 2015, comparing the percentage of HTA recommendations with the jurisdictional regulatory agency approval the same year showed 7 percent (2014) versus 29 percent (2015) for CADTH: 35 percent versus 37 percent for SMC: 35 percent versus 44 percent for HAS; 56 percent versus 57 percent for IQWIG; and 91 percent versus 100 percent for PBAC.

CONCLUSIONS:

This study shows that the parallel submission mechanism to enable synchronizing HTA and regulatory decision making is effective in Australia, whilst there remains a synchronization disconnect in other countries; although this may be improving. The extent of decision timing disconnect, influence of company strategy and type of HTA outcome were also studied. This initial analysis suggests gaps between the timing of regulatory approval and HTA recommendation for HTA agencies outside of Australia.

VP157 What Is The Response To Immuno-Oncology By Health Technology Assessment Agencies?

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https://doi.org/10.1017/S0266462317003956 Published online by Cambridge University Press