Conclusions. This was the first time that the Decit team provided hands-on methodological assistance the development of a health policy. Not all steps recommended in the SUPPORT Tools were feasible due to time restraints. We observed that rapid evidence synthesis products were helpful to inform decision-making.

OP131 Rapid Review For Policy: Interchangeability Of Biological Medicines

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Introduction. Due to the high judicialization rates which pressure the financing of biologic medicines by the Brazilian Unified Health System (Sistema Único de Saúde - SUS), it has been decided to formulate the National Policy for Biologic Medicines. After identification of problems and prioritization, interchangeability based only on economic criteria was the main problem to be confronted. The primary objective of this study was to identify political options to approach the problem of interchangeability in systematic reviews.

Methods. We conducted a rapid evidence synthesis for policy based on an adaptation of the SUPPORT tools, and searched in six literature databases. The selection of studies was performed in a systematic, transparent and independent manner. The International Network of Agencies in Health Technology Assessment (INAHTA) members were consulted to learn how this practice occurs worldwide.

Results. We included seven systematic reviews and one policy brief, whose options to approach the problem were: production of robust scientific evidence on interchangeability; implementation of a pharmacovigilance system; appreciation of the clinical efficacy in the practice of interchangeability; and educational strategies for healthcare professionals in Brazil. Nine countries responded to our query.

Conclusions. Evidence-informed policy has a central role for the Brazilian Ministry of Health. The present rapid evidence synthesis for policy will subsidize decision making regarding the interchangeability of biologic medicines within the Brazilian Unified Health System.

OP132 What Future For Drugs After An Early Dialogue Procedure?

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Introduction. The French health technology assessment (HTA) body, Haute Autorité de la Santé (HAS), started to provide early advice on evidence generation plans to pharmaceutical manufacturers in 2010. It became an official mission in 2016. Requests are eligible when the product has a new mechanism of action, if there is an unmet or partially met medical need in the claimed indication and when the pivotal study has not yet started. This analysis aims to provide a first overview of clinical developments for which pharmaceutical companies sought an early dialogue with HAS.

Methods. For each product that went through an early dialogue procedure with HAS, information regarding the clinical development was collected on pharmaceuticals companies' pipelines, clinicaltrials.gov, the website of the European Medicine Agency (EMA) and HAS's internal database.

Results. By the end of 2018, HAS has performed 84 early dialogues of which 53 were conducted in collaboration with the EMA and/or others European HTA bodies. They were mainly focused on phase III trials. Following early dialogue, the clinical study for which the company sought advice was not yet implemented in 25 cases. When the clinical trial was effectively launched, results were negative in 10 cases, positive in 11 cases and the study was still ongoing for 29 products. In nine cases, the clinical development was officially withdrawn or suspended before the initiation of the trial. Overall, only eight medicinal products were appraised by HAS, they all obtained a clinical added value score.

Conclusions. The success rate of clinical development for products that underwent an early dialogue procedure tends to be higher than data from literature, although it is likely to decrease in follow-up analysis. This could be partially explained by HAS's eligibility criteria that restrict early dialogues to promising products and by the scientific recommendations provided to pharmaceuticals companies.

OP135 CAR T-cell Therapy HTA Informs Australian Policy

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Introduction. Chimeric antigen receptor (CAR) T-cell therapy is offered as a once-only treatment for patients with certain cancers that are not responsive to standard treatment. While clinicians, patients and their families increasingly seek access to CAR T-cell therapy, there is no revenue stream to support access through public or private health systems.

Methods. The New South Wales (NSW) Ministry of Health and Victorian Department of Health and Human Services oversighted a health technology assessment (HTA) to explore the status and geography of regulatory frameworks supporting delivery of CAR T-cell therapy, evidence for the safety, efficacy and cost, clinical trials conducted or underway and manufacturing aspects.

Results. CAR T-cell therapies are approved in the European Union and United States of America, and being considered in Australia, Canada, China and Japan. Efficacy, safety and cost-effectiveness is limited by the size and single-arm design of early stage trials and variation between them. While overall response ranges from 36–93 percent, early results for some cancers are less favorable. Durability of treatment effect is unknown,

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