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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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INTRODUCTION:

Immunotherapies are a relatively new innovative class of drug that have garnered excitement in the fight against cancer. In 2011, the immunotherapy drug, ipilimumab, was approved. Since then, four additional drugs have gained approval. This analysis evaluates the initial reception of immunotherapies by Health Technology Assessment (HTA) agencies.

METHODS:

The Context Matters Data Model was used to evaluate the regulatory and HTA agency decisions surrounding the five approved immunotherapies through November 2016: atezolizumab, elotuzumab, ipilimumab, nivolumab, and pembrolizumab. Thirty-three labels from Australia, Canada, Europe, and the United States, and ninety-two assessments from Agenzia Italiana del Farmaco (AIFA), Gemeinsamer Bundesausschuss (Federal Joint Committee; G-BA), Haute Autorité de Santé (French National Authority for Health; HAS), Institute for Clinical and Economic Review (ICER), Institute for Quality and Efficiency in Health Care (IQWiG), National Institute for Health and Care Excellence (NICE), Pharmaceutical Benefits Advisory Committee (PBAC), pan-Canadian Oncology Drug Review (pCODR), and Scottish Medicines Consortium (SMC) were found. Using a sample t-test and a chi-squared test, reimbursement agencies' decisions were evaluated, and the clinical and economic factors that went into these decisions were examined.

RESULTS:

Of the evaluated reviews: sixty-four were for melanoma indications, fourteen were for non-small-cell lung cancer (NSCLC) indications, and seven were for kidney cancer indications. Many of the reviews did not reach any decision, but 75 percent of HTA decisions ($n = 72$; $p = .0000$) reached were positive. Elotuzumab, approved for multiple myeloma, received a positive decision from G-BA and a negative one from SMC. There was an association between different disease conditions or drugs and the rate of positive decisions.

For reviews that had clinical reasons for their decisions, 72.9 percent ($n = 59$; $p = .0000$) had positive clinical rationales that were associated with positive decisions ($p = .000$). Economic rationales for decisions were more mixed, with only 48.4 percent ($n = 31$; $p = .0000$) receiving positive decisions. Positive economic evaluations were also associated with positive decisions ($p = .000$). Atezolizumab, approved only in the United States at the time of this writing, has yet to be reviewed by any of the HTA agencies.

CONCLUSIONS:

Immunotherapies are promising new options for the treatment of cancer. Thus far, reception by HTA agencies has generally been positive.

VP159 Strengthening Primary Health Care In Nigeria By Patient Involvement

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INTRODUCTION:

The Health system in Nigeria is structured into three tiers which include tertiary health care, secondary health care and primary health care (PHC). The latter forms the grassroots system of delivering basic health services to communities in both rural and urban centers. However PHC in Nigeria have been affected by poor service delivery. This has resulted in underuse of PHC due to the acceptance and utilization of health services delivered through this system. This research seek to bridge the gap of inequality, reaffirm that implementing PHC is a human right/duty and fosters patient and consumer involvement for economic, social and environmental sustainability of PHC.

METHODS:

A qualitative method of research was adopted using a participatory research model. The relative data was sourced secondarily from recent findings (July 2015) carried out in seventy-three primary health centers across Anambra State, Benue State, Kaduna State,

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