OBJECTIVES: Many key pharmaceutical markets (including England, Scotland, and Wales) have now increased their use of economic evaluations, with the use of health economic evaluation increasing. The objective of this study was to identify recently launched molecules in Japan that were priced using the cost-plus calculation vs. cost-comparison pricing method and to evaluate the rationale behind their pricing decisions.

METHODS: A targeted literature review was conducted for new drugs launched in March 2011 and August 2014, 71 (34%) molecules had a novel mechanism of action for their respective indication, while 140 (66%) did not. Of the 71 novel molecules, 53 (75%) molecules underwent cost-plus pricing, while 18 (25%) underwent cost-comparison pricing. Of the 18 likely underwent cost-comparison pricing either due to their novel or imitated clinical efficacy or similar mechanism of action as those of existing molecules or due to the crowdedness of the space, 3 of the 18 underwent cost-comparison pricing due to their mechanisms of action being broadly defined. Of the 140 non-novel molecules, only 7 (5%) molecules were priced under cost-plus pricing despite not being first in class. It can be conclusively determined that while the novelty of a molecule's mechanism serves as the main driver for which pricing method is used by the MHLW, it is not the only driver behind the decision.

OBJECTIVES: In several countries, incremental cost-effectiveness ratio (ICER) "thresholds" aid in the healthcare decision-making process by helping prioritize the distribution of resources across interventions. The aim of the study was to assess the use of ICER thresholds in the P&R process, and understand the evolution of ICER thresholds over time. METHODS: A targeted literature review was conducted using search terms to address the following research questions: (i) How have ICER thresholds changed over time to reflect advances in medical technology? (ii) What is the societal willingness to pay (WTP) per QALY? (iii) How do the ICER values of interventions treating different diseases compare? PubMed and Grey Literature were searched for relevant studies published in English between January 1970 and September 2014. RESULTS: This review summarizes evidence from 48 studies. Literature revealed that countries use explicit and implicit ICER thresholds during the P&R process. In the US and UK, thresholds were established in 1982 and 1999 respectively, and despite significant advances in medical technology, these have not been updated. Our review indicates that the estimated societal WTP in the US is between $100,000–$297,000/QALY, and it has been recommended that the ICER threshold be raised to at least $200,000/QALY. Additionally, our review shows that ICER values vary significantly for different therapeutic areas based on medication cost, unmet need, and severity. For example, the average ICER value for an intervention to treat Type 2 Diabetes in the US is approximately four-fold that of Type 2 Diabetes ($22,663/QALY). CONCLUSIONS: Researchers cite that ICER thresholds are dynamic, and should change over time to account for innovation in technology, improvements in quality of care, and changing economic conditions. In addition to end-of-life care, efforts should be made to establish different thresholds for diseases with high unmet needs to facilitate patient access to novel therapies.