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Overview of the Japanese HTA reform towards pharmacoeconomic requirements in 2016

Primarily regarding pharmaceuticals, extensive discussion of value-based approaches to reimbursement and pricing of medical technologies are often heard in western countries. The UK's NICE, since 1999, has established value-based assessment for the decisions on reimbursement in terms of cost-QALY (Quality-adjusted Life Years) ratio. Although France and Germany are less positive towards employing the QALY outcome, both of them have been converging on similar methods, which so far consider the relative clinical benefit and cost-benefit ratios to determine the reimbursement rates. In Asia, the UK NICE method using a cost-QALY ratio for health technology assessment (HTA) has been established in some countries such as Korea, Taiwan, and Thailand. Reflecting the trend, in 2011, Japan officially announced the start of serious consideration being given to the use of cost-effectiveness methods for pricing new medical technologies, with a pilot introduction in 2014. As of the beginning of 2014, the new policy on the details of cost-effectiveness methodology has not been determined, except for a summary agreement in the government committee that suggested employing an HTA methodology similar to that of NICE, but leaving the details for future discussion yet. Also the pilot introduction was postponed until 2016. Regarding those changing situations, the concept and methods for HTA must be more pivotal for Japanese value-based healthcare in the near future.

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Isao Kamae is a physician, Project Professor of Health Technology Assessment and Public Policy, Graduate School of Public Policy, The University of Tokyo, Japan, and concurrently serves as a research director for Health Economics and Policy, The Canon Institute for Global Studies (CIGS), Tokyo. He is also Visiting Professor at Kobe University Graduate School of Medicine, Japan, Visiting Professor, Meiji Institute for Global Affairs (MIGA), Meiji University, Japan and Visiting Professor of Health Economics, Guanghua School of Management, Peking University, China. He is well known as one of the founders for the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) Asia Consortium and the founding President of ISPOR Japan Chapter in 2005 - 2009, and the first Asia-origin member on the ISPOR Board of Directors 2004-2006. His research interest highlights methodological issues on cost-benefit function and ratios theory, and its application for the Japanese-style value-based pricing. He has been actively collaborating with the world-class institutes, which includes IQWiG, Germany, School of Pharmacy, University of Washington, and Center for the Evaluation of Value and Risk in Health, Tufts Medical Center in US, The ESSEC Business School in France. He is on the editorial board for *Journal of Medical Economics*. He served as the guest editor of the ISPOR official journal, *Value in Health*, 2nd Asia-Pacific Issue in 2009.