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environment allows us to identify four ideal-types of HB-HTA units: the independent group, the integrated-specialized units, the standalone units and the integrated-essential units. **CONCLUSIONS:** Our results provide useful information on how different organizations face the challenges of HB-HTA. The findings and can be beneficial for policy-makers and professionals implementing HB-HTA and may give an overview on the next steps that the HB-HTA units could follow to further improve their current ways of working.

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CURRENT PERCEPTION OF UPCOMING COST-EFFECTIVENESS REQUIREMENTS IN JAPAN: A SURVEY ON THE PERSPECTIVE OF PHARMACEUTICAL INDUSTRY

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OBJECTIVES: In anticipation of official requirements of economic evidence by the Japanese government from April 2016, the present study aims to assess past experience and current capability of the industry to submit the economic evidence to the government, and to identify what the industry perceives for their capacity building. **METHODS:** A self-administered questionnaire was distributed to a person who was in charge of economic evidence or those most relevant (e.g., those in charge of market access), within every 72 member companies of Japanese Pharmaceutical Manufacturers Association, in March 2015. Semi-structured interviews were conducted with three HEOR experts of the pharamceutical industry to assess the consistency of the survey results. **RESULTS:** 18 companies responded to the survey with the response rate of 25%. 12 companies had no experience submitting economic evidence to the government, mostly because of no merit for the industry. 8 companies had health economics experts. 14 companies answered they have great concern about lack of clarity and transparency in the way how the government would use economic evidence submitted. Most of the respondents were concerned about patient access, additional costs, human resource, and data availability. They expressed their unfavorable response to the new policy in the context of creating new business opportunities, and had a sense of resistance towards the use of ICER threshold for evaluation. The interviewee's responses were consistent with the survey results. **CONCLUSIONS:** Our survey observed that industry's concerns regarding the upcoming policy are high and their preparedness is limited. For the industry to respond appropriately to the new policy, further improvement in transparency of requirements will be a key, in addition to capacity building in the industry.

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MAKING COLLABORATIVE RELATIVE EFFECTIVENESS ASSESSMENTS RELEVANT: EXPERIENCE OF 4 EUNETHTA PILOTS ACROSS PHARMACEUTICALS AND MEDICAL DEVICES

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OBJECTIVES: There is growing interest, activity, and funding to increase the level of HTA collaboration in Europe, with the aim of reducing duplication, increasing efficiency, and improving evidence-based decision making. The expectation for the next 3 years of EU HTA collaboration is that learnings from early pilot activity will transform the process into a scalable, sustainable process by 2020. **METHODS:** EUnetHTA has undertaken 12 pilots evaluating the ability to undertake collaborative Relative Effectiveness Assessments (REA). Johnson & Johnson reviewed its participation in 4 of the pilots: two pharmaceuticals, two medical devices. One of each was alongside regulatory approval and one of each post launch. **RESULTS:** J&J contributed to a third of EUnetHTA pilots: 2 of 6 drugs; 2 of 6 devices. Experience identified that the issues required to achieve a sustainable relevant platform differ between pharmaceuticals and medical devices. For Pharmaceutical developers, the biggest challenges appear to be practical process issues, such as the timing of the REA report for inclusion in local processes, and policy issues related to uptake of reports within member states. For medical device developers, the main challenges appear how to predict which technology is likely to be selected for collaborative REA, what decision is likely to be informed within EU member states, and when in the product lifecycle the review will occur. **CONCLUSIONS:** For collaborative REA to move from pilot 'proof of concept' to being a sustainable platform, as intended by the European Commission by 2020, the differing issues between various healthcare sectors need to be recognized and addressed separately. Stakeholders engaged in developing technologies, as well as those who will use the outputs within member states need to be engaged to design and align on processes capable of delivering the reductions in duplication and providing the efficiency gains proposed by policy makers.

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EUNETHTA TOOLS AND METHODS – FACILITATING UPTAKE BY TRAINING ACTIVITIES

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OBJECTIVES: Provide training activities to facilitate uptake and ensure the optimal use of the EUnetHTA tools and methods. In the last decade, EUnetHTA (the European network for Health Technology Assessment), has developed several tools and methods to facilitate joint production of HTAs by Partners. In order to favour their implementation and practical use, providing training is required. Additionally, EUnetHTA Stakeholders expressed an interested in trainings about the same topics. **METHODS:** Partners and Stakeholders were surveyed to identify their training needs, collect their training format preference and identify which tool and methods to prioritize. A training program including both face-to-face and online activities was set up. Training opportunities were advertised using news items on the intranet and on the public site, pamphlets, newsletters and direct e-mail. Tool and method developers created the material and provided the activities. A feedback was requested from participants after each training session; specific questions were included in the annual general survey for Partners. **RESULTS:** Partners have been offered three face-to-face courses and several webinars which reached 90 people from 27 agencies and 25 countries. e-learning material (webcasts or recorded training sessions) were also created. All participants were satisfied or very satisfied, 70 % indicated having changed their practice following the training event. Stakeholders have been offered three face-to-face courses, which reached 70 participants (mostly patient organisations and manufacturers). All participants were satisfied of very satisfied **CONCLUSIONS:** EUnetHTA has succeeded in establishing a training program. Because EUnetHTA is a transnational network, use of e-learning should be extended so that more Partners will be able to increase their knowledge on EUnetHTA tools and methods in order to efficiently produce joint HTA information. Stakeholders also benefited from the training program to get a better comprehension of both HTA and EUnetHTA tools and methods. However, cost of pursuing this activity will need to be further assessed.

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IDENTIFYING PRACTICAL GAPS TO COMPLY WITH COST-EFFECTIVENESS GUIDELINE IN SELECTING COMPARATORS IN SOUTH KOREA

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OBJECTIVES: It has been argued that the selection criteria of comparator treatments suggested by the cost-effectiveness (CE) guideline in Korea are too restrictive and unrealistic for a valid CE assessment. The use of inappropriate comparators could result in an incorrect value assessment of a new drug leading to invalid reimbursement decisions. Thus, we conducted a study to investigate practical gaps in comparator selection to improve the validity of CE analysis. **METHODS:** We performed an online survey among all staff of the 35 member companies of the Korea Research-based Pharmaceutical Industry Association (KRPIA) whose workplace duty is related to CE evidence generation and/or submission to the government. In the questionnaire, we presented a hypothetical situation based on each of the practical gaps identified by the focus group interviews (FGI) and asked the respondents whether they had experienced it. A total of 50 out of 90 people included in the survey responded to the survey between November 11 and 26, 2014, yielding a response rate of 53.8%. **RESULTS:** Among the eight gaps presented in the survey, the highest proportion of respondents experienced "difficulty in obtaining reliable market share data needed to select a comparator" (94%), followed by "drug widely used for a long time selected as comparator for new drug because it was recognized as a standard treatment" (88%), "uncertainties in indirect comparison" (78%), "therapeutically nonequivalent drugs as comparators" (72%), and "price of new drug compared with price of generic product rather than initial price of original product" (70%) . The lowest number of respondents experienced "inclusion of off-label drugs as comparators" (36%). **CONCLUSIONS:** We expect our investigation results to improve the quality of CE guidelines for valid selection of comparators in South Korea as well as other countries, and, consequently, help assess the true value of pharmaceutical interventions.

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STEPS TOWARDS INTRODUCING A SYSTEM OF HEALTH TECHNOLOGIES ASSESSMENT IN UKRAINE

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OBJECTIVES: Health Technology Assessment (HTA) is an integral part of modern health care system of developed countries. It is carried out to study decision-making and policy-making in health care based on objective information and evidence base. In Ukraine HTA reports are the one of the sources of evidence-based medicine which are used to develop medical and technological documents on standardization of medical care. **METHODS:** The introduction of HTA in Ukraine requires its own methodology. For the development of this methodology a systematic review of the literature for HTA was performed. The sources were analyzed for the possibility of adaptation in Ukraine. **RESULTS:** On the basis of the detected data, and based on the knowledge gained from ISPOR distance learning and short courses an instruction was designed to conduct analytical work with sources of scientific information on the possible inclusion of drugs to medical and technological documents. Several types of analytical work were included in the instruction: - Analytical work with sources of scientific information on the possible inclusion of drugs to medical and technological documents; - Systematic search of information sources; - Construction of tables of evidence; - Transferal of ready HTA reports to the national health system; - Conducting of HTA reports. **CONCLUSIONS:** Introduction of the system of medical technology assessment is a multilevel process that requires creation of appropriate scientific and technical base, training of qualified specialists and amendment of relevant regulations. An important component of this process is the exchange of experience and knowledge in this area through access to networks such as INAHTA, HTAi, EUnetHTA, and others.

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INCREASING TRANSPARENCY AND THE PATIENT VOICE IN HTA OF NEW MEDICINES

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OBJECTIVES: Following a review into access to new medicines in NHS Scotland, SMC was directed to improve transparency and increase access to new medicines used at the end of life and for rare conditions.This paper outlines the experience with introducing these changes in the first year. **METHODS:** SMC advises NHS Scotland on the clinical and cost-effectiveness of all new medicines. In January 2014, we began to implement a number of recommendations to improve public transparency and increase access to new medicines used at the end of life and for rare conditions. Changes introduced include: holding all SMC meetings in public to increase understanding of how the committee works; introducing a more flexible approach