NEW DRUGS EVALUATION IN SPAIN: THE JOINT COMMITTEE OF NEW DRUGS EVALUATION EXPERIENCE

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OBJECTIVES: To evaluate the activity of the Joint Committee for New Drugs Evaluation (JCJDE) in Spain. Analyze the drugs evaluated since the JCJDE was founded, their scores and their potential correlation with the American CDER-FDA scores. Analyze the timeliness between the new drugs commercialization and its evaluation publication by the JCJDE members. METHODS: The JCJDE Standard Operation Procedure were web-based obtained. The drugs evaluations were collected gathering information from different publications and from the Regional Drug evaluating centres, evaluated for hit rate. RESULTS: Most of the 60 drugs evaluated had a high prescription potential in the Primary Care (PC) setting and were reimbursed by the Spanish National Health System. The decision algorithm has 4 key criteria to evaluate the new drugs: efficacy, safety, convenience and costs. The drugs were scored ranging from 0 (insufficient experience with the drug) to 4 (relevant therapeutic improvement). 89% of the drugs evaluated had 0–1 scores, and none of the drugs evaluated reached the maximum score. The median time of drug evaluation publication was 7 months since product launch (ranging from 4 to +31 months). Andalusia and the Basque Country have been the most active and fastest Regions to publish the JCJDE evaluations. CONCLUSIONS: The JCJDE is a valuable instrument to increase efficiency in new drugs evaluations in the PC setting. Additionally, we have checked various guidelines and strategies defined to regulate the introduction of such technologies in health systems established by members of EuroScan or other agencies. RESULTS: Many omic technologies have been “on the horizon” and have shown promising results at the experimental level so as to be of interest to horizon scanners. But in many cases, those promising results haven’t then developed into real products to be applied in the health care sector. Many factors have contributed to this failure to cross the paradigm, in the system diagnosis-patient-technology introduction or management of technologies and the promotion of individualized medicine or pharmacogenetics. Different actions and initiatives established by some HTA agencies in terms of developing guidelines and rationales that could help producers and systems in the adoption of these kinds of technologies have been analyzed. We have identified some omic technologies for the diagnosis and prognosis of different genetically complex diseases. CONCLUSION: New emerging omic technologies have opened new possibilities to more accurate diagnosis and treatments; moreover they have provided invaluable information that could guide preventative actions on health. However, we should consider the ethical and social consequences that could be caused by implementing preventative actions based on susceptibilities and not on certainties.

THE ROLE OF HTA AGENCY IN DRUG REIMBURSEMENT DECISION-MAKING PROCESS IN POLAND (HTA IMPACT)

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OBJECTIVES: The objective of this study was to assess what extent HTA outcomes have been incorporated in drug reimbursement decision-making process in Poland. METHODS: To assess HTA impact, following research questions were investigated: 1) How many different health problems currently prioritized by policy-makers have received HTA Agency’s attention? 2) How many different drug technologies with HTA recommendations have been included on the current reimbursement lists? In total, we reviewed the HTA recommendations disseminated by the Appraisal Body of HTA Agency in Poland concerning drug technologies in the period from September 6, 2007 until February 2, 2009 were studied. The most recent reimbursement lists issued 23 February 2009 by Ministry of Health and 7 July 2008 by National Health Fund were utilized. The list of prioritised health problems issued 23 February 2009 by Ministry of Health was studied as well. HTA recommendations were divided into positive and negative guidance. Drug technologies, appraised by HTA Agency, were classified into two groups: 1) eligible (a drug technology indicated for a prioritized health problem), and 2) not eligible (a drug technology not indicated for a prioritized health problem). RESULTS: As many as 59% and 54% of different indications were prioritized by Ministry of Health without any input from HTA process. In total, 40 negative and 43 positive HTA recommendations were issued. Only 18 of 43 (42%) drug technologies with a positive guidance were included on the reimbursement lists. At the same time as many as 6 of 40 (15%) of medicines with negative HTA recommendation were listed. HTA Agency appraised 58 eligible and 25 non-eligible drug technologies. There were 32 positive HTA recommendations in the first group, of which 18 (56%) were included on the reimbursement lists. CONCLUSIONS: The HTA impact on drug reimbursement decisions in Poland is partially achieved and could be further enhanced.

A REVIEW OF THE USE OF PROS IN SUBMISSIONS TO NICE

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OBJECTIVES: To review the use of Patient Reported Outcomes (PROs) in HTA submissions to date, with respect to the types of findings based on PROs, and the quality of the evaluations of the PROs-based evidence. METHODS: A review of the NICE website with respect to HTA appraisals that incorporated a PRO as part of the evidence base. Focus was on appraisals that departed from the 2007 reference case, and the use of the EQ-SD. RESULTS: At the time of review, 142 appraisals had been published, with 59 in progress. In particular, two case studies were identified, somatropin in growth hormone deficiency and Alzheimer’s disease. In GH deficiency, QOL was the primary outcome of interest and 23 scales were evaluated across 17 RCTs. In spite of pooling and use of generic instruments, there was insufficient evidence to conclude that somatropin had an effect on quality of life (QOL). In observational study, EQ-SD results were 40% higher than disease-specific QOL-AGHDA; committee recommended use of QOL-AGHDA, and treatment guidelines that recommended treatment for fewer patients than currently being treated. In Alzheimer’s, multiple scales on QOL less clear (with duplex for example, one study showed benefit, one was neutral, one showed worsening). CONCLUSIONS: PRO information has been incorporated in HTA appraisals, but there are significant limitations on the quality of evidence using PROs, due to study design (small sample size primarily), and lack of evidence for mapping value based on PROs.