PHP154 SUPPORTING PAYERS WITH COLLABORATIVE HTA TOOLS IN MAKING EVIDENCE-BASED DECISIONS: THE UNITED STATES EXPERIENCE AND INTERNATIONAL NEEDS IN EUROPE AND GLOBALLY

OBJECTIVES: In 2011 was introduced the early benefit assessment with the new pharmaceutical restructuring act (AMNOG) in Germany. Only new launched pharmaceuticals were assessed since this date. At the beginning of June were the first calls for AMNOG drugs which made available for the market before 2011. This was due to show relevant criteria for calling a launched product and to analyze which issues and consequences are possible in the AMNOG process. METHODS: In the first step was described the political situation before and after the AMNOG and the potential criteria for a call of launched drugs in the law. Afterwards it was shown the dossier development and assessment, hearing, G-BA decision and price negotiation. There were demonstrated possible issues and differences between assessments of new and launched products in this procedure. RESULTS: There is only a small time frame for dossier development and assessment. Manufacturers and concerned institutions have to define to plan and prepare the dossier in an expected time. Several pharmaceuticals mostly admitted for more than one indication, why there could be a high number of clinical trials available. The assessment of prior 2011 launched drugs is very difficult, because there was a retrospective change of frame conditions. The main reason for a call are the market volume and revenues, remaining patent protection and the expected assessments of competitors, triggered by admission of new drugs in next time. CONCLUSIONS: In the next years can be expected, that G-BA will assess more pharmaceuticals from indications that have a great influence for costs in German health care. The methods and criteria have to be discussed with all involved parties.

PHP155 A COMPARATIVE STUDY OF THE MULTIPLE TECHNOLOGY ASSESSMENT PROCESS IN THE UK AND AUSTRALIA

OBJECTIVES: Personalized medicine is the use of diagnostic testing, including genetic factors, for the refinement of therapy for the use of high cost procedures, devices, and medicines. This study compares the processes for making coverage decisions on multiple technologies between the UK and Australia. METHODS: Comparative study of assessments published by UK’s National Institute for Health and Clinical Excellence (NICE) and Australian Institute of Health and Welfare (AIHW). RESULTS: The coverage of medical procedures, devices, and pharmaceuticals has been assessed separately by different committees using conventional approaches of economic evaluation in both UK and Australia. In 2005, NICE introduced a process to assess multiple technologies (medicines, devices, medical procedures), such as several drugs for the same condition, or one drug for several conditions. By contrast, Australia recently introduced an integrated assessment specifically for multiple, co-dependent technologies (personalized medicine products), such as medicines and their companion diagnostic tests. Health technologies are co-dependent if their use needs to be combined to achieve or enhance the intended clinical effect of either technology. A new drug (e.g. gefitinib for patients with negative mutation for the activating mutation of the epidermal growth factor receptor gene) is a co-dependent technology. The co-dependent technology assessment process was established in response to concerns that 1) one technology in the co-dependent is reimbursed (e.g. a medicine is covered by the drug formulary while the companion test to determine responders is not covered by Medicare), and 2) the assessment of a co-dependent technology should consider the benefits and costs of their joint use, as distinct to the benefits and costs of each technology alone. Analysis is underway to compare the timeliness and recommendations for personalized medicine products between the UK and Australia. CONCLUSIONS: Important lessons are to be learned from the existing experiences as health technologies are increasingly used either sequentially or simultaneously in the continued development of personalized medicine.

PHP156 AMNOG – SUMMARY OF OUTCOMES OF EARLY BENEFIT ASSESSMENT AND REIMBURSEMENT NEGOTIATION FOR NEW DRUGS IN GERMANY

OBJECTIVES: The AMNOG has been in place for new drugs in Germany since 01/01/2011. The AMNOG includes early benefit assessment in comparison to one predefined ‘appropriate comparator’ therapy and negotiation of reimbursement price. The objective of this research was to review and compare the outcomes of all benefit assessment which had had in place a final decision until June 2012. METHODS: A review based on all published documents of the AMNOG processes (benefit dossier submitted, IQWiG assessment reports and final G-BA decisions). This investigation focuses on the comprehensive description and comparison of outcomes of assessment and final decision. RESULTS: Until June 2012, a total of 30 (8 %) AMNOG processes were finalized. For 4 processes no dossier was submitted. An additional benefit was partially credited 7 (50 %) out of the 14 new drugs by the IQWiG and 10 (71 %) by the G-BA. The IQWiG differentiated 39 subpopulations and the G-BA considered 31 subpopulations in the final decisions. The IQWiG credited 26 out of 39 subpopulations (67 %) with ‘no proof of additional benefit’. A total of 3 (8 %) subpopulations was credited with ‘significant additional benefit’ 2 (5 %) with ‘marginal’ and 6 (16 %) with ‘additional benefit not quantifiable’. The G-BA finally credited 18 out of 31 subpopulations (58 %) with ‘no proof of additional benefit’ or ‘less benefit’. A total of 2 (6 %) subpopulations were credited with ‘significant additional benefit’, 5 (16 %) with ‘marginal additional benefit’, and 6 (20 %) with ‘additional benefit not quantifiable’. CONCLUSIONS: The AMNOG evaluation of additional benefit differentiates a high number of subpopulations. Obviously the number of subpopulations and the outcomes varied between IQWiG assessment and final G-BA decision. So far, the majorities of subpopulations were credited with ‘no proof of additional benefit’. First analyses from reimbursement negotiations suggest that this may restrict price agreement.

PHP157 TO WHAT EXTENT DOES THE FEDERAL JTC UNDERSTAND THE EVIDENCE BASED RECOMMENDATIONS BY IQWiG

OBJECTIVES: The Act on the Reform of the Market for Medicinal Products (AMNOG) funds, effective since 01.01.2011, implemented an early benefit assessment of drugs after launch in Germany. The Institute for Quality and Efficiency in Health Care (QiViG) assesses the therapy and the drug to facilitate PAG input. The selection process of PAG for involvement in the process is well defined for G-BA. TLV, NICE and SME though TLV uses PAG not related to the disease area under concern. The AMNOG evaluation of additional benefit differentiates a high number of subpopulations. Obviously the number of subpopulations and the outcomes varied between IQWiG assessment and final G-BA decision. So far, the majorities of subpopulations were credited with ‘no proof of additional benefit’. First analyses from reimbursement negotiations suggest that this may restrict price agreement.