Differente European HTA Systems

and the various benefits an electronic platform such as the AMCP eDossier may provide. The dossier development and assessment, hearing, G-BA decision and price negotiations. 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 stakeholders have little time to plan and prepare early expectations. HTAaguements typically admitted for more than one indicator, 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 criteria for a call are the market volume and revenues, remaining patient 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 be assess more pharmaceuticals from indications that have a great influence on costs in German health care. The methods and criteria have to be discussed with all involved parties.

PHP153 Supporting payers with collaborative HTA tools in making evidence-based decisions: the United States experience and international needs in Europe and globally

Bourguignon J1, Luinge M1,2, Hauserle N3, Drapella M4
1University of Utah, College of Pharmacy, Salt Lake City, UT, USA, 2Dynamium Healthcare Innovations, Toronto, ON, ON, Canada, 3UMITT, Hull, Hall, Austria, 4IGES Institut GmbH, Berlin, Germany, 5IMPROV Limited, Alexandria, VA, USA

OBJECTIVES: Health plans and other decision making bodies regularly request that pharmaceutical and biotechnology companies provide a standardized dossier containing detailed information - not only on the drug's safety and efficacy, but also on its overall clinical, economic, and humanistic value relative to alternative therapies. Independent focus groups and multi-country surveys identified several challenges related to convenient, real-time collaboration to access information and its overall clinical, economic, and humanistic value relative to alternative therapies. Independent focus groups and multi-country surveys identified several challenges related to convenient, real-time collaboration to access information and its overall clinical, economic, and humanistic value relative to alternative therapies.

METHODS: In the United States, the Academy of Managed Care Pharmacy (AMCP) partnered with Dynamium Healthcare Innovations to launch an electronic platform to meet immediate needs of US (Health Care Decision Makers (HCDMs). The platform would incorporate all the key components of decision making processes, and was designed with leading HCDMs. A survey was also fielded to over 50 US decision makers and payers from 13 other countries to provide their feedback and input into their local HTA needs. Local country HTA guidelines and formats (i.e. AMP format in the US) from 30 countries was incorporated into the overall design of the platform.

RESULTS: The US HCDM survey results indicated the following challenges: a) Difficulty navigating through large volumes of information (300 + pages) to use for internal reviews, b) Risks associated with review of information that is outdated or not useful, c) Inconsistent completeness of information, and d) Time taken to navigate through a large number of documents to reflect a plan's own population patterns. The international survey revealed similar challenges and unmet needs by HCDMs that were similar to their US counterparts. The feedback is being incorporated into the development of an international version of the platform.

CONCLUSIONS: Experiences from the United States and other countries validated the unique needs of each region in conducting HTA reviews and the various benefits an electronic platform such as the AMCP eDossier may provide.

PHP154 A Study Comparing the Different Processes for Patient Input in Six Different European HTA Systems

Hicks N1,2, Touni M2
1Commutateur, Paris, France, 2University Claude Bernard Lyon 1, Lyon, France

OBJECTIVES: The patient perspective is considered critical for policy decision makers. It is unclear how this perspective is incorporated within different HTA processes. The research identified and compared how selected European HTA agencies incorporate the patient view in the decision making process for drugs.

METHODS: We identified websites of six relevant European bodies: England (NICE), France (HAS), Germany (IQWIG and GBA), Scotland (SMC) and Sweden (TLV). We searched for: how PAG representatives are selected, how they provide input & contribute to the decision making process and how they are supported by HTA agencies. Findings were transferred to Excel spreadsheet and sent to respective agencies for validation. Five of the six HTA responded. RESULTS: No weighting exists on how Patient Advocacy Group (PAG) input is measured with respect to other data submissions. Important differences were observed in the engagement of PAG as part of the HTA assessment. HAS appears to have little or no process for PAG involvement. NICE signed with leading HCDMs. A survey was also fielded to over 50 US decision makers and payers from 13 other countries to provide their feedback and input into their local HTA needs.

CONCLUSIONS: The patient perspective is a significant contributor in the HTA decision making process. Although all HTA agencies rely on patient information, significant differences exist in methods of selection, input, impact and effort to support PAG input. Although such differences are likely linked to cultural differences there is a need to improve and standardize PAG input and integration in HTA decision making.

PHP155 A Comparative Study of the Multiple Technology Assessment Process in the UK and Australia

Goddard Ward R1,2
1Hammond Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA, 2University of New South Wales, Sydney, NSW, Australia

OBJECTIVES: Personalized medicine is the use of diagnostic testing, including genotyping, to refine selection for the use of high-cost procedures, devices, and medicines. This study compares the processes for making coverage decisions on multiple technologies between UK and Australia. METHODS: Comparative study of assessments published by UK’s National Institute for Health and Clinical Excellence (NICE) and Australia’s Australian Institute of Health and Welfare (AIHW). 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 (e.g. gefitinib for patients with tested positive for an activating mutation of the epidermal growth factor receptor gene in tumor). 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 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

Claus V1, Freyer D2, Kotowa W2, Mathes J2
1Novartis Pharma GmbH, Nuremberg, Germany, 2IGES Institut GmbH, Nuremberg, 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 assessments which had had in place a final decision until June 2012.

METHODS: A review based on all published documents of the AMNOG processes (benefit dossiers 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: In total of n=14 AMNOG processes were finalized. For further 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 ‘marginally’, 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 ‘marginally additional benefit’, and 6 (20%) with ‘additional benefit not quantifiable’. CONCLUSIONS: The AMNOG assessment 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 majority of subpopulations were credited with ‘no proof of additional benefit’. First results from reimbursement negotiations suggest that this may restrict price agreement.

PHP157 To what extent Does the federal Joint Committee follow the evidence-based recommendations by IQWIG

Weber B1, Schmitz S2, Schiffler-Rohde J1
1Bayer, Berlin, Germany, 2Pfizer Deutschland GmbH, Berlin, Germany

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 (IQWIG) assesses the additional benefit of a drug based on a dossier submitted by the pharmaceutical manufacturer. Based on this assessment and the statements by industry, scientific community and patient organizations the Federal Joint Committee (FJC) reviews and decides on the extent of the additional benefit being the basis for price negotiations between the National Association of Statutory Health Insurance Funds and the pharmaceutical manufacturer. The objective is to investigate possible differences between the scientific assessments by IQWIG and the...