OBJECTIVES: Switzerland’s regulation of prices for reimbursed drugs is based on referencing across countries and within the therapeutic class for products with comparators. The SwissHTA initiative involving all key stakeholders in the healthcare systems (sickness funds, industry, physicians, academia, Kanton) has published consensus papers for new benefit criteria and measurements. METHODS: A comparative analysis of the cost-effectiveness thresholds in reimbursement assessments in HTA systems in Germany and the UK. RESULTS: In terms of clinical benefit assessment the suggestion by SwissHTA followed accepted evidence-based methods to Germany the SII changes to the initial benefit assessment before application by applying disease specific standards. This disease focus allows also accepting different levels of evidence given the characteristics of the disease. This pragmatic approach allows Swiss decision-makers accepting lower evidence levels at the time of launch (e.g. in case of comparison with non-Swiss standard of care) coupled with a post-reimbursement commitment. The Swiss method looks similar to the medical benefit application by NICE. In terms of health economic (HE) assessment Switzerland and the Netherlands focus on cost-effectiveness comparisons across the whole system as in the UK. Such an approach avoids the application of arbitrarily defined cost-effectiveness thresholds. In Germany the HE focus is solely based on cost comparisons. In terms of decision-making in Germany in the Swiss method is based on an assessment of the available evidence against a theoreti- cal maximum standard of evidence. In the UK coverage decisions are based on cost-effectiveness assessments allowing for context-specific adjustments. In the SwissHTA recommendation a multi-criteria decision-making should be applied with an equal focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.). CONCLUSIONS: In comparison to HTA systems in Germany and UK the SwissHTA recommendations seems to be more pragmatic and would follow a broader multi-criteria decision making approach.

PHP154

PRODUCT QUALITY ASPECT IN REIMBURSEMENT OF MEDICAL DEVICES: COMPARISON OF TURKEY VERSUS EUROPE

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Objectives: FDA has long recognized that dramatic changes in adverse event reports due to medical devices and recalls may reflect quality flaws. While some of this increase can be explicated by FDA’s greater outreach emphasizing reporting requirements, failure to design and manufacture products cause more than half of all product recalls. Therefore, FDA’s concern regarding low quality prod- ucts remains. In the EU, medical device pre-market quality is assured by CE mark authorization. This regulation is the prerequisite for market registration also in Turkey. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance. METHODS: This study investigates whether post-market quality assurance is affected by less adverse events (‘better health outcomes’) can be accessed through local reimbursement policies. First, it is investigated whether there are reimbursement rules in Europe acting as post-market quality assurance. Then, a comparison is made with Turkey’s existing reimbursement scheme. RESULTS: Our comparative analysis reveals only Belgium and France implement quality or brand based reimbursement rules. In Turkey, there is no quality based reimburse- ment scheme, however current reimbursement application guideline requirements may apply to medical devices for lower quality products. Our Results show in addition to pre-market regulations, post-market quality can be assured by local reimburse- ment authorities. CONCLUSIONS: There are several opportunities to improve quality assurance at the CE mark application stage for the medical device industry; i.e. enhancing visibility of comparative quality to harness market forces and increasing the collab- oration between stakeholders. From health policy perspective, implementation of novel quality based mode of provide providers to prove that they’re meeting quality standards and benefitting patients while cutting costs. Therefore, adding a focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.).

PHP156

A COMPARISON OF ADDITIONAL BENEFIT SCORES IN GERMANY (G-BA) AND FRANCE (HAS)

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Objectives: The French HTA agency, the HAS, has recently released the SwissHTA recommendation a multi-criteria decision-making approach. The SwissHTA recommendation a multi-criteria decision-making should be applied with an equal focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.). The aim of this study was to compare the additional benefit score issued under AMNog to IAB scores granted by the HAS. METHODS: All G-BA’s additional benefit scores until June 1st 2014 and HAS IAB score were com- pared. RESULTS: In Germany, a total of 76 completed early benefit assessments. From the best available score perspective, the G-BA assessed the additional benefit as considerable in 20% of drugs assessed (score 2), as minor in 30% of drugs assessed (scores 1-2), and as non-relevant in 48% of drugs assessed (score 0). No drug has been given a major additional benefit (score 3) and 4% of drugs were directly allocated to a reference price group. In France, the multi-criteria committee has approved a total of 20 cases (IAB 1), an important improvement in 1.3% of cases (IAB II), a moderate improvement 2.5% of cases (IAB III), a minor improvement in 9.2% of cases (IAB IV) and no clinical benefit (IAB V). CONCLUSIONS: In 86.8% of cases the G-BA assigned an additional benefit (scores from 1 to 4) to more than half of drugs whereas the HAS granted an additional benefit rating to less than 14% of cases. This study suggests that there is a more favourable benefit rating in Germany than in France.

PHP157

HTA STATUS OF BIOSIMILARS ACROSS THE UK AND IRELAND

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Objectives: The potential to revolutionise the health care landscape by reducing cost savings and increasing access to innovative medicines. The biosimilars marketplace in the UK and Ireland is relatively new, however the landscape is rapidly developing. The objective of this analysis was to map the HTA status of biosimilars in the UK and France and provide insight for stakeholders involved in the assessment of new biosimilars. METHODS: The HTA status of all EMA authorised biosimilars was identified by searching the websites of all four HTA agencies in the UK and Ireland, namely, NICE, the SMC, the AWMSG, and the NCPE. All previously assessed medicines and on-going technology appraisals were screened for the inclusion of biosimilars using the non-proprietary (common name) and proprietary (brand names). RESULTS: Sixteen (84%) of the nineteen biosimilars submitted for EMA assessment have been arranged by the SMC (49%) have been considered by HTA agencies. The SMC has approved 100% of the biosimilars it has considered (n=7), the largest positive reimbursement rate amongst all HTA agencies. The SMC has not considered the largest number of biosimilars (n=11), of which five, (45%) received a positive reimbursement status. Both NICE and the NCPE have approved one biosimilar, however three additional biosimilars are currently being considered by NICE. CONCLUSIONS: The reimbursement status of biosimilars in the UK and Ireland may impact the-investigation and any potential approval, funding or reimbursement decision. Biosimilars may be considered for future approval, funding or reimbursement decision. Biosimilars may be considered for future approval, funding or reimbursement decision. The timing of HTA submissions to different HTA agencies may play an important factor in the reimbursement status of biosimilars given that this land- scape is relatively new and approval processes may influence the availability of future HTA agencies. The timing of HTA submissions to different HTA agencies may play an important factor in the reimbursement status of biosimilars given that this land- scape is relatively new and approval processes may influence the availability of future HTA agencies.

PHP158

DOES NOT REACHING AN AGREEMENT ON THE FINAL NICE SCOPE HAVE ANY IMPACT ON THE FINAL APROVAL OR ADOPTION OF THE THERAPEUTIC? CAMeauvAY, H., Meuntra L., Van Engen A.

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Objectives: Identifying the right patient population, comparator and endpoints is key to increase the likelihood of reimbursement. Manufacturers do not always agree with payers’ views on these items. Disagreement may lead to funding rejection. We assessed the rate of matches between manufacturers and NICE and their impact on the approval or rejection of a HTA application. METHODS: All manufacturer submissions (MS) from January 2011 until June 2014 were reviewed. For these submissions, the initial proposed scope, the manufacturer’s comments, and the final scope and appraisal were collected. All submissions were classified in terms of acceptance or rejection. RESULTS: In all, 101 MS of which 57 were suspended and 7 were rejected. In the time period reviewed there were 101 MS of which 7 were suspended and 48% of the remaining cases were approved. In 51% of the remaining cases were approved. In 51% of the remaining cases were approved. In 51% of the remaining cases were approved. In 51% of the remaining cases were approved. In 51% of the remaining cases were approved. The final scope implemented all and some of the manu- facturer’s comments in 56% (40/71) and 28% (29/71) of submissions, respectively.