OBJECTIVES: Switzerland’s regulation of prices for reimbursed drugs is based on references 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, Kantons) has published consensus papers for new benefit criteria and measurements. METHODS: A comparison was performed comparing the cost-effectiveness measurement methods and assessments in HTA systems in Germany and the UK. RESULTS: In terms of clinical benefit assessment the suggestion by SwissHTA follows accepted evidence-based methodology while Germany’s AMNOG looks at an application by applying disease specific standards. This disease focus also allows accepting different levels of evidence given the characteristics of the disease. This pragmatic approach also 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) evaluation, Swiss methodology is focused on post-market cost and efficiency outcomes of new product 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 the decision is based on an assessment of the available evidence against a theoretical 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 Swiss HTA recommendations seems to be more pragmatic and would potentially follow a broader multi-criteria decision making approach.

PHIP15

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

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Background: In Turkey, the PHARMACeUTICAL experts, Ankara, Turkey

OBJECTIVES: FDA has long recognized that dramatic change 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 product- uncts remains. In the EU, medical device pre-market quality is assured by CE mark authorities. 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 (measured by less adverse events and recalls) 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 of brand based reimbursement rules. In Turkey, there is no quality based reimburse- nent scheme, however current reimbursement application guideline requirements may act as a gate keeper 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 system in Turkey, by increasing cost-effectiveness outcome (Has) of drugs whereas the HAS granted an additional benefice rating to less than 14% of drugs assessed (Score 4 and 5). No drug has been granted a major additional benefit (score 5) and 4% of drugs were directly allocated to a reference price group. In France, the previously mentioned commitment to a major improvement (AIB) at an important improvement in 1.3% of cases (AIB II), a moderate improvement 2.5% of cases (AIB III,) a minor improvement in 9.2% of cases (AIB 4) and no clinical benefit (AIB 5). CONCLUSION: The FDA 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 this study. This study suggests that there is a more favourable benefit rating in Germany than in France.

PHIP17

HTA STATUS OF BIOSIMILARS ACROSS THE UK AND IRELAND

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OBJECTIVES: 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 Ireland 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 appraisal applications were screened for the inclusion of biosimilars using the non-proprietory (common name) and proprietary (brand name) names. RESULTS: Eighty (84%) of the nineteen biosimilars submitted to EMA have been assessed (score 1); 59% (11) of which 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 the UK agencies considered. The AWMSG has 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 will impact the uptake of their use. The timing of HTA submissions to different HTA agencies may play an important factor in the reimbursement status of biosimilars given that this landscape is relatively new and advancing. The HTA agencies are the key players in the biosimilar approval process. The HTA agencies may be interested in collaborating with payers’ views on these items. Disagreement may lead to funding rejection. We assessed the rate of mismatches between manufacturers and NICE and their impact on the final HTA status. However, this was not assessed. The analysis performed did not account for volume and pricing outcomes. The HAs need to choose how they will assess the biosimilars’ impact on HTA submissions.

PHIP18

DOES NOT REACHING AN AGREEMENT ON THE FINAL NICE SCOPE HAVE ANY IMPACT ON THE FINAL APRAISAL ORAL DISCUSSION? (HAS)

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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 mismatches between manufacturers and NICE and their impact on the final HTA status. However, this was not assessed. The analysis performed did not account for volume and pricing outcomes. The HAs need to choose how they will assess the biosimilars’ impact on HTA submissions.

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