PHP58

THERAPEUTIC POSITIONING REPORT: NEW COLLABORATIVE NETWORK OF DRUG ASSESSMENT IN SPAIN - THE START OF P&R BASED ON RELATIVE EFFECTIVENESS?

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OBJECTIVES: Therapeutic Positioning Reports (TPRs) were introduced to the Spanish P&R process in May 2013. TPRs evaluate comparative efficacy and safety and introduce usage and monitoring criteria for new drugs and existing drugs seeking reimbursement. The procedure was set-up by the Spanish Medicines Agency (AEMPS) and the Ministry of Health with the aim to accelerate the P&R process and to generate a single, national relative effectiveness report avoiding additional regional evaluations, contributing to reducing the long-delays in market access timelines experienced in the last few years. The objective of this ongoing work is to describe and analyze both the metrics of the process and the contents and results of TPRs. **METHODS:** Descriptive study based on public information available from the European and Spanish Medicines Agencies (May 2013-ongoing). **RESULTS:** From June 2013 to May 2014 the Therapeutic Positioning Coordinating Group (TPCG) has officially launched 60 TPR plus 7 use protocols (UP) at the request of the Interministerial Price Council (IMPC). 75% of TPR involve new chemical entities (82% of those with a positive opinion from the CHMP between May 2013-April 2014) and assess a single entity (48% specialty care) indicated, mainly, for patients with neoplastic (28%) and endocrine (18%) diseases. All UP affect targeted therapies with approval between Jan2010-Dec2012. Since its establishment in May 2013, the TPCG has released 26 TPR (57% of those expected according to the pre-established procedure -3 months working time) with a median release time of 7,1 months. Only 1 has been published. The rest await for P&R decisions. Other 5 pilots have been published in parallel. In total 5 TPR recommend to further restrict the European label. **CONCLUSIONS:** TPR are not being released at the expected rate. Follow up is necessary to predict its impact in P&R and market access in regions across Spain.

PHP59

ARE THERE ANY COMMONALITIES IN PAYER REQUIREMENTS AND REIMBURSEMENT PATHWAYS FOR MEDICAL DEVICES IN THE DACH (GERMANY, AUSTRIA, SWITZERLAND) REGION?

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OBJECTIVES: Medical devices constitute a set of important health technologies for the care of patients. While there are similarities between some reimbursement systems, each market has its own unique characteristics. This article focuses on the reimbursement procedures for medical devices in the DACH countries (Austria, Germany, Switzerland), and aims at finding commonalities in payer requirements and reimbursement pathways. **METHODS:** Reimbursement application pathways for inpatient and outpatient medical devices were evaluated for Austria, Germany and Switzerland. The key items being analysed for similarities and differences in each setting were transparency, clinical and health economic evidence requirements, submission timelines and the length of the whole reimbursement application process. **RESULTS:** In the inpatient setting, the evidence requirements for clinical data are different between the analysed countries: The lowest clinical evidence requirements are seen in Germany, while the highest are given in Switzerland (in some scenarios). In terms of health economics the requirements are medium to low. A medium rating was given for Austria and Switzerland (in some scenarios) as a health economic analysis is required (e.g. cost comparison), and a low rating was applied to Germany as limited economic information (cost assessment/ comparison) needs to be submitted. The length of the application process is well defined in Austria and Germany and vague in Switzerland. In the outpatient setting the requirements for clinical and health economic data are significantly increasing. Clinical requirements are getting close to pharmaceutical methods whereas health economic evidence is requested in all DACH countries. The length of the reimbursement process is not clearly defined in all three countries. **CONCLUSIONS:** Despite varying reimbursement processes within the DACH region, there are some important similarities between the evidence requirements which may help manufacturers to guide market access and reimbursement strategy decisions in order to drive successful submissions and applications of innovative medical devices.

PHP60

THE RELEVANCE OF HEALTH SERVICES RESEARCH FOR THE PHARMACEUTICAL INDUSTRY IN GERMANY –RESULTS OF A REPRESENTATIVE ONLINE SURVEY

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OBJECTIVES: The necessity for manufacturer of pharmaceuticals and medical devices seem to deal with health services research (HSR). Health care reform acts and revisions of HTA method guidance documents in many European countries continue to point out the importance of real-life consequences. The objective of the study was to evaluate the self-reported importance and the own activities of pharmaceutical companies in Germany concerning health services research. **METHODS:** Between December 2013 and February 2014 an online survey among members of the German Pharmaceutical Industry Association (BPI) was accomplished. Similar surveys were conducted in 2009 and 2011. **RESULTS:** 59% of 109 addressed companies took part in the survey. The participants were representative for Germany concerning research-orientation, size and type of products. For 88% of the participating companies HSR is of importance. This high rate remained constant compared to the last surveys. For most of the companies HRS yields valuable contributions for the negotiations with payers (96%), in the AMNOG evaluation process (89%) and for optimization of placement of marketed products (94%). 50% of the companies conducted HSR studies over the last years, respectively are currently conducting HSR studies or participate in joint projects, whereas 69% plan to conduct HSR studies in the near future. All these numbers increased since the last surveys. **CONCLUSIONS:** The results of the survey clearly pointed out the high and still increasing importance of HSR and real-life studies also in the health care industry. Although a considerable amount of uncertainty concerning the specific methodological requirements remain it is widely accepted that the quality of data and analyses is crucial for acceptance by payers. As HSR projects require considerable human and financial resources alliances and joint projects between industry, academia and payer are aspired.

PHP61

INTEGRATION OF COST–EFFECTIVENESS ASSESSMENT IN THE MARKET ACCESS SCHEME OF DRUGS AND MEDICAL DEVICES IN FRANCE

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OBJECTIVES: In France, drugs and medical devices costs concern an important part of health care expenditure. Several reforms have been put in place over the past years in order to limit these expenditures, in particular price cutting policy. Cost-effectiveness assessment was integrated in France in the market access scheme of health products by the Social Security Financing Act for 2012 and is required since October 3rd 2013. This new mission was assigned to the Health Economics and Public Health Committee (CEESP) of the French National Authority for Health (HAS) and is become compulsory for innovative health products and are likely to have a significant impact on the health insurance expenditures. The objectives of this work were to see how the cost-effectiveness assessment has been integrated in France and to discuss the impact of this assessment on the health products market access. **METHODS:** The work consists in analyzing the process of the economic evaluation achieved by the HAS since October 3rd 2013. **RESULTS:** Economic evaluation is a new step in the market access scheme. In order to respect the legislated timeframe of 90 days, it is simultaneously conducted with the medical assessment by the Transparency Commission of the HAS. For each health products, an efficiency opinion is delivered by the CEESP. It presents the methodological conformity according to HAS guidelines and a conclusion about the efficiency, on the basis of the Incremental Cost-Effectiveness Ratio (ICER). Currently, 15 dossiers were eligible for cost-effectiveness assessment. First assessments permit to confirm that the procedure is operational. The average processing time was 94,8 days. **CONCLUSIONS:** In France without efficiency threshold value, the CEESP can't conclude absolutely on the efficiency of health product. We don't know how the ICER will be considered by the French Healthcare Products pricing Committee (CEPS) at the time of pricing negotiation with the pharmaceutical industry.

PHP62

ANALYSIS OF COST-EFFECTIVENESS ASSESSMENTS IN FRANCE BY THE FRENCH NATIONAL AUTHORITY FOR HEALTH (HAS)

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OBJECTIVES: In France, cost-effectiveness assessment is required since October 3rd 2013 for innovative health products and are likely to have a significant impact on the health insurance expenditures. The objective of this work is to report first cost-effectiveness assessments, achieved by the Health Economics and Public Health Committee (CEESP) of the French National Authority for Health (HAS). **METHODS:** The investigation consists in analyzing medico-economic dossiers submitted at the CEESP between October 2013 and October 2014. This analysis is based on the opinion delivered by the CEESP, the methodology used in the model and the process of the assessment achieved by the HAS. **RESULTS:** At the time of writing the abstract, 15 dossiers were eligible for cost-effectiveness assessment. All dossiers were based on cost-utility models. Two dossiers presented a negative opinion due to the methodological conformity according to HAS guidelines. For dossiers with a positive opinion, the Incremental Cost-Effectiveness Ratio (ICER) were between 5 866€/QALY (for a subgroup analysis) and 194 531 €/QALY. Main methodological reserves made by the CEESP concerned comparators, time horizon, robustness of clinical data, utility measures. The average processing time was 94,8 days. For the moment, no price has been published in the Official Journal. **CONCLUSIONS:** The first assessments permit to confirm that the procedure is operational. In light of these first assessments, an update of the HAS methodological guidelines should be done. In France, without efficiency threshold value, the CEESP can't conclude absolutely on the efficiency of health products. Thus, we don't know what will be the place of the ICER in the pricing negotiation between the pharmaceutical industry and the French Healthcare Products pricing Committee (CEPS).

PHP63

ACCESSING THE MEDICAL DEVICE MARKET IN THE PEOPLE'S REPUBLIC OF CHINA--POLICY CHANGES SINCE THE RESTRUCTURING OF THE CHINA FDA

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OBJECTIVES: The objective of this research is to provide an overview of the regulatory process of medical devices in China. Potential challenges related to medical device registration and major policy changes are highlighted especially since the restructuring of the China FDA in March 2013. The results of this research are aimed at informing regulatory bodies, health policy decision makers, national and international Health Technology Assessment networks, as well as medical devices manufacturers. **METHODS:** A systematic review was conducted from 2009-2013 to identify the challenges and opportunities in the Chinese medical device regulatory process searching the PubMed, Science Direct, Scopus databases and Zhongguozhiwang. The PRISMA guidelines were applied for the search. In addition, an analysis of