OBJECTIVES: The Moroccan government announced new public and hospital prices for 5308 drugs in April 2014. These price cuts came into force in June 2014. The study examines the price changes and analyzed the potential impact of the price cuts on pharmaceutical companies operating in the market. **METHODS:** Standard statistical methods were used to analyze government provided data in order to identify general trends within the pricing notification. Secondary sources were then examined to determine the general pricing rationale. **RESULTS:** The price notification included 5308 drugs (note duplication occurs where a brand name has multiple formulations). Examining public prices: 390 of the drugs were newly listed on the list for public purchase, a further 2968 saw no price increase and two drugs saw modest price increases. Public price declines were seen for 1948 drugs with the level of decline covering a range of 1635 percentages between 0.006% and 78.6%. Average public price, excluding drugs with no decline, saw an average decline of 13.6% and median decline of 6.5%. All the 5308 drugs already had an existing hospital price, however 114 of these drugs saw no pricing change. Of the 5194 drugs which did see a price decline this varied across a range of 2559 different percentages between 0.001% and 79.8%. The average hospital price decline, excluding drugs which saw no decline, was 9.3% and the median was 5.8%. **CONCLUSIONS:** The large range of pricing declines suggests that the prices were not indicative of a formulaic event such as currency fluctuation changes. This also means that there is a differential impact on pharma companies, with certain parts of their portfolio being more protected than others.

PHP51

TRENDS IN TIME TO MARKET ACCESS IN EUROPE - IS IT GETTING BETTER?

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OBJECTIVES: Unequal access due to delays or non-availability of medicines denies patients treatments they need and contributes to inequality across Europe. The EFPIA previously monitored access delays via the "Patients Waiting to Access Innovative Therapies (WAIT)" indicator, however; this has not been updated since 2011. Following the 2012 EC Transparency Directive 89/105/EEC mandating no more than 120 days of delay for national pricing and reimbursement decisions, an updated evaluation is needed. **METHODS:** IMS MIDAS data was used to identify the first sale for all EMA-approved non-generic, non-biosimilar products since 2008 in 15 EU markets. The delay (from approval to first sale) was noted for each product and market and compared to the EFPIA Patients WAIT indicator for 2008-2010. Annual average delays were calculated over the 2008-2013 period and for available products, an analysis of minimum and maximum delay performed for each market. Additional analyses were performed for trends within and across markets, and to identify progress and variations. **RESULTS:** Improvements across the 2008-2012 period give cause for optimism in most European markets, as delays have fallen sharply in almost all markets, from an average of 524 days in 2008 to 281 days in 2012, with only Greece showing no real improvement. However; absolute availability of new medicines has varied greatly by market, with same-year availability of EMA-approved medicines declining to just 41% on average in 2013. Notable declines were seen in Greece, Spain, Romania and Portugal, suggesting that economic difficulties may lead some governments to refuse reimbursement, rather than simply delay decisions. **CONCLUSIONS:** This updated access analysis shows that while delays are shortening, absolute access for patients is not always improving. Some new access rules such as "class C" drugs in Italy (access without funding), may send misleading signals, and underscore the need for monitoring of true access across Europe.

PHP54

MARKET ACCESS FOR MEDICAL DEVICES: ADAPTING TO CHANGE

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OBJECTIVES: Market Access (MA) is key for medical devices given recent changes in regulation from one side, and pressures on costs from the other side. Nevertheless, there is scant evidence on how MA works in the medical device industry and whether it works effectively. The aims of the present study are to illustrate current gaps in MA for medical devices and to recommend future actions to make this function more effective. **METHODS:** We conducted a literature review aimed at gathering a clear picture of current state of the art on MA for medical devices and at highlighting major gaps vis-à-vis other industries (e.g. pharmaceuticals). Based upon the review's findings, we carried out an e-survey to small, medium, and large device companies operating in the EU in order to understand: i) how MA is perceived and actually organised, ii) which are the main perceived obstacles to MA, iii) how companies invest in market access and at which stage of medical device development, and iv) what the main challenges are to a more efficient market access process. **RESULTS:** The findings of the literature review and preliminary results of the e-survey are presented. **CONCLUSIONS:** MA is an under-developed function in the medical device industry and in certain cases its role is not fully exploited. Although the pharmaceutical industry doesn't represent a fully appropriate benchmark, MA for medical devices is even less developed when compared to its full potential. A different approach is needed to deal with new changes in the regulation and policy arenas aimed at synergistically encompassing knowledge, expertise and operating tools from public affairs, medical departments, pricing & reimbursement, health economics and marketing.

PHP55

QUALITATIVE RESEARCH ON THE IMPACT OF EUROPEAN HOSPITAL PROCUREMENT PRACTICES ON MARKET ACCESS FOR DISPOSABLE MEDICAL DEVICES

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OBJECTIVES: In European hospitals, budgetary pressure is driving centralized purchasing and increasing the importance of procurement in market access. Centralized purchasing is thought to lead to cost savings through stronger negotiating power, economies of scale and reduced inventory. The objective of this study was to understand the procurement methods for disposable medical devices employed by European hospitals and their impact on market access. **METHODS:** A review of hospital purchasing practices was conducted in France, Germany and England, including published articles and government websites. Twelve 45-60 minute telephone interviews were conducted with hospital decision makers (purchasers, pharmacists and clinicians) in 2013. **RESULTS:** Most disposable medical devices are evaluated at the facility level by committees made up of clinicians, procurement specialists, pharmacists and management. France and Germany require listing on the facility formulary and typically procure via tendering and group purchasing. England has a national procurement body but hospitals regularly purchase products directly from the manufacturer. All three countries report that austerity measures are causing many facilities to limit the number of products per category. Product trials and clinician preference are seen as the main drivers of adoption however clinicians are under increasing pressure to justify costs. Hospital purchase decisions are increasingly likely to be based on non-product specific attributes such as total cost of purchasing including volume discounts, broad portfolio of products, and administrative costs. **CONCLUSIONS:** In the current environment, market access for disposable medical devices will require a strong economic argument in addition to evidence of superior quality. Although clinicians still drive the adoption of consumable medical devices, in the absence of a strong clinician preference, non-product specific attributes may determine market access. Manufacturers can support their economic messaging along categories of inventory reduction and a broad portfolio of products that allows for administrative efficiencies and reduced shipping costs.

PHP56

THE IMPACT OF THE INFORMATION SYSTEM OF MEDICAL DEVICES IN PORTUGAL

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OBJECTIVES: The Portuguese National Health System (NHS) identified the need to easily access information that allowed identification of all medical devices (MDs) with their respective manufacturers, distributors, characteristics, and purposes. The objective of the creation of an information system is to collect, store and analyze data of each MD and to provide NHS resources management, health technology assessment (HTA), as well as data about the Portuguese market. **METHODS:** A system consisting of a database that is a repository, and an application system that stores the information was built. For the registry of information all MDs should disclose their respective instructions of use, labels and price. The concept of unique medical device and a process to assign a code to each device was designed, and tested by collecting data from NHS acquisitions. The prescription of medical devices is made by code, with all information online. A model for communication between the health regulatory agency and market operators was also devised, as well as rules and codes of procedure. **RESULTS:** The creation of this system in 2011 allowed for the coding of 20% of all registered MDs (n=838000) up to June 2014. This has allowed for the elimination or withdrawal of 16% (n=136000) of references, thus keeping the registries up to date. The coding permitted the comparison of devices and the management of total expenditure in MDs by hospitals of the NHS. **CONCLUSIONS:** The system provides solid information about available MDs in the market, their respective manufacturer, distributor and pricing to which they are sold to the NHS. The system is a support for decision makers, payers, and HTA processes. It facilitates the management and traceability of medical devices in hospitals and has impact on reimbursement, access and pricing varies by market.

PHP57

PRICING OF MEDICINES IN POLAND – TWO-YEAR OVERVIEW OF HOW THE NEW LAW AFFECTED COSTS OF REIMBURSEMENT

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OBJECTIVES: Rapid increase of costs of reimbursement in Poland led to redesign of the drug pricing mechanisms. As a result a new law which brought revolutionary changes to the health care system was introduced in 2012. The aim of this work is to summarize the two years of new drug policy in Poland and to present mechanisms that resulted in substantial savings in reimbursement costs. **METHODS:** Few savings-generating mechanisms were implemented in the new reimbursement law: negotiations of prices, new method of calculation of reimbursement limit (resulting in higher co-payment) and also formal obstacles in obtaining prescriptions for reimbursed products (some reimbursed drugs, i. e. antibiotics, due to formal issues are prescribed with 100% co-payment). The first and the third reason result in lower overall costs of reimbursed medicines, while the second reason influences the proportion of costs borne by the National Health Fund. We have analyzed data on prices of reimbursed drugs before 2012 and after implementation of the new law (currently the prices may change every two months). We have then compared the amount of sales of those drugs, costs of reimbursement and patients' co-payment. For some reference groups (i. e. oral aromatase inhibitors) we made in-depth analysis of pricing mechanisms. **RESULTS:** In 2012 total public expenditures amounted to 2.3 billion EUR, 83% of the planned budget, which gave 460 million EUR savings as compared to 2011. In 2013 the drug budget was executed in 87%, resulting in 430 million EUR savings. Saving were driven by price negotiations, but also by mechanisms of lowering the reimbursement limit, i. e. in case of oral aromatase inhibitors the reimbursement limit was lowered by half during 2012-2013. **CONCLUSIONS:** The new reimbursement law resulted in substantial savings in costs of drugs. The success is however relative, as costs of drugs were partially shifted towards patients.

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