**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.