Overall, the topic areas "Market Launch", "Price Negotiations" and "Process" were most controversial. Regarding stakeholder groups, those experts belonging to Pharmaceutical industry displayed the largest differences to those of the Payor group. 16 experts answered the open-ended question about "costs of dossier process" ranging between €100,000 and €500,000 per drug assessed. **CONCLUSIONS:** We performed a structured survey analysis with experts to assess the new German benefit assessement process based on their one year experience. Several topics and items of high controversy between the affected stakeholders were identified. However, due to the limited quantitative outcomes experience with the AMNOG process to date future research is needed to increase our knowledge about the legislation.

PHP24

SHOULD PHARMACIST REMUNERATION SYSTEMS IN EUROPE BE REFORMED IN ORDER TO INCREASE GENERIC MEDICINE DISPENSING?

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OBJECTIVES: The use of generic medicines, which can generate large savings to health care budgets, should be supported by incentives on both the supply side and the demand side. Pharmacists' remuneration can influence the choice of the dispensed drug. The aim of this study is to provide an overview of different pharmacist remuneration systems for generic medicines in Europe, with a view to exploring how pharmacist remuneration systems can contribute to generic medicine dispensing. **METHODS:** Data were obtained from a literature review, a Master thesis in Pharmaceutical Care at the University of Leuven and a mailing sent to all members of the Pharmaceutical Group of the European Union with a request for information about the local remuneration systems of community pharmacists and the possible existence of reports on discounting practices. **RESULTS:** Pharmacists' remuneration in most European countries consists of the combination of a fixed fee per item and a certain percentage of the acquisition cost or the delivery price of the medicines. This percentage component can be fixed, regressive or capped for very high-cost medicines and acts as a disincentive for dispensing generic medicine. Information on discounting for generic medicines, which is common practice in several European countries, tends to be confidential. Data showed that discounts varied from 10% to 70% of the wholesale selling price. **CONCLUSIONS:** Pharmacists should not be financially penalized for dispensing generic medicines. Therefore, their remuneration should move towards a fee-for-performance remuneration instead of a price-dependent reimbursement which is currently used in many European countries. Such a fee-for-performance remuneration system provides a stimulus for generic medicines dispensing as pharmacists are not penalized for dispensing generic medicines. More and more European countries are moving towards such a remuneration system. Pharmacists' remuneration systems also need to account for the loss of income to pharmacists from prohibiting discounting practices.

PHP25

THE PHARMACEUTICAL INDUSTRY AS PARTNER IN INTEGRATED CARE CONTRACTS - POTENTIAL IMPROVEMENT OR VAIN ATTEMPT? FIRST EXPERIENCES FROM GERMANY

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OBJECTIVES: After the Pharmaceutical Market Restructuring Act (AMNOG) took effect in 2010, almost all pharmaceutical companies consider how to position themselves differently in health care related value chains. The law offers new options for the pharmaceutical and medical devices industry to reorganize their business models in order to become an active and equal partner in integrated care contracts with insurance companies. This paper examines key success factors for collaborating with other stakeholders. **METHODS:** Due to the distinctiveness and topicality of integrated care contracts, four cases of selective contracting between the industry and insurance companies were scrutinized. On this basis, experts of all parties (pharmaceutical industry, health care providers, insurance companies, and management companies) were interviewed. **RESULTS:** Whereas insurance companies and health care providers, as well as health care providers and the pharmaceutical industry have gained experience in cooperating with each other (e.g., in clinical trials), fears of contacts between insurance companies and the pharmaceutical industry still exist. They need to be abolished by establishing capable structures and a bi-lateral willingness to cooperate. Pivotal elements of selective contracting can be allocated to four segments, namely markets (exceed certain thresholds such as number of patients enrolled), products (targeting of "real" care-gaps and physicians' relief), management (distribution of tasks, evaluation concepts), and financial mechanisms (gain-sharing as means to achieve revenue and profitability). First experiences in Germany have proofed technology-based contracts to be suitable for inexperienced companies to start with. The level of complexity of selective contracts and the timely component are often underestimated. **CONCLUSIONS:** Pilot projects are now being implemented into practice which underpins their topicality and the importance of adequate evaluation. Their success depends on the inclusion of relevant partners and the intelligent combination of the stakeholders' various strengths. The objective is to develop concepts which are applicable outside of Germany on international markets.

PHP26

REGISTRIES OF MEDICAL DEVICES IN THE EUROPEAN UNION

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OBJECTIVES: In early 2012, there were a number of serious events in the implant area. A recent example are the defective breast implants of the French company Poly Implant Prothese. The second incident concerns 'metal on metal' (MoM) hip implants. These events raised public awareness and started a scientific discussion in academia and politics on safety issues and monitoring medical devices. Apparently, there is a big lack in the surveillance of medical devices. Therefore, the objective of this work is to detect existing implant registries in the European Union. **METHODS:** A systematic review of the literature was carried out to identify different types of implant registries in the European Union Member States (EU MS). The systematic search for implant registries was performed in the databases PubMed, Medline, CRD York. All results up to April 2012 were considered. **RESULTS:** Ninety-nine registries in the EU MS for different types of implants were identified. As demonstrated, most registries exist in the field of cardiac implants and arthroplasty (34 and 30 within Europe). The distribution of implant registries showed variation in the different EU MS. For a lot of implant categories, none or very few registries could be identified. Some countries run more registries than others (UK 15, Portugal 1). **CONCLUSIONS:** The results show that there is only a limited number of reviews on registries and a centralized monitoring system in the EU MS is missing. Our results reveal a lack of transparency concerning number, aim, structure and quality of registries. This is crucial, as registries work as an early warning systems for identifying and notifying patients at risk. [The research is supported by the German Federal Ministry of Education and Research (BMBF), project grant No. 01EX1013B as part of the Centre of Excellence for Medical Technology].

PHP27

IMPLEMENTATION OF THE TRANSPARENCY DIRECTIVE IN HUNGARY: SPECIAL FOCUS ON TIME LIMITS FOR PRICING AND REIMBURSEMENT DECISIONS

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OBJECTIVES: Transparency Directive (TD) (89/105/EEC) aims to foster the transparency of measures regulating the pricing and reimbursement decisions of pharmaceuticals in European Union Member States. TD establishes a number of fundamental principles including strict timelines for the pricing and reimbursement (P&R) process. Our study focuses on the implementation of the Transparency Directive in Hungary with special focus on time-limits for P&R decisions. **METHODS:** We analyzed official decisions in 103 P&R submissions (positive cases with decisions only) made by the National Health Insurance Fund Administration (NHIFA) between 2004 and 2010. Most of the cases belonged to pharmaceuticals with new active ingredients and without reimbursement at the time of submission. We excluded generic drugs and cases without P&R decision from the analysis. In order to determine the market access time we calculated the time period between the registration date of the drug by the European Medicines Agency (EMA) or by the National Institute of Pharmacy (NIP) and the P&R decision. **RESULTS:** The average time period from registration to P&R decision was 721 days (min: 46 days, max: 2696 days); from registration to P&R submission was 481 days (min: 1 days, max: 2581 days), from P&R submission to P&R decision was 214 days (min: 7 days, max: 990 days). Hungarian patients get access later to those medicines with centralized EMA registration compared with medicines with national registration procedure by NIP (average elapsed time from registration to positive decision was 827 days by EMA, 513 days by NIP). **CONCLUSIONS:** Periods needed for decisions are generally in accordance with the 90+90 days recommendation of the TD. There is a positive change in pricing and reimbursement process in Hungary; decision procedure was shorter in 2010 than it was in 2004. Hungarian patients get new, better medicines later if the registration was done by EMA.

PHP28

REASONS FOR PROJECT DISCONTINUATION IN THE PHARMACEUTICAL INDUSTRY

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OBJECTIVES: Drug development productivity has decreased over the past 10 years. The objectives are to a) better describe the reasons for discontinuations and b) help define the scale of the issue around discontinuing products and additional indications for reasons related to an anticipated lack of pricing and reimbursement flexibility. **METHODS:** A restricted and confidential survey to four pharmaceutical companies on their discontinued projects for lead and follow-on indications during the period 2005-2009. Reasons for discontinuation distinguished two major categories, 'technical' (including failure to meet safety or efficacy targets) and 'commercial' reasons. **RESULTS:** The four companies reported a total of 1,053 projects which had been active during the period 2005-2009. Of those, 51% were discontinued (n=541) by the end of 2009; 332 were lead indications and 209 were follow-on indications. About 72% of discontinuations for lead indications were for technical reasons. The pattern for follow-on indications is more complex. Technical reasons triggered a smaller proportion of discontinuations, presumably because many were addressed with the lead indication. However, a greater percentage of the discontinuations were after Phases II and III, implying higher costs to this point. Portfolio prioritisations and exiting the disease area accounted for 20% of discontinued projects. **CONCLUSIONS:** The results for lead indications reinforce previous results about the growing importance of non-technical i.e. commercial reasons as drivers for project discontinuations, around 20-25% in our sample. However, our results show for the first time an analysis for follow-on indications and where no comparison to previous literature is possible.