Prices are freely set during ATU but adjusted backward based on final negotiated price once product is approved; 2) For new innovative medical devices and medical procedures which are no part of any past or current public funding, 'forfait innovation" has been introduced in 2009. It is a temporary funding conditioned by setting up of a clinical or health economic study. Eligibility assessment is made by the French health technology assessment body (HAS) and final funding decision lies on the Ministry of Health. It covers partial or total costs of medical procedure/medical device and hospitalisation; 3) For innovative biology and anatomo-cytopathology medical procedures not yet reimbursed, a temporary funding has been introduced in 2015, known as RIHN, conditional to the conduct of prospective and comparative data collection. Additional funding options are available through translational, clinical or health economic research programs. **CONCLUSIONS:** French policy makers have developed an effective armamentarium of procedures to allow early access to innovation with immature data and to collect additional data supporting further coverage decisions.

PHP323

HEALTH CARE SYSTEM INEFFICIENCIES RELATED TO MEDICINES: ANY POTENTIAL ROOM FOR IMPROVEMENT?

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OBJECTIVES: Health care efficiency related to drug use is highly debated while ageing, growing prevalence of chronic diseases and greater use and development of more innovative and expensive products incur substantial burden on health insurance systems. Study objective was to assess health care system inefficiencies related to medicines to identify where efficiency gains might be made. **METHODS:** A literature review was conducted at macro-economic level from World Health Organization, Organization for Economic Co-operation and Development, and European Commission official websites, completed by an interview of European health care providers, patient groups representatives, HTA and payers' experts, as well as search in Medline database, national health authorities' websites and available grey literature to illustrate the different categories of inefficiencies. **RESULTS:** Health care system inefficiencies related to medicines can be classified in five categories: 1) irrational use of medicines, e.g., polypharmacy when not medically necessary, lack of treatment coordination, non-conformance with prescribing guidelines, prescribing inefficiency, poor treatment adherence, off-label use of medicines, and drug wastage; 2) non-availability of appropriate treatment options in some therapeutic areas or for specific sub-groups (e.g. elderly and paediatric populations); 3) shortage of mature products due to industry issues to competitively supply the market; 4) disparities in drug access between and within European countries; 5) suboptimal framework in terms of health technology assessment, as well as drug pricing and reimbursement setting rules, e.g., drug budget silo, different procedures between drug classes, lack of indication-specific pricing or incomplete information related to pharmaceutical prices across countries which might lead to inefficient resource allocation. **CONCLUSIONS:** These health care system inefficiencies deserve attention and should be addressed whenever possible by initiating dialogues between policy makers, patients, health care providers, payers and industry to enhance development of pharmaceuticals addressing unmet medical needs, efficient use of pharmaceuticals, thus contributing to sustainability of health care systems.

PHP324

THE DYNAMIC EVOLUTION OF EXTERNAL PRICE REFERENCING IMPLEMENTATION IN VARIOUS COUNTRIES

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OBJECTIVES: External Price Referencing (EPR) is used in many countries, but its scope and design vary substantially in different settings. The objective of this paper is twofold: first, to review the available evidence on the implementation of EPR across countries and, second, to assess whether differences in the design of the EPR policy may affect positively or negatively its impact within a country. **METHODS:** A systematic literature review using a keyword strategy was conducted both in the peer review and grey literature from 2000 to 2015 in order to record current and historical developments of EPR systems. **RESULTS:** 152 studies were identified with relevant titles and abstracts, 114 of which were included for analysis. EPR is usually implemented to regulate the prices of pharmaceuticals but there are significant differences across countries in the structural elements of EPR. The features that we focused our review on were: the scope of EPR, the products included, the main role of EPR in the final pricing decision, how stakeholders are involved in the design and whether there is an appeals process to regulator decisions. The size of the basket along with the criteria used for the basket country selection, the method used for the reference pricing calculation and the frequency of price revisions were also reviewed. Finally, discrepancies over time in the way countries are dealing with exchange rate fluctuations and any wealth adjustments to the EPR calculation are recorded and compared between countries. **CONCLUSIONS:** Countries use EPR systems as cost-containment measures. However, EPR may have a number of unintended consequences. The substantial variety in the design and operation of EPR systems likely influences the impact that EPR has within the country that it is being applied to.

PHP325

KEY DRIVERS FOR MARKET PENETRATION OF BIOSIMILARS IN EUROPE

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OBJECTIVES: Potential drivers and barriers of biosimilar uptake were mainly analysed through qualitative approaches. The study objective was to conduct a quantitative analysis and identify drivers of biosimilar uptake of all available biosimilars in the European Union (EU). **METHODS:** A three-step process was established to identify key drivers for the uptake of biosimilars in top ten EU Member States (MS) pharmaceutical markets (Belgium, France, Germany, Greece, Hungary, Italy, Poland, Spain, Sweden and UK): 1) Literature review to identify incentive policies in place to enhance biosimilars adoption; 2) Assessment of biosimilar market dynamics based on database analysis; 3) Regression model analysis on price using the following explicative variables: incentive policies, price difference between the biosimilar and the originator product, distribution channel, generic uptake and generic price cut, pharmaceutical expenditure per capita and market competition. **RESULTS:** At study cut-off date, 20 biosimilars were available on the market. Incentive policies applied to biosimilars were found to be heterogeneous across countries and uptakes of biosimilars were also very heterogeneous between different therapeutic classes and countries. Results from the model demonstrated that incentive policies and date of first biosimilar market entry were correlated to biosimilar uptake. Pharmaceutical expenditure per capita and the highest generic uptake were inversely correlated with biosimilar uptake. Average generic price discount over originator, and the number of biosimilars showed a trend toward statistical significance for correlation with biosimilar uptake but did not reach the significance threshold. Biosimilar price discount over original biologic price, number of analogues, and distribution channel were not correlated with the biosimilar uptake. **CONCLUSIONS:** Understanding drivers of biosimilars uptake becomes a critical issue to inform policy decision makers. This study showed that incentive policies to enhance uptake remain an important driver of biosimilar penetration while biosimilar price discounts have no impact. Future research is warranted when the biosimilar market gains maturity.

PHP326

SETTING RECOMMENDATIONS FOR GOOD PRACTICE OF HEALTH TECHNOLOGY ASSESSMENT IN THE EGYPTIAN MINISTRY OF HEALTH

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OBJECTIVES: Technology assessment provides information to policy makers in order to inform decisions about the adoption and diffusion of health care technology. This study aims to develop recommendations for good practice of health technology assessment (HTA) in the Egyptian Ministry of health to ensure transparency, accountability and efficiency. **METHODS:** A focus group of decision makers that included experts in health economics, healthcare policy, pricing and reimbursement systems in Egypt was established. The focus group has reviewed the principles of good practice of HTA available on ISPOR web site , the Egyptian laws and the World Health Organization guidelines on good governance in medecine . Focus group meetings were held to develop core recommendations before preparing a draft report. The recommendations were developed by using the Quasi-Delphi method. **RESULTS:** Revisiting the Egyptian guidelines for economic evaluations reporting, establishing a clear system for setting priorities for HTA and engaging all key stakeholders to consider a wide range of evidence were the core recommendations for setting a good practice for HTA in Egypt. HTA should be an unbiased and transparent exercise and its findings need to be communicated appropriately to different decision makers. Addressing issues of generalizability and transferability should also be considered when undertaking HTA in Egypt. **CONCLUSIONS:** Effective pharmaceutical pricing and reimbursement systems, based on HTA, are essential for allocation of our limited resources that can lead to efficient sustainable health care system. The focus group defines and gains a consensus on a set of recommendations adopting good HTA practice that provides a support of a transparent and uniform process in the evaluation of clinical benefits and costs of pharmaceuticals. These recommendations will enhance access to clinically effective and cost-effective care, improve the efficiency of care and achieve better health for the Egyptian population.

PHP327

A PROSPECTIVE ASSESSMENT OF ATTITUDES AND EXPERIENCES AMONG UROLOGISTS REGARDING OFF LABEL USE OF BCG VACCINE IN SERBIA

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OBJECTIVES: To assess current attitudes of urologists to „off-label" prescribing of BCG vaccine for high grade non-muscle invasive bladder cancer (NMIBC) and carcinoma-in-situ (CIS), as well as to perform a pharmacoeconomic evaluation of BCG vaccine manufactured by local pharmaceutical company. **METHODS:** The attitudes and experiences of urologists regarding „off-label" use of BCG vaccine for intravesical immunotherapy of bladder cancer, have been evaluated by using non-probability snowball sampling technique and specifically designed questionnaire. Clinical, social, economic, ethical and regulatory factors have been included. Snowball sampling has involved urologists from ten different hospitals in the Northern, Central and Southern Serbia, greatly experienced in intravesical BCG immunotherapy. **RESULTS:** BCG is used for intravesical immunotherapy, and has become the standard care for NMIBC and CIS. BCG therapy may reduce the risk of tumour progression, appearing to be better in preventing recurrences compared to chemotherapy, but with significantly more side effects. „Off-label" use is the use of a medicinal product for another indication, another patient group, another dose or by another route of administration as indicated in the package insert. It was noted that BCG was in the „off-label" use in a 50,0% hospitals which had a problem with purchase of BCG for immunotherapy (regarding worldwide shortages). It was estimated that there were 1095 patients with bladder cancer in Serbia per year. The model according to which 18 vials of domestic BCG vaccine are used for immunotherapy per patient per year, projected the net budget savings of 593 862.30 €

per year. **CONCLUSIONS:** This research could support the further clinical studies of BCG vaccine of local manufacturer, for new indications (NMIBC and CIS). That would enable lower costs per patient, higher quality, availability and the continuous supply of immunotherapy.

PHP328

THE IMPACT OF EXTERNAL PRICE REFERENCING WITHIN AND ACROSS A COUNTRY'S BORDERS

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OBJECTIVES: External Price Referencing (EPR) is widely used to regulate drug prices. The objective of this paper is to review the impact of EPR systems on selected health-system outcomes internationally. **METHODS:** A systematic literature review using a keyword strategy was conducted both in the peer review and grey literature from 2000 to 2015. **RESULTS:** 152 studies were identified with relevant titles and abstracts, 102 of which were included for analysis. The available evidence suggests that, at a national level, EPR can achieve cost-containment only in the short-term and might undermine the availability and affordability of medicines; there is little evidence on the long-term impact of EPR. The level of list prices within countries is influenced predominantly by the features of EPR systems. At the international level, there is evidence that EPR causes cross-country spillover effects, price instability, and price convergence towards the average price; however, price differences among countries are still observed. It has also been argued that price convergence might reduce revenues and therefore present a disinvestment criterion towards industry innovation. Finally, launch delays vary significantly across countries as launching depends on the income level, the market size and the pricing regulations of each country. **CONCLUSIONS:** If EPR is coordinated among countries it has the potential to enhance welfare and equitable access to medicines across countries and to potentially promote industry innovation through frequent value based price adjustments. However, it is difficult to prevent manufacturers from "gaming" EPR systems and, thus, it usually impacts negatively on individual country prices and bears unexpected consequences in countries applying such policies.

PHP329

OBSTACLES FOR ADOPTION OF VALUE ADDED MEDICINES: CALL FOR POLICY CHANGES FOR VALUE RECOGNITION OF REPURPOSED MEDICINES

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OBJECTIVES: Value added medicines are defined as "medicines based on known molecules that address health care needs and deliver relevant improvements for patients, health care professionals and/or payers". Current obstacles to their value recognition from health technology assessment (HTA) and pricing and reimbursement (P&R) perspective in Europe continue to exist creating a disincentive for further development. Study purpose was to identify key obstacles for adoption of value added medicines and elaborate on policy recommendations. **METHODS:** A literature review targeting health care inefficiencies related to HTA and P&R rules was completed by interviews with health care providers, patients and payers; this was followed by a focus group with representatives of pharmaceutical industry developing medicines in this field. **RESULTS:** Various obstacles have been identified that prevent optimal utilisation of value added medicines in terms of: 1) HTA obstacles, e.g. through existing generic medicines stigma, budget silos and current HTA framework; 2) Pricing obstacles, e.g., through pricing policies pushing price down such as internal/external reference pricing or tender/procurement policies; 3) Lack of reward for manufacturers, e.g., due to uncertainty about reward of investment to bring evidence requested by HTA bodies. This situation called for policy changes and the industry panel provided 2-level recommendations: 1) To get P&R rules that should offer the possibility for HTA pathways taking into account special characteristics of value added medicines such as enlarging scope of benefit considered in decision-making to include, for example, patients' and health care providers' preferences; 2) To enforce pricing policies rewarding value added medicines development such as acknowledgement of value differentiation in tenders policies. **CONCLUSIONS:** Current P&R rules in place in some countries prevent full recognition of value added medicines benefits and calls for policy changes to foster appropriate incentives to enhance their value recognition and encourage manufacturers from bringing such products to the market.

PHP330

HOW DO COST-CONTAINMENT MEASURES IMPACT PHARMACEUTICAL INDUSTRY?

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OBJECTIVES: To ensure financial stability in the pharmaceutical system, governments introduced cost-containment measures, including austerity measures, such as price cuts and mandatory discounts. These policies are highly likely to negatively impact pharmaceutical companies that could result in closures of national subsidiaries or reduction of staff. This research aims at collecting evidence on observed consequences in recent years. **METHODS:** We surveyed the development of performance indicators of the pharmaceutical industry (sales, staff, subsidiaries) as well as major cost-containment measures through a questionnaire with competent authorities on pricing and reimbursement in 46, mainly European, countries. **RESULTS:** Responses were received from 14 countries (thereof 10 EU Member States, 2 EFTA countries, Canada and Russia). Major cost-containment measures reported included price revisions/reductions (Canada) and/or price cuts (Cyprus, Czech Republic), introduction of statutory claw backs (Austria, Hungary), change in reference countries (Estonia) and the introduction of the preferential price policy (The Netherlands). 6 countries did not report any deterioration of pharmaceutical industry's industry, whereas negative developments in the pharmaceutical sector were observed in Canada, Hungary, Norway, Spain and Switzerland. Reasons indicated for these developments included the global economic downturn (Canada), market consolidation processes (Canada, Spain) and the strategic decision taken by national representatives of generic companies to close their sales or market access departments (Norway, Switzerland). When they announced cost-containment measures, governments were frequently confronted with opposition of pharmaceutical industry (e.g. media campaigns, legal challenges) who expressed their concern of negative consequences for the performance of the pharmaceutical sector. In two countries (Hungary, Spain) industry proposed alternative solutions to prevent the implementation of planned cost-containment measures. **CONCLUSIONS:** While cost-containment measures contributed to impact negatively the performance of pharmaceutical industry in some cases, their consequences appeared to be less severe than previously expected. This suggests that cost-containment is less relevant than other performance-impacting factors.

PHP331

ARE DRUG PROCUREMENT PROCEDURE AND AWARD CRITERIA IN EU HOSPITAL SETTING STANDARDIZED AND DO THEY TAKE INTO ACCOUNTS EFFECTIVE SUPPLY QUALITY?

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OBJECTIVES: Overview of the state of the art and a general framework of the current public hospital drug procurement differences in the most important EU countries, looking for cases of service quality feedback on past contracts used as additional award criteria. **METHODS:** Literature review and analysis on public reports investigating the current experience in drug procurement for the hospital sector, in the most important European and OECD countries. **RESULTS:** The centralized procurement is carried out by Ministry of Health, social health insurance institutions or procurement agency (in Denmark and Norway). Tender is a key tool for procuring medicines for the public sector in many countries worldwide and it is considered to be of high relevance in hospital sector. In some countries as Romania and Slovakia a mix of tendering and negotiation practices take place, while in other countries (Cyprus, Estonia, Italy, Latvia, Malta Norway, Sweden, UK) tendering is largely the most diffuse procedure to procure most medicines for hospitals. Although the introduction of service quality in award criterion, it is just a promise on future activities, the procurement mechanisms lack of a) an effective EU standardization of the procedures; b) feedbacks of supplier quality of the previous services as award criteria (e.g., on time delivery). **CONCLUSIONS:** The introduced policy to purchase medicines is tendering with the aim of increasing the health resource saving by lowering contract price. However, the costs originated by a low quality service during contract are not taken into account as an award criterion. The introduction of the quality feedback could induce a reduction of effective low-quality service related costs during the contract.

PHP332

REAL WORLD EVIDENCE IN EUROPE: A SNAPSHOT OF ITS CURRENT STATUS

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OBJECTIVES: This research aims to provide a comprehensive summary of Health Technology Assessment (HTA) recommendations for the use of real world evidence (RWE) in Europe. **METHODS:** A search strategy was applied in Medline, Embase, The Cochrane Library, and Pubmed that combined different terms for "real world evidence", "HTA agency", and "guidelines". We limited our searches to European countries and a time frame of 13 years (January 2003 – May 2016). We also performed a rapid literature search on the websites of HTA agencies. Titles and abstracts of potential studies were reviewed by one researcher. **RESULTS:** Overall, 326 citations were identified: 111 abstracts were screened, 65 met the inclusion criteria for full-text review. No explicit guidance and rules were found for the conduct of RWE studies. No information was provided on the type of RWE data that should be collected, the study design, the data collection tools to be used, or the statistical analysis methods to be used. Nevertheless, 22 papers reported data on general trends in the use of RWE. HTA agencies in France, Germany, and the UK acknowledge the importance of gathering RWE for establishing the value of a new drug. RWE is mainly collected and used for reimbursement activities, for regulatory and post-marketing commitments, and for drug development. It is used to supplement clinical trial data offering valuable information on treatment patterns, resource use, effectiveness or quality of life, thus enhancing the generalisability and transferability of RCT results. Several challenges have been noted in collecting RWE: its liability to different forms of bias (information, selection, confounding bias), its sometimes poor quality, and the limited availability of policies on this topic. **CONCLUSIONS:** As the importance of RWE in decision-making processes continues to grow, more efforts should be put into harmonising and standardising the collection and analysis of RWE as well as into developing policies.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

PHP333

THE EVOLUTION OF RISK-SHARING AGREEMENTS IN THE PROCESS OF UPDATING THE NATIONAL LIST OF HEALTH SERVICES IN ISRAEL

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OBJECTIVES: As part of the annual process of updating the Israeli National List of Health Services (NLHS), the four Israeli health-plans are allocated a pre-determined governmental budget to cover the use of the new technologies. Thus, the health plans face considerable financial risk if the utilization is substantially higher than what was estimated at the time of listing. Risk-sharing agreements (RSAs) have