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