per year. CONCLUSIONS: This research could support the further clinical studies of RWE in decision-making in pharmacovigilance and real world evidence. CONCLUSIONS: Our study is the first to report such an analysis, and it suggests that RWE may be a valuable tool for decision-making in drug development and utilization. The results of our study provide support for the use of RWE in decision-making and may help to inform future real-world evidence studies.

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 systems 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: 352 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 similar to the reference list price, the level of local price reference, and the introduction of the preferential price policy (The impact of external price referencing). The added medicines and elaborate on policy recommendations.

PHP29 OBSTACLES FOR ADOPTION OF VALUE ADDED MEDICATIONS: CALL FOR POLICY CHANGES FOR VALUE RECOGNITION OF REKUPPOSED 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) processes differ among countries. This study aims at providing a comprehensive overview of the most diffuse obstacles impeding the introduction of value added medicines in the hospital pharmacy setting and to potentially promote industry innovation through frequent value based price adjustment. 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 utilization 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 international reference pricing or tendering/price agreements; 3) Lack of reward for manufacturers, e.g., due to uncertainty about reward of investment to bring evidence required by HTA bodies. This situation called for policy changes and the implementation of 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 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 the industry. METHODS: A literature review targeting 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 for pharmaceutical price reimbursement in 46 EU/EEA countries, Canadian provinces, and the US. Responses were received from 14 countries (thereof 10 EU Member States, 2 EFTA countries, Canada and Russia). Major cost-containment measures reported included price reductions/revisions (Canada) and/or price cuts (Cyprus, Czech Republic, Hungary). Real estate, intellectual property rights, and drugs from emerging countries (Estonia) and the introduction of the preferential price policy (The Netherlands). 6 countries did not report any deterioration of pharmaceutical industry’s financial performance. Key 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 concerns. The introduction of cost-containment measures contributed to impact negatively the performance of the pharmaceutical sector in some countries, 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 ACCOUNT 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 important procedure to procure medicines is tendering with the aim of increasing the health resource saving by lowering contract price. However, the costs originated by a quality service during contract is not taken into account as an award criterion. The introduction of the service quality of award criterion, in it is a 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 criterion (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 quality service during contract is not taken into account as an award criterion. The introduction of the service quality of award criterion, in it is a 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 criterion (e.g., on time-delivery).

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 Web of Science, which combined different terms for “real world evidence”, “HTA agency”, and “guidelines”. We limited our searches to European countries and a timeframe of 13 years (January 2003 – May 2016). We also performed a rapid review of HTA agency reports available as well as published papers on the use of RWE. RESULTS: A total of 111 abstracts were screened, 65 met the inclusion criteria for full-text review. Of these, 33 were from 11 European countries (Austria, Belgium, Denmark, France, Germany, Italy, Norway, Sweden, Switzerland, UK, and Spain). CONCLUSIONS: 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 informing and standardising the collection and analysis of RWE as well as developing policies.

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

PHP333 THE EVOLUTION OF RISK-SHARING AGREEMENTS IN THE PROCESS OF THE NATIONAL LIST OF MEDICINES SERVICES IN ISRAEL

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OBJECTIVES: The objective of this study was to examine the evolving nature of the 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 were frequently confronted with opposition of pharmaceutical industry (e.g., media campaigns, legal challenges) who expressed their concerns. The introduction of cost-containment measures contributed to impact negatively the performance of the pharmaceutical sector in some countries, their consequences appeared to be less severe than previously expected. This suggests that cost-containment is less relevant than other performance-impacting factors.

PHP334 How to enhance the supply of immunotherapy.

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