ject, applicable to both single and multi-company projects. Any obligatory internal processes should be completed in tandem. RESULTS: Health outcomes studies, pharmacoeconomic evaluations, and risk-sharing agreements for the access of new pharmaceuticals were identified as projects of high priority to implement in the following years. CONCLUSIONS: The steps outlined in this guidance, although not completely exhaustive, will support all those wishing to go about setting up a joint working project in Catalonia (Spain), and to assist through the remainder of it. This guide is not a substitute for suitable regulatory or legal advice.

**PHP201**

**MAPPPING AND ANALYSING PHARMACEUTICAL POLICY SETTINGS WORLDWIDE**

**Manfrieda H**, 1Koutuba GJ 2, Shen J3, Holtorf AP4, Kato 2

1National School of Public Health, Athens, Greece, 2National and Kapodistrian University of Athens School of Medicine, Athens, Greece, 3ABBott, Basel, Switzerland, 4Health Outcomes Strategies LLC; Basel, Switzerland, 5Lyeron Research Institute, Budapest, Hungary

BACKGROUND: In the light of increasing expenditure for health services it is important to elaborate policies which maximise efficiency. Pharmaceuticals account for about a fifth of total health care expenditure and are often target of health care efficiency policies. The aim of this study is to classify and grade pharmaceutical supply and demand control policies across the globe and cluster systems by regulatory rigidity. METHODS: Pharmaceutical policies and market data across 65 countries were researched in the literature with emphasis on pricing, reimbursement, dispensing, expenditure and demand control domains. Policies were classified by domains and graded through a multi-country expert survey for the degree of regulation. Cluster analysis helped to group countries by policy type. RESULTS: Pricing policies for on-patent products (with increasing degree of rigidity: cost reimbursement, direct pricing, value-based pricing, etc.) plus-pricing, conditional-pricing, reference-pricing, state dictates and tenders. Cost control policies include: discounts, rebates, price-sharing agreements, price-volume agreements, price controls, pay-backs, clamping effects, price cuts, free samples and tenders. Reimbursement policies include: variants of ATC-based internal referencing, variants of statutory copayments, and variants of ATC4-based internal reference pricing. PSURs: in Europe in resource demand and expenditure control for Bio and/or compulsory substitution. Demand controls include: educational campaigns, prescription aids, indicative prescription guidelines, indicative INN prescription, prescription monitoring, quotas, targets, predefined budgets, compulsory INN prescription, mandatory electronic prescription, compassionate use guidelines, prior/posterior approvals, sanctions and incentives for target/guidelines adherence. Cluster analysis identified a set of countries using an intermediate regulation policy and another, a more rigid approach. These did not differ significantly (p < 0.20) concerning pharmaceutical expenditure as % of GDP. CONCLUSIONS: A variety of policies were used in recent years for controlling pharmaceutical expenditures. Countries fall into two subsets based on the intensity of the regulation. More regulated systems do not appear to be associated with lower pharmaceutical expenditure.

**PHP202**

**THE COST-EFFECTIVENESS OF PERIODIC SAFETY UPDATE REPORTS (PSURS) FOR BIOLOGICS IN EUROPE**

**Bouvy J1, Ebbers H2, Schellekens H3, Koopmanschap MA4**

1Erasmus University Rotterdam, Rotterdam, The Netherlands, 2Utrecht University, Utrecht, The Netherlands, 3Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: The safety profile of new drugs is usually not fully established upon market entry, giving cause for Europe’s comprehensive pharmaceutical guidelines system. A key regulatory vehicle to communicate the outcomes of pharmacovigilance and ongoing safety effects is the periodic safety update report (PSUR). We summarize a product’s performance and facilitate risk-benefit assessment of its benefit-risk profile. We assessed the cost-effectiveness of all PSURs submitted in Europe between 1995-2009 for biologics, using a societal perspective. METHODS: We evaluated two regulatory scenarios: Full Regulation (pharmacovigilance including PSURs) and Limited Regulation (pharmacovigilance without PSURs). We assessed the source of regulatory action for all urgent safety issues that were identified for biologics during 1995-2009. In two out of 24 urgent safety issues (systemic spread of botulinum toxin and edema after use of dibotermin-alfa), PSURs were the regulatory instrument that identified the safety issue and we assumed these issues would have been discovered five years later under limited regulation. Estimations from the literature and Markov-chain life tables were used to calculate costs and effects of PSURs for biologics. RESULTS: The incremental cost-effectiveness ratio (ICER) of Full Regulation versus Limited Regulation was €342,110 per quality-adjusted life year gained. Extensive sensitivity analyses indicated a low probability of the Full Regulation scenario being cost-effective. Only two parameters resulted in a more favorable ICER: a 100% risk reduction after identification of the urgent safety issues (base-case assumption was 25%) and a high risk (1 in 1,000 patients) of severe systemic spread after use of botulinum toxin (base-case assumption 1 in 10,000 patients). CONCLUSIONS: Regulatory cost-effectiveness analysis is a feasible instrument for assessing the added value of parts of the drug regulatory framework. In light of high costs of regulatory compliance, cost-effectiveness should be a consideration in deciding whether or not safety-related regulatory actions are required.

**PHP203**

**UTILIZATION OF THE HUNGARIAN PUBLICLY FINANCED HEALTH CARE SYSTEM BY THIRD (NON EU) COUNTRY CITIZENS**

**Kovács G1, Boncz I2, Kornfeld A3, Eger S4**

1Ministry of Food and Drug Safety, Chungcheongbuk-do, South Korea, 2Sungkyunkwan University, Suwon, South Korea, 3Korea Institute for Health and Social Affairs, Seoul, South Korea, 4University of Vienna, Vienna, Austria

OBJECTIVES: The number of citizens from third countries (outside of European Union or states) permanently living in Hungary is 250,000 and annually ca. 25,000 people get permit to settle. Current study aims at exploring what group of foreigners, when and for what type of service use publicly financed health care. METHODS: Data was retrieved from National Health Insurance Fund Administration of Hungary (NHIFA) and Central Statistical Office. Current study’s base was processing the last five years’ statistical data (2007-2012), concerning health care of third country citizens permanently living in Hungary. We analyzed the volume, place and medical relationship of these services. RESULTS: In the last 5 years third country citizens required inpatient care 9144 times (61% in Budapest), emergency care 11776 times (63% in Budapest), out-patient care 7206 times (57% in Budapest). Patient accessed health care providers due to medical problems in the following medical fields: obstetrics (19%), surgery (18%), laboratory (18%), pediatrics (7%), and ophthalmology (6%). Most of the patients are from Ukraine (42 %), China (22 %), Vietnam (11 %), ex-Yugoslavia (6 %) and Russia (6 %). Analysis by nationalities shows that Chinese population needs health care of their own relatively few times (for instance, 2011: 5%, in 2012: 5%) and even these are almost exclusively done in Budapest. In contrast USA citizens see doctors relatively often (2011: 8%, 2012: 8%), mainly in relation to diagnostics and surgery. CONCLUSIONS: The utilization of Hungarian publically financed health care system by third country citizens. When planning health care capacity, this crucial fact must be taken into consideration.

**PHP204**

**PHARMACEUTICAL REGULATION IN EUROPE AND ITS IMPACT ON CORPORATE R&D**

**Marshall L1, Eger S2**

1University of Vienna, Vienna, Austria, 2Medical University of Vienna, Vienna, Austria

OBJECTIVES: Many European countries regulate drug prices in order to cope with rising health expenditures. On the other hand, price regulation distorts incentives to invest in pharmaceutical R&D. We evaluate the impact of price regulation on pharmaceutical R&D expenditures. METHODS: We analyze a sample of 20 leading pharmaceutical companies between 2000 and 2008. The share of R&D expenditure for the drug company has been the control for other determinants of R&D such as cash flow, company size, leverage ratio, growth rate, and Tobin’s q. RESULTS: Our results suggest a nonlinear relationship between European sales ratio and R&D intensity. Beyond a threshold of 83% sales generated in Europe, a higher presence in Europe is associated with lower R&D investments. CONCLUSIONS: Price regulation has a negative impact on pharmaceutical R&D investments. Policy makers must take long term effects of regulation into account.

**PHP205**

**ELICIT THE RELATIVE IMPORTANCE OF KEY ELEMENTS FOR BENEFIT-RISK ASSESSMENT: A COMPARISON AMONG GENERAL POPULATION, HEALTH AUTHORITY AND MEDICAL DOCTORS**

**Hs H1, Na HS2, Chuong MW2, Byun JH3, Kwon SH4, Park KY5, Lee EK6**

1Ministry of Food and Drug Safety, Chungcheongbuk-do, South Korea, 2Sungkyunkwan University, Suwon, South Korea, 3Korea Institute for Health and Social Affairs, Seoul, South Korea

OBJECTIVES: This research was designed to find out the key attribute for benefit-risk assessment using swing weight method in general population, health authority and hospital doctors. METHODS: We selected six important elements for each benefit and risk assessment based on previous study. The elements of benefit assessment consisted of disease severity, size of population affected by disease, improvement of efficacy/effectiveness, improvement of quality of life. The attributes of risk assessment contained overall incidence of adverse events, overall incidence of serious adverse events, discontinuation rate due to adverse events, drug or food interactions, drugs of potential misuse, risk management. RESULTS: Among risk attributes are key elements for benefit-risk assessment using swing weight method in general population, health authority and hospital doctors. We selected the source of regulatory action for all urgent safety issues that were identified for biologics during 1995-2009. In two out of 24 urgent safety issues (systemic spread of botulinum toxin and edema after use of dibotermin-alfa), PSURs were the regulatory instrument that identified the safety issue and we assumed these issues would have been discovered five years later under limited regulation. Estimations from the literature and Markov-chains life tables were used to calculate costs and effects of PSURs for biologics. RESULTS: The incremental cost-effectiveness ratio (ICER) of Full Regulation versus Limited Regulation was €342,110 per quality-adjusted life year gained. Extensive sensitivity analyses indicated a low probability of the Full Regulation scenario being cost-effective. Only two parameters resulted in a more favorable ICER: a 100% risk reduction after identification of the urgent safety issues (base-case assumption was 25%) and a high risk (1 in 1,000 patients) of severe systemic spread after use of botulinum toxin (base-case assumption 1 in 10,000 patients). CONCLUSIONS: Regulatory cost-effectiveness analysis is a feasible instrument for assessing the added value of parts of the drug regulatory framework. In light of high costs of regulatory compliance, cost-effectiveness should be a consideration in deciding whether or not safety-related regulatory actions are required.

**PHP206**

**COVERAGE WITH EVIDENCE DEVELOPMENT IN SWEDEN – FORMALITY OR EFFECTIVE WAY TO REDUCE UNCERTAINTY?**

**Kemppainen A1, Schroeder M2, Rosén, H1**

1Creation- Ceutical, Paris, France, 2Creation- Ceutical, Copenhagen, Denmark, 3University Claude Bernard Lyon 1, Lyon, France

OBJECTIVE: TIV (formerly LFN) is responsible for reimbursement decisions in Sweden. They regularly give temporary reimbursement with request for additional

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