the submissions that failed to demonstrate efficacy (52%). Characteristics associated with a PFR were being a biologic product, having an appropriate comparator, showing sufficient clinical evidence and being priced at a similar/lower price than the comparator. **CONCLUSIONS:** The presence of patient input was not associated with a PFR. The lack of significant association could be attributed to external factors that are not captured in CADTH's summary reports and the limited sample size of data available. It remains unclear how patient input is integrated into the decision making process.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP6
STUDY OF THE SANITARY GEOGRAPHY OF COLOMBIA: A BIG DATA APPROACH

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OBJECTIVES: This study aims to propose a new geographic administrative organization of Colombian municipalities for health care management purposes. Rather than responding to arbitrary political boundaries, this division should answer to health needs and capacities, in order to facilitate the development of targeted policies to reach universal coverage and improve access to health services. **METHODS:** To achieve this, a big database was created: it contains information about different health-affecting topics: economic development, socio-cultural background, public and transportation services, environmental conditions and health indicators, supply and demand. These topics were measured with over 70 variables. After that, using a principal-component analysis, one or two indicators were created per topic. These indicators were used to build clusters that latter allowed the development of sanitary regions. Afterwards, another study was made in which people were tracked from their residence to the places where they received health services. Then, the country was divided into regions reflecting those migration flows. Finally, the study mingles both information -the clusters and migration networks- to determine a sanitary geography of Colombia. **RESULTS:** Using the methodology, this study proposes six clustering methodologies that are statistically significant and consistent with the reality of Colombia. Also, many networks were proposed, but 5 of them represented the national situation closely. Combining these alternatives, the study achieves its goal and creates a satisfactory segmentation of the country that is valuable for public policy. **CONCLUSIONS:** The proposed categories serve well the needs that originated this study and are an appropriate framework for health care management purposes. In fact, the Colombian Ministry of Health has used it as an input for telemedicine and first infancy projects and health care reform. Its main conclusion is that health cannot be worked using political divisions. It is fundamental to use supply, demand and context criteria to determine regions useful for policymakers.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP7
UNDERSTANDING STAKEHOLDER PERSPECTIVES ON MEDICARE'S COVERAGE WITH EVIDENCE DEVELOPMENT (CED) POLICY

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OBJECTIVES: To understand key stakeholder recommendations for the Centers for Medicare & Medicaid Services (CMS) regarding the application of its CED policy, the outcome of national coverage determinations (NCD) in which Medicare makes coverage contingent on additional evidence collection through a registry or prospective trials, and identify primary concerns with the policy across various stakeholders. **METHODS:** The authors analyzed stakeholder comments submitted to CMS during a public comment period on draft updates to the agency's 2006 CED policy. The comment period was from November 29, 2012 to January 28, 2013. Comments were retrieved from CMS' Medicare Coverage Database and assessed to understand stakeholder positions on issues related to the CED process. **RESULTS:** Of the 27 stakeholders who submitted comments to CMS, over half were from the life sciences industry. The majority of stakeholders called for CMS to provide more clarity on how the agency plans to address operational issues with CED implementation. Stakeholders who may be impacted by the issuance of a CED, such as manufacturers, are seeking greater transparency from CMS on policies and processes for applying CED as well as greater clarity on the parameters for executing CED studies. Specifically, 17 stakeholders called on CMS to prohibit CED at the local level and restrict its application to the NCD process while 12 stakeholders recommended CMS to provide clear timelines for the duration of CED studies. In addition, 11 stakeholders requested clarity from CMS on how it intends to collaborate with the Food and Drug Administration (FDA) on post-market evidence requirements, urging that CED should not duplicate or replace FDA's authority. **CONCLUSIONS:** Going forward, CMS will likely continue to invoke CED with increasing frequency and potentially on a broader range of products. Therefore, clearer guidance from CMS is critical to ensuring continued stakeholder engagement through Medicare's coverage determination process.

PHP8
A LONG WAR BEGINS: BIOSIMILARS VERSUS PATENTED BIOLOGICS – A RETROSPECTIVE ANALYSIS OF THE EU-5 AND JAPANESE ERYTHROPOETINS MARKETS

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OBJECTIVES: Analyze factors influencing Erythropoietins (EPO) biosimilars (copies of patented EPO) (BIOSIM-EPO) uptakes in key global markets. Identify, if possible, country profiles where BIOSIM-EPO have taken market shares. **METHODS:** Countries inclusion criteria: legal definition and regulatory framework for biosimilars close to the EU ones; at least 3 years of experience with BIOSIM-EPO in 2012; national biological market value higher than US$ 2.5 billion. Factors evaluated: national EPO market sizes, EPO retail/hospital distribution mixes, existence of policy incentives that promote BIOSIM-EPO prescriptions or substitution and BIOSIM-EPO prices relative to reference EPO. Data on medicine volumes, values and ex-manufacturer prices for all EPOs (alfa, BIOSIM-EPO (EPO alfa biosimilar), beta and second-generation ones) were provided by IMS Health. Volumes were calculated in DDD (Defined Daily Doses) and prices in euros per DDD. Data were available from 2007 until 2012. **RESULTS:** EU-5 and Japan have been included. Germany: small-sized market, dominant retail market distribution, incentives to prescribe BIOSIM-EPO (quotas) and to substitute patented for 'bioidenticals' EPO, high BIOSIM-EPO uptakes (30.4% in 2012). Spain and Italy: medium-sized markets, dominant hospital distribution, no incentives, 11.5% and 8.6% BIOSIM-EPO uptakes respectively. Japan: the largest market, mixed distribution channels, no incentives, 6.8% BIOSIM-EPO uptake. France: large-sized market, dominant retail market distribution, no incentives, 5.8% BIOSIM-EPO uptake. The UK: the smallest market, mixed distribution channels, no incentives, 2.0% BIOSIM-EPO uptake. The price differences between BIOSIM-EPO and their reference play no role at a global level (e.g. -10.8% in Germany and -26.9% in Japan). **CONCLUSIONS:** This study proved that EPO markets are highly country specific. There is no single specific profile for countries in which BIOSIM-EPO have significantly penetrated the market. Providing national prescription and substitution incentives is the only determining factor for BIOSIM-EPO uptakes. National EPO market sizes, EPO retail/hospital distribution mixes and BIOSIM-EPO prices relative to reference EPO are not significant factors.

PHP9
MEDICAL DEVICES IN JAPAN – A MARKET ACCESS LABYRINTH?

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OBJECTIVES: With a total volume of €24 billion a year, Japan is the world's second largest medical device market behind the US. It imports about 35% of the medical devices from abroad. Although imports have been increasing steadily over the past years, Japan still struggles to have similar access to advanced medical devices as the US and Europe. This research aimed to have a closer look at the Japanese medical device market, and further explore access barriers. **METHODS:** This research was conducted through in-depth secondary research and interviews with a variety of stakeholders including payers, academics, and KOLs in Japan. **RESULTS:** Unlike most markets where an FDA or CE mark is sufficient, medical devices in Japan require a separate in-country regulatory approval before reimbursement. Not only is this process long (approximately 2.2 years) but the requirements are much more stringent compared to the US or EU, often requiring local clinical data. This has resulted in many large med-tech companies staying away from the Japanese market. **CONCLUSIONS:** It is important for foreign manufacturers to understand the implications of the Japanese regulatory barriers and address them in their foreign market strategies allowing them to assess product viability early on.

PHP10
PRICE DYNAMICS OF EXTERNAL REFERENCE PRICING-BASED SYSTEMS IN EUROPE

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OBJECTIVES: Concerns due to external reference pricing (ERP) have been expressed by industry regarding spill-over effects. It is also often argued that ERP can lead to a downward price convergence. The objective of this project was to gain better understanding of price dynamics of ERP-based systems using a simulation model. **METHODS:** A simulation model (developed for the EU Commission) was built to simulate the impact of ERP as main criterion to set drug price across 28 European Union Member States, Iceland, Norway and Switzerland. Base case scenario simulated ERP price for a fictitious drug based on real ERP characteristics. Twenty fictitious scenarios simulated ERP price when introducing changes in ERP characteristics and/or exogenous effects such as genericisation, changes in exchange rates, price cuts. These scenarios were chosen based on the potential rapid and important price erosion attributed to ERP. Impacts of these scenarios were classified depending on changes in average drug price versus the base case. **RESULTS:** Applying solely ERP led to a low average drug price decrease (about 15% at 10 years), with an apparent equilibrium reached in approximately 7-8 years. Price differentials between countries remained substantial over 10 years (about 30%), suggesting a limited impact of ERP in price convergence. Even if impact differed depending on scenarios, all tested scenarios induced price decreases and demonstrated the spill-over effects of ERP. Frequent price revisions, iterative price cuts, large country baskets, price calculation methods, genericisation impact and prices' sources were among the most influent parameters on the evolution of the drug price over time through ERP-based systems. The repetition and combination of various policies generated average price decrease of 92% at 10 years. **CONCLUSIONS:** This study is the first that quantifies the impact of various ERP policies on price erosion. This is a useful tool to support policy decision making.

PHP11
TIME LAGS FROM FDA DRUG APPROVAL TO PUBLICATION OF COST-UTILITY ANALYSIS

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OBJECTIVES: Cost-utility analysis (CUA) provides valuable information on the value of medical technology and is used by many payers to inform coverage and