

approach to costing and uptake among populations considered. **CONCLUSIONS:** Rx-to-OTC switches are a real opportunity to realise savings for budget holders and productivity gains for employers. More robust economic models are required to estimate the impact of the switches in Europe.

#### PHP32

##### MARKET ACCESS VARIATION FOR LIFESTYLE DISEASE DRUGS IN EUROPE

Bastian AW<sup>1</sup>, Gea-Sanchez S<sup>2</sup>, Tangari M<sup>1</sup>

<sup>1</sup>Bridgehead International, London, UK, <sup>2</sup>City London University, London, UK

**OBJECTIVES:** Health policy and funding for medications classed as 'lifestyle' have received considerable scrutiny by public health officials as well as politicians. This has limited public funding and reimbursement for these products in many European countries. A detailed assessment of the variation in payer coverage policies for lifestyle medications across Europe was conducted. **METHODS:** The top 'lifestyle' indications and associated medications were identified from a literature search using WHO, PubMed, and ScienceDirect. Selection criteria for the medications included being first-to-market in the identified indication or being referenced as the only off-label treatment for the specified use. Public reimbursement databases (16) were used to analyze the health technology assessment and reimbursement decisions across European countries (14) for each lifestyle indication. Reimbursement was classified as favourable (broad/restricted but accessible) or no coverage (not funded). Where available, justifications for coverage decisions were analysed to determine the drivers of positive and negative coverage decisions. **RESULTS:** Lifestyle indications where products have achieved high levels of reimbursement include Dyspepsia (100%), Delaying Menstruation (91%), Restless Leg Syndrome (87%), and Alcohol Dependence (85%). Those with the worst coverage are Hair Loss (0%), Hypoactive Sexual Desire Disorder (0%), Erectile Dysfunction (13%), and Weight Loss (15%). Of the 14 countries researched, those offering the most favourable coverage environments for lifestyle treatments were: Belgium (70%), France (69%), and Austria (69%). The countries with the most limited (no available) coverage for lifestyle drug therapies were The Netherlands (13%) and Sweden (25%). Four general characteristics are associated with better access to market: Cross-Usage in Other Indications, Areas with High Societal Costs, Diseases that Affect Family Planning, and Older Therapy Areas. **CONCLUSIONS:** With pressure on public health resources, European payers are resistant to the allocation of funds for medications with lifestyle indications. Despite this, barriers to reimbursement vary substantially across European markets.

#### PHP33

##### IMPACT OF 2011 GERMAN HEALTH CARE REFORM ON GLOBAL MARKET ACCESS STRATEGIES

Honoré AC<sup>1</sup>, Marinoni G<sup>2</sup>, Ando G<sup>2</sup>

<sup>1</sup>IHS, Zurich, Switzerland, <sup>2</sup>IHS, London, UK

**OBJECTIVES:** This study seeks to evaluate the impact of the 2011 German health-care reform (AMNOG) on the global pricing and reimbursement landscape and its influence, if any, on global market access strategies. **METHODS:** Key local regulators were interviewed to understand the scope and mechanism of the mandatory early benefit assessment as well as its implications in terms of pricing and market access on a national and global level. Primary research consisted of in-depth phone interviews with six regulatory stakeholders and industry representatives in Germany. Secondary research was based on data from national and regional health-care authorities, national statistics offices and IHS Global Insight Healthcare and Pharmaceutical services. **RESULTS:** AMNOG has put an end to free pricing in Germany by correlating price to added therapeutic benefit scores and opening the reference pricing system to all patented medicines. The total transparency of the early benefit assessment and pricing processes can influence prices not only in Europe but also worldwide. The availability of results from the Federal Joint Committee (G-BA)'s benefit assessment can affect the pricing and reimbursement status of pharmaceuticals worldwide, while international reference pricing can put downward pressure on prices in at least 22 other countries. **CONCLUSIONS:** The German reform will have an impact beyond the country's borders. Germany has traditionally been an early pharmaceutical launch market but the end of free pricing and the prospect of lower price levels for products of no and minor-to-moderate added value may require a complete reconsideration of the optimal launch sequence. While AMNOG has revolutionized the pricing and reimbursement landscape in Germany, from a global perspective, the reform is not particularly innovative. Germany's new pricing process is comparable to the French model whereby perceived degree of innovation directly impacts medicine prices, and comes near to the Swiss and Austrian models.

#### PHP34

##### PRICING INSIGHTS ACROSS THERAPY AREAS AND EUROPEAN COUNTRIES - A DISCUSSION OF INTERNATIONAL PRICE REFERENCES AND IMPLICATIONS FOR PARALLEL TRADE AND PRESCRIPTION PATTERNS OF PHARMACEUTICAL PRODUCTS

Frenzel A<sup>1</sup>, Haas G<sup>1</sup>, Pechstein M<sup>1</sup>, Degans C<sup>2</sup>

<sup>1</sup>IMS HEALTH, Frankfurt/Main, Germany, <sup>2</sup>IMS HEALTH, London, UK

**OBJECTIVES:** This analysis compares pricing levels across 15 European countries and 10 therapy areas in 2010. The differences in the price levels are related to parallel imports and the innovativeness of prescriptions. **METHODS:** From IMS PRICING INSIGHTS pricing information for pharmaceutical products is accessed at the pack level from 15 countries (EU5-Austria-Ireland-Sweden-Norway-Denmark-Portugal-Greece-Poland-Hungary-Romania) for 2010. Currency rates are fixed at 2010 levels. For the ten therapy areas, product baskets are constructed for the comparisons: The therapy areas are defined as Anatomic-Therapeutic-Chemical (ATC) classes at level 2. The top 100 products by sales in the EU5 in these classes

enter the comparisons. Prices are compared at the manufacturer and the public sales levels. IMS MIDAS identifies imports related to the products in the baskets. The innovativeness of products is operationalized as the number of months between the overall first introduction and the introduction in the countries. **RESULTS:** The first result is that international drug price comparisons are extremely sensitive to methodological issues, e.g. sample selection, exchange rates. Differences in price build-up structures between countries would dominate cross-country price differences, if not accounted for. Differences between countries exist at the ex-manufacturer-level, differences between public sales levels tend to be larger. Price level differences between countries are not consistent across all analyzed therapy areas. Higher price levels are related to parallel trade rates across countries and to an earlier access to new pharmaceutical products. **CONCLUSIONS:** The analysis shows price differences across countries related to manufacture pricing and regulation structuring the price build-up and taxes. Higher price levels are linked to an earlier access to innovative products. Parallel trade flows into countries with higher price levels, usually from countries with lower price levels, causing scarcities. Differences in economic development and purchasing powers need to be analyzed to evaluate these differences in pricing levels.

#### PHP35

##### IS VALUE BASED PRICING EXECUTED IN REAL LIFE SITUATION? - GLOBAL PERSPECTIVES

Mukku S<sup>1</sup>, Mallinson M<sup>2</sup>

<sup>1</sup>Double Helix Consulting Group, London, UK, <sup>2</sup>Double Helix Consulting, London, UK

**OBJECTIVES:** Value assessment of interventions is conducted in some form or the other, although the importance given to different domains of decisions differ by markets. The research is aimed to analyse how perspectives on value assessment of pharmaceuticals or device interventions vary across regions. The research also analysed how products at launch increase the chances of approval, shorten time to reimbursement and remain competitive within the value based pricing agenda. **METHODS:** The research involved desk research as well interviews with key influencers and decision makers in major markets beyond Europe. More than 25 telephone or face to face interviews with key stakeholders were conducted. **RESULTS:** The research indicated that most countries, other than those that use international price referencing for setting prices use some form of value assessment method before fixing the reimbursement level and price of the product. The decisions are predominantly based on level of unmet needs, severity of diseases, level of innovation, clinical differentiation of the new product against its comparators and how well the product fits its natural place in the treatment pathway. Many forward regions claim to use value based assessments to set the price of new launches, most operate within boundaries. In principal value based pricing should not be fenced with limitations such as cost/QaLY thresholds, budget impact and price-volume agreements. However in real life these measures are common in markets all over the world, the main reason being the limitations in health care budgets. **CONCLUSIONS:** It is very challenging to reward products based on their intrinsic value without introducing other hurdles within the current economic environment. However it also is critical to reward innovation for future investments in R&D of new drugs. Health care reforms in the future will raise the bar of innovation and differentiation making it more challenging for the Pharmaceutical industry and all those involved in developing new medicines.

#### PHP36

##### PERCEPTIONS OF POLICY MAKERS AND SCIENCE ADVICE BODY STAFF ON SCIENCE ADVICE IN HEALTH IN EUROPE

Conde Espejo P, Palma Ruiz M, Sarria-Santamera A, Segovia C

Instituto de Salud Carlos III. Ministry of Science and Innovation, Madrid, Spain

**OBJECTIVES:** EuSANH is a network of science advisory bodies in Europe. The project Eusanh-ISA is funded by 7th framework programme of DG Research. It aims to improve the quality, effectiveness and efficiency of science advice for health across Europe. Within this project the objective of this work is to learn about the perceptions of policy-makers (PM) and science advise bodies' (SAB) staff concerning the relationship between these two groups, and the current use of science advice (SA) in policy making. **METHODS:** Two questionnaires were designed targeting both PM involved in developing health policy (such as government ministers, officials and senior public servants within national and/or local health services) and senior staff with extensive experience working in a SAB. The questionnaire was sent to 25 PM and to 29 SAB staff. Descriptive analysis was carried out. **RESULTS:** Nineteen PM (3 Belgium, 1 Czech Republic, 1 Lithuania, 2 the The Netherlands, 2 Poland, 1 Romania, 5 Spain, 3 Sweden and 1 UK) and 25 SAB staff (1 Belgium, 1 Czech Republic, 1 Italy, 1 Lithuania, 4 the The Netherlands, 1 Poland, 3 Romania, 11 Spain, and 2 from Sweden) responded the questionnaire. Factors seen as barriers for the relationship between PM and SAB are the differences in timing, interest, and difficulties to translate policy problems into research questions. The communication was seen as informal. PM and SAB considered that usefulness of SA could be improved with more clarity, brevity, simplicity and concise reporting. Transparency, independence, existence of procedures to adequately deal with conflict of interest, rigor and systematization of knowledge are factors ranked with highest value. **CONCLUSIONS:** Proposals to improve the SA process are "organising regular high level meetings" and "improve the trust between decisors and researchers".

#### PHP37

##### REGIONAL DRUG EVALUATION IN SPAIN: A COMPARISON AMONG COMMITTEES

Hernández-Pastor LJ<sup>1</sup>, Huerta A<sup>2</sup>

<sup>1</sup>GlaxoSmithKline, Tres Cantos, Madrid, Spain, <sup>2</sup>GlaxoSmithKline, Tres Cantos, Madrid, Spain