use in the community (spillover effect).

CONCLUSIONS: Evergreening drugs successfully compete with generics, offsetting cost containment strategies including generic medication substitution or a hospital RDF, particularly so if hospitals include evergreening or brand drugs on their RDF. For effectiveness, prescriptions should be coordinated at the state level rather than from a payer perspective, or hospitals should implement strategies to systematically switch patients to generic drugs at discharge.

PHP13
THE EFFECT OF LAW FOR ECONOMICAL USE OF MEDICATIONS 2006 ON THE NUMBER OF PHARMACIES BETWEEN 2007-2010
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OBJECTIVES: In 2006 a law for the economical use of medications was introduced into the Hungarian legislation. This law – among others – facilitated the foundation of new pharmacies. The aim of our study is to analyse the effect of that legislation on the number of pharmacies. METHODS: Data were derived from the pharmaceutical database of the Hungarian Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analysed the 5 years period between 2006-2010. The number of pharmacies were analysed according to the number of population of different settlements. RESULTS: The number of community pharmacies increased from 2030 (2006) to 2576 (2010) by 546 pieces (26.9 %). The number of pharmacies showed a different pattern according to the size of population of settlements. In villages with a population of 0-449, 500-999 and 1000-1999, the number of pharmacies decreased (5 pieces / 3.6 %; 18 pieces / 20.0 %; 23 pieces / 10.6 % respectively). In cities with a population between 2000-4999 we found a slight increase in the number of pharmacies (11 pieces / 3.0 %). In bigger towns there was a clear increase in the number of pharmacies: 5000-9999 population 579 pieces / 26.0 %; 10000-4999 194 pieces / 7.4 %; 50000-9999 population 125 pieces / 33.0 % and over the population of 10000: 158 pieces / 42.9 %. CONCLUSIONS: After the introduction of the new law for the economical use of medications in 2006, the number of pharmacies significantly changed in Hungary. However, this change in the number of pharmacies was unequal accordind to the size of the population: in villages with a population lower than 2000 people there was a decrease, while in cities with bigger population the number of pharmacies significantly increased.

PHP14
2010-2012 GLOBAL HEALTH CARE REFORMS AND THEIR IMPACT ON PRICING, ACCESS AND HEALTH OUTCOMES STRATEGY
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OBJECTIVES: In 2012 major health care reforms were proposed and implemented in a number of nations, for example, Affordable Care Act in the United States, AMNOG in Germany, HSPT in France, KGV in Switzerland, Ustawa Refundacyjna in Poland and NHS proposed reform in the UK. These reforms have major implications on pricing, market access and HEOR strategy for drug and device manufacturers. METHODS: To understand the implications of these trends, we analyzed 2009-2012 reform bills and proposed changes worldwide. Additionally, we interviewed public and private payers, key opinion leaders and payer-influencers to understand implications of these reforms on drug and device manufacturers. Stakeholders ranked various data collection methods on a scale of 1-10 (1-least important and 10-most important). RESULTS: The global health care landscape is expected to undergo significant change during 2012-2016. In the United States, government will play increased role as a single payer, especially with Medicare, Medicaid, and coverage of primary care. In Europe, the 20% National Health System spending will increase to 40% by 2020. The proposed changes in system will impact pricing, access and health outcomes. The “value-based” purchasing and price transparency legislation will increase the importance of data and evidence. CONCLUSIONS: This analysis shows that global health care landscape is expected to undergo significant change during 2012-2016. Discussions with payers, KOLS and payer-influencers highlighted increased importance of HEOR data in the future.

PHP15
THE IMPACT OF ORPHAN DRUG INCENTIVES ON INNOVATION AND PRICING IN NICH THERAPEUTIC MARKETS: A SYSTEMATIC REVIEW OF THE LITERATURE
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OBJECTIVES: To review the impact orphan drug (OD) legislation has had on innovation and pricing of therapeutic products for rare diseases in the US, EU, and Japan. METHODS: Systematic literature review and grey literature study combining literature searches, grey literature searches, and expert interviews to summary principles and experiences. RESULTS: 130 articles were included in the analysis. 31 out of 46 OD legisltation were focused on the EU. 110 out of 156 ODs were evaluated for pricing and 7 discussing pricing outcomes. Increasingly strong study designs have been used to validate that OD legislation has increased cross-market approvals and suggest the increasing role of small biotechnology companies. Select results also show a positive relationship between disease prevalence and the likelihood of indicated ODs and is bolstered by well controlled regression-continuity studies showing sustained innovation in higher prevalence OD markets. However, some concerns are raised regarding innovation in low prevalence conditions and contexts. Major policy changes are expected to boost the generic market. However, small pricing gaps between generic and branded drugs, the lack of mandatory substitution and INN prescription, little price discounting and little education towards the public might explain the slow uptake of generics in Japan, relative to the West. CONCLUSIONS: Although the “Brand Lover” assumption is candidly used to explain the lack of traction by generic drugs, this view finds the lack of policy incentives to be a bigger problem, and might better explain current levels of generics penetration. Shall the authorities be willing to encourage generic uptake more effective policy incentive are needed.

PHP16
GENERIC DRUG MARKET ACCESS IN JAPAN
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OBJECTIVES: The Japanese generic drug market is not well developed. The generic volume share is 20% of the total market vs. 74% and 64% in the USA and UK. The slow uptake of generics is often explained by the “Brand Lover” profile of Japan. No formal review of drug policy has been undertaken to understand the slow uptake of generics. METHODS: We reviewed the current Japanese generic drug policy enacted by the Ministry of Health, Labour and Welfare (MHLW), and the Japanese Generic Medicines Association (GMA) and analyzed the impact of policy changes issued in 2002, 2006 and 2010. They required that prescriptions specify if substitution generics are acceptable, and provide some modest financial incentives for pharmacies and hospitals to substitute only with the patient’s agreement. In 2012, INN prescription is encouraged but not requested. The recent introduction of Japanese DRG hospital funding, and the 2011 Japan-India Economic Partnership Agreement, which opened the Japanese market to Indian generic drug manufacturers, are expected to boost the generic market. However, small pricing gaps between generic and branded drugs, the lack of mandatory substitution and INN prescription, little price discounting and little education towards the public might explain the slow uptake of generics in Japan, relative to the West. CONCLUSIONS: Although the “Brand Lover” assumption is candidly used to explain the lack of traction by generic drugs, this view finds the lack of policy incentives to be a bigger problem, and might better explain current levels of generics penetration. Shall the authorities be willing to encourage generic uptake more effective policy incentive are needed.

PHP17
ROLE OF SUBGROUP ANALYSES FOR TECHNOLOGY ASSESSMENT AND COVERAGE DECISIONS
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OBJECTIVES: Cost effectiveness analyses play a critical role in determining coverage of novel drugs and devices. Increasingly, payers are demanding subgroup analyses to determine indications which would be covered by the national health system or insurance agency. METHODS: To understand and review trends in use of subgroup cost effectiveness analysis, we reviewed NICE HTAs for products approved in 2011-2012. Manufacturer submissions for CEA were compared to final review. RESULTS: Subgroup analyses were identified and case studies were developed to further understand the use of subgroup analyses and cost effectiveness models. RESULTS: Decisions made by NICE in 2011-2012 show increasing trends towards the use of subgroup analysis for determining indications for coverage by national payer bodies. During 2011-2012, 80% of the assessments included subgroup analyses. Approximately half of them included cost effectiveness analyses for various subgroups. Interestingly, the ICER values estimated by NICE for the same subgroups showed a large variation (1x-3x fold difference) compared to ICER values estimated by manufacturers. Selected case studies highlighted that for several products NICE is recommending treatments only for subgroups whose ICER values are within the cost effectiveness threshold. CONCLUSIONS: New products need robust broader population and subgroup analyses for insurance coverage.

PHP18
THE EFFECT OF LAW FOR ECONOMICAL USE OF MEDICATIONS 2006 ON THE CATCHMENT POPULATION OF ONE PHARMACY IN HUNGARY BETWEEN 2007-2010
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OBJECTIVES: In 2006 a law for the economical use of medications was introduced into the Hungarian legislation. This law – among others – facilitated the foundation of new pharmacies. The aim of our study is to analyse the effect of that legislation on the catchment population of community pharmacies. METHODS: Data were derived from the pharmaceutical database of the Hungarian Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analysed the 5 years period between 2006-2010. The main indicator of our analyses is the average population of one pharmacy (catchment population) in the counties of Hungary. RESULTS: The average catchment population of a pharmacy was 4933 inhabitants (= 592, standard deviation, SD) in 2006, while in 2010 it decreased to 3 888 (± 450) inhabitants per pharmacy. We found the largest catchment popula-
tion in 2006 in the following counties: Vas (6,326 inhabitants/pharmacy), Pest (5,913 inhabitants/pharmacy), and Nógrád (5,855 inhabitants/pharmacy), while the smallest: Bács-Kiskun (3,225 inhabitants/pharmacy), Békés (3,458 inhabitants/pharmacy) and Somogy (3,441 inhabitants/pharmacy) had the lowest. CONCLUSIONS: Between 2007-2010, as the consequence of the increasing number of pharmacies, the average catchment population of pharmacies decreased significantly. The regional differences among counties did not change during the study period and remained high.

PHE1
COMPREHENSIVE VALUE ESTIMATION OF ADALIMUMAB-BASED TREATMENTS: COVET STUDY
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OBJECTIVES: The value of a drug can be expressed as cost needed to increase a unit of health. However, summarizing the economic value of a molecule with multiple implications is a complex process. The COVET study was conducted to facilitate a comprehensive economic evaluation of adalimumab across all approved indications. METHODS: An algorithm was developed to estimate the total economic value of adalimumab. This value was calculated as the sum of the incremental cost-utility ratios for treating rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, and psoriasis from an Italian National Health Care (NHC) perspective. Estimates of the cost per quality-adjusted life year (QALY) gained by using adalimumab instead of standard therapy were derived from previously developed economic models. The sum was weighted by the prevalence of each of the diseases considered. Through a systematic literature review, the cost per QALY gained was extrapolated. Using a Boston matrix was developed to establish the relationship between demand and health supply. A one-way sensitivity analysis (SA) performed to assess the robustness of the results. RESULTS: The total economic value of adalimumab in Italy amounted to €34,700 per QALY gained. The sensitivity analysis showed a cost per QALY gained ranging between €27,447 and €40,412. The analysis of the Boston matrix indicated that, with the exception of psoriasis, the cost per QALY gained by using adalimumab instead of standard therapy was below the common WTP threshold. In comparison with innovative molecules, the total economic value of adalimumab was positive and sustainable. CONCLUSIONS: This study provides an estimate of the cost-effectiveness of adalimumab across all approved indications that is below the threshold value for health care interventions. The results should encourage decision makers to facilitate patient access to this cost-effective treatment. They may also promote research to develop innovative molecules that are even more cost-effective.

PHP2
PHARMACOVIGILANCE IN QATAR – A PHARMACIST SURVEY
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OBJECTIVES: Active domestic pharmacovigilance programs are necessary as adverse drug reaction (ADR) data from other countries may overlook safety patterns in local populations. The success of any surveillance system relies upon active participation of reporters. The objective of this study was to describe pharmacist reporting of suspected ADRs in Qatar to inform policy recommendations to the Supreme Council of Health. METHODS: A 27-item survey was developed following comprehensive literature review of relevant published research. Questions encompassed broad domains including pharmacist knowledge of and experiences in reporting suspected ADRs, attitudes towards health professional pharmacovigilance roles, perceived barriers and facilitators to reporting, and recommendations for improvements in this process. The web-based survey was formatted for electronic delivery and response for self-administration in English or Arabic by a convenience sample of over 500 Qatar pharmacists. RESULTS: The survey remained open for two months between April 30 and June 30, 2011. Of the 142 (25%) total responses, 116 (81.6%) surveys were completed beyond demographic data and included information about prior suspected ADR reporting experiences. Knowledge of ADR terminology and reporting purpose among the 116 (20%) responding pharmacists was high, but only 34 (30%) had ever made a suspected ADR report in Qatar. Most respondents expressed positive attitudes towards pharmacist roles in pharmacovigilance activities, but inability to recognize a potential ADR or subsequently accessing a reporting form were perceived barriers, with enhanced training and efficacy in report submission corresponding identified facilitators to future participation. Hospital pharmacists were 7 times more likely than ambulatory-care based pharmacists to have reported a suspected ADR in Qatar. CONCLUSIONS: Pharmacists are more likely to engage in pharmacovigilance activities if supported by increased training and transparency in the reporting process. A national infrastructure with capacity to collect and manage suspected ADR reports and promote patient and medication safety is exigent.

PHP3
THE EARLY BENEFIT ASSESSMENT OF NEW PHARMACEUTICALS IN GERMANY (“AMNOG”): A STRUCTURED SURVEY ANALYSIS ONE YEAR AFTER ENACTMENT
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OBJECTIVES: In January 2011, the act for restructuring the pharmaceutical market (“AMNOG”) was introduced in Germany. We analyzed the effects one year after AMNOG’s implementation in a descriptive study. The research focused on surveying affected stakeholders, systematically summarizing their experiences, and identifying the main conundrums of controversy. METHODS: A structured survey with 42 questions and an open-ended question was developed based on statements during the AMNOG legislation: Payors, Pharmaceutical Industry, National Regulatory Bodies, Scientific Experts, Patients, Care Providers, Politicians, Pharmacies and External Service Providers. The benefit assessment process was structured in 6 topics: Market Access, Early Benefit Assessment, Arbitration Procedure, Arbi- tration, Arbitration Procedure, Cost-Benefit Analysis and Process. 45 experts participated in the structured survey (26% response rate), which consisted of closed questions supplemented by optional open-ended questions (total 47 items). Descriptive statistical and dissimilarity analyses were performed. RESULTS: Between the 9 stakeholder groups, several items were highly controversial: negotiation position of statutory health insurances (“GKV-Spitzenverband”) in rebate level negotiations (distance index L1 = 1.17), use of European price reference in the arbitration process L2 = 1.08) and several others such as transparency of the benefit assessment process L3 = 0.95. Different response profiles were observed between stakeholders but they yielded relatively low dissimilarities on cost-benefit assessment.