results. **CONCLUSIONS:** The current study extends the evaluation into Europe to confirm that as reimbursement decision makers continue to rigorously review new drug therapies, accurate, robust, peer-reviewed published and generalisable real-world data will become particularly important for outcomes- or performance-based access schemes and health care budget management both in the US and Europe.

PHP38

THE SURVEY OF THE JAPAN-STYLE PREMIUM SCHEME IN PHARMACEUTICAL PRICING DECISIONS

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OBJECTIVES: To review the new drugs which were listed in the past on the Medical Fee Schedule of Japan, and to clarify the profile of the quasi value-based pricing in the Japan-style premium scheme. **METHODS:** The information on pricing decisions with premium was searched, extracted, and analyzed from the government documents open to public on the website of the Ministry of Health, Labour and Welfare in Japan. The four drug categories were focused due to data availability: 1) antihypertensive; 2) antidiabetic; 3) antibiotic; and 4) psychotropic, listed from April 1998 through April 2013. The information relevant to the premium decision included listing dates, drug prices, premium categories, premium rates, and also clinical evidence that could be associated with the premium decision. **RESULTS:** Among total 106 of new drugs, 27 have been identified with premium, whilst 79 with no premium. For each category, there existed 12 antihypertensive (single agent), 25 antidiabetic, 52 antibiotic, 17 psychotropic. That is, the acquisition rate of premium for each category was 17%, 20%, 31% and 24%, respectively. The high proportion, 85%,of the rewarded premium categories was recognized in the category of "Usefulness II", i.e., the 3rd ranked premium, while only one drug obtained the premium of innovativeness, the highest ranked premium. Regarding the benefit associated with the premium, both of clinical and humanistic outcomes seemed to be accepted for decision-making although the criteria for the decisions were not clearly indicated. **CONCLUSIONS:** The profile of the Japan-style premium scheme was clarified based on the survey over the new drugs listed in 1998 to 2013. The information extracted in our study will be useful for further investigations to improve the Japanese quasi value-based pricing methods.

PHP39

THE STRUCTURE AND PROCESS OF WORK OF SPANISH REGIONAL COMITTEES ASSESSING MEDICINES: PRELIMINARY RESULTS

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OBJECTIVES: Spain has a decentralized health care systems with several levels of decision-making. After a drug is approved by the Spanish Agencia del Medicamento, regional committees (RC) conduct evaluate and assess those drugs for their use in ambulatory settings making recommendations to health professionals within its territory. The objective of this study is to analyze the structure and process of work of those RC. **METHODS:** RC were contacted by phone and informed about this study. A web based questionnaire was ellabored including questions on: 1) General information of the RC; 2) Procedure of work of RC; and 3) Criteria used for the selection of medicines to asess and the procedures followed to. A link was sent by email to contact persons of the RC of the Spanish 17 Autonomous Comunities (AC). **RESULTS:** To this date 10 RC (59%) have submitted their answers and 3 regions (18%) have responded indicating the absence of this type of structure or process in their region. These 3 regions, though, make recommendations usually conducting their own assessments or using assessments conducted by other regions. 7 RC have a normalized process of work (5 is open to the public). 8 RC have more than 8 members. All RC evaluate medicines prescribed for outpatients purchased through pharmacies (5 of them exclusively), and 5 conduct also assessments of drugs used in hospitals. 9 RC use as comparator the standard treatment for a given indication. Economic evaluation is performed through budget impact (6 RC), cost-effectiveness (5 RC); and cost-minimization (2 RC). 6 RC make public their assessments through public web pages and 2 using electronic bullletins. **CONCLUSIONS:** Preliminary data indicate that the majority of Spanish regions conduct their own drug assessments, and most of them have established RC, whose structure and process of work show some variability and indicate certain degree of duplication.

PHP40

CROATIA'S EU ACCESSION IN THE CONTEXT OF INTERNATIONAL REFERENCE PRICING: WHAT WILL BE THE WIDER IMPACT FOR PRICING AND REIMBURSEMENT?

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OBJECTIVES: To assess the implications of Croatia's accession to the European Union for the pricing and reimbursement landscape both in Croatia and other EU member states, focusing on international reference pricing. **METHODS:** Changes to Croatia's laws governing drug pricing and reimbursement were examined in detail, in relation to their likely effects on drug prices in Croatia and in other EU member states through international reference pricing. The IHS International Reference Pricing Matrix was used to determine impact of Croatian prices on other markets likely to include Croatia in their reference pricing basket. Interviews were conducted with representatives of the pharmaceutical industry in Croatia, and regulators in Croatia and other EU member states, to gauge their views. **RESULTS:** The existence of comparatively low prices of medicines in Croatia is likely to result in some downward pressure on pricing in countries which include all EU countries in the IRP basket of countries. However, this impact is not likely to be felt immediately, and only for the few therapeutic areas where Croatia's prices are among the lowest in Europe. Changes to Croatia's international reference pricing basket are unlikely to result in any great changes, although in certain areas, price reductions can be expected. **CONCLUSIONS:** Some downward pressure on prices in other EU markets is likely as Croatia becomes a reference market for IRP, although this is likely to be limited in scope in the short term, with only particular products and therapeutic groups affected. Over the longer term, as more markets add Croatia to their reference-pricing baskets, this pressure is likely to intensify.

PHP41

GENERIC SUBSTITUTION IN IRELAND – THE VIEWS OF KEY STAKEHOLDERS

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OBJECTIVES: The Health (Pricing and Supply of Medical Goods) Act 2013 passed in June 2013 provides for generic substitution in Ireland. The aim of the study was to ascertain the views of the stakeholders i.e. patients, pharmacists and prescribers on generic substitution,prior to the Act's introduction. **METHODS:** Three stakeholder specific surveys were developed to assess knowledge of and attitudes to generic substitution. Convenience samples of health care professionals and patients were gathered until data saturation was achieved. Descriptive quantitative and qualitative analysis was undertaken. **RESULTS:** A total of 742 health care professionals and 330 patients responded. The study highlighted 4 areas where prescribers and pharmacists differed; (1) Prescribers ranked cost-savings as the most important information to impart to patients while pharmacists advocated therapeutic equivalence as highest. (2) Pharmacists considered that more patients would be agreeable to generic substitution (52%) as compared to 41% of prescribers. (3) Prescribers considered that generic substitution would have a greater effect (25%) on patient care than pharmacists (14%). (4) 19% of prescribers supported generic substitution in all cases and 76% with some exceptions, compared to 16% and 84% for pharmacists respectively. More than 80% of patients were on between 1 and 8 medicines daily, and of these >50% reported that they were on generic medicines. More than 80% would be happy with generic substitution, while more 75% of those interviewed considered generic drugs to contain the same drug, to be as effective and as safe as branded medicines. **CONCLUSIONS:** To prevent possible confusion and concern among patients it is important that health care professionals acquire the necessary tools and knowledge to manage transition into and rollout of this new system, so that they can work together to ensure the obvious benefits of the new system are maximised.

PHP42

AN ANALYSIS OF PRISCRIPTION AND REIMBURSEMENT OF POTENTIALLY INAPPROPRIATE MEDICATION (PIM) IN A GERMAN PRACTICE NETWORK

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OBJECTIVES: Potentially inappropriate medication (PIM) in the elderly increases the risk of adverse drug reactions (ADR) and consequently has an impact on both patients' quality of life and health care costs. In 2010, the PRISCUS list was published in Germany to identify PIM and to propose adequate substitution medication. The objective of the study was to assess both the prevalence and reimbursement of PIM in a German practice network applying the PRISCUS list. Moreover, costs for proposed surrogates were evaluated. **METHODS:** Patients fulfilling the following criteria were included: (1) insured at the local health fund AOK Bavaria, (2) treated by physicians of the practice network, and (3) aged ≥65. Data was provided from AOK Bavaria and contained 214,177 anonymized prescriptions between Q1/2009 and Q4/2011. Information included age, gender, date of prescription and ATC-Code. Since no information on dosage or package size was given, medication and its application duration were differentiated in acute and long-term medication by expert opinion. Costs were calculated by applying the concept of DDD. **RESULTS:** On average, 16.0% of the patients received at least one PIM prescription each quarter. 13,736 prescriptions were classified as PIM (6.4%; 68.7% to women). Out of these, psycholeptics such as Zopiclon (11.8%) and calcium antagonists such as Nifedipin (7.9%) were prescribed most frequently. Total costs of PIM-prescriptions were calculated to be 446,430€ (mean 40,585€ per quarter; min. 32,869€; max. 50,024€). When assuming prescription of surrogates, costs varied between 267,990€ and 935,826€. **CONCLUSIONS:** PIM represents both a medical and economic burden to the German health care system. From an economic perspective, substitution of PIM may result in cost disadvantages. Thus, there is little economic incentive for health insurances to further promote the substitution of PIM. Future research should take a broader perspective and include costs of PIM-related ADR to fully evaluate the economic impact of PIM in the elderly.

PHP44

HOW DOES PRESCRIPTION OF GENERIC DRUGS SPREAD OUT?: DATA MINING AND VISUALIZATION BY USING PRESCRIPTION DATA FORM ACUTE CARE HOSPITALS NATIONWIDE

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OBJECTIVES: To clarify the spread with prescription of generic drugs and the shift from brand drug market by using nationwide administrative data. **METHODS:** For the sample, out of 30 drugs seen as the parameter for generic drugs in France, 27 have been selected after considering their availability in Japan. For those drugs unapproved in Japan, they were replaced by other drugs with the same effects, and anticancer agents as well as radio contrast agents were added. New drugs listed to National Health Insurance list around the same time were also included for comparison. Database was created by extracting the data of patients who were