is overlap in the criteria to qualify for funding. Many countries consider drugs for additional funding if a drug can be used in more than one indication and cannot be grouped to a specific DRG. Other criteria identified relate to, for example, drug prices and indications. Some countries grant additional reimbursement for drugs prior to assessment by a national reimbursement process, while others only grant general reimbursement after the drug has been available for a certain period of time and funding decisions are based on historical data. In most countries, additional reimbursement is considered annually. Hospitals and expert groups can suggest additional reimbursement for expensive drugs to the responsible authority.

CONCLUSIONS: Many countries have adapted to the need for additional funding for expensive drugs, and have established systems to grant this funding to hospitals. There are differences in criteria to qualify for, and timelines for receiving, additional funding after drugs are launched.

PHP148
Pay-for-performance: balancing cost and care
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OBJECTIVES: Initiatives aimed at improving both the quality and efficiency of United States health care are commonly grouped under the broad category of “pay-for-performance” (P4P) programs. Typically this programs award bonuses to providers that attain pre-determined quality and cost goals, but may also impose financial penalties on those that fail to meet those goals. Funded by the Affordable Care Act, P4P programs have recently expanded significantly within the public sector and are expected to grow. This project was designed to review Medicare P4P cost measures, using the implications for providers and recommend possible alternatives. METHODS: Two P4 programs, both well known under the health reform law and having potential to impact a large portion of the Medicare population were reviewed: 1) Medicare Accountable Care Organizations (ACOs), and 2) the Physician Value Based Payment Modifier (VBBP). Each program’s cost measurement components and calculation methodologies were isolated, described and evaluated for the likely impact on providers. RESULTS: A number of differences were noted, including: (1) for the ACO and VBBP programs are based on payments made under Medicare Part A (Hospital Insurance) and Medicare Part B (Supplemental Insurance) but do not include Medicare Part D (Prescription Drug Benefit) costs. Whether performance is measured against the provider’s historic costs, or compared to national benchmarks, only Medicare Parts A and B costs are included. CONCLUSIONS: Medicare Part D costs are not included in the cost measure calculation, thereby eliminating marks, only Medicare Parts A and B costs are included.

PHP149
Review of Pricing and Reimbursement Systems in South-Eastern Europe
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OBJECTIVES: To provide an up-to-date description and comparative analysis of pricing and reimbursement policies in South-Eastern Europe (SEE), and to identify factors influencing reimbursement decisions. METHODS: Payers and decision makers in Slovenia, Croatia, Romania and Bulgaria were interviewed by questionnaire. An additional interview was conducted with a covered country legislation and policy expert (Published 2009–2014), and relevant documents from web sources including national hospital insurance funds, drug agencies, ministries of health, Eurostat, pharmacoeconomic databases, and conference proceedings. RESULTS: The four countries spent 5.1–8.8% of gross domestic product on health in 2012. Price controls are commonly used, applied via negotiation with marketing authorisation holders or directly through the application of copayments. Key policies are based on international and internal reference pricing. Bulgaria, Romania and Slovenia base pricing on the lowest manufacturing or retail price, while Croatia uses average price. Reimbursement requires demonstration of clinical and economical benefits over current standard therapy. When the importance of benefits are recognised and recommendations from reference health technology assessment authorities in Europe are published, budget impact analyses focusing on key drivers such as target population and price are applied. Cost containment mechanisms are also applied, including net price negotiation, rationing, decision postponement, payback, clawback and risk sharing, with the aim of protecting overall budgets. Legislative changes to pricing and reimbursement systems are very common. Out-of-pocket expenses in Romania and Bulgaria are among the highest in Europe, while the reimbursed retail price difference is largely covered by supplementary insurance in Slovenia and Croatia. CONCLUSIONS: The middle/lower income SEE countries use reference pricing, and have some of the lowest prices in the European Union. Reimbursement of innovative drugs is restricted, there are downward trends in pricing, and risk-sharing agreements based on outcomes are finance-driven.

PHP150
Pricing and Reimbursement Environment for a Biologic Obtaining a License in a Second Indication in European Countries
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OBJECTIVES: To gain a better understanding of the pricing and reimbursement processes and systems, including agreements at national, regional, and local levels with regards to a biologic obtaining a license in a second indication in the UK, France, Italy, and Spain. METHODS: In countries with a large national system (UK, France), five telephone interviews were conducted, and in Italy and Spain there were also local or regional systems. 17 and 18 interviews, respectively, were conducted. Stakeholders included payer-advising clinicians, hospital administrators and pharmacists, regional payers/health insurers.

RESULTS: In the UK and France, pricing and reimbursement is agreed at a national level, with few restrictions at regional and local levels. In the UK, NHS England is likely to be responsible for funding of new biologics and relies on guidance from NICE before adopting a product in a new indication; therefore, demand for a high-risk cost-effective drug in Thailand, there is no price discrepancy commission is important; funding usually is through the coverage guidelines of the NICE. In addition to demonstrating clinical benefits, pharmacoeconomic studies may be required for high-cost drugs. In contrast, in Italy, although AIFA needs to approve a new product on a national level, subsequent requirements vary by region and sometimes specific location. Similarly, in Spain, once approved nationally, regions develop their own recommendations, and local decisions are made by hospital formularies. Evidence requirements in Italy and Spain vary at a national, regional, and local levels.

CONCLUSIONS: A biologic obtaining a license in a new indication must undergo the same procedure as a new product. The process and restrictions for biologics may be stricter than for other medications due to the perceived high cost. The level of national, regional, and local requirements and restrictions varies; it is important that appropriate evidence is submitted to decision makers at each level.

PHP151
Cost and Quantity Characteristics of Medical Devices in Slovakia
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OBJECTIVES: Medical devices, together with pharmacotherapy are supportive treatments for acute and chronic diseases. The place of their dispensing and direct sale is the dispensers of medical devices. Many medical devices are reimbursed from public health insurance funds entirely, for others, particularly advanced functional types of medical devices provided to medical institutions the tendering procedure of reimbursed medical devices from public health insurance funds amounted $n$ monthly packages $=8.1$ mil and $n$-value% = $12.7$ mil €. The highest shares had the group medical devices for incontinence and urinary retention $n$-package $=7.7$ mil, $n$-package $=86.9$, $n$-value% $=3.9$ mil, $n$-value% $=30.9$, the group planters and bandaging materials $n$-package $=0.5$ mil, $n$-package $=6.1$, $n$-value% $=2.6$ mil, $n$-value% $=10.2$) and medical devices for ostomates $n$-package $=0.4$ mil, $n$-package $=4.6$, $n$-package $=6.1$, $n$-value% $=1.6$ mil, $n$-value% $=5.9$) Direct to the sale of medical devices for diabetes $n$-package $=0.5$ mil, $n$-value% $=7.8$ mil and $n$-value% $=1.1$ mil €. The highest shares had the group medical devices for incontinence and urinary retention $n$-package $=5.7$ mil, $n$-package $=50.3$, $n$-value% $=26.2$, the group planters and bandaging materials $n$-package $=3.5$ mil, $n$-package $=30.9$, $n$-value% $=2.0$ mil, $n$-value% $=20.4$) and medical devices for diabetics $n$-package $=0.5$ mil, $n$-package $=4.5$, $n$-package $=0.7$ mil, $n$-value% $=7.3$.

CONCLUSIONS: Medical devices are reimbursed from public health insurance funds or paid by patient and their proportion constitutes 7.1% in packages and 11.1% in EUR.

PHP152
The Greek health care reform after troika’s involvement: the potential impact on global pricing and access strategy
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OBJECTIVES: Troika’s measures to support Greece’s financial recovery have targeted all sectors of economy including health care. Since 2012, policy reforms have changed the way health care is funded, managed and delivered, and how pharmaceuticals are priced, accessed and reimbursed. This study examines the changes to the Greek system and tries to understand the wider possible impact on global pricing and access strategies. METHODS: To better understand the recent reforms we conducted a literature review of public domain sources, including the Greek Government Gazette, PubMed and other websites. Searches were conducted in English and Greek-language, and materials were translated into English. From our findings a road map diagram was developed, and this was validated by interviews with health policy experts. RESULTS: Part of troika’s campaign to reduce public spending has seen the Greek government focus on pharmaceutical markets and introduce policies to contain costs. The drug budget for 2014 has been cut to 2 billion euros, a billion lower than 2013. Considerable price cuts have been agreed on both novel and generic agents on top of lobbys and rebates for high cost drugs. Prescribing is controlled through electronic prescription and physician budget caps. Introduction of price-volume agreements and risk sharing schemes are being considered, however the infrastructure to support implementation is still under development. Demonstrating value by health economics and outcomes research can still help manufacturers to achieve premiums. CONCLUSIONS: With a small population and an ever-decreasing reimbursement budget, the responsibility to overlook Greece when developing a product launch strategy. However, with Greek drug prices being referenced by several EU and non-EU countries, ignoring Greece means the manufacturer would not be an option, especially UK considering the potential impact on the big prices EU. Understanding the reforms and assessing the impact on launch sequencing will be key in developing optimal pricing strategies.

PHP153
Swisswhita recommendation as an optimal approach for pragmatic HTA evaluations? An international comparison
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OBJECTIVES: Switzerland’s regulation of prices for reimbursed drugs is based on referencing across countries and within the therapeutic class for products with comparators. The SwissHTA initiative involving all key stakeholders in the health care systems (sickness funds, industry, physicians, academia, Kanton) has published consensus papers for new benefit criteria and measurements. METHODS: A comparative analysis based on the cost-effectiveness assessments in HTA systems in Germany and the UK. RESULTS: In terms of clinical benefit assessment the suggestion by SwissHTA follows accepted evidence-based methodology. In Germany the cost-effectiveness analysis is a prerequisite for market registration also for products with less than half of all product recalls. Therefore, FDA’s concern regarding low quality products and the increase in adverse event reports due to medical devices and recalls may reflect quality flaws. While some of this increase can be explicated by FDA’s greater outreach emphasizing reporting requirements, failure to product design and manufacturing process cause more than half of all product recalls. Therefore, FDA’s concern regarding low quality product- unts remains. In the EU, medical device pre-market quality is assured by CE mark authorization. This regulation is the prerequisite for product registration also for Turkey. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance. METHODS: This study investigates whether post-market quality assurance (measured by less adverse events/better health outcomes) can be accessed through local reimbursement policies. First, it is investigated whether there are reimbursement rules in Europe acting as post-market quality assurance. Then, a comparison is made with Turkey’s existing reimbursement scheme. RESULTS: Our comparative analysis reveals only Belgium and France implement quality or cost-effectiveness assessments allowing for context-specific adjustments. In the SwissHTA recommendation a multi-criteria decision-making should be applied with an equal focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.). CONCLUSIONS: In comparison to HTA systems in Germany and UK the SwissHTA recommendations seem to be more pragmatic and would follow a broader multi-criteria decision making approach.

PIHP14

PRODUCTIVITY ASPECT IN REIMBURSEMENT OF MEDICAL DEVICES: COMPARISON OF TURKEY VERSUS EUROPE

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Objectives: FDA has long recognized that dramatic increase in adverse event reports due to medical devices and recalls may reflect quality flaws. While some of this increase can be explicated by FDA’s greater outreach emphasizing reporting requirements, failure to product design and manufacturing process cause more than half of all product recalls. Therefore, FDA’s concern regarding low quality products uncts remains.

In the EU, medical device pre-market quality is assured by CE mark authorization. This regulation is the prerequisite for product registration also for Turkey. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance.

Methods: This study investigates whether post-market quality assurance (measured by less adverse events/better health outcomes) can be accessed through local reimbursement policies. First, it is investigated whether there are reimbursement rules in Europe acting as post-market quality assurance. Then, a comparison is made with Turkey’s existing reimbursement scheme.

Results: Our comparative analysis reveals only Belgium and France implement quality or cost-effectiveness assessments allowing for context-specific adjustments. In the SwissHTA recommendation a multi-criteria decision-making should be applied with an equal focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.).

Conclusions: In comparison to HTA systems in Germany and UK the SwissHTA recommendations seem to be more pragmatic and would follow a broader multi-criteria decision making approach.

PIHP15

A COMPARISON OF ADDITIONAL BENEFIT SCORES IN GBA (G-BA) AND FRANCE (HAS)

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Objectives: The Pharmaceutical Health Technology Assessment in Germany (G-BA) and France (HAS) assesses the additional benefit of the drug, compared to an appropriate therapy. AMNOG law is perceived to be one of the toughest drug evaluation processes in Europe. The G-BA assesses the additional benefit of the drug, compared to an appropriate therapy. AMNOG law is perceived to be one of the toughest drug evaluation processes in Europe.

Methods: The G-BA assigned an additional benefit (scores from 1 to 4) to more than half of drugs whereas the HAS assigned an additional benefit rating to less than 14% of case. This study suggests that there is a more favourable benefit rating in Germany than in France.

RESULTS: In Germany, a total of 76 completed early benefit assessments. From the best available score perspective, the G-BA assessed the additional benefit as considerable in 20% of drugs assessed (score 2), as minor in 30% of drugs assessed (score 1), as unquantifiable in 22% of drugs assessed (Score 4) and none in 38% of drugs assessed (Score 5). No drug has been granted a major additional benefit (score 3) and 4% of drugs were directly allocated to a reference price group. In France, the majority committed to minor improvements in 9,2% of cases (IAB 5), an important improvement in 1,3% of cases (IAB II), a moderate improvement in 2,5% of cases (IAB III), a minor improvement in 9,2% of cases (IAB 4) and no clinical improvement in 86,8% of cases. From the best available score perspective, the G-BA assigned an additional benefit (scores from 1 to 4) to more than half of drugs whereas the HAS assigned an additional benefit rating to less than 14% of case. This study suggests that there is a more favourable benefit rating in Germany than in France.

CONCLUSIONS: This study showed that the G-BA showed that the rebate was significantly reduced by 13% for products that demonstrated additional benefit.

PIHP16

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