

is overlap in the criteria to qualify for funding. Many countries consider drugs for additional funding when 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 additional 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 these 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. Fueled 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, discuss the implications for provider prescribing patterns, and recommend possible alternatives. **METHODS:** Two P4P programs, both well known under the health reform law and having potential to impact a large portion of the Medicare population, were evaluated: 1) Accountable Care Organizations (ACO), and 2) the Physician Value Based Payment Modifier (VBPM). Each program's cost measure components and calculation methodologies were isolated, described and evaluated for the potential to influence prescribing patterns. **RESULTS:** Cost measures for the ACO and VBPM 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 prescription drug expense from the performance rating. This methodology may encourage providers to shift Part B drug costs to Part D, thus limiting patient access to therapies that may only be covered under Medicare Part B.

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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 literature survey covered country-specific legislation and publications (PubMed 2009-2014), and relevant documents from web sources including national hospital insurance funds, drug agencies, ministries of health, Eurostat, pharmacoeconomic and outcomes research conference proceedings, the Organisation for Economic Co-operation and Development, and Business Monitor International. **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 indirectly 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 pricing. 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 KEY EUROPEAN COUNTRIES

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OBJECTIVES: To gain a better understanding of the pricing and reimbursement processes and evidence requirements 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 largely national system (UK, France), five telephone interviews were conducted; as Spain and Italy also have local and regional systems, 17 and 18 interviews, respectively, were conducted. Stakeholders included

payer-advising clinicians, hospital administrators and pharmacists, regional payers, and local payers. **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, demonstrating cost-effectiveness is key. In France, the ASMR issued by the transparency commission is important; funding usually is through the *groupe homogène de séjour*. 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 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.

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COST AND QUANTITY CHARACTERISTICS OF MEDICAL DEVICES IN SLOVAKIA

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OBJECTIVES: Medical devices, together with pharmacotherapy are supportive treatment of many acute and chronic diseases. The place of their dispensing and direct sale is the dispenser of medical devices. Many medical devices are reimbursed from public health insurance funds entirely, for others, particularly advanced functional types of medical devices, there must the patient participate on the price or he can buy them according own decision. **METHODS:** The target of the work was to analyse the data from paid databases of Slovak authority National Center for Health Information that collects the outputs of provided health care services. The most recent data were from 1.1. - 30.9.2014. **RESULTS:** Referring to the Center for Health Information until 30.9.2013 there were 226 registered establishments that sell medical devices. Their specialization were dispenser of medical devices (n=163), dispenser of orthopedic devices (n=48) and dispenser of audioprothetic devices (n=15). Expenditure of reimbursed medical devices from public health insurance funds amounted n-monthly packaging=8,8mil and n-monthly value=12,7 mil €. The highest shares had the group medical devices for incontinence and urinary retention (n-packages=7,7 mil, n-packages%=86.9, n-values=3,9 mil €, n-value%=30.9), the group plasters and bandaging materials (n-packages=0,5 mil, n-packages%=6.1, n-values=2,6mil €, n-value%=10.2) and medical devices for ostomates (n-packages=0,4 mil, n-packages%=4.6, n-values=1,6 mil €, n-value%=8.1). Direct sale of medical devices to the patients reached n-monthly packaging=0,9 mil and n-monthly value=1,1mil €. The highest shares had the group medical devices for incontinence and urinary retention (n-packages=5,7 mil, n-packages%=50.3, n-values=2,6 mil €, n-value%=26.2), the group plasters and bandaging materials (n-packages=3,5 mil, n-packages%=30.9, n-values=2,0 mil €, n-value%=20.4) and medical devices for diabetics (n-packages=0,5 mil, n-packages%=4.5, n-values=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.

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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 clawbacks 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 expenditure on health care, it is tempting 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 may no longer be an option, especially when considering the indirect effect on the big EUS prices. Understanding the reforms and assessing the impact on launch sequencing will be key in developing optimal pricing strategies.

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SWISSHTA RECOMMENDATION AS AN OPTIMAL APPROACH FOR PRAGMATIC HTA EVALUATIONS? AN INTERNATIONAL COMPARISON

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