tions on epidemiological data; 12 specified that the uncertainty surrounding epidemiological data should be addressed, especially in terms of the transferability of international data. The party responsible for the conduct of the analysis (therefore responsible for providing the epidemiological data) was named by 20 guidelines, of which 14 explicitly referred to the marketing authorization holder. Furthermore, an acceptable level of evidence was mentioned only by 4 guidelines (Australia, Austria, Poland, and Scotland) and included surveys, registers, databases and experts' opinions. The relevance of epidemiological data for final reimbursement decisions was explicitly mentioned by 5 guidelines (Australia, Israel, Russia, Scotland, and South Africa). However, consequences for unacceptable epidemiological evidence (i.e., cases not following recommendations or requirements) were only indicated by Russia and Scotland in the form of refraining from giving positive reimbursement advice. **CONCLUSIONS:** Population-level epidemiological data is mentioned in 77% of the guidelines, but those focus mostly on issues of data transferability. Only few countries (19%) address the role of population-level epidemiological data for reimbursement decisions. To reduce decision uncertainty, approaches to address the often occurring paucity of epidemiological evidence should preferably be part of all pharmacoeconomic guidelines.

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ENSURING THAT PHASE III PROGRAMS ARE DESIGNED TO MEET THE EVOLVING HTA REQUIREMENTS ACROSS THE EU5

Lucas F[1], Secker-johnson R[2]
[1]*Pope Woodhead and Associates, St. Ives, UK,* [2]*Cambridge University, Cambridge, UK*

OBJECTIVES: We investigated commonalities and significant differences in HTA evidence requirements in the EU5 (Germany, France, UK, Italy and France) and the implications on phase III programmes, focusing on three key, rapidly evolving elements of HTA: choice of the comparator, Health-Related Quality of Life (HRQL) and effectiveness. **METHODS:** In-depth, semi-structured 60-min telephone interviews were undertaken with 34 HTA experts across the EU5 (17 from HTA bodies and Academia, 17 from pharma). **RESULTS:** An active comparator in phase III is mandated or clearly preferred in all EU5 countries for HTA/payer purposes. It tends to be the therapy most commonly used in clinical practice, although best practice or cheapest therapy may be selected. Countries vary in the degree of flexibility in the approach to comparative evidence. UK appears to be the most flexible in the choice of comparator and acceptance of indirect evidence. Germany is the most demanding (e.g. head-to-head data vs. multiple, specific comparators for multiple sub-populations). HRQL is increasingly important in HTA, yet all respondents agreed that, in practice, HRQL is still only supportive to 'hard' end-points such as morbidity and mortality. Challenges in capturing HRQL as a measure of clinical benefit and/or a way to derive utilities, were discussed. Demonstrating effectiveness is becoming increasingly relevant to HTA, although efficacy data from phase III trials still have the major role – the greatest challenge is the generalisation of results to the wider, real-world patient population. Countries differ in their flexibility to addressing the demonstration of effectiveness. **CONCLUSIONS:** Increased, and sometimes contradictory, HTA-driven demands for evidence place strain on phase III trials. Hopefully, as Germany, the UK and France .adapt their processes, and Spain and Italy develop fuller capability, harmonisation of core HTA requirements will enable pharma to design more efficient evidence programmes. Suggestions derived from this research will be presented.

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TIME TO MARKET ACCESS FOR INNOVATIVE DRUGS IN THE UK, FRANCE, AND BELGIUM

Maervoet J[1], Toumi M[2]
[1]*Deloitte, Diegem, Belgium,* [2]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: It is often considered that the UK grants access to new medicines upon marketing authorisation (MA) approval, while patients in countries such as France or Belgium gain access only after significant delays. The objective is to quantify differences in time to market access between the UK (excluding Scotland), France and Belgium and to identify contributing factors. **METHODS:** We reviewed submission and approval dates for all new chemical or biological entities that were granted a MA by the European Commission (EC) between August 2006 and July 2011. Generics, fixed dose combinations, new formulations, and vaccines were excluded. Information was collected from official health authority sources (i.e. regulatory, health technology assessment, and pricing agencies; official journals; national formularies). Results are presented as median days pre- and post-marketing authorisation (MA was defined as day 0). **RESULTS:** For the 111 drugs we identified, EC approval was granted a median of 428 days after submission of the application and 64 days after the Committee for Medicinal Products for Human Use issued a positive opinion. A first analysis suggested more drugs were marketed in England (n=97), than in France (n=74) or Belgium (n=62). NICE guidance, however, was only issued for 29 products (21 positive opinions) after a median of 399 days following MA. In France and Belgium, ministerial reimbursement decisions were published in the Official Journal after 279 and 348 days, respectively. The time needed for Belgian companies to submit a reimbursement dossier was variable (median: 68 days; IQR: 21-235 days after MA). **CONCLUSIONS:** As product uptake is negligible until NICE issues a positive guidance, English patients have access to only a limited number of innovative drugs. French authorities appear to grant access to more products and have shorter review timelines than their Belgian and English counterparts. Dossier submission timelines may contribute to delays in Belgium.

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MARKET ACCESS OF DRUGS IN FRANCE AND MEDICO-ECONOMIC ASSESSMENT

Rémuzat C[1], Toumi M[2], Aballea S[3]
[1]*Creativ-Ceutical France, Paris, France,* [2]*University Claude Bernard Lyon 1, Lyon, France,* [3]*Creativ-Ceutical, Paris, France*

OBJECTIVES: Describe and analyze the impact of the recognition of the Economic and Public Health Assessment Committee (CEESP) as an official committee, part of the French National Authority for Health (HAS), within the new code of social security for drug market access. **METHODS:** We browsed website of French government, reviewed grey literature relating to the introduction of health economic criteria in the recommendations of the CEESP and interviewed decison makers. **RESULTS:** The remit of CEESP is to determine efficient strategies and edit recommendations to support price negotiations. Products eligible for economic assessment will be selected based on criteria to be defined and some areas of uncertainty remain to be addressed. (1) Criteria for product selection: all products that state innovative improvement, product with sales above €10 million per year, new mode of action and products with potential extension of target population are likely to be assessed; orphan designated product are not. At time of approval, the scope of assessment will be relatively narrow and outstanding questions addressed during reassessments 3 to 5 years later. (2) How the Transparency Committee (TC) and CEESP will resolve divergent opinions: While TC only focus on clinical trials, CEESP is expected to have a broader perspective. As both committees operate independently, it is urgent that a clear process is established to clarify the resolution of divergent opinion. (3) Methodology used for economic assessment: HAS published guidelines for economic analysis. They remain very flexible even if some specific recommendations were made (e.g. no cost benefit analysis, loss of productivity not included in reference case, deterministic and probabilistic sensitivity analysis required). Finally no information is available to inform how CEEPS opinion will impact pricing negotiation. **CONCLUSIONS:** Although application decrees are still to be issued, there are important areas of uncertainty surrounding introduction of health economics in market access of drugs in France.

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BIOSIMILAR PRICING: PAST, PRESENT AND FUTURE

Wild L, Forster L
InterPhase P&MA, London, UK

OBJECTIVES: Compared to small molecule generics, biosimilars have different price drivers due to greater manufacturing complexity and stronger regulatory hurdles. We looked to investigate historic trends in biosimilars pricing and assess what may change in the future. In addition, we aimed to understand how the recent FDA guidelines will shape pricing of biosimilars in the US. **METHODS:** In order to understand the historic trends shaping biosimilars pricing, we conducted secondary research into the pricing of 14 biosimilars in EU5 markets. Focusing on qualitative analysis, we assessed three potential factors that shape current pricing: 1) Launch date; 2) Number of biosimilars available; and 30 Therapy area. Primary research was conducted by surveying a selection of payers in order to understand the current price drivers and how these will potentially change in the future. We also assessed their expectations on how FDA pathway regulations will affect pricing in the US. **RESULTS:** Historical analysis of biosimilar pricing indicated similar pricing across the sample, with average pricing at a 20-30% discount relative to the originator. These results indicated no significant correlation between the number of biosimilars available, launch date or therapy area, suggesting that common drivers such as development and manufacturing costs shape pricing across therapy areas. Payers noted that future manufacturing costs (particularly for monoclonal antibodies), regulatory hurdles, and phase IV trial requirements will maintain upward pressure on biosimilar prices, but increasing competition over time would likely bring down prices relative to originators. **CONCLUSIONS:** Historically, biosimilar pricing has been driven by the date of launch and therapy area, in addition to the high R&D costs of manufacturing. Predictions for the future indicate that biosimilars pricing will maintain current levels due to competing pressures. Payers in the US foresaw similar pricing trends, but did not expect as great a level of discounting seen in the EU.

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STAKEHOLDERS'S VIEWS OF THE SOCIAL INSURANCE REFORM IN GREECE

Mylona K, Skroumpelos A, Tsiantou V, Karampli E, Pavi E, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: The social security system in Greece was characterized complex and fragmented and unlike other countries, the existence of many insurance agencies did not create any competition in the health system. In March 2011, the National Organization for the Provision of Health Care (EOPYY) was established. The aim of the study was to highlight stakeholder's insights on the establishment of EOPYY and their perceptions for the applicability of the reform. **METHODS:** A qualitative study, using the method of semi-structured interviews was conducted using an open-ended questions guide. In order to identify stakeholders at the very top of the 'power' list (decision makers) as well as people and groups whose opinion matters in shaping reform policies (opinion leaders), we undertook a stakeholder mapping and 24 targeted stakeholders were found. In total 17 interviews were conducted, tape recorded, transcribed and content analyzed. **RESULTS:** According to the interviewees, the setting-up of EOPYY was considered necessary and valuable, taking into consideration that it will contribute to the consolidation of the benefits and the enhancement of the Welfare State, the establishment of a modern system of primary health care and the enhancement of its negotiation power. Regarding the so far implementation of the reform, stakeholders have reservations and are skeptical about the specific goals and the orientation of the Organization. Notably, concerns were focused on the reimbursement method of the doctors, on the selection criteria and on the lack of a specific mission. **CONCLUSIONS:** Although, the stated objectives of the implementation of EOPYY appear positive and ambitious, the