3.4% in an observation unit to adults. French paediatric short-stay definition (patient in a bed monitored hourly). Compared to the clinicians’ prognosticated rate, 1.3% less children were admitted as short-stay. Flexible observation units should be recommended. OBJECTIVES: To identify current telemonitoring funding, we reviewed the sources and mechanisms used to pay for pilot projects, and then reviewed national and regional health care funding systems to evaluate the readiness to finance telemonitoring. RESULTS: There are important differences in financing telemonitoring among European countries. While pilots exist in all countries, these are financed on a project basis from European Union, national or regional funds, outside regular healthcare budgets. Budget silos, disease reference groups, and ICD-9 procedure items from all 17 Spanish AC were extracted from official list (681 items) and Catalonia the least complete (50 items). The lowest CV was for the most complex element: the monitoring and alert service component. Options include: no reimbursement (the current option), a periodic fixed fee or capitation. To enable telemonitoring, payers need to establish new codes and rules to include: no reimbursement (the current option), a periodic fixed fee or capitation. To enable telemonitoring, payers need to establish new codes and rules to reimbursing telemonitoring in Europe: are payers ready? Flostrand S1, Garde E2, Toumi M3 1CReative-Ceutical, Paris, France, 2Sanofi, Paris, France, 3University Claude Bernard Lyon 1, Lyon, France OBJECTIVES: As evidence and experience of telemonitoring grows, health care payers are confronted with multiple challenges to reimburse these new healthcare solutions. This study evaluated the current reimbursement systems in five European markets (France, Germany, Italy, Spain, and the UK) to determine readiness for telemonitoring and to identify changes required to permit telemonitoring to develop in the future. METHODS: To identify current telemonitoring funding, we reviewed the sources and mechanisms used to pay for pilot projects, and then reviewed national and regional health care funding systems to evaluate the readiness to finance telemonitoring. RESULTS: There are important differences in financing telemonitoring among European countries. While pilots exist in all countries, these are financed on a project basis from European Union, national or regional funds, outside regular healthcare budgets. Budget silos, disease reference group (DRG) changes and contractual funding are key barriers to payer readiness for telemonitoring. In Spain, only one telemonitoring DRG act is defined, while in France and Italy, defining telemonitoring acts for reimbursement is underway. In these countries, payers are reluctant to pay for the monitoring and alert service component. In Spain, regional authorities are advancing pilots at different speeds but system reforms have not yet been undertaken. Only in the UK, the English NHS has moved from pilots to deployment through financing at the Primary Care Trust level. CONCLUSIONS: European reimbursement systems do not yet accommodate telemonitoring, and pilots and device purchases will not sustain this therapeutic solution. To enable telemonitoring, payers need to establish new codes and rules to pay for telemonitoring by health care professionals, and decide how to pay for the most complex element: the monitoring and alert service component. Options include: no reimbursement (the current option), a periodic fixed fee or capitation. Any option requires careful framing and the benefits of telemonitoring need further exploration.

PHP100

did IQWiG’s drug appraisals in connection with G-BA’s directives change prescribing behavior of German physicians? Valentin M1, Neises G2, Salek S3 1University of Applied Science, Iserlohn, Germany, 2ABDA, Berlin, Germany, 3Cardiff University, Cardiff, UK OBJECTIVES: To assess the impact of different formats of G-BA’s (Federal Joint Committee) directives had on the prescription behavior of health care professionals (HCPs) prior to the introduction of the AMNOG legislation (i.e. Directives re-structuring the German pharmaceutical market). METHODS: A retrospective study of the IQWiG’s (Institute for Quality and Efficiency in Healthcare) review of pharmaceutical products covered by a G-BA directive during a 5-year period (2005-2010). An event list reporting the interaction of G-BA, IQWiG and BMC (German Minister of Health) with AMNOG (Chamber of Pharmacists, Nuremberg) was extracted from official websites. Regression analyses retrieved from IMS data bases (Intercontinental Marketing Services) were conducted defining a 95% confidence interval. Time points where actual sales exceeded or decreed this confidence interval were reconciled with the list of events concerning AMNOG and had impacted on G-BA. AMNOG was required a mean of 1304 days to generate a directive followed by 567 days required by IQWiG to complete its review. IQWiG achieved a mean output of 15 projects per year, which is half of what NICE achieved in the same period. The format of the final report had a strong influence on the overall review. These findings indicate that G-BA’s directives did not influence the annual number of prescriptions during the five year period. CONCLUSIONS: The new set of law – commonly known as AMNOG is targeting two important weaknesses of the previous systems, which are clearly identified by this study. Thus, clear ambitious timelines should be defined, especially for the most time consuming review stages, namely completion of the report plan and adherence to the principle of evidence based medicine for all reviews.

PHP101

Biosimilars are not generics from payer perspective. Shepley J1, Bauland M2, Kragtner C3 1CfHealthCare, London, UK, 2CfHealthCare, Nürnberg , Germany, 3Cf Research Matters, Basel, Switzerland OBJECTIVES: To review the barriers and opportunities in market access for biosimilars. METHODS: Both primary & secondary research were used in this study. Primary research was conducted with payers, physicians, pharmacists and biosimilar manufacturers. RESULTS: The US and EU are currently the largest consumers of biologics in the world. However, other markets are expected to see strong growth over the next few years. As many biologics are expected to go off-patent in the near future, (thereby creating an attractive opportunity for biosimilars); the complex structure of biologics makes the manufacturing process of biosimilars extremely difficult, and with EU legislation currently requiring phase I-III clinical trials to be conducted for all new biosimilars the developmental costs and barriers to entry of biosimilars is high. With respect to the costs per treatment, the price of biologics are significantly higher than for small molecules creating a use limiting factor in many markets; for this reason biosimilars are recognised by payers and physicians as being cost-effective. However, payers confirmed that cost-saving alone will not ensure access for biosimilars and physicians are hesitant to adopt biosimilars due to safety and efficacy concerns. CONCLUSIONS: With the use of biologics rapidly increasing, patient expectation is expected to occur in the near future and the low numbers of competitors, companies are presented with a new and attractive market with the production of biosimilar. Although there are several challenges to entering the market (including the intense approval process) biosimilars are recognized and are treated differently from generics by payers. With drug costs increasing and concerns over the safety and efficacy of biosimilars, reduced costs of biosimilars together with clinical reassurance will enable broader acceptance and use of biosimilars in new markets.

PHP102

Biosimilars: Pricing & Reimbursement in Germany: Key Insights from Sickness Funds Chaudhari SD, Boche B1 1Institutional, Umbrother, Middlesex, UK OBJECTIVES: While the European biosimilars market is still in its infancy, these products are facing tough market access conditions and have yet to match the success of small-molecule generics. With the increasing cost consciousness of the payers and potentially safety concerns, it is imperative to explore the key pricing and reimbursement drivers and barriers for biosimilars from the payer’s lens. In addition, the research aims to provide insights into strategies for their successful ‘market access’ in the German healthcare system. METHODS: This research was based on a combination of secondary and primary research to evaluate the key success factors for biosimilars. Secondary research of published data such as G-BA’s assessment of biosimilars, current policies, sector-specific research articles contributed towards a framework to understand the key factors affecting payer’s attitudes towards biosimilars, which was then validated through a telephone survey of 10 sickness funds in 2011. RESULTS: A multitude of factors determine price sustainability for biosimilars in Germany. The attitudes of sickness funds toward biosimilars vary, which affect price dynamics as well as the cost containment measures to encourage/ inhibit its use. While the use and prescribing of biosimilars is subject to quotas and penalties encouraging its use, some sickness funds’ focus on price is moderated by concerns about the safety of biosimilars. Overall, in order to provide access to these products, payers are increasingly framing their data expectations from future biosimilars. Payer expectations vary, based on the stage of the disease/indication, the level of unmet need, and the number of available alternatives. In a climate of increasing pricing concerns, securing marketing approval is no longer the end of the road for biosimilars. Hence, unlike generics, biosimilars cannot be merely ‘sold’ but need to be ‘marketed’.

PHP103

Global health care reforms and pricing, access and health outcomes strategy.