developing the candidates, with investigational oncology drugs representing the largest proportion of orphan diseases. In 2013, 930 orphan diseases were under a third of publicly disclosed BT therapies. In therapeutic areas with already available treatment options, such as Hepatitis C Virus infections and advanced mela-
noma, there is still potential for drug candidates to gain BT designation if they can be shown to provide an alternative to effective or insufficient treatment options, based on the standard of care. **CONCLUSIONS:** Our investigation has highlighted the FDA’s focus on finding breakthrough candidates within oncology as well as rare genetic or orphan diseases that do not have alternative treatment options. Additionally, candidates offering alternative options to non-responders have also secured a place on the list, which is likely to grow as increased interest and awareness is generated.

**PHP16**

**MEDICO-ECONOMIC EVALUATION IN FRANCE: METHODOLOGY AND IMPACT ON THE PRICING AND REIMBURSEMENT SYSTEM**

Furet G, Marimoni G, Ando G

1INS Global, Paris, France; 2INS, London, UK

**OBJECTIVES:** From October 2013, some pharmaceutical products will be required to undergo a RAR (reimbursement and evaluation in France). The aim of this study was to interview key stakeholders involved in this conceptual change in order to under-

stand how this reform will be implemented and how it will affect market access in France. **METHODS:** Primary research was conducted between April and June 2013 with stakeholders from the French National Authority for Health (HAS), the Economic and Public Health Evaluation Commission (CEESP), the Transparency Commission (TC) and relevant French ministries. Interviews lasted between 45 and 75 minutes and focused on the methodology for medico-economic assess-
ment and its implications on the French pharmaceutical pricing and reimbursement (P&R) process. **RESULTS:** Medico-economic evaluation in France will be based on cost-utility or cost-effectiveness analyses, depending on whether or not quality of life is an important outcome. Cost-utility analyses will rely on QALYs (quality-adjusted life years), whereas cost-effectiveness analyses will rely on survival. The medicines will be reimbursed based on the cost of the intervention, its effectiveness and potentially the development of prescribing guidelines, on the other. Medicines will be subjected to a medico-economic assessment based on their level of innova-

tion and/or on their financial impact on the health care budget. **CONCLUSIONS:** France is a major player in the field of the medico-economic assessment (MEV) in the pharmaceutical arena. The new medico-economic assessment will come with a twist on the Anglo-Saxon approach, as there will be no associated ICER (incremental cost-effectiveness ratio) above which the medicine will not be reimbursed. While there is still some level of uncertainty with regards to the medi-
cines that will be subjected to this assessment (as stakeholders have yet to put a quantitative value on a “significant impact” on the health care budget), the direction of travel is toward greater pressure on pharmaceutical prices.

**PHP17**

**OVERCOMING THE HTA HURDLE IN GERMANY: KEY CONSIDERATIONS FOR A MANUFACTURER IN THE PHARMACEUTICAL MARKET**

Rustcliffe N, Balston S, Chetty M

PFMR Associates, London, UK

**OBJECTIVES:** In 2011, we saw the introduction of an evidence-based pricing approach for generic pharmaceuticals in Germany. The process arose from the Act of the Reform of the Market for Medicinal Products (AMNOG) and all new drugs must undergo clinical benefit assessment by the Federal Joint Committee (G-BA) fol-

lowed by the National Body (with the G-BA as the main body) that decides whether additional benefit has been demonstrated. A review of the final GBA assess-
ments published to date was undertaken and the aim was to evaluate the implica-
tions for manufacturers considering Germany as a launch country. **METHODS:** A total of 164 junior students, 95 were intervention and 69 control groups, were studied. The junior story telling demonstrated a significant improvement in student’s knowledge (34.5% of change) and there was no significant decrease in student knowledge observed after a 4 week period. **CONCLUSIONS:** Availability of information on the effectiveness of intervention for improving and promoting appropriate antibiotics use can facilitate implementation of strategies in this field. Regarding the effectiveness of storytelling, it is therefore recommended that decision-maker place greater emphasis on the use of such interventions.

**PHP20**

**RELEVANT DECISION-MAKING CRITERIA IN GERMAN HOSPITAL FORMULARIES**

Rubesam T1, Jain M2, Ploch E1

1University of Gloucestershire, Cheltenham, UK, 2BioMarin Europe Limited, London, UK

**OBJECTIVE:** Hospital formularies are usually the gatekeepers for pharmaceutical drugs. Typical majority members of hospital formularies are physicians, although most of the time the formulary is chaired by a pharmacist. As German hospitals are facing a difficult economic environment the question arises: what kind of decision-making criteria are applied when pharmaceutical drugs should be added to the formulary list? Information regarding this topic is scarce due to the confidentiality of the formulary list. Only few studies have looked into this for Germany. **METHODS:** A total of 588 public, private, and ecclesi-

astic hospitals in Germany have been contacted to participate in an online-survey regarding the structure of their hospital formulary, roles of members and applied decision-making criteria. **RESULTS:** Thirty-five of 588 hospitals (6%) have finally participated and filled out the complete questionnaire. Out of the 35 participants, 29 were pharmacists (82.9%) and 6 were physicians (17.1%). 34.3% of the hospitals have no guidelines for their decision-making and 65.7% of the hospitals with guide-

lines have written (48.6%) or verbal (17.1%) guidelines. Out of these, 78.3% discuss decision-making criteria, but only 47.8% talk about the relative importance of the discussed decision-making criteria. **CONCLUSIONS:** A third of the participating hospitals do not have guidelines for their decision-making process and only half of the guidelines discussing decision-making criteria also talk about the relative importance. Hospital formular-

ies in Germany do not seem to be transparent in their decision-making process. In addition the top 3 decision criteria in the existing guidelines include 2 economical criteria which lead to the question of dominance of economical versus medical or other criteria. Further research needs to look at the real applied decision-making criteria and how much impact economical criteria have on decision-making in German hospital formularies.

**PHP21**

**2.5 YEARS OF AMNOG IN GERMANY – AN ANALYSIS OF BENEFIT ASSESSMENT METHODS AND PRICE NEGOTIATION TRENDS**

Dahmen, Schmoeller M

IMS Consulting Group, Muenchen, Germany

**OBJECTIVES:** In 2011, the AMNOG law changed the price-setting procedure for drugs in Germany and required new manufacturers to submit their applications to the Federal Joint Committee (G-BA) for newly launched or, upon specific request, already market products. The G-BA decides on the level of additional benefit which impacts the reim-

bursement price negotiations with German sick funds. The objectives of this study were thus to: 1) Identify ways in which manufacturers can optimize the benefit representative drug dispensing data from ambulatory care). The statistical analy-

sis was performed using SAS Enterprise Guide 4.1. **RESULTS:** The average price of medicines in the NHS market reduced significantly. Until March 2013, the average price of generics reduced 59.0% and brands 12.9%. The margins of pharmacies and wholesalers decreased in 2012. As a consequence, the outpatient pharmaceutical market decreased €7.5 million and the NHS expenditures €465.1 million between 2010 and 2012. However, hospital market in 2012 remains at the same level observed in 2010. In the first quarter of 2013, outpatient market reduced another 93.3 million and NHS, that do not 21% is due to the reduction of distribution margins. **CONCLUSIONS:** Even before the MoU, several changes led to a great reduc-

tion of the public expenditure in 2011. This impact worsened after the MoU, with direct effects on the reduction of the remuneration of pharmacies and wholesalers. Urgent strategies that ensure the accessibility and affordability of medicines while preserving the sustainability of both the NHS and the network of pharmacies are required, as well as policies to monitor the prescribing, dispensing and utilization of medicines and concrete changes in the inpatient NHS expenditure.