guidelines and pricing and reimbursement legislation. **RESULTS:** The survey analyses pharmacoeconomic guidelines of the National Council on prices and reimbursement for inclusion of new INN in the positive drug list in Bulgaria. Requirements for efficacy, safety, benefits, adverse events, comparator, standard treatment, drug utilization, budget impact, patient population during the premarketing and postmarketing period of change in order to provide data with higher utility for decision-making process. From April 2013 to July 2015 over that period more than 36 new INNs were accepted for reimbursement in Bulgaria. A guideline with an HTA approach must be drafted for all INNs of submitted disadvantaged was introduced in April 2015. The experience in that field of other MSs is summarized and compared. **CONCLUSIONS:** The study evaluates how NCPFR develops recommendations and reimbursement decisions on the basis of one step procedure which shortens the pricing and reimbursement process in comparison with other EU MSs. No previous study to evaluate the submitted pharmacoeconomic information by the expert of the NCPFR. Particularly available and HTA appraisals may be subjectively biased.

**PHP206**

**HOW DOES THE ADDITIONAL BENEFIT EXTENT OF ORPHAN DRUGS IMPACT PRICE NEGOTIATIONS IN THE GERMAN OUTPATIENT SECTOR?**

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**OBJECTIVES:** For orphan drugs an additional benefit is granted by market authorisation of the EMA. In case orphan drugs exceed an annually turnover of 1 m Euro (based on ex. pharmacy prices) in the outpatient sector recently authorized orphan drugs have to undergo an assessment of the additional benefit extent by the Federal Joint Committee. Based on the results pharmaceutical manufacturer and the head association of the statutory health insurance negotiate rebates. The objective of this analysis is to assess whether the additional benefit extent of orphan drugs does impact the rebate size of the price negotiations. **METHODS:** In a first step orphan drugs were selected by an assessment of additional benefit extent were analyzed within the German market. The dependency between additional benefit extent and rebate size of negotiations is assessed by correlation analysis. This analysis is based on relevant public available data of the Federal Joint Committee. **RESULTS:** The median time between marketing approval and a final HTA decision was 115 days. Provincial funding decisions under pCODR joint negotiations in Ontario, Manitoba, and Saskatchewan, to 32% in Prince Edward Island). At the time of analysis 16% of drugs were still awaiting provincial funding approval, while 10% received no funding primarily after a “no funding” pCODR recommendation. The median time between marketing approval and a final pCODR decision was 200 days; the median time between that final decision and receiving the first funding approval was 115 days. Provincial funding decisions under pCPA joint negotiations took longer (median of 118 days) compared to those negotiated separately (80 days). **CONCLUSIONS:** It takes nearly four months for provinces to begin funding new drugs after a final HTA decision is issued, with funding decisions in other jurisdictions lagging further behind. Multiple levels of pricing and reimbursement process implemented by the provinces.

**PHP207**

**QUANTITATIVE ASSESSMENT OF CANADIAN PROVINCIAL PUBLIC FUNDING DECISIONS ON ONCOLOGY DRUGS FOLLOWING pCODR ECONOMIC EVALUATIONS FOR 2013 AND 2014**

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**OBJECTIVES:** Canadian provinces are encouraged to follow HTA recommendations conducted under pCODR for cancer drugs, but have ultimate authority over the final reimbursement decision on public drug plans. In order to understand the impact of pCODR on market access, this study monitors funding decisions across the individual jurisdictions we conducted a quantitative analysis of all pCODR’s oncology assessments completed in 2013-14 and consequent funding decisions implemented by the provincial pharmaceutical agencies. **DATA:** Data, obtained from the pCODR database, which contains all 27 assessments completed in 2013 and 2014, were used to estimate median time to pCODR final decision and the time to first funding approval in one of the nine provinces excluding Quebec. We also examined the probability of obtaining public drug plan approval in Canada based on the pCODR recommendation. **RESULTS:** On average, 74% of the assessed results in a favourable decision by the provinces, compared to 88% with a favourable pCODR recommendation. However, positive provincial funding decisions varied considerably (88% in Ontario, Manitoba, and Saskatchewan, to 32% in Prince Edward Island). At the same time of analysis 16% of drugs were still awaiting provincial funding approval, while 10% received no funding primarily after a “no funding” pCODR recommendation. The median time between marketing approval and a final pCODR decision was 200 days; the median time between that final decision and receiving the first funding approval was 115 days. Provincial funding decisions under pCPA joint negotiations took longer (median of 118 days) compared to those negotiated separately (80 days).

**CONCLUSIONS:** It takes nearly four months for provinces to begin funding new drugs after a final HTA decision is issued, with funding decisions in other jurisdictions lagging further behind. Multiple levels of pricing and reimbursement process implemented by the provinces are likely impacting market access for new drugs in Canada.

**PHP208**

**VALUE JUDGMENT OF HEALTH INTERVENTIONS FROM DIFFERENT PERSPECTIVES: ARGUMENTS AND CRITERIA**

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**OBJECTIVES:** The healthcare sector is evolving while life expectancy is increasing. These trends put greater pressure on resources, prompt reforms, and demand transparent decision-making processes to assess the worth of health interventions. Besides (cost) effectiveness, many criteria play a role when determining the value of interventions. There is no consensus on the core arguments. This study aimed at retrieving the most widely recognized arguments used in making decisions about patient treatments and prioritizing interventions, and to compile a smaller set that would seem most relevant to different stakeholders. **METHODS:** A landscape review was performed on the database of InSightEMBASE. Initial search retrieved over 2000 articles. After a selection based on reference to healthcare, policy issues, or social justice, 64 papers were included. Data were extracted and a full table was made, including all arguments found, next, identical or largely overlapping criteria were excluded and 44 arguments were identified. **RESULTS:** The final set of arguments, categorized by type (clinical, social justice, ethical, and policy). Examples of arguments included in the final set are: Longevity, need, dignity and public health value. **CONCLUSIONS:** The argument, relevance to stakeholders was scored on three levels (not, partly, and completely relevant). Many arguments play a role in making decisions about patient treatments, but not all are relevant to all interventions. Moreover, they may interact with each other. Therefore, systematic and analytical approach to decision-making criteria/payers also sought to expedite access to these therapies. **METHODS:** The FDA website, the EMA, the HTA agencies, and the comparator is the basis for approval in Canada. **CONCLUSIONS:** Most of the 16 pairings were registered first in the US. The FDA evaluation period was shorter compared to other regulatory agencies. Some HTA agencies are yet to consider many pairings whilst others have dissimilar views on their additional clinical benefit.

**PHP209**

**FDA BREAKTHROUGH MEDICINES: HAVE THEY CAUSED BREAKTHROUGH HEADACHES FOR HTA AGENCIES?**

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**OBJECTIVES:** FDA breakthrough therapy designation was created in 2012 to expedite the registration of new health care technologies for use by patients with serious or life-threatening diseases/conditions. Breakthrough therapies are eligible for other FDA expedited reviews and drug designations and priority review. We sought to determine whether other regulators and HTA agencies/payers also sought to expedite access to these therapies. **METHODS:** The FDA website, the EMA, the HTA agencies, and the comparator is the basis for approval in Canada. **RESULTS:** The FDA approved 14 breakthrough medicines as at 31 December 2014 for use in 16 unique patient populations (i.e. pairings). The mean time from submission to approval was 164 days. Twelve pairings are orphan drugs and 9 are for patients with cancer. As of 20 June 2015, 13 had been registered in the EU (mean time 326 days), 8 in Canada (275 days) and 9 in Australia (N/A). Four of the 15 pairings had been assessed as NICE (all recommended), 5 by IQWiG (4 additional benefit not quantifiable, 1 minor additional benefit), 6 by the TC (ASMR rating = II (2), III (1), IV (4), V (2)), 6 by CADTH/ pCODR (6 recommended, 2 not recommended) and 7 by the FRAC (all recommended). **CONCLUSIONS:** Most of the 16 pairings were registered first in the US. The FDA evaluation period was shorter compared to other regulatory agencies. Some HTA agencies are yet to consider many pairings whilst others have dissimilar views on their additional clinical benefit.

**PHP210**

**THE ORIENTATION OF HTA AS A COVERAGE DECISION-MAKING TOOL IN THE MIDDLE EAST AND NORTH AFRICA REGION**

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**OBJECTIVES:** HTA orientation aims to characterize the extent to which health technology assessment (HTA) is currently being used to determine pharmaceutical coverage in the Middle East and North Africa (MENA) region. The objectives are to assess how many and which decision-makers are currently undertaking this activity, the extent of its formalization and how it is integrated into the decision-making processes of the public sector in the region. The targets of the study are: HTA agencies/payers in the MENA region, and any other relevant agencies in the Middle East and North Africa. **METHODS:** In-depth, qualitative interviews were conducted with a total of 11 payer decision-makers and 20 industry stakeholders in Egypt, Saudi Arabia, Turkey and the United Arab Emirates (UAE). Published literature and government websites were also reviewed. Primary and secondary research focused on current and evolving reimbursement decision-making processes in these countries in addition to potential policy reforms. **RESULTS:** Of the countries considered, HTA focused on evaluation of specific pharmaceuticals appears to have gained the most traction in Saudi Arabia, where one of the public-sector payers has begun undertaking in-depth pharmacoeconomic (PE) analysis. In Egypt, while a PE unit has been established, its present role is to support the country’s Drug Pricing Committee on a case-by-case basis. In Turkey, while a PE unit is required for reimbursement submission, budget impact is reported to remain the primary driver of national-level decision-making. Meanwhile, in the UAE, there is little evidence that the insurers increasingly responsible for coverage under the country’s healthcare reforms are using formal HTA. **CONCLUSIONS:** The extent of HTA formalization and the specific areas of the healthcare system in which HTA operates vary across the MENA region, in line with the broader policy framework. Champions of further HTA development are gaining increasing traction across the MENA, alongside arrangements such as risk-sharing schemes, with significant consequences for pharmaceutical access.

**PHP211**

**ORPHAN DRUGS ASSESSMENT IN GERMANY: A COMPARISON WITH OTHER INTERNATIONAL HTA AGENCIES**

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**OBJECTIVES:** Examine orphan drugs assessed by the German Federal Joint Committee (G-BA) between January 2011 and May 2015 and compare their assessments with those of other international HTA agencies. **METHODS:** GBA
orphan drugs assessments between January 2011 and May 2015 and compar-ison with assessments conducted by HTA agencies in France, Netherlands, the UK and Canada, to examine similarities and differences in benefit evaluations, reimbursement and drug access. RESULTS: Germany has 23 completed assess-ments for 21 orphan drugs during the time frame. 9 received non quantifiable additional benefit claim, and 3 significant. Out of 5 drugs where different patient subgroups were identified, only 1 (vacavir) received different ratings across two patient subgroups (marginal and significant). This 21 orphan drug sub-set of the 104 resolutions in Germany. In France, 20 out of 27 products had only non-RCT evidence. For 6 products the G-BA concluded that the data were insufficient to recommend for reimbursement. Comparing the additional benefit ratings assigned in Germany with the French ASMR ratings, we found significantly differ-ent value assessments for 15 (78.9%) out of 19 drugs reviewed in both countries. In the Netherlands, HTA’s by the National Health Care Institute were available for 7 (33.3%) drugs: 5 (23.8%) were reimbursed, all with restrictions. SCM reviewed 14 (66.7%) drugs of which 5 (23.8%) were not recommended (3: non-submission and 2: evidence insufficient). Of the 9 (42.9%) drugs that were recommended, 6 had a negotiated patient access scheme (PAS). NICE reviewed 5 (23.8%) drugs, 4 of which were for oncology and not recommended for reimbursement. Only one (4.8%) drug (pirfenidone) was recommended for restricted use based on a PAS. Canada’s CADTH has published 111 (46.8%) drugs, where 39 (17%) were recommended, 50 (22%) restricted and 22 (9.9%) not recommended. CONCLUSIONS: Among the countries examined, Germany had the highest number of orphan drugs assessed. Differences in HTA assessment criteria lead to noticeably different benefit evaluations, recommendations and, ultimately, drug access.

PHP212
AN ANALYSIS OF GERMAN AMONG RE-VIEW ASSESSMENTS AND LEARNINGS FOR MANUFACTURERS
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OBJECTIVES: The primary focus of manufacturers’ reimbursement submissions in Germany is on demonstrating the added benefit of a product versus the appropri-ate comparator. Authors noticed that the decisions made by the G-BA are not explained in a result in a time-limited approval, after which there should be a review. This study analyses any completed reviews conducted by the G-BA. METHODS: G-BA deci-sions were searched to identify restricted decisions and subsequent reviews. Data were collected on the restrictions and the reasons these were addressed in the reviews. The reviews, were analysed. RESULTS: 20% (27/135) of all decisions identified were time restricted. Restrictions were mainly applied to products with small or no added benefit. The most common reason for a restriction was incomplete evi-dence profiles, and the most common restriction period was three years. Of the 27 restricted decisions, two had reviews, two restriction periods had been extended and five more decisions are expected by the end of 2015. An analysis of the most recent extended review showed that the manufacturer was granted suffi-cient time to collect additional evidence and that the G-BA adjusted its recom-mendations in a favourable manner once evidence was provided. However, during the vemurafenib review the level of added benefit did not change from the original evaluation. This indicates the manufacturer did not present sufficient data to address the original criticism and was therefore unable to raise the level of added benefit. Furthermore, it is evident that the G-BA takes regulatory guidance into con-sideration in decision making. CONCLUSIONS: The results indicate that restricted decisions provide manufacturers with the opportunity to collect additional data and improve the final added benefit recommendation. If manufacturers address the G-BA’s criticism of the original submission, more favourable added benefit levels can be achieved during the review. Furthermore, it shows that EMA decisions influ-ence G-BA decision making.

PHP213
ASSESSING PHARMACEUTICALS WITH LIMITED EVIDENCE IN GERMANY – CURRENT EXPERIENCE
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OBJECTIVES: Benefit assessment usually requires RCT data. Orphan drugs are granted additional benefit by law, but not drugs with conditional or exceptional approval or PUMA. The objective of this study was to assess how their status is handled in benefit assessment. METHODS: All resolutions until June 2016 were analyzed whether they have been approved by EMA under these circumstances. Those which do were assessed regarding underlying evidence, extend of additional benefit and other aspects of the resolution. RESULTS: 7 out of 104 resolutions (7%) met these criteria – 5 with conditional approval, 1 with exceptional circumstances and 1 PUMA. 2 out of 7 products had only non-RCT evidence. For 6 products the IQWIG found no additional benefit and for 1 product a major additional benefit. The G-BA increased three products to minor (or considerable) additional benefit, even though one approval was based only on a case series. However, for three products the result was still “additional benefit not proven”. 4 out of 7 resolutions had been limited. CONCLUSIONS: Special regulatory status gives no formal advantage in benefit assessment. However G-BA seems to take their status into account and using limitations to account for future evidence.

PHP214
CURRENT CHALLENGES AND OPPORTUNITIES TO MARKET ACCESS IN BRAZIL, ARGENTINA, MEXICO AND COLOMBIA
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OBJECTIVES: To define the current processes and key decision makers involved in gaining market access in Brazil, Argentina, Mexico and Colombia, and identify opportunities and challenges to access these countries. METHODS: The websites of the appropriate authorities and agencies in each country and the Decision Resources Group’s ‘Global Market Access Solution’ database were reviewed. RESULTS: The healthcare systems in Brazil, Argentina, Mexico and Colombia are decentralised, while that of Colombia in centrally managed. All countries have a national health service for all residents, but the proportion of the population that relies solely on this varies greatly between countries. In Brazil, 25% of the popula-tion relies on private health insurance, while only a small proportion of the popula-tion relies on private insurance in the other countries. In Mexico and Argentina, residents in formal employment are obliged to enrol in one of the social security schemes. In Brazil, Argentina and Colombia, national formularies include the mandatory minimum healthcare provision. In Mexico, the national formulary is not binding and the different social security schemes decide which treatments to cover. The role of health technology assessment (HTA) in the reimbursement process in Brazil, Mexico and Colombia, HTA is criti-cal in the reimbursement decision process, while in Argentina it has been mostly used to assess treatments for catastrophic illnesses; although there is a drive to include HTA in the decision process for oncology indications. HTA is used to evaluate pharmaceuticals, and challenges include decentralised healthcare systems and high use of generics. CONCLUSIONS: Most countries have a decentralised system where reimbursement decision making occurs at the regional level or at the social security agency level. There is not yet in Argentina. We have identified current opportunities and challenges for the different countries

PHP215
FROM CENTRALIZED MARKETING AUTHORIZATION TO NATIONAL REIMBURSEMENT – A CHALLENGING JOURNEY FOR NEW MEDICAL PRODUCTS WITH PLACEBO CONTROLLED TRIALS
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BACKGROUND: Is the governing principle ruling all aspects of a new medical product. Marketing authorization organizations and health tech-nology agencies focused on the reimbursement aspects of a new product are both subjected to the decisions in relation to孤儿 drug claims. The positive clinical evidence from placebo-controlled trials, establishing the efficacy of a product against placebo is a common approach, as only patients who did not succeed with the available treatment options are willing to participate in these trials. OBJECTIVES: To review the national requirements for the reimbursement of new medical products with a positive centralized marketing authorization based on placebo-controlled clinical trials. We will demonstrate that the acceptance of placebo-controlled trials is handled differently between counTRIES and that different strategies on the process these data are necessary. METHODS: We focused on the national health technology agencies of five representative European countries, including the United Kingdom, France, Germany, Sweden and the Netherlands. A targeted desktop research on the published methodology and the decisions regarding medical products with a marketing authorization based on placebo controlled trials for the most recent years was conducted. RESULTS: The methodological requirements to get reimbursement for a medical product with placebo-controlled trials are not standardized across EU member states. The requirements vary significantly between countries, leading to heterogeneous decisions. CONCLUSIONS: Getting a positive decision for reimbursement is challenging for products which have mar-keted on placebo-controlled trials. The national requirements and thresholds for reimbursement are very different and highly dependent on the governing principle for evaluation, ranging from quality of life based decisions to comparator driven additional benefit decisions.

PHP216
LIMITATION OF BENEFIT ASSESSMENTS IN GERMANY – CURRENT EXPERIENCE
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OBJECTIVES: Resolutions on early benefit assessment can be granted with a time restriction, termed “limited”. As a consequence companies are required to resubmit their data later. The objective of the present study was to assess reasons for limita-tion. METHODS: The following three criteria are given for limiting a resolution: incomplete data on patient relevant endpoints, limited quality of evidence, and missing data can be provided at a later stage. Assessment was based on resolutions with limitations published until June 2016. For each resolution reasons for limita-tions were identified and requirements for a resubmission were captured using supporting documents (“Tragende Gruende”). RESULTS: 26 out of 130 resolutions (20%) were limited with limitations ranging from 1 to 5 years. In 18 resolutions (69%) G-BA made reference to missing data on endpoints. In further 18 resolutions the G-BA explicitly referred to limited quality of evidence. Expectations for better data in the future are mentioned in 13 resolutions (50%). More information on what data is required for a reassessment is provided in 8 resolutions (31%). CONCLUSIONS: Most limitations are made even though they do not meet all legal criteria. Missing information on the requirements for reassessment increases the risk for subse-quent failure.

PHP217
REIMBURSEMENT AND PRICING OF INNOVATIVE MEDICINES: EU POLICIES AND IMPLICATIONS FOR MARKET ACCESS
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OBJECTIVES: The use of innovative medicines has been associated with increased healthcare-related expenditure in the EUS (Italy, France, Spain, UK and Germany). In some countries, this has raised concerns in the clinical and economic assess-ment of such medicines and has led to the introduction of additional criteria to