of sixteen countries from the region according to different criteria: characteristics, quality using Drummond’s checklist), use of local data, addressed inputs limita-
and results transferability. RESULTS: Economic evaluations are used in CEE
countries for informing decision making, while critically considering methodology,
and study’s reliability. Experts acknowledged limited generalizability of study
results, especially between different geographic regions. Meanwhile, despite these con-
fincies, facing limited health technology assessment (HTA) capacity experts were
still using foreign evidence. At the same time, the usefulness of studies published in
CEE and former Soviet countries to inform their decision making is limited because of
insufficient transparency in reporting, unaddressed uncertainty, limited insight on
inputs and transferability of results. Although local costs, baseline risk and resource
use data are required, experts accept evidence originating from health care settings
outside CEE and former Soviet countries regarding relative cost and utilities val-
ues. CONCLUSIONS: HTA priority setting and transferability assessment of economic
evidence are important issue in health care decision making in CEE and former
Soviet countries. Financial capacity is limited because of insufficient outputs.
Therefore, purpose, quality, transparency, and transferability should be addressed explicitly in
published economic evaluations originating from CEE and former Soviet countries.

PHP237
TEN YEARS OF DEVELOPMENT STUDIES IN HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL: PROFILE OF STUDIES AND OPERATIONAL INDICATORS
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BACKGROUND: The Department of Science and Technology (DECT) at the Ministry of Health (MoH), since 2003, has financed studies to support demands from
the MoH technical areas regarding the decision making process about health technologies. OBJECTIVES: To analyze DECT performance in financed Health Technology
Assessment (HTA) studies to improve the capacity building of HTA in Thailand. METHODS: A retrospective descriptive study based on the analysis of docu-
ments and official records built in a single database in Excel containing the studies promoted by DECT from January 2003 to November 2013. The variables pre-
classified and collected from Brazilian Network for Health Technology Assessment’s database, SISKBRATS, were revised by two reviewers and confirmed or supplemented with data
from the Database of Health Research, Annual Reports Management by DECT, and Final Reports and Cooperation Agreements by co-financing partners. RESULTS: 284
HTA projects were financed entirely for R$ 25 million (± R$ 1,69 million) between 2003
and 2013. The average value financed was R$ 346 thousand and the average bias was ± R$ 61 thousand. Of these, 57% (162/284) are pharmacotherapy; and 35% (99/248)
are HTA projects that were financed entirely. This HTA legislation and the already-published HTA reports, claiming that the process was challenging to demonstrate
hard clinical evidence and create robust cost-effectiveness in public health decision making. Therefore, price negotiations are sometimes lengthy. Risk sharing and novel payment-by-result schemes are often agreed to mitigate
risks. CONCLUSIONS: Payers are not yet familiar with the potential value of ATMPs,
and, in most cases specific evaluation criteria don’t exist. Manufacturers need to
invest in educating Payers on the huge differences between ATMPs and traditional
therapies, particularly to show that manufacturing costs are substantial, and work
together to identify relevant measures for clinical and economic evaluations of
this new therapy class.

PHP241
ROMANIAN QUICK-HTA DEVELOPMENT IN 2013
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OBJECTIVES: The objective of this study was to provide an external assessment of
the Romanian HTA legislation, the already-published HTA reports, and the process
taken during the Romanian HTA reports. RESULTS: The introduction of quick-HTA began mid-June 2013 when MoH released the leg-
isation in the Romanian HTA Unit with an acceptance rate of about 80%. Most of the drugs accepted for reimbursement were oncological (23%), other main therapeutic areas were diabetes with 16 drugs/indications receiving positive evaluations, rheumatology (14%), oncology, haematology (8%) and neurology (7%). The HTA included also biosimilars, all of them receiving positive decisions. Unfortunately, early 2014, the new Government abrogated
this HTA legislation and the already-published HTA reports, claiming that the process was challenging to demonstrate hard clinical evidence and create robust cost-
effectiveness in public health decision making. Therefore, price negotiations are sometimes lengthy. Risk sharing and novel payment-by-result schemes are often agreed to mitigate
risks. CONCLUSIONS: Payers are not yet familiar with the potential value of ATMPs,
and, in most cases specific evaluation criteria don’t exist. Manufacturers need to
invest in educating Payers on the huge differences between ATMPs and traditional
therapies, particularly to show that manufacturing costs are substantial, and work
together to identify relevant measures for clinical and economic evaluations of
this new therapy class.

PHP242
HTA IN THE BRAZILIAN HEALTH CARE SYSTEM AND POTENTIAL LESSONS LEARNED FOR OTHER BRICS STATES
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OBJECTIVES: The objective of the study was to provide an external assessment of
recent HTA institutionalization in Brazil, and identify a set of lessons learned potentially applicable to BRICS States. METHODS: This research is based on a quan-
titative and qualitative assessment of literature. A literature survey between 2000 and 2014 was
conducted in English, Spanish and Portuguese in PubMed/Medline, Science Direct, LILACS and Scielo Epidemiological and socio-economic data was retrieved from
national health accounts as well as WHO/PAHO, OECD and World Bank. For the
Brazilian National Committee for Incorporation of Technologies (CONITEC), avail-
able reports on the incorporation of medicines into the National Unified System (SUS) for the first two years of operation (2012 and 2013) were analyzed. A matrix
containing quantitative and qualitative criteria was elaborated to analyze reports
by the outcome of decision, therapeutic class, author (s) of the request and public consultation. RESULTS: A total of 92 available CONITEC reports for 2012 (n=38, 33 for medicines) and 2013 (n=54, 42 for medicines) were analyzed. 45% of reports on medicines recommended incorporation into the SUS. Most of the positive recom-
mandations were clearly related to public health priorities as identified by the gov-
ernment, translating a strong commitment for improved access to medicines within
the SUS i.e. anti-cancer drugs. Overall, the creation of the CONITEC represents a
substantial step toward the institutionalization of HTA, with more transparency and
accountability in decision-making processes, considering ethical, organizational
and legal aspects. CONCLUSIONS: Whereas lowest in Russia, India and
South Africa and at a transitional stage in China, Brazil has a comparable
degree of institutionalization of HTA as countries with a long-lasting HTA experi-
ence. A best-practice assessment in the area of HTA within the BRICS has still to be
taken. Transferability of lessons learned might be a strong tool for improving
HTA development within the BRICS.

PHP243
IS IG-BRA STRATEGICALLY DISCOUNTING THE BENEFIT ASSESSMENT OF RELATIVELY HIGH COST DRUGS?
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OBJECTIVES: Advanced-therapy medicinal products (ATMPs), such as gene therapy,
cell therapy, and tissue engineering are a class of medicines in the EU that offer prospects in prevention and treatment of fatal and/or chronic debilitating
diseases where no effective treatments exist. However, with complicated mecha-
nisms of actions and benefits often being anticipated in the longer term, it is chal-
genlenging to demonstrate hard clinical evidence and create robust cost-effectiveness
models that Payers have come to expect at the launch of pharmaceuticals. Thus, a
strategy to discount the benefit assessment of ATMPs launched in EU to outline access pathways and review the clinical and economic evidence requirements. METHODS: Secondary research identified ATMP approv-
als in the EU and a framework was created to develop hypotheses on clinical and
economic evidence requirements, considering alternative routes to market. Hypotheses were then validated during in-depth interviews with key stakeholders
across EU. RESULTS: Payers are not yet familiar with the potential value of ATMPs,
and, in most cases specific evaluation criteria don’t exist. Manufacturers need to
invest in educating Payers on the huge differences between ATMPs and traditional
therapies, particularly to show that manufacturing costs are substantial, and work
together to identify relevant measures for clinical and economic evaluations of
this new therapy class.
OBJECTIVES: Gemeinsame Bundesausschuss (G-BA) states that it assesses additional cost of comparator, and clinical, grounds, but it also requires that manufacturers submit drug and comparator costs. This raises the possibility that G-BA's assessment might be influenced by price, possibly to provide leverage during subsequent price negotiations. This research tests the hypothesis that high cost drugs [relative to the comparator] are more likely to receive negative reimbursement decisions from the HTA agency. The following variables were collected from the Federal Gazette publication or the "Beschluss" document: additional benefit assessment, annual cost per patient of drug and comparator, estimated target population. The Scottish Medicines Consortium (SMC) clinical rationale for the same drugs and indications were collected to control for clinical efficacy. After excluding orphan drugs, reviews using best supportive care comparators, and reviews without SMC reviews, 58 reviews remained for analysis. G-BA's additional benefit assessments were ranked from least benefit to most. The influence of drug cost relative to the comparator on the G-BA assessment was estimated via an ordered logit model. The model also included controls for the (log) size of the target population and clinical efficacy (SMC's clinical assessment). RESULTS: An increase in the cost difference between the drug and the comparator is estimated to result in a modest, statistically significant increase in the odds of receiving an additional benefit assessment greater than a "no additional benefit" assessment. The results support the null hypothesis that G-BA is strategically discounting its assessment of relatively high cost drugs. The positive estimated relationship is consistent with manufacturer's setting higher prices for more beneficial drugs (The data available provide no way to statistically account for this plausible source of endogeneity). Our results provide no support for rejecting the null hypothesis that G-BA assesses added benefit independently of drug cost.

PHP244 DEVELOPMENT OF HTA IN TURKEY
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OBJECTIVES: The aim of this study was to assess the development of HTA in Turkey. In this regard, organizations structures of the Ministry of Health (MoH) and Social Security Institution (SSI) and presentations of first HTA meeting held in April 2014 have been analyzed. RESULTS: There are three main HTA agencies in Turkey. One is under the payer institution called SSI. The HTA committee of the association called the new health technologies to define whether they will be reimbursed or not. In other words, this committee is the major decisive HTA committee. Other two HTA committees are under the MoH. One of these is under the General Directorate of Health. The other one is in the Pharmacological and Medical Devices. This committee assesses certain drugs which are specifically asked to be evaluated by the SSI, MoH or other Ministries. One of the projects completed by this committee is the evaluation of top 100 selling drugs according to the effect of price, regulation, market and medical drugs to evaluate the potential of new examination and treatment methods. Regulatory Authorities can request a Post-authorization Safety (PASS) to recommend the treatment for medical drugs (§35a SGB V) with the new potential analysis, among other requirements. In one of the first applications in Germany, the IHW, London, UK

PHP245 DISEASE BURDEN IN BRAZIL AND HEALTH TECHNOLOGY ASSESSMENT: A RETROSPECTIVE OF TEN YEARS OF SUPPORTING
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BACKGROUND: Defining health technology assessment priorities has been a challenge for the Department of Science and Technology who adopted a prioritization methods. One of the projects completed by this committee was the evaluation of top 100 selling drugs according to the effect of price, regulation, market and medical drugs to evaluate the potential of new examination and treatment methods. Regulatory Authorities can request a Post-authorization Safety (PASS) to recommend the treatment for medical drugs (§35a SGB V) with the new potential analysis, among other requirements. In one of the first applications in Germany, the IHW, London, UK

PHP246 FIRST EXPERIENCES WITH THE NEW TESTING EXAMINATION AND TREATMENT METHODS IN GERMANY: IS THIS A NEW ALMOG CLONE?
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OBJECTIVES: In a new regulation the Federal Joint Committee (G-BA) can pass a proposal to a new examination and treatment methods with not sufficiently proven benefit, but which show potential as essential treatment alternatives (§137e SGB V). The objective of the present study was to compare the requirements for a successful application with the existing AMNOG (Law on the Economic and Market) HTA Company. The applicants must submit valid data on the potential of the method in question, among other requirements. In one of the first applications in Germany, the IHW, London, UK

PHP247 CORRELATION BETWEEN END-OF-LIFE STATUS OF A TREATMENT AND LIKELIHOOD OF A PATIENT ACCESS SCHEME IN THE SETTING OF A NICE REVIEW IN THE UK
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OBJECTIVES: This study aims to assess the existence of a correlation between the applicability of end-of-life treatment criteria and the likelihood of NICE requiring a Patient Access Scheme (PASS) to recommend the treatment for funding. METHODS: A review of all patient access schemes in existence as of March 2014 for NICE-recommended drugs was conducted to assess how many of those were for medicines which met the end-of-life treatment criteria and whether the supplementary criteria for end-of-life treatments had any bearing on the final NICE recommendation. RESULTS: In total 42 PASS were identified. Of those, end-of-life treatment criteria were met and had bearing on the final NICE guidance in 7 cases (16.7%). End-of-life treatment criteria were considered but were not met in full in the case of 3 NICE reviews (in one of the three NICE considered that end-of-life criteria were not met in another review, even though the manufacturer had not applied for those criteria to be considered in the present review). End-of-life treatment criteria were also considered for one additional review where they were a focal point of the manufacturer appeal against the NICE guidance. In one additional case, end-of-life criteria were applied for but had no bearing on the final NICE guidance as the cost-effectiveness threshold was met without the application of special consideration. CONCLUSIONS: The high correlation between end-of-life criteria and the likelihood of a PASS is not consistent with a Pareto's setting higher prices for more beneficial drugs (The data available provide no way to statistically account for this plausible source of endogeneity). Our results provide no support for rejecting the null hypothesis that G-BA assesses added benefit independently of drug cost.

PHP248 THE COSTS AND EFFECTS OF POST-AUTHORISATION SAFETY STUDIES FOR NEW ACTIVE SUBSTANCES
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OBJECTIVES: At market entry, there usually is uncertainty regarding a new medicine’s benefit-risk profile. Therefore, regulatory authorities may request additional pharmacovigilance (PVV) activities. Regulatory Authorities can request a Post-Authorisation Safety Study (PASS) as a registry, database study, survey, or clinical trial to reduce the uncertainty regarding certain safety risks. We aimed to assess the costs and effects of PASS for centrally approved new active substances (NAS) in Europe in 2007. METHODS: We compared two scenarios for all NAS (n=47): (1) Full regulation: routine PVV activities (spontaneous adverse drug reaction (ADR) reporting) with additional PASSs for some NAS; (2) Limited regulation: only routine PVV activities. For a follow-up period of six years after marketing we assessed the safety-related labeling changes for NAS and identified the source of these changes (PASS, spontaneous ADR reporting or other). Data on labeling changes was extracted from the German (A54) database. The costs associated with the PASS for NAS were estimated using costs of all requested PASSs. RESULTS: For 23 of the 47 NAS, at least one PASS (33 PASS in total) was requested in 2007. After a 5-year follow-up period 8.1% of NAS had at least one labeling change with PASS per NAS. Requested PASS were the source of -4% of all costs of new safety information identified. The total estimated costs of the 33 requested PASS were between €50 and €150 million. CONCLUSIONS: For the 2007 cohort of NAS approved in Europe, the total costs of the requested PASS were substantial and yet these PASS contributed to the identification of only 4% of all new safety information identified post-marketing for NAS. However, PASS primarily aim to reduce uncertainty regarding safety risks and the (societal) value of this uncertainty reduction might not fully be captured by assessing health effects alone.