PHIP194
PHARMACOECONOMIC GUIDELINE FOR POSITIVE DRUG LIST APPLICATION PURPOSES IMPLEMENTED IN BULGARIA
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OBJECTIVES: The economic evaluation of new medicines is substantial for allocating the limited healthcare budgets. In Bulgaria, according to the legislation for pricing and reimbursement of medicinal products, applicants have to be included in the Positive Drug List, pharmacoeconomic assessment will be performed according to the criteria based on efficacy, therapeutic effectiveness, safety, and pharmacoeconomic parameters. However, until recently there were no detailed guidelines for applicants available and in April 2015 methodological recommendations were implemented. The objective of methodological recommendations is to achieve optimal assessment of candidate medicinal products applying for the PDL inclusion. The Expert Group of real-world questions on Pricing and Reimbursement of medicinal products, Bulgarian Drug Agency, and experts from academia developed a guideline, following the good practices of other countries to provide standardized approach to economic evaluation of medicinal products. Furthermore, the guideline was developed in five sections including requirements for provided data for efficacy, therapeutic effectiveness and safety, as well as pharmacoeconomic parameters. Applicants need to prepare their applications according to the requirements provided by these methodological recommendations.
There should be a clear and unambiguous conclusion about the benefits of the medicinal product, subject to evaluation over the existing alternatives, the clinical significance and its place in therapy. If there is an economic evaluation conducted with a candidate medicinal product for taken from official publication or published by HTA agencies in Europe it is necessary to be provided with respective motives for positive or negative decision.
CONCLUSIONS: The implemented pharmacoeconomic parameters will facilitate the sidewalk in effectiveness based on objective and transparent information which will allow the decision makers to justify the reimbursement of new medicinal products based on scientific evidences and available resources.

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DIFFERENCES BETWEEN THE EFFICACY OF BIOSIMILARS AND ORIGINATORS: ANALYSIS AND CONSIDERATIONS FOR THE COST-EFFECTIVENESS ANALYSIS FROM A PAYSERS PERSPECTIVE
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OBJECTIVES: Before biosimilars entered the market the decision-making process for payers regarding generics was straightforward. As the active pharmaceutical ingredient (API) is the same molecule, a cheaper generic version would always be more cost-effective than its original counterpart. This changed with the coming of biosimilars of erythropoietins-stimulating agents. Several publications pointed out that biosimilars are often more efficacious than their originator versions.
A payer no longer could solely rely on price comparison, but had to factor the efficacy difference when he was trying to limit drug expenditures. The question arose whether the efficacy gaps are only observed in erythropoetins or are general for all biosimilars.
CONCLUSIONS: Pharmaceuticals with similar to the originator version resulting in a better price-efficacy-ratio for the biosimilars.

PHIP196
INFLUENCE OF PATIENT-REPORTED OUTCOMES (PRO) ON MARKET ACCESS DECISIONS IN MARKETS WITH CENTRALIZED HEALTHCARE SYSTEMS
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OBJECTIVES: To understand how PRO data from clinical trials are utilized in market access decision making in oncology and other therapy areas in markets with centralized healthcare systems. METHODS: We searched the scientific literature and the EMA database, and regulatory and HTA websites for the EMA, the UK, France, and Germany were searched to identify PRO data included in regulatory and HTA submissions of four oncological drugs: bevacizumab, pemetrexed, sunitinib, and crizotinib. Interviews were conducted with 10 payers from different countries with centralized healthcare systems in 2014. An online assessment was conducted (December 8, 2014, to March 4, 2015) with 5 completed surveys (France, Greece-GER sector, and 2 partially completed surveys (Australia and South Korea) by payers from the RTI Health Solutions Global Payer Advisory Panel. RESULTS: Reviews of HTA and reimbursement decisions indicate that HTA bodies have varying levels of familiarity and confidence in PRO data. All 10 payers indicated that it is worthwhile to collect PRO data, but they indicated the need for well-documented and high-quality data to be included in the Positive Drug List, pharmacoeconomic assessment will be performed according to the criteria based on efficacy, therapeutic effectiveness, safety, and pharmacoeconomic parameters. However, until recently there were no detailed guidelines for applicants available and in April 2015 methodological recommendations were implemented. The objective of methodological recommendations is to achieve optimal assessment of candidate medicinal products applying for the PDL inclusion. The Expert Group of real-world questions on Pricing and Reimbursement of medicinal products, Bulgarian Drug Agency, and experts from academia developed a guideline, following the good practices of other countries to provide standardized approach to economic evaluation of medicinal products. Furthermore, the guideline was developed in five sections including requirements for provided data for efficacy, therapeutic effectiveness and safety, as well as pharmacoeconomic parameters. Applicants need to prepare their applications according to the requirements provided by these methodological recommendations.

PHIP197
STREAMLINING THE ACCESS DECISION PROCESS FOR GERMAN PATIENTS TO RECEIVE REIMBURSED TREATMENTS IN ANOTHER EUROPEAN UNION MEMBER STATE
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OBJECTIVES: The European Union Directive (2011/24/EU) requires member states to establish cross-border access pathways that will facilitate the sickness fund and the treatment provider in the other country. CONCLUSIONS: To overcome these barriers we suggest manufacturers and/or the provider of the highly specialised treatment to engage with the MDK (Medizinische Dienst der Krankenkassen - Medical Services of Health Insurances) to define the requirements of the patient dossier, and to agree a checklist to bring a degree of objectivity in to medical need assessment. Additionally, we suggest working with the major sickness funds to negotiate a reimbursement rate, in advance of the patient being identified for the treatment. Establishing these processes and making Health Care Practitioners aware of them would reduce approval times for German patients to access highly specialised treatments delivered in another EU member state.

PHIP198
NUB STATUS – AN ANALYSIS COMPARING RESULTS OF 2015 VS. 2014 - LEADING THERAPEUTIC AREAS CONFIRMED
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OBJECTIVES: Within the German hospital landscape (in-patient), NUBs (Neue Untersuchungs- und Behandlungsmethoden) [new treatment and examination methods] represent a key method to achieve reimbursement for new, cost-intensive drugs, medical products or procedures. NUBs are paid on top of hospital budget and hence increase healthcare costs. The objective of this study was to provide an overview on the proportion of drugs (vs. methods, medicinal products) and their respective indications for 2015 and compare these to the results of 2014. METHODS: The German DRG database issued by the IKN (Institut für Hospital Remuneration System) is used to analyse NUB subgroups sorted according to key therapeutic indications for the years 2015 and 2014. Additionally the number of NUB (status 1 and 2) subgroups that went through the AMNOG process up to June 2015 is being analysed. RESULTS: Out of 670 NUB submissions 159 (24%) are classified as drugs in 2015. Results for the year 2014 were 618 NUB submissions with 133 (22%) drugs. The analysis also compares proportion of drugs in different NUB classification levels for 2015 and 2014. RESULTS: Out of 14 (8%) NUB 1 status 14 (9%) drugs in 2015 and 2014. Leading therapeutic areas were identified. Chances to grant a successful NUB 1 status approval for drugs and procedures are examined. Out of 56 drugs that were given NUB 1 status, 29 (52%) had passed through AMNOG process until June 2015. 43 drugs with NUB status 1 and 24 (55%) that had passed the early benefit assessment by June 2014 (55%). CONCLUSIONS: Drug applications are more likely than procedures to be given NUB status 1 and thereby initiate reimbursement negotiations with the SHI. Results of 2015 confirm the findings for 2014. Oncology products showed the highest success rates in two consecutive years. Oncology products are often high priced therapies and use the NUB system to enter the G-DRG system for future reimbursement.

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ARE VACCINATIONS REALLY DIFFERENT TO PHARMACEUTICALS WITH RESPECT TO MARKET ACCESS IN GERMANY? Driessench D1, Vollmer L1, Krone FA2, Walzer St
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OBJECTIVES: Although AMNOG was introduced to reorganize the medicines market, it is not applicable for vaccines. Immunization in Germany is organized de-centrally under the responsibility of the social health insurance. The aim of this study was to compare patient access and compensation for vaccines and pharmaceuticals in the process. METHODS: The market access route was analyzed systematically and mapped the pathology by identifying key processes, stakeholders, applicable regulations and laws, pricing and negotiation setting and supply chain conditions. RESULTS: Based on the diagram of the pathway the payers could assess the specifics for vaccination market. The Standing Committee on Immunisation (STIKO) by the Robert Koch Institute decides regularly on vaccination recommendations. Vaccinations are obligatory provisions of the SHI and based on a regulation within the G-BA defines details and requirements, type and scope. Further, SHIs can provide optional benefits.

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VALUE IN HEALTH 18 (2015) A335-A766
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