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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 applied to be included in the Positive Drug List, pharmacoeconomic assessment shall 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. **METHODS:** A working group of representatives from National Council for 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 in Bulgaria. **RESULTS:** The guideline is structured 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 evaluations conducted with a candidate medicinal product for other health systems 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 guideline will facilitate the appraisal of medicinal products 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 IMPLICATIONS FOR THE COST-EFFECTIVENESS-ANALYSIS FROM A PAYERS 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 was the same molecule, a cheaper generic version would always be more cost-effective than its original counterpart. This changed with the upcoming of biosimilars of erythropoiesis-stimulating agents. Several publications pointed to differences in effectiveness between original and generic versions. Therefore, 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 biologicals. **METHODS:** We searched the scientific literature and the EMA database for comparative studies for all currently approved biosimilars in Europe. Data for the quantity needed to reach a given therapeutic effect, was extracted. Subsequently the prices from a German payers perspective were taken from official tariffs and applied to the price-efficacy-equation. **RESULTS:** Until Q1/2015 19 biosimilars were granted market authorization in Europe. Analysis showed that erythropoetins are the only ones with relevant efficacy differences between originator and generic version. All other biosimilar agents were equivalent to the reference drug according to EMA standards. Price information was not available for three drugs currently not marketed in Germany. For all other drugs the prices of the generic versions were significantly below the originator version resulting in a better price-efficacy-ratio for the biosimilars. **CONCLUSIONS:** Except for erythropoetin biosimilars no differences in efficacy could be observed in the analyzed study data. Therefore it seems legitimate for payers to limit their view to the price in the price-efficacy-ratio when making reimbursement decisions regarding biosimilars.

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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 disease areas in markets with centralized healthcare systems. **METHODS:** PubMed/MEDLINE, Embase, ISPOR databases, 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 oncology drugs: bevacizumab, pemetrexed, sunitinib, and crizotinib. One-on-one 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 (China, France, Germany, Taiwan, the UK) 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 in clinical trials for oncology, particularly in phase 3 and postmarketing studies. Payers speculated that PRO data will increase in importance over the next 5-10 years and could be a key differentiator for new therapies. Payers offered little differentiation in the importance of PRO data by cancer type. Payers indicated that the quality of the PRO evidence is paramount. Adoption of PRO data by national and international cancer guidelines is key for centralized markets. Literature review findings corroborated with payer interviews indicated that inclusion of PRO data for crizotinib was crucial to achieving a price premium in Germany, with additional benefit based on PRO data on symptoms and quality of life. **CONCLUSIONS:** There is growing recognition that the patient perspective is important in market access decision making in centralized markets and PRO data can be a key differentiator among therapeutic options.

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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 pathways that enable patients to receive reimbursed treatment in another European Union country. These cross-border access pathways are becoming increasingly relevant for highly specialised medical technologies such as proton beam therapy and gene therapy, which are delivered by only a handful of providers across Europe. The objectives of our study were to understand how approvals for reimbursed cross-border treatments in the context of highly specialised treatments work in Germany, and to identify any barriers and practical steps to overcome these. **METHODS:** We have investigated the case-by-case access decision pathway for German patients to receive highly specialised treatments in another country using secondary research, and awareness surveys with Health Care Practitioners. **RESULTS:** We found the biggest barrier for cross-border treatment access are delays in the case-by-case approval process caused by (a) low awareness of cross-border access pathways amongst Health Care Practitioners, (b) the lack of well-defined guidelines on how to make the case for medical need, and (c) case-by-case reimbursement negotiations between 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 (Medizinischer Dienst der Krankenkassen - Medical Service of Health Insurance) 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 first 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.

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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 represent additional funding for hospitals. The objective of this analysis 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 InEK (Institute for 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 1 (positive status) products 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 (NUB 1-4). Leading therapeutic areas are identified. Chances to grant a successfull 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 1 status 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?
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OBJECTIVES: Although AMNOG was introduced to reorganize the medicine products 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 analyze the market access route and compare that to the AMNOG process. **METHODS:** The market access route was analyzed systematically and mapped the pathway by identifying key processes, stakeholders, applicable regulations and laws, pricing and negotiation setting and supply chain conditions. **RESULTS:** Based on the results of the systematic analysis we could ascertain specifics for the vaccination market. The Standing Committee on Immunisation (STIKO) by the Robert Koch Institute decides regularly on vaccination recommendations. Vaccinations are obligatory provisions of the SHIs and based on a regulation within with the G-BA defines details and requirements, type and scope. Further, SHIs can provide optional benefits