shows a positive development within the region's HTA. The Regional Decrees were impactful however the HTA reports are not fully compliant to the scoping document and it is central to understand the reason behind the challenge.

PHP231

QUALITY OF LIFE – A RARELY ACKNOWLEDGED KEY CATEGORY WITHIN THE AMNOG PROCESS IN GERMANY

Eheberg D[1], Shlaen R[2], Batscheider A[2], Gohlke A[2]
[1]*IMS HEALTH, Munich, Germany,* [2]*IMS Health, Munich, Germany*

Increasingly, quality of life becomes a more important part of the HTA assessments of new products. Assessing quality of life is trickier than changes in clinical parameters as changes of quality of life tend to occur slower and with a high level of variance. Additionally, it is sometimes necessary to assess quality of life indirectly, especially in cognitive disorders. However, the available data are often driven by the requirements for marketing authorization and rarely fit to the requests of HTA agencies. Quality of life is, among mortality, morbidity and safety, one of the key patient relevant outcomes categories in the AMNOG (Arzneimittelmarktneuordnungsgesetz; Law on the Reorganization of the Pharmaceutical Market) process in Germany. **OBJECTIVES:** Our focus was to review the impact of quality of life data presented by manufacturers since the introduction of the AMNOG in 2011 on the level of additional benefit claimed by the manufacturer and the evaluation by the Federal Joint Committee (G-BA) and the Institute for Quality and Efficiency in Healthcare (IQWiG). **METHODS:** We screened the IMS HTA database and the assessments published on the G-BA website for assessments including additional benefit claims based on quality of life. We compared these with the corresponding IQWiG reports and the final decision of the G-BA (if available). **RESULTS:** Data on quality of life was part of 36 additional benefit claims. In most cases, IQWiG (n=23) and G-BA (n=28) considered quality of life data as well. However, in 6 cases IQWiG and G-BA assessed quality of life, even though the manufacturer didn't include these data. There are only few additional benefit claims acknowledged by G-BA based on quality of life. **CONCLUSIONS:** Even though quality of life is seen as highly relevant factor for the HTA assessment of a new drug or technology, it is rarely taken into consideration.

PHP232

UNDERSTANDING THE ROLE OF SUBGROUP ANALYSIS AND TESTS FOR HOMOGENEITY OR INTERACTION IN THE AMNOG DOSSIER

Hofmann-Xu L[1], Bonduelle D[2], Eheberg D[3]
[1]*IMS Health Germany, Munich, Germany,* [2]*IMS HEALTH GmbH & Co. OHG, Munich, Germany,* [3]*IMS HEALTH, Munich, Germany*

OBJECTIVES: Although subgroup analysis in clinical trials is often criticized, it is still considered an important part of the AMNOG Dossier when describing effect modification in different patient groups. An identification of effect modification in the subgroups will either support or weaken the total additional benefit (*Zusatznutzen*) of a drug. The purpose of this article is to give a detailed background with regard to the statistical inference in subgroup analysis and a brief review of the effect of tests for homogeneity/interactions on the final grading of the additional benefit, according to the decision from IQWiG. **METHODS:** This article covers: Understanding tests for homogeneity, individual versus pooled data and influence of subgroup analysis on recent IQWiG benefit assessment. A research of the recently published AMNOG Dossiers was performed. A description was given to the number of drugs that had an additional benefit and the subgroups that were involved. Clustering analysis was performed to investigate the hidden structrue in the subgroups. Regression models were used to analyze the relationship of the subgroups and the additional benefit. **RESULTS:** Some subgroups such as age, gender and weight play a major role in the AMNOG assessment. Other subgroubs are more specific for certain disease areas e.g. BMI or hypertension for diabetis. In a worst case the benefit of a drug may disappeare when a certain subgroup is taken into consideration. **CONCLUSIONS:** Subgroups exert a profound influence upon the overall effect of a drug. Despite of the weakness of the statistical inference, subgroup analysis plays an important role in the AMNOG Dossier. Some subgroups are frequently related to the overall effect of a drug and some might even change the whole story in the AMNOG Dossier. In conclusion, subgroup analysis should be understood properly and the results should be interpreted carefully.

PHP233

THE INVERSE CORRELATION BETWEEN INTERNAL AND EXTERNAL RISK UNDER INTERNATIONAL REFERENCE PRICING: AN ANALYSIS OF SIX EUROPEAN COUNTRIES

Marinoni G, Lockwood C, Ando G
IHS, London, UK

OBJECTIVES: To index six countries on the basis of the risk they pose to pharmaceutical prices with regards to international reference pricing (IRP), from both an internal (how IRP is used by the country) and external (how other countries use this country for IRP) perspective. **METHODS:** Details on IRP methodologies were obtained from primary and secondary research. Achievable drug price levels in Bulgaria, France, Germany, Portugal and Romania were derived from these markets' IRP formula and the relative drug price levels in their reference markets (based on existing literature). Furthermore, based on the IRP formulas and relative drug price levels of each of the markets referencing these five and the United Kingdom, the markets most likely influenced by the six were identified. This number of markets, the fraction of them representing major pharmaceutical markets, and the relative price levels in each of the six countries were assigned weightings to rank them by external risk. **RESULTS:** While Bulgaria, Portugal and Romania represent the greatest internal risk for pharmaceutical prices (i.e. greatest risk of obtaining a low price as a result of IRP), these markets fall into the low and moderate risk segments in the external risk index. Conversely, while France, Germany and the UK pose the greatest external risk (i.e. as a function of the number of significant markets referencing them), they fall into the low and moderate risk segments in the internal risk index. **CONCLUSIONS:** The inversion seen between the two risk indices reflects a key aspect of the current IRP landscape. Namely, mature markets exert considerable influence on prices internationally, while their use of IRP exerts limited downward pressure on their own prices. Conversely, while IRP policy in emerging markets is more likely designed to secure the lowest possible prices, these markets carry less influence on prices internationally.

PHP234

AN ARCHETYPE FOR CLASSIFICATION AND COMPARISON OF HTA ACTIVITIES IN LATIN AMERICA

Skaltsa K[1], Allen N[2], Van Engen A[3], Blogg K[4]
[1]*Quintiles Consulting, Barcelona, Spain,* [2]*Centre for Innovation in Regulatory Science, London, UK,* [3]*Quintiles Consulting, Hoofddorp, The Netherlands,* [4]*Quintiles Consulting, Reading, UK*

OBJECTIVES: HTA processes are being implemented in Latin America in an effort for a more efficient resource allocation. The objective of this study was to explore the HTA environment and classify its diversity based on previously developed taxonomies. This enables the comparison within the region, as well as with other regions in which similar maps have been developed, such as Europe. **METHODS:** Two taxonomic groupings were used as described in Allen et al 2013 Health Policy 113; 305– 312. The first one is based on the position of a national HTA agency in relation to the position of the regulatory and the coverage body. The second set focuses on the key tasks performed by the HTA agency. The following countries were examined: Mexico, Cuba, Costa Rica, Colombia, Venezuela, Ecuador, Peru, Bolivia, Brazil, Uruguay, Argentina and Chile. No information on HTA activity could be identified for the rest of the countries on official websites or publications. **RESULTS:** Seven different archetypes were identified by combining different values of the two taxonomic sets in these twelve countries. There were two main groups identified: one consisting of Brazil, Cuba and Chile where the HTA and coverage decisions are performed by the same agency and regulatory is independent, and the other one consisting of Costa Rica, Venezuela, Peru and Bolivia where no HTA process was identified and external evaluations or decisions from reference countries are used to inform decisions. **CONCLUSIONS:** Although the landscape is expected to change in the coming years, this first high-level overview shows that currently, there is a high degree of heterogeneity in HTA processes in Latin America despite the fact that these countries tend to share expertise in various levels, with few countries following similar processes and a number of countries with no HTA bodies in place at any decision level.

PHP235

COMBINING HEADROOM AND RETURN ON INVESTMENT ANALYSIS TO RANK POTENTIAL COMMERCIAL VALUE OF SIX MEDICAL DEVICES IN DEVELOPMENT

Markiewicz K[1], van Til JA[1], Steuten LMG[2], IJzerman MJ[3]
[1]*University of Twente, MIRA Institute for Biomedical Technology & Technical Medicine, Enschede, The Netherlands,* [2]*University of Twente, Enschede, The Netherlands,* [3]*MIRA Institute for Biomedical Technology & Technical Medicine and University of Twente, Enschede, The Netherlands*

OBJECTIVES: The development process of medical devices strongly depends on the financial resources available and the expected return on investment to manufacturers. The aim of this paper is to analyse the potential commercial viability of two disruptive and four incremental medical devices in different stages of development. **METHODS:** The headroom method combined with the return on investment analysis was performed for one therapeutic and five diagnostic devices for different clinical target areas. Information regarding maximum additional benefit that could be obtained with new device, the estimated production price and expected sales volume was gathered from literature and expert opinions. A willingness-to-pay threshold for one additional QALY of €30,000 was assumed for headroom analysis. **RESULTS:** The devices were ranked according to their potential commercial viability. The analysis showed that two disruptive and two incremental devices had reasonably good balance between headroom and unit cost, and two incremental devices had no good balance. The device with the highest potential commercial viability was a disruptive therapeutic device for the cartilage repair treatment in the first clinical trial stage, with estimated headroom for the cost of the new treatment: €74,600 and an expected production cost of the therapy: €8,000 per unit. The market volume size was calculated based on the incidence of cartilage defects: 65% in routine knee arthroscopies. The disruptive diagnostic device for home brain monitoring of epilepsy patients in the prototype stage of development had the lowest potential commercial viability, with an estimated headroom of €81,000 and an expected production costs per unit: €120,000 that resulted in the unfavorable return on investment. **CONCLUSIONS:** The headroom method combined with a return on investment analysis, offers insight in the potential commercial viability of medical devices under development. The research on the impact of that analysis on actual R&D decision making will still be determined.

PHP236

TRANSFERABILITY OF ECONOMIC EVALUATIONS TO CENTRAL AND EASTERN EUROEPAN AND FORMER SOVIET COUNTRIES

Mandrik O[1], Knies S[2], Kaló Z[3], Severens JL[4]
[1]*Institute of Health Policy & Management, Erasmus University Rotterdam, Kiev, Ukraine,* [2]*Institute of Health Policy & Management, Erasmus University Rotterdam, Rotterdam, The Netherlands,* [3]*Eötvös Loránd University (ELTE), Budapest, Hungary,* [4]*Erasmus University Rotterdam, Rotterdam, The Netherlands*

OBJECTIVES: Data availability and decision makers methodology requirements are two important factors influencing transferability of economic studies. Applying qualitative assessment of experts' opinion and systematic review of published economic studies, we aimed to analyze transferability of economic evaluations in Central and Eastern European (CEE) and former Soviet countries. **METHODS:** Firstly, eleven reimbursement experts from eight countries were interviewed on their background and current practice of using economic evaluations, opinion regarding transferability of economic evaluations and importance of individual Welte's transferability factors. Secondly, we analyzed peer-reviewed English-language economic evaluations