shows a positive development within the region’s HTA. The Regional Decrees were informed, 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

Eberberg, D1, Shihan K2, Batscheider A3, Gohlke A3

1IMS Health, Munich, Germany; 2IMS Health, Munich, Germany; 3IMS Health, Munich, Germany; 4IMS 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. In this country, the position of the coverage and regulatory body is not a key aspect, especially because of the tax-relevant outcomes categories in the AMNOG (Arzneimittelmarktneuordnungsverordnung).

In the Reorganisation 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 few differences between the countries, Portugal and Bolivia, respectively. G-BA based on quality of life.

**CONCLUSIONS:** Even though quality of life is seen as highly relevant 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 HETEROGENEITY IN THE AMNOG Dossier**

Hofmann Xu1, Ronduelle D2, Eberberg D3

1IMS Health Germany, Munich, Germany; 2IMS HEALTH GmbH & Co. OHG, Munich, Germany; 3IMS 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 with all-cause mortality was performed. The significance of the additional benefit claims and the additional cost 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 structure in the subgroups. Regression models were used to test the relationship of the subgroup and the additional benefit claiming for the rest of the countries on official websites or publications.

**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 few differences between the countries, Portugal and Bolivia, respectively. G-BA based on quality of life.

**CONCLUSIONS:** Even though quality of life is seen as highly relevant for the HTA assessment of a new drug or technology, it is rarely taken into consideration.

**PHP235 COMBATING HEADROOM AND RETURN ON INVESTMENT ANALYSIS TO RANK POTENTIAL COMMERCIAL VALUE OF SIX MEDICAL DEVICES IN DEVELOPMENT**

Markiewicz K1, van Til J1, Steuren LMGT2, IJzerman M3

1University of Twente, 2MBA Institute for Biomedical Technology & Technical Medicine, Enschede, The Netherlands, 3Erasmus University Rotterdam, Rotterdam, The Netherlands

**OBJECTIVES:** The development process of medical devices strongly depends on financial resources available and the expected return on investment by 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 five out of the six medical devices. The first set of countries shares expertise in various levels, while most countries follow similar processes. The second set focuses on the 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 two countries. These countries tend to share expertise in various levels, but with few countries following similar processes and a number of countries with no HTA bodies in place at any decision level.

**PHP236 THE INVERSE CORRELATION BETWEEN INTERNAL AND EXTERNAL RISK UNDER INTERNATIONAL REFERENCE PRICING: AN ANALYSIS OF SIX EUROPEAN COUNTRIES**

Marnon G1, Lockwood C, Ando G

1IBS, 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 method life of six countries were obtained from primary and secondary research. Achievable drug price levels in Bulgaria, France, Germany, Portugal and Romania were derived from these market’s key stakeholders' informal discussions 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's (UK) maximum price, we calculated a relative volume for each of the six were identified. The number of markets, the fraction of them representing major pharmaceutical markets, and the relative price levels in each of the six countries were assigned weights to rank them by external risk.

**RESULTS:** While Bulgaria, Portugal and Romania represent external IRP risk for pharma companies (€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: €74,600 and an expected production cost of the therapy: €8,000 per unit.

**PHP237 NEW PHARMACEUTICALS IN DEVELOPMENT: WHICH ONE IS THE MOST VALUABLE TO INVEST IN?**

Mandiri O1, Knes K2, Kali P3, Severiens J4

1Institute of Health Policy & Management, Erasmus University Rotterdam, Rotterdam, The Netherlands, 2Eötvös Loránd University (ELTE), Budapest, Hungary, 3Erasmus University Rotterdam, Rotterdam, The Netherlands

**OBJECTIVES:** The aim of this study was to explore the key aspects that could be considered an important part of the AMNOG Dossier when describing effect modification in the clinical target areas. Information regarding maximum additional benefit that could be obtained with new device, the estimated production price and expected sales volume were gathered from the literature and expert opinions. A willingness-to-pay threshold for one additional QALY of £30,000 was assessed for headroom analysis.

**RESULTS:** The devices were ranked according to their potential commercial viability: an analysis based on the Headroom index and two incremental devices had very high commercial viability. The device with the highest potential commercial viability was a disruptive therapeutic device for the cartilage repair 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: €74,600 and an expected production cost of the therapy: €8,000 per unit.

**PHP238 THE INVERSE CORRELATION BETWEEN INTERNAL AND EXTERNAL RISK UNDER INTERNATIONAL REFERENCE PRICING: AN ANALYSIS OF SIX EUROPEAN COUNTRIES**

Marnon G1, Lockwood C, Ando G

1IBS, 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 method life of six countries were obtained from primary and secondary research. Achievable drug price levels in Bulgaria, France, Germany, Portugal and Romania were derived from these market’s key stakeholders' informal discussions 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's (UK) maximum price, we calculated a relative volume for each of the six were identified. The number of markets, the fraction of them representing major pharmaceutical markets, and the relative price levels in each of the six countries were assigned weights to rank them by external risk.

**RESULTS:** While Bulgaria, Portugal and Romania represent external IRP risk for pharma companies (€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: €74,600 and an expected production cost of the therapy: €8,000 per unit.