A COMPARISON OF COVERAGE AND REIMBURSEMENT DECISIONS IN GERMANY (AMNOG) AND SCOTLAND (SMC)

INTRODUCTION & OBJECTIVE

- Germany and Scotland are arguably among the first countries that manufacturers submit their evidence to
  - in order to get reimbursed
- In Germany, with the introduction of the new AMNOG (Arzneimittelmarktneuordnungsgesetz) on January 2011, the pricing regulators for newly authorized pharmaceuticals and their reimbursement by statutory health insurance providers has altered
- There are three main government stakeholders in the AMNOG process: the Institute for Quality and Efficacy in Health Care (IQWiG), the Federal Joint Committee (G-BA) and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)
- Pharmaceutical companies have a different reimbursement strategy in both countries due to the different profit and market access regulations
- The list price is still set by the manufacturers upon launch. Nevertheless, a commonly undisputed fixed reimbursement price is set by the GKV-Spitzenverband and IQWiG. IQWiG is the statutory payer for the majority of the health care insured individuals in Germany. It is responsible for the negotiation and decision-making process with the G-BA, the statutory payer for the majority of primary care insured individuals in Germany. IQWiG is an independent institute that is responsible for assessing the added effectiveness of new pharmaceuticals
- The G-BA makes a reimbursement decision that results in a so-called Reimbursement Decision (RD) that determines whether a medicine is reimbursable by statutory health insurance
- The SMC evaluates the submissions of medicines in Scotland for reimbursement

METHODS

- All AMNOG and SMC decisions made in 2011–2012 were identified (see poster PHP36)
- The only clinical benefit assessment made by G-BA was taken into account for this study
- In case of a G-BA decision, the benefit assessment is performed for every available subpopulation and the outcome may be different for each of them
- For this purpose, the study, the most positive outcome was selected and taken into consideration as the final benefit outcome for the whole product.
- In case of previous publication of price rebate negotiations, the outcome of the GKV-Spitzenverband is considered. However, none of the manufacturers allowed for the website to be disclosed. Hence, a general search was conducted to identify price rebate negotiations
- The SMC website was searched to identify all reimbursement decisions for the same period of time. However, three cases were identified where the application process of some medicines in Scotland failed in Germany. Hence, the SMC website was hand searched to identify individual decisions made post December 2012
- All matching AMNOG-SMC cases were identified and compared in terms of clinical benefit assessment and reimbursement decisions

RESULTS

- Cases
  - From January 2011 to December 2012, 41 G-BA decisions, covering 66 subgroups, and 129 SMC cases were included
- Twenty-four matching cases were compared, as these were assessed by both G-BA and SMC
- The 24 common cases along with the clinical benefit assessment outcome and the reimbursement decision are presented in Table 1 and Table 2, respectively

AMNOG

- In 7 cases (29%) the G-BA acknowledged considerable benefit, in 3 cases (13%) minor additional benefit, in 5 cases (24%) no benefit and in 8 cases (38%) the submitted evidence was not sufficient for a benefit to be demonstrated (no proof of benefit)
- For the 21 cases, the price negotiations were completed, while for the remaining 3 the process was still ongoing
- For 17 products (81%), the negotiations led to an agreed refund amount. For 4 cases (5%) no agreement was reached. Hence, the price was set by the arbitration board (fixed reimbursed amount)
- Finally, in 3 cases (5%), no amount was defined as the manufacturer decided not to launch the product in Germany
- It seems that a positive list is created in Germany, as none of the assessed products were rejected for reimbursement
- The negotiated price rebate was available only for 29 cases. On the grounds of the benefit assessment, the negotiated price rebate ranged from 4.7% to 56% (based on manufacturer’s selling price)
- Of the 41 identified AMNOG cases, 7 products were labelled as orphan drug. Only one of the orphan drugs was assessed by both G-BA and SMC: the remaining 6 were assessed by SMC and excluded from this study

SMC

- In SMC, a product of interest can demonstrate superiority, non-inferiority or inferiority over the comparator. The SMC acknowledged superior benefit in 15 cases (57%) and therapeutic equivalence in the remaining 9 cases (35%)
- The SMC recommended to reimburse 16 products (57%), of which 6 (28%) were restricted to a specific population or time period. SMC rejected 8 cases (31%) based on weak-economic evidence. For 4 of the restricted products, the restriction was related to the cost effectiveness outcomes

Comparing AMNOG versus SMC

- Both G-BA and SMC have a different approach to the same clinical benefit assessment in only 11 cases (60%) with the AMNOG implementing a more rigorous process with respect to clinical evidence in comparison to SMC
- Only G-BA is required to reimburse all assessed products, whereas evidently SMC can reject a product for reimbursement or restrict its use to a certain population if it assesses no value for money
- Finally, it was observed that the SMC assessment process starts either at the same time or a few months later than the AMNOG process

REFERENCES


DISCUSSION

- AMNOG and SMC have their own analytical framework to decide upon a reimbursement and/or recommendation. This may lead to different outcomes for the same product in Germany and Scotland, respectively
- The list price of a product is still freely set by the manufacturer upon launch and the patients can freely get access to it until the final benefit assessment. When the benefit assessment is completed, AMNOG final prices may resemble generic prices for products that demonstrate a minor additional benefit
- This study was limited to publicly available information. Contextual factors such as the social, economic, health care and political environments as well as the constraints imposed by history and institutional frameworks were also not incorporated into this study
- It would be ideal to extend this research by including more countries. International comparison may contribute to a better understanding of the implications that different pricing and reimbursement policies may have on the global market access environment

Table 1. Clinical benefit assessment per product, HSA agency and agreement status

Table 2. Reimbursement decision - recommendation per HSA agency

- Cost-effectiveness analysis is a crucial factor influencing the SMC reimbursement decision. The SMC may decide not to reimburse a product if the benefit is insufficient for a benefit to be demonstrated (no proof of benefit)
- It would be ideal to extend this research by including more countries. International comparison may contribute to a better understanding of the implications that different pricing and reimbursement policies may have on the global market access environment