Trend analysis of G-BA decisions - what factors influence the likelihood of recommendations?

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Objectives

The first step in the route to reimbursement of a new product in Germany through the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) process is an assessment of additional benefit, conducted by the Gemeinsamer-Bundesausschuss (G-BA) and is mandatory for new active substances entering the German market as of January 1st, 2011. The assessment is basically a comparison of the new drug with the best existing therapy for the same indication (so called “comparator therapy”), or with best supportive care in case of orphan drugs. At the end of the assessment the G-BA will award a rating of the additional benefit (i.e. the added value) of the drug. Additional benefit of a new substance is classified as major, considerable, minor, unquantifiable or ‘no-benefit’. This rating will be the basis of the subsequent price negotiations with the payer groups. The result of the G-BA assessment will significantly influence the reimbursement price of a drug in the German market. We conducted an analysis to compare trends of G-BA decisions for new technologies and orphan technologies. Further analysis was conducted to identify differences in disease areas which may support companies planning a European launch of a new product.

Methods

A validated, longitudinal MAP BioPharma database containing all additional benefit decisions made by the G-BA was analyzed[1,2]. Orphan analysis was conducted for products with European Union (EU) orphan designation. Analysis by disease area classified products into British National Formulary (BNF) categories. Reviewed assessments were not accounted for in the analysis.

Results

In 2011-2014, G-BA assessed 105 new technologies and concluded 47% of products had no additional benefit, 25% had minor additional benefit, 21% had considerable additional benefit and the remaining 8% had unquantifiable additional benefit. From 2012 to 2014, there appears to have been a reduction in the number of decisions of ‘no additional benefit’ and simultaneously an increase in the number of products classified as having considerable additional benefit (Figure 1). No technologies have been classified as having major additional benefit. G-BA are unable to classify an orphan treatment as having no additional benefit due to the nature of orphan designation thus zero ‘no-benefit’ decisions of orphan products have been made but the G-BA decided that 38% (n=16) of orphan products had unquantifiable additional benefit and 19% had considerable additional benefit (n=3) (Figure 2). 35% of G-BA decisions were for malignant disease and immunosuppression products (n=37) and this is the category with the best recommendation rate as 15 products were found to have considerable benefit and only 8 were deemed to have no additional benefit (Figure 3). Products in the infections category also had a good recommendation rate but other commonly submitted products such as those for the endocrine and central nervous system, faired less well with the majority classed as having no benefit. Submissions within each category were fairly consistent over time with the exception of products for the endocrine system: 11 of the 17 assessments were in 2013 and 7 of the 11 assessed were found to have no additional benefit.

Figure 1. G-BA Benefit Assessment Summary of all new products since the AMNOG process began

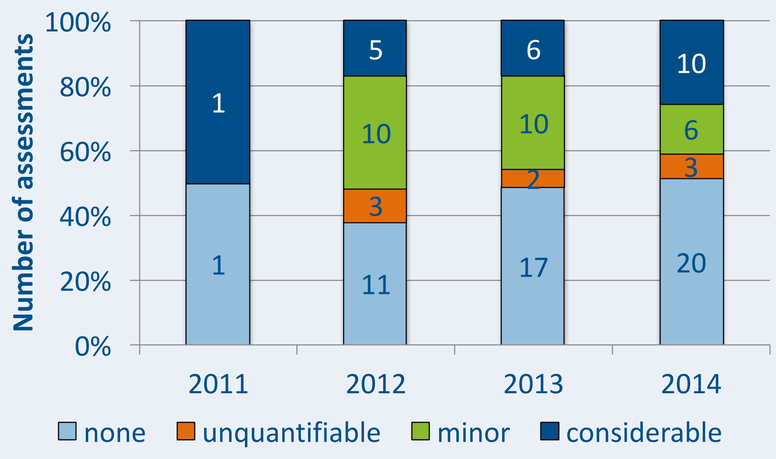


Figure 2. G-BA Benefit Assessment Summary of all new orphan products since the AMNOG process began

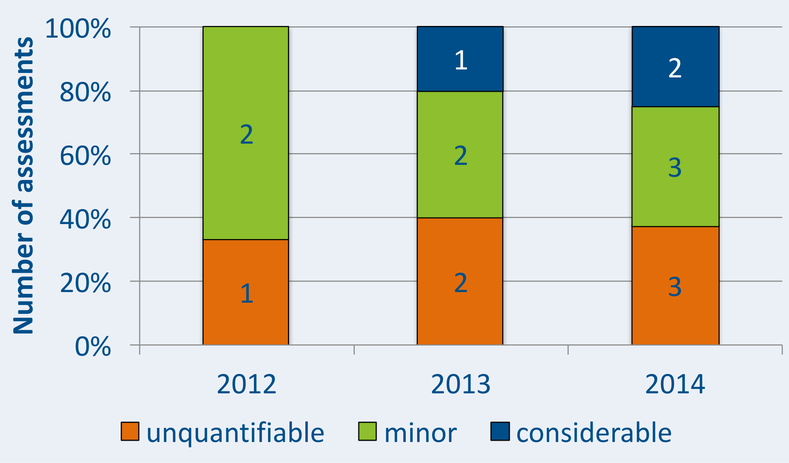
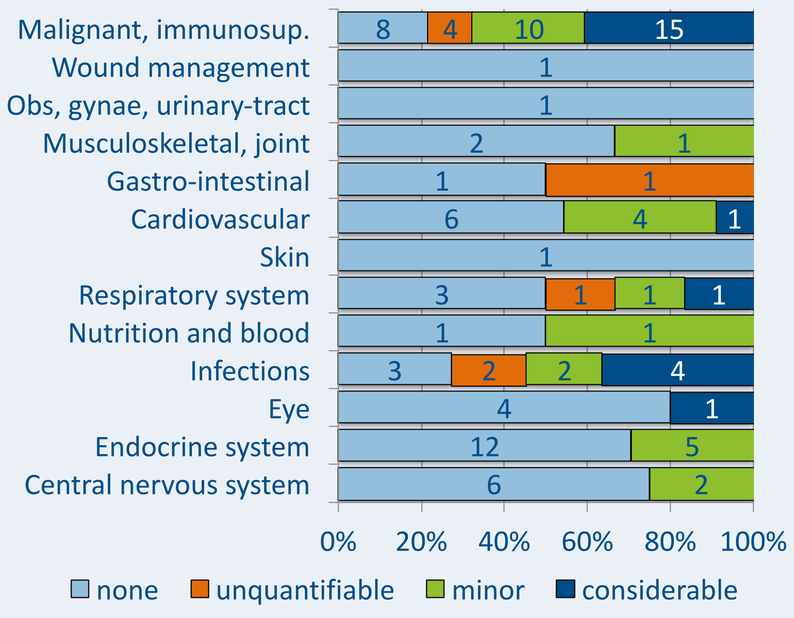


Figure 3. G-BA Benefit Assessment Summary of all new orphan products since the AMNOG process began



Conclusions

A high proportion of G-BA decisions have classified products as having no or unquantifiable additional benefit over the comparator indicating that obtaining a high price in Germany is challenging. However, a higher additional benefit rating is more likely for orphan, malignant disease and immunosuppression and infection products and thus negotiating a higher price for these products is more likely.

This needs to be interpreted with caution as market access is not simply dictated by the additional benefit assessment, but should be considered in a broader context. In particular, two very specific and beneficial aspects of the G-BA and AMNOG process must be considered:

1. Patients in Germany are fortunate to gain immediate access to new medicines as soon as they are launched and that this access is at a price of the manufacturer's choosing.
2. Orphan drugs are treated quite differently in Germany compared with many other countries, since for products with an annual turnover of no more than 50 million euros in the statutory health insurance scheme, an additional medical benefit is assumed by law[3] and they are not subject to a full assessment by the Institute for Quality and Efficiency in Health Care (IQWIG).

References:
1. MAP BioPharma HTA database and trends analysis. Selected charts available at: http://www.mapbiopharma.com/germany
2. G-BA recommendations obtained from the G-BA website: https://www.g-ba.de/informationen/nutzenbewertung/
3. Gemeinsamer Bundesausschuss. Benefit assessment of pharmaceuticals. The special case of orphan drugs. http://www.english.g-ba.de/benefitassessment/information/

Acknowledgements:
Chris Wolters - Wachenhausen Law, Lübeck, Germany.
Alexander Natz - Natz Law, Düsseldorf, Germany.

Presented at ISPOR 20th Annual International Meeting; Philadelphia, USA; May 16-20, 2015. Poster No. 142