AMNOG DOSSIERS AS A CHALLENGE FOR PHARMACEUTICAL COMPANIES: IS THERE A CORRELATION BETWEEN VOLUMES AND ADDED MEDICAL BENEFIT?

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BACKGROUND

- On the date of launch in Germany, it is mandatory for pharmaceutical companies to hand in an AMNOG dossier to the Federal Joint Committee (FJC).
- In order to realize a higher drug price than that of its appropriate comparator (defined by FJC) the FJC must determine that an additional medical benefit exists.
- Six categories for an added medical benefit exist: less benefit, none, minor, considerable, major, and non-quantifiable. For orphan drugs, contrary to non-orphan drugs, an added medical benefit is considered to exist by default. However, companies need to quantify the extent of the added medical benefit.
- The effort and resources required to assemble an AMNOG dossier are extensive, and oftentimes, they are underestimated by companies. One major challenge is the extensive mandatory data requirements, which go beyond those of European Medicines Agency (EMA) or Food and Drug Administration (FDA).

OBJECTIVES

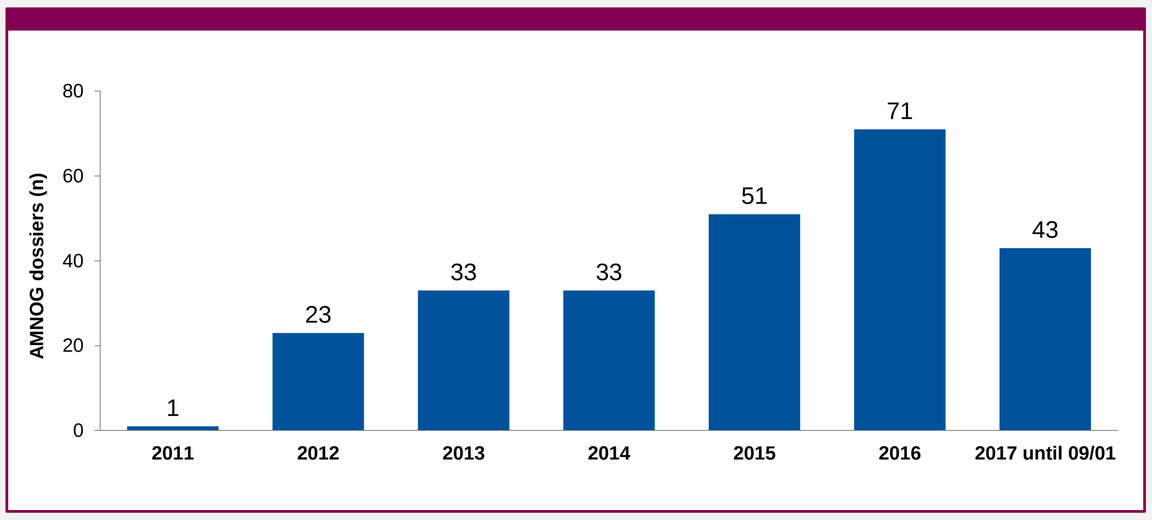
- The objective of the study was to elucidate whether there is a correlation between volumes (number of pages) of dossiers and the added medical benefit acknowledged by the FJC. The volumes of module 4 can be considered as a proxy for the amount of evidence and data on the drug of interest. Module 4 is the central part of a dossier, as it contains clinical data on which added medical benefit is assessed.
- As for orphan drugs and contrary to non-orphan drugs, the existence of an added medical benefit is assumed by default, non-orphan and orphan drugs were analyzed separately.
- In addition, patterns of volumes of dossiers regarding indication and year of publication were analyzed.

METHODS

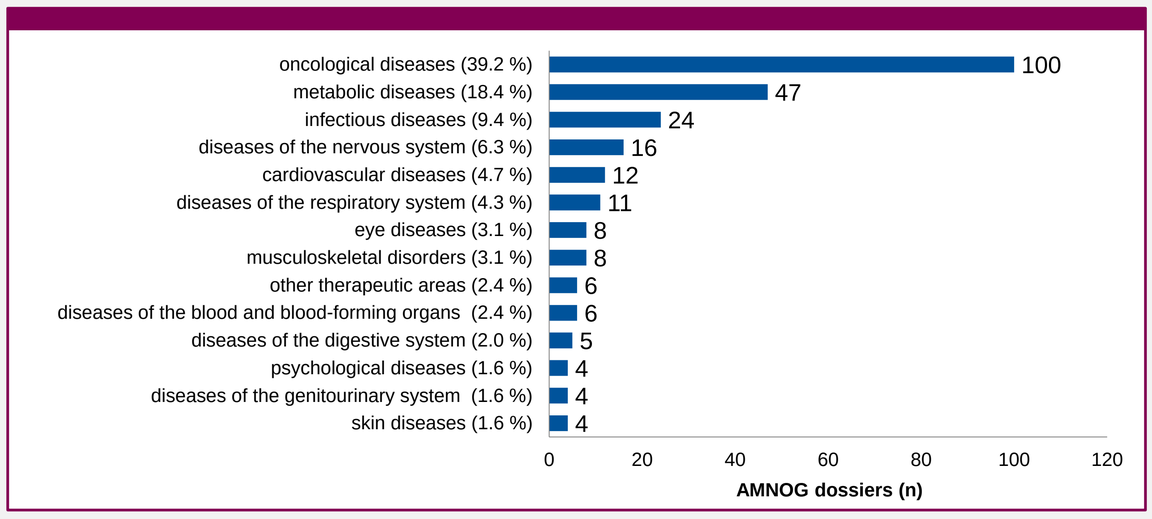
- Analyses were conducted by text-mining the website of the FJC (https://www.g-ba.de/informationen/nutzenbewertung/) and all submitted PDF files. Results were combined with insights of an in-house business intelligence database on outcomes of AMNOG procedures.
- Volumes of module 4 were compared in a descriptive manner to the respective added medical benefit to conclude on a possible correlation.
- Total volumes (module 1–4) were used to describe patterns over time and among indications.

RESULTS

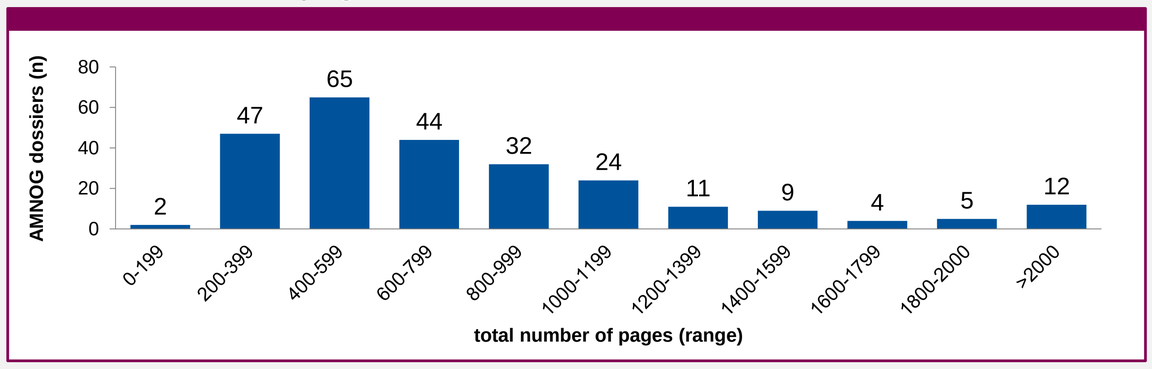
- Since the enactment of AMNOG in 2011, 255 AMNOG dossiers have been submitted to the FJC. There is a steady increase in the number per year; whereas in 2012, 22 AMNOG dossiers were published, this number rose to 71 in 2016 (2017 until 09/01, when there were 43 AMNOG dossiers).



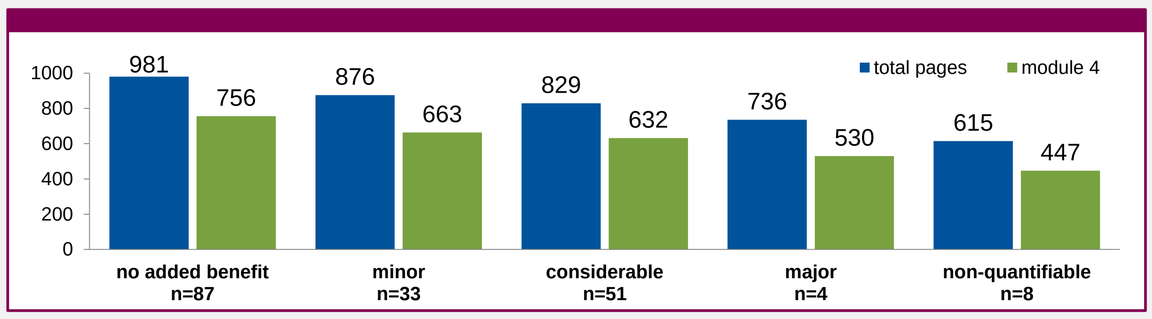
- 39.2 % of the dossiers were in the field of oncology, followed by metabolic diseases (18.4%).



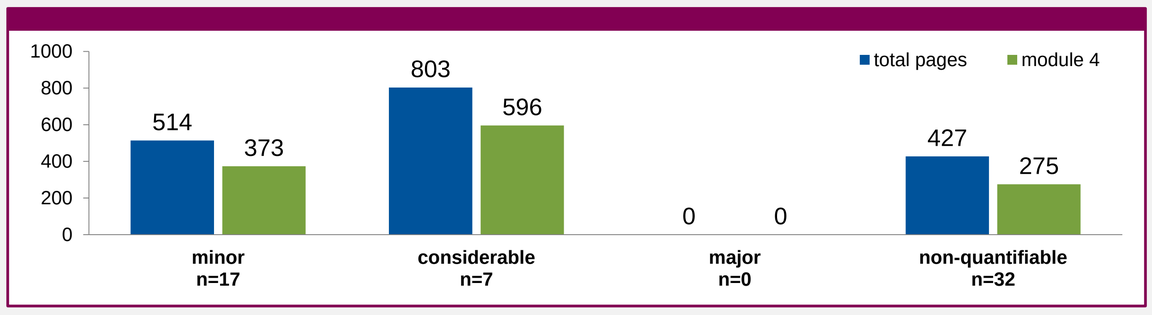
- Mean number of pages was 829, with a maximum of 3,465.



- For non-orphan drugs, there is an inverse trend between the mean volumes of module 4/total pages of dossier and added medical benefit: major (530/736 pages), considerable (632/829), minor (663/876), and no added medical benefit (756/981), and non-quantifiable (447/615). The largest dossiers were those with no added medical benefit: 756 pages for module 4 and 981 total pages for all modules.



- In orphan drugs, however, the added medical benefit did correlate with the mean volume of module 4/total pages of dossier: considerable (596/803), minor (373/514), and non-quantifiable (275/427).



CONCLUSIONS

- Between 2012 and 2016 the annual number of AMNOG dossiers nearly tripled.
- Writing an AMNOG dossier is labor and resource intensive, as various functions within a company have to be involved. Hence, as a general rule, intensive recalculation of clinical data is required.
- For non-orphan drugs, uncertainty regarding the presumed added medical value seems to translate into greater volume of the dossiers.
- The inverse effect in orphan drugs might be attributable to the fact that more comprehensive clinical data might facilitate emphasizing the clinical value of drugs, thus leading to a higher rating.
- Combination of well-curated business intelligence and cleverly text-mined data from the available dossiers can offer insights on a range of issues within the Health Technology Assessment processes in Germany.

Presented at ISPOR 20th Annual European Congress | 4-8 November 2017 | Glasgow, Scotland | Session IV | PHP258

Funded by Xcenda GmbH