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 a company. 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.

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/unternehmen/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).

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.