NON-QUANTIFIABLE BENEFIT WITHIN THE GERMAN AMNOG SYSTEM: FACTORS CONTRIBUTING TO TIME LIMITS SET FOR BENEFIT RESOLUTIONS AND POTENTIAL IMPLICATIONS ON PRICE DISCOUNTS

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BACKGROUND
• Since 2011, pharmaceutical companies have been obliged by German law to submit a benefit dossier for a new product when it is launched on the German market or authorized for new indications [Reform of the Market for Medicinal Products (AMNOG)].
• The assessment, conducted by the German health technology assessment (HTA) body Gemeinsamer Bundesausschuss (Federal Joint Committee, FJC), is evidence-based and can result in “major,” “considerable,” “minor,” “non-quantifiable,” “not,” or even “loss” benefits.
• Additionally, the FJC can set a time limit for its resolutions, requesting that the pharmaceutical company submit new evidence for a de novo assessment.

OBJECTIVE
• This study explored the number of assessments (including all [sub]-labels) with non-quantifiable benefit resolutions, both in the orphan drug (OD) and non-OD setting, in order to investigate the set time limits relative to the clinical evidence and their implications on price discounts negotiated with the National Association of Statutory Health Insurance Funds.
• In addition, information about European Medicines Agency (EMA) market authorization details and their possible impact on the decisions made by the FJC were analyzed.

METHODS
• Information on FJC resolutions with the outcome “non-quantifiable” were retrieved from a database containing all AMNOG dossiers that were published on the FJC website. The data cut-off was 16 August 2017.
• The results identified as “non-quantifiable” were subsequently classified in OD or non-OD assessments. Among all findings, information on time limits and clinical evidence was extracted.
• Information regarding market authorization details of the analyzed drugs was obtained from the EMA website.
• Price discounts were analyzed using the LAUER-FISCHER WEBAPOI® InfoSystem.

RESULTS
• Since the enactment of AMNOG in 2011, 559 (sub)-labels have been assessed by the FJC until 16 August 2016; of which, 84 assessments were OD (Figure 1A).
• The majority of non-quantifiable added benefits were granted after 2014 (73.8 %), with an increase in proportions of the total 61 relevant resolutions with a non-quantifiable added benefit were identified (10.9 % of all assessments), including 44 OD assessments.
• Since the enactment of AMNOG in 2011, pharmaceutical companies have been obliged by German law to submit a benefit dossier for a new product when it is launched on the German market or authorized for new indications [Reform of the Market for Medicinal Products (AMNOG)].
• The assessment itself, conducted by the German heath technology assessment (HTA) body Gemeinsamer Bundesausschuss (Federal Joint Committee, FJC), is evidence-based and can result in “major,” “considerable,” “minor,” “non-quantifiable,” “not,” or even “loss” benefits.
• Additionally, the FJC can set a time limit for its resolutions, requesting that the pharmaceutical company submit new evidence for a de novo assessment.

CONCLUSIONS
• The likelihood of a time limit set by the FJC in terms of a non-quantifiable benefit increase with the decrease in the evidence level of data presented in the dossier.
• Since the clinical trials for OD approval are often single-armed, due to the rarity and severity of the disease and are often combined with immature data, it is more likely to get a time limit set by FJC for OD drugs, which generally contain data based on RCT.
• It seems to be that market authorization decisions made by EMA might influence a time limit for the benefit resolutions made by the FJC. This is possibly triggered by the common ground of less comprehensive data or immature data submitted for both assessments (often due to the OD status of the drug).
• Furthermore, it seems plausible that a time-limited resolution negatively influences the extent of the price discount negotiated with the National Association of Statutory Health Insurance Funds in the OD setting.