AMNOG BENEFIT ASSESSMENT IN GERMANY AND ITS IMPACT ON PRICE NEGOTIATIONS

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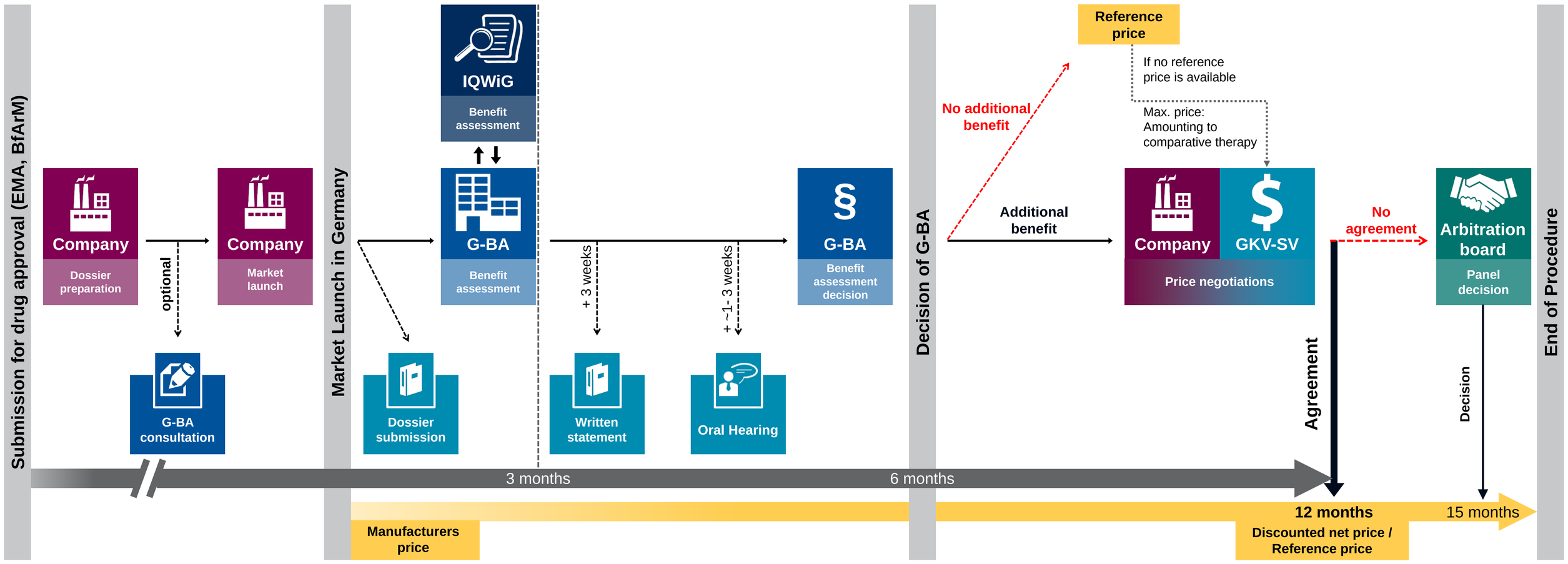
Background / Objectives

- Since the enactment of the AMNOG in 2011, pharmaceutical companies are required to prove the added medical benefit of newly approved drugs including new area of application compared to the standard of care in Germany.
- This added medical benefit is evaluated by the Joint Federal Committee (G-BA) and the Institute for Quality and Efficiency in Health Care (IQWiG).
- The aim of this study was to investigate the effect of the outcome of the benefit assessment on the negotiated reimbursement price with the National Association of Statutory Health Insurance Funds (GKV-SV).

Methods

- A database containing all evaluated AMNOG dossiers from 2011 until the end of April 2019 was analyzed.
- Information on G-BA assessments and decisions on the added medical benefit were extracted.
- Prices at the time of launch including alterations were obtained from the Lauer-Taxe®.
- Benefit assessments were qualitatively and quantitatively analyzed for predictors of assessment outcome, major pitfalls and impact on price negotiations.

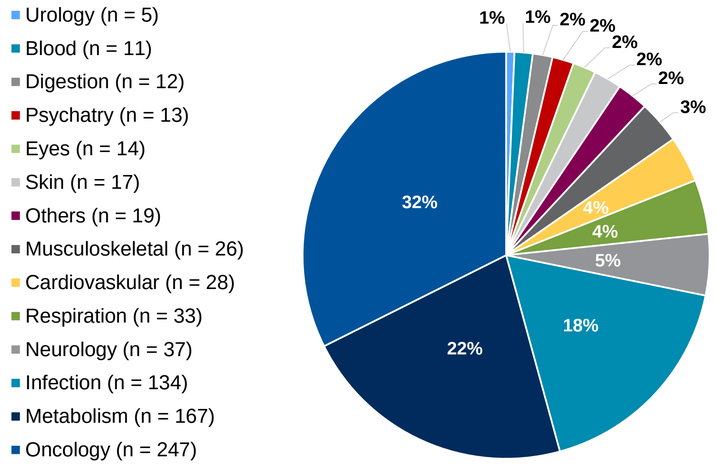


Results

Table 1: Institutions involved in Market Authorization and AMNOG Benefit Assessment

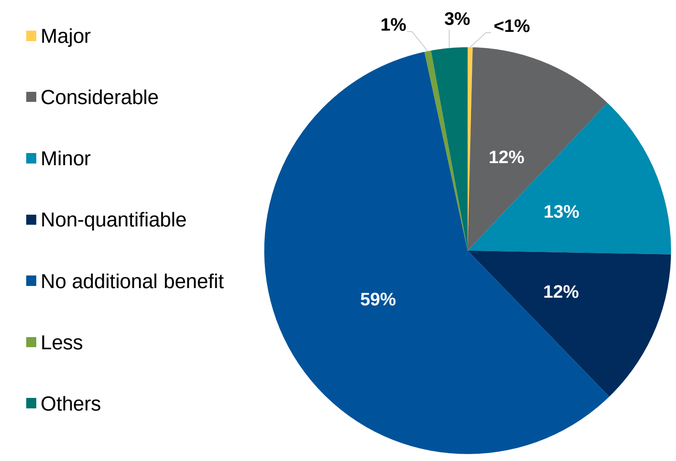
Institution	Role
EMA	**European Medicines Agency** o Market authorization in Europe (centralized procedure) o European Union agency for the evaluation of medicinal products o Responsible for scientific evaluation, supervision and safety monitoring of medicines in the EU
BfArM and PEI	**Federal Institute for the evaluation of medicinal products and Federal Institute for Vaccines and Biomedicines** o Market authorization in Germany (decentralized procedure) o Responsible for scientific evaluation, supervision and safety monitoring of medicines in Germany
G-BA	**Federal Joint Committee** o Appraises the evidence based on the manufacturer dossier, IQWiG´s assessment report (IQWiG assessment is not binding) o Decides on the medical added benefit
IQWiG	**Institute for Quality and Efficiency in Health Care** o Assessment of benefit dossiers on behalf of the G-BA o Appraisal of added benefit, but no formal decision-making body (can be overruled by G-BA, leading to an addendum) o Advises G-BA
GKV-SV	**National Association of Statutory Health Insurance Funds** o Association of health insurance funds at federal level in accordance with section 217a of Book V of the German Social Code (SGB V) o Responsible for price negotiations with the manufacturer
Arbitration Board	o Decides on reimbursement price if negotiations with GKV-SV fail o Consists of impartial 3 members and two representatives of each GKV-SV and the pharmaceutical company o Reimbursement price is retroactive to the 13th month after market launch

Figure 1: Distribution of Assessed AMNOG Dossiers



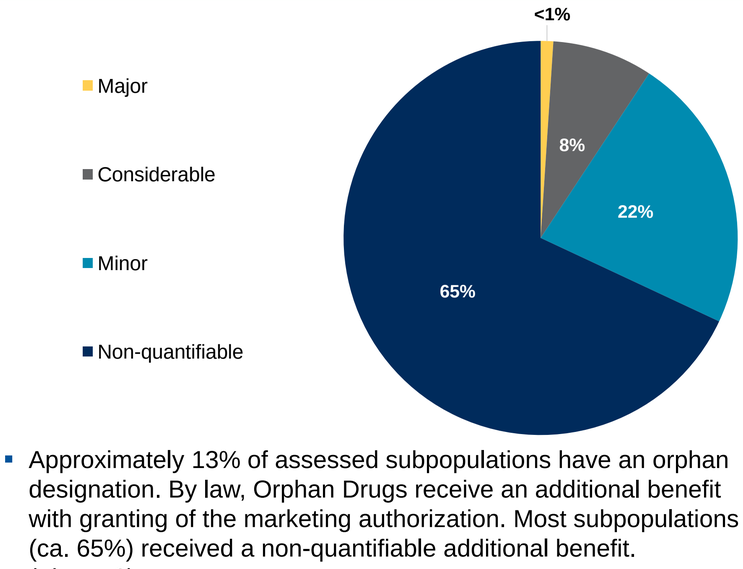
- 391 AMNOG assessments were published from January 2011 to April 2019 and conclusively assessed by G-BA. These dossiers included 763 separately evaluated indications and relevant subpopulations (Figure 1).
- Most assessed subpopulations were in the field of oncology (247), metabolic disorders (167), and infectious diseases (134).

Figure 2: Outcome of AMNOG Asssments



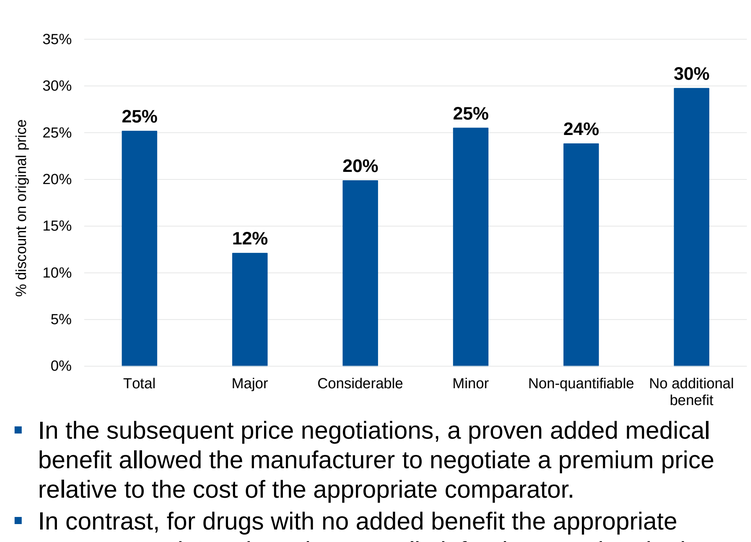
- Approximately 37% of the assessed subpopulations received an added benefit whereas 59% received no added benefit. Other outcomes were a lesser benefit or discontinued procedures. (Figure 2).

Figure 3: Outcome of Orphan Drug AMNOG Assessments



- Approximately 13% of assessed subpopulations have an orphan designation. By law, Orphan Drugs receive an additional benefit with granting of the marketing authorization. Most subpopulations (ca. 65%) received a non-quantifiable additional benefit. (Figure 3).

Figure 4: Discount on original price



- In the subsequent price negotiations, a proven added medical benefit allowed the manufacturer to negotiate a premium price relative to the cost of the appropriate comparator.
- In contrast, for drugs with no added benefit the appropriate comparator determines the upper limit for the negotiated price and discounts are higher (approx. 30% discount) (Figure 4).

Conclusions

- Since 2011 benefit assessments have become a key component in pricing new drugs in Germany. Between January 2011 and April 2019, 391 benefit assessments with 763 subpopulations were submitted and appraised.
- By law, Orphan Drugs are granted an additional medical benefit by AMNOG rules. Most assessments resulted in a non-quantifiable benefit.
- Compliance with the rules of procedure of G-BA/IQWiG and submission of comparative evidence towards the appropriate comparator defined by G-BA is crucial to receive an added benefit. Major pitfalls are quality of evidence (e.g. RCT vs. single arm study), patient relevance of endpoints and the deviations from the appropriate comparator therapy.
- Receiving an added medical benefit influences price negotiations positively whereas no added benefit results in higher rebates on the reimbursement price. No added benefit leads to a lower price and may result in the decision by the company to withdraw from the market.

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