**AMNOG Benefit Assessment for Oncologic and Orphan Drugs in Germany: Implications for Price Discounts**

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**BACKGROUND**

- The Act on the Reform of the Market for Medical Products (AMNOG) (Arzneimittelmarkt- Neuordnungsgesetz) became effective in 2017, and upon-market registration, pharmaceutical companies are obliged by law to submit a benefit dossier to the Federal Joint Committee (FIC) in order to prove the existence of a patient-relevant medical benefit in mortality, morbidity, and health-related quality of life (HRQoL).
- The acceptance of a patient-relevant medical benefit by the FIC is crucial, since only companies with products that have been accepted by the FIC are allowed to negotiate a discount on the list price with the National Association of Statutory Health Insurances (Spitbu) for 6 months (Gesetz zur Neuordnung des Arzneimittelmarktes – AMNOG) in addition to a mandatory discount (15% SGB V).
- Whereas companies have free set the price for the first 12 months after launch, negotiated discounts become effective immediately after this period.
- Until now, no systematic analyses have been conducted addressing factors that might influence the magnitude of discounting.
- Oncologic and orphan drugs are usually high-priced and therefore are of most interest in this process.

**OBJECTIVES**

- The aim of this evaluation was to identify potential factors influencing final negotiated discounts for oncologic and orphan drugs.

**METHODS**

- A literature containing detailed information on existing discounts or specific indications and data of all dossiers with published benefit ratings until June 2016 was analyzed.
- The official database (Laurus) was used to calculate discounts on ex-factory prices.
- As no official information on discounts is publicly available, the change of ex-factory price before and after the end of negotiations equals the discount.
- All assessments were related with respect to:
  - Result of the benefit assessment (major, considerable, minor, non-quantifiable, or no additional benefit). [Table 1](#table1)
  - Size of target population (TP).
  - Existence of HRQoL evidence.
  - Type of target population (TP)
  - Acceptance of appropriate comparator by the manufacturer as set by the FIC

**RESULTS**

- Since AMNOG became effective, 93 benefit assessment dossiers were compiled and a benefit rating was published for 93 oncologic and/or orphan drugs.
- Of this: Onco=44/Orph=49.
- Of this: Onco=5.
- Of this: Onco=7/Orph=3.
- Of this: Onco=1.
- Of this: Onco=15.
- Of this: Onco=16/Orph=9.
- Under negotiation=8.
- Price negotiation=47.
- Price negotiation=28.
- Price negotiation=29.
- Price negotiation=22.
- Price negotiation=16.
- Price negotiation=12.
- Price negotiation=11.
- Price negotiation=10.
- Price negotiation=9.
- Price negotiation=7.
- Price negotiation=6.
- Price negotiation=5.
- Price negotiation=4.
- Price negotiation=3.
- Price negotiation=2.
- Price negotiation=1.

**CONCLUSION AND DISCUSSION**

- Early consultation with the FJC and discussion on the appropriateness of the comparator, the existence of evidence and price negotiations positively.
- Health economic modeling (eg, budget impact analysis) might help to fill possible gaps in evidence and price negotiations positively.
- Further research might lower the initial price that was set at market introduction as estimated by the manufacturer was smaller compared to the size calculated by the FIC.
- In an attempt to come to a benefit rating, counterintuitively, smaller target populations, tend to be correlated with higher discounts.
- A small target population (and thus a low budget impact) is not a safe harbinger for discounts being high.
- The mean discount was 12% in the group that followed recommendations compared to 33% in the group that did not follow recommendations.

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