Global Access Implications of Germany's New GSAV LAW for Orphan Drugs

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Introduction

G-BA Orphan Exemption

- New pharmacological therapies in Germany are subject to early benefit assessments by the G-BA
- If the G-BA deem no additional benefit is offered, premium pricing cannot be negotiated
- EMA-designated orphan medicines were guaranteed an additional benefit (if the annual turnover from outpatient treatment sales was below €50 million)

Aug 2020: GSAV Law

- Now, orphan drugs granted non-quantifiable additional benefit by the G-BA can be subject to post-launch data collection
- Further, the annual sales threshold will now apply to both in- and out-patient drug usage

Research aims and methods

- This research evaluates the potential impact of the GSAV law through examining any orphan drug subject to a new benefit assessment after exceeding the €50 million threshold
- Orphan drugs exceeding this threshold were identified and publicly-available IQWiG & G-BA assessment information extracted (01-JAN-2020–31-DEC-2020)

Results: Orphan drugs that exceeded the €50m threshold in 2020

Drug	Indication	EMA approval	Initial GBA (Before €50m threshold reached)		Final IQwiG (After €50m threshold reached)		Final GBA (After €50m threshold reached)		Time (EMA to final G-BA)
			Date	Outcome	Date	Outcome	Date	Outcome	(months)
Tezacaftor / ivacaftor	CF (aged 12 yrs+, F508del heterozygous)	31-OCT-2018	16-MAY-2019	Minor	01-OCT-2020	Not proven	17-DEC-2020	Not proven	25.6
Tezacaftor / ivacaftor	CF (aged 12 yrs+, F508del homozygous)	31-OCT-2018	16-MAY-2019	Considerable	01-OCT-2020	Lesser	17-DEC-2020	Not proven	25.6
Avelumab	Merkel cell carcinoma	18-SEP-2017	16-MAR-2018	Not-quantifiable	01-JUL-2020	Not proven	01-OCT-2020	Not proven	36.5
Asfotase alfa	Pediatric-onset hypophosphatasia	28-AUG-2015	17-MAR-2016	Not-quantifiable	15-JAN-2020	Non-quantifiable	02-APR-2020	Non-quantifiable	55.2
Niraparib	Ovarian, fallopian tube, or primary peritoneal cancer	16-NOV-2017	07-JUN-2018	Not-quantifiable	15-JAN-2020	Not proven	02-APR-2020	Not proven	28.6

Results: Key points

Four orphan therapies across five indications were subject to a new IQWiG benefit assessment due to exceeding the annual €50 million threshold in 2020

3 were originally designated by the G-BA to offer non-quantifiable additional benefit, 1 minor benefit and 1 considerable benefit

The subsequent IQWiG benefit assessments were: 3 not proven, 1 non-quantifiable and 1 lesser

The final G-BA resolutions for 4 were not proven and 1 not quantifiable (being issued an average of 34.3 months post-EMA marketing authorization [range: 25.6-55.2 months])

Conclusions

This research suggests that many orphan drugs that were initially designated as having an additional benefit by the G-BA would not achieve this designation without orphan privileges granted under AMNOG, even allowing for up to 3 years of additional post-launch data collection

Given the importance of the German market and visibility of net prices, the GSAV law could significantly impact orphan drug access globally