TIME RESTRICTIONS OF BENEFIT ASSESSMENTS FOR MEDICINAL PRODUCTS IN GERMANY

Current experience

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BACKGROUND

Resolutions on early benefit assessment can be granted by the HTA bodies G-BA and IQWiG with a time restriction, termed “limited”.
Such a restriction requires three conditions:

Missing data

a. … on patient relevant endpoints

b. … at the time of benefit assessment

c. … in order to proove additional benefit.

However, anecdotal evidence sometimes indicates that time restrictions are used as a compromise in case the G-BA cannot otherwise agree on a certain resolution.

When giving a time restriction, pharmaceutical companies are required to resubmit a dossier presenting the currently available data. Companies are allowed to appeal and ask for an extension.

It is important to exactly understand why the G-BA has defined a time restriction in order to either address these issues in a resubmission or discuss with G-BA when this data might be available.

RESEARCH QUESTION

The following analysis addresses three research questions:

1. Do the time restrictions correspond to the requirements given by law?
2. What data does G-BA especially request for resubmission?
3. When have time restrictions been extended?

METHODS

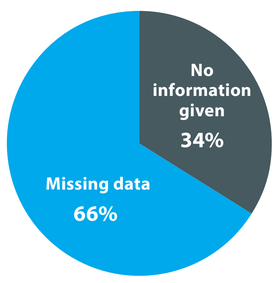
As of June 2015 G-BA has adopted 135 resolutions of benefit assessment. Of these, 29 resolutions with a time restriction have been identified and analysed in detail:

- 17 resolutions have been passed for drugs in oncology: Vemurafenib, Eribulin, Ponatinib, Crizotinib, Regorafenib, Vandetanib, Axitinib, Ipilimumab (twice), Dabrafenib, Pertuzumab, Bosutinib, Cabozantinib, Idelalisib, Sipuleucel-T, Vismodegib, Afatinib
- 2 resolutions relate to diseases of nervous system: Fingolimod, Extract of Cannabis Sativa
- 4 resolutions refer to diabetes: Saxagliptin, Saxagliptin/Metformin, Sitagliptin, Sitagliptin/Metformin
- 6 resolutions have been adopted in other indications: Lomitapide (Hypercholesterolemia), Belatacept (Kidney Transplantation), Ocriplasmin (Retinal Diseases), Ataluren (Muscular Dystrophy), Alipogene Tiparvovec (Hyperlipoproteinemia Type I)

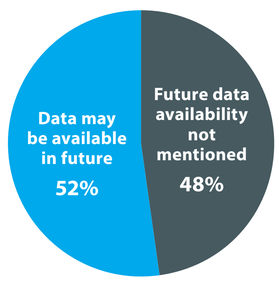
1.

Missing data

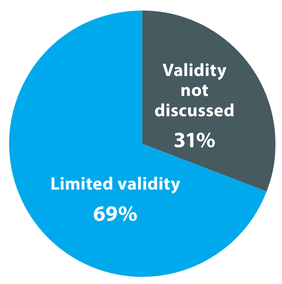
a. … on patient relevant endpoints



b. … at the time of benefit assessment



c. … in order to proof additional benefit

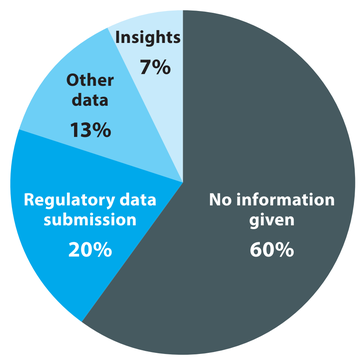


DISCUSSION

- With 29 out of 135 resolutions in total time restrictions as an outcome are not unlikely.
- Most time restrictions are set by G-BA even without meeting all legal requirements.
- As a result it can be difficult to anticipate if the G-BA will set a time restriction or not.

2.

Data requirements for resubmission

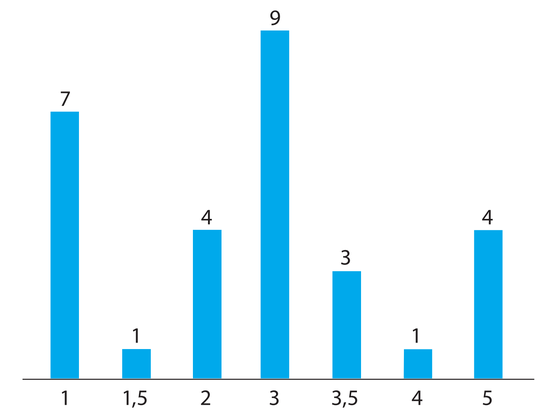


DISCUSSION

- In most restrictions the G-BA does not specify which data is required for a resubmission.
- It is not clear what would happen if a company would submit identical data.
- This lack of guidance makes preparation for a resubmission challenging.

3.

Duration of restriction



DISCUSSION

- Restrictions are for up to five years
- For four products it was possible to extend the limitation – up to three additional years
- Hence it is worthwile to discuss options for extensions with the G-BA

CONCLUSION

1. Most time restrictions in German benefit assessments do not correspond with the requirements given by law.
2. In most restrictions the G-BA does not specify what (additional information) is required for resubmission, making this process subject to trial and error.
3. At least in some situations it was possible to extend the duration of the time restriction after discussion with G-BA.

REFERENCES

Documents related to all resolutions on benefit assessments can be found under G-BA (URL: www.g-ba.de/informationen/nutzenbewertung)

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