

EMA & G-BA – A COMPARISON OF TIME LIMITATIONS OF EUROPEAN MARKETING AUTHORIZATIONS AND GERMAN ADDED BENEFIT ASSESSMENTS FOR NEW PHARMACEUTICALS.

Schulze KL, Volmer T
SmartStep Consulting GmbH,
Hamburg, Germany

ISPOR Europe 2019
Bella Center Copenhagen, Denmark
4 November 2019
RESEARCH POSTER SESSION I

OBJECTIVES:

When authorizing new pharmaceuticals, the European Medicines Agency (EMA) can issue limitations on the respective marketing authorizations. The Federal Joint Committee (G-BA) as the German Health Technology Assessment (HTA) institution decides on limitations within the early benefit assessment (EBA) acc. to Germany’s social code book’s §35 SGB V. This research aims to determine whether there is a correlation between the limitations of EMA and G-BA.

METHODS:

A quantitative evaluation comparing EMA and G-BA decisions was conducted regarding the reasons and duration of the limitations. As a data basis, the EMA’s published *List of medicinal products under additional monitoring* as of 22 February 2019 was used and all authorizations from the following categories were assessed: Conditional Marketing Authorization (CMA), Authorization Under Exceptional Circumstances (AUEC), Additional Monitoring (AM), Post-Authorization Safety Study (PASS). Information on six former CMAs was also used. Following this approach, all 436 G-BA EBAs until 3 March 2019 have been assessed for limitations and linked with the respective EMA rationale.

RESULTS:

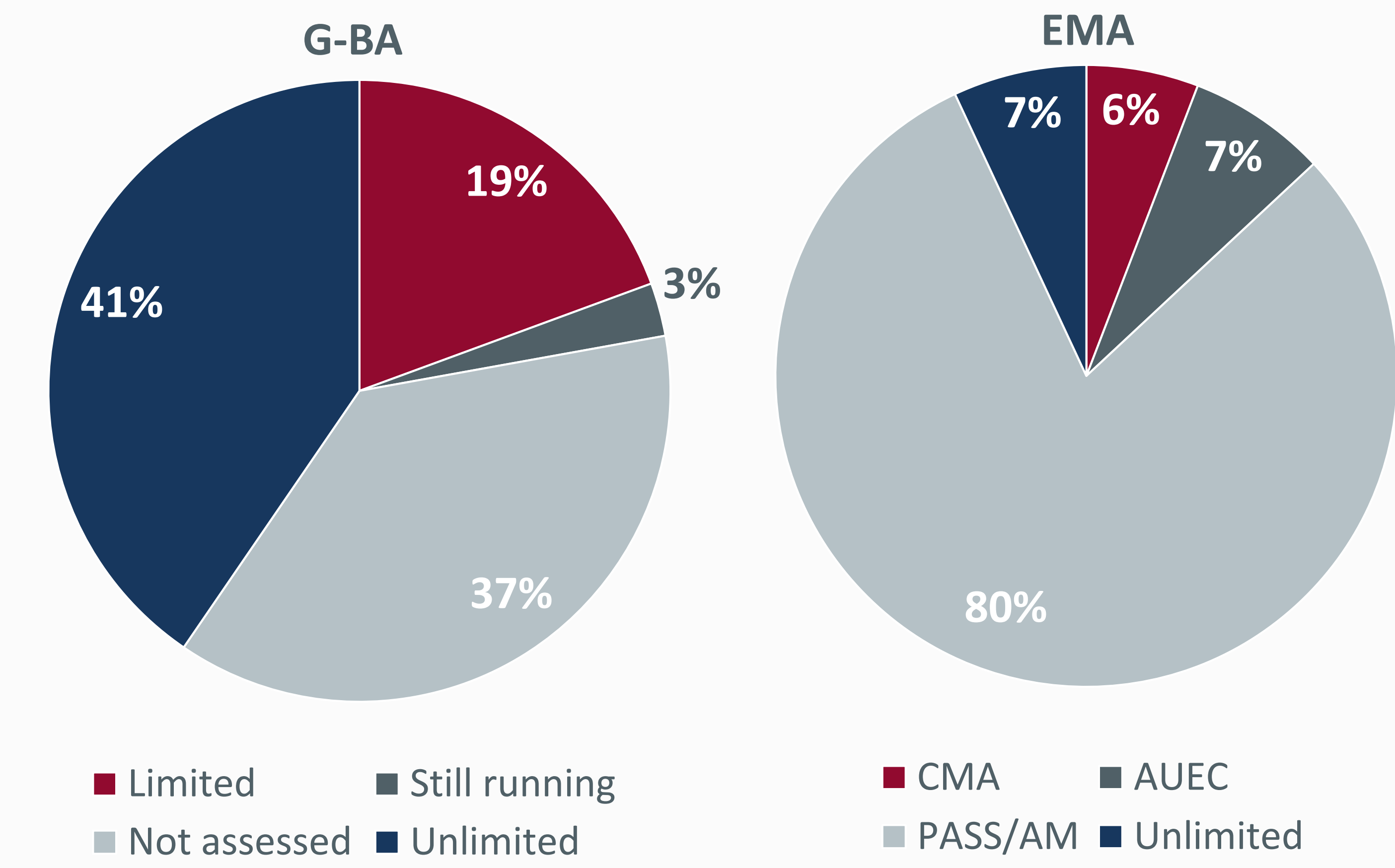
The distribution of evaluated limitations on marketing authorizations and EBAs is shown in Figure 1 and Table 1.

Table 1: Overview of absolute distribution

		EMA			
		CMA	AUEC	PASS/AM	Unlimited
G-BA	Limited	16	5	24	25
	Still running	0	1	9	n. e.
	Not assessed	4	12	119	n. e.
	Unlimited	2	8	136	n. e.
	Total	22	26	288	25

n. e.: not evaluated

Figure 1: Overview of relative distribution



The descriptive analysis shows that CMAs issued by the EMA also received a limitation in the majority of cases (89%) with similar reasons by the G-BA. In contrast, EMA authorizations with the status AUEC only led to a limitation by the G-BA in 36%, authorizations with status PASS/AM just in 15% of the cases. Only in two CMA cases the G-BA has made a different choice than the EMA: Brentuximab Vedotin & Avelumab. Limitations of the G-BA (average length: 32.8 months) are on average 8.7 months shorter than the duration of EMA’s CMAs (average length: 41.6 months). Only one decision of the G-BA runs much longer than a CMA of the EMA: Daratumumab is still limited by the G-BA – in total for nearly 5 years – while the EMA converted the CMA to MA after one year.

Temporal limitations issued by the G-BA for cases without EMA limitations have mostly been justified by missing data to prove an additional benefit over the appropriate comparator but not with respect to safety or efficacy data.

CONCLUSION:

This analysis illustrates that the German HTA institution G-BA decides in a similar way like the regulatory institution EMA. Having no restrictions after the marketing authorization process of the EMA does not automatically result in ‘no limitations’ in the EBA process headed by the German G-BA. The G-BA deviates more strongly from the EMA decisions, especially in cases of the AUEC, PASS and AM approval restrictions, due to missing data on additional benefit versus the determined ‘appropriate comparator’, which in itself is determined by the G-BA.

References:

<https://www.g-ba.de/bewertungsverfahren/nutzenbewertung//>
<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/medicines-under-additional-monitoring/list-medicines-under-additional-monitoring>

Conflict of interest:

The authors have been working as consultants for several pharmaceutical companies. This study was performed without any financial support by any external company.