AMNOG EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY – A SPECIFIC CHALLENGE FOR ANTIDIABETICS

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Objectives

A remarkable majority of antidiabetics could not prove an additional benefit (AB) during EBA in Germany resulting in low reimbursement prices and, therefore, in a great amount of market withdrawals. To investigate more detailed the amount of antidiabetics with no or any AB and of market withdrawals as well as the specific obstacles for antidiabetics during EBA and their effects on medical care, a retrospective analysis of EBA was conducted.

Methods

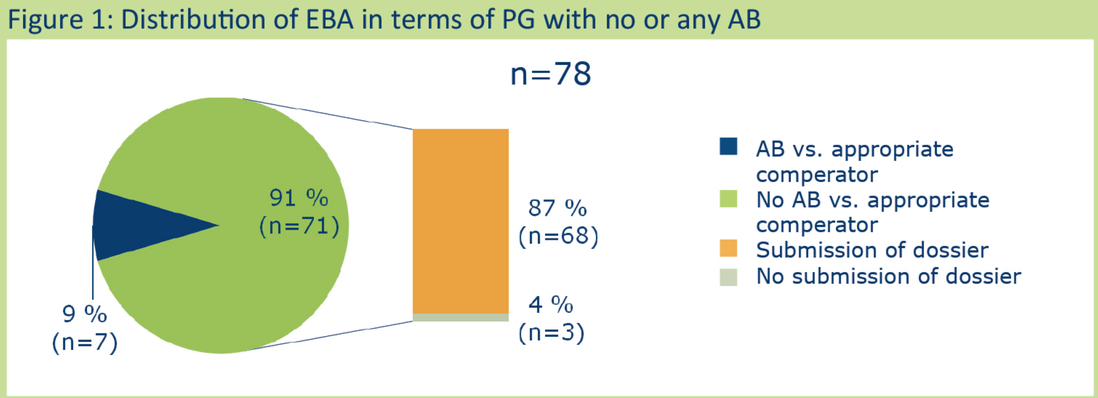
In total, 27 benefit assessments entailing 78 patient groups (PG) of 23 antidiabetics (medicinal products, MP) were finalized until 31 May 2016[1] in the context of EBA. The analysis was conducted with regard to the AB granted vs. the appropriate comparator for PG as well as with regard to the antidiabetics withdrawn from the German market vs. antidiabetics available in the German market. The results are presented as percentage shares depending on the amount of AB or no AB for PG and the number of MP underwent EBA .

The insulin consumption based on defined daily dose (DDD) between 1997 and 2004 at the expense of the statutory health insurance (SHI)[2,3] were analyzed.

Results

Amount of antidiabetics with no or any AB and market withdrawals

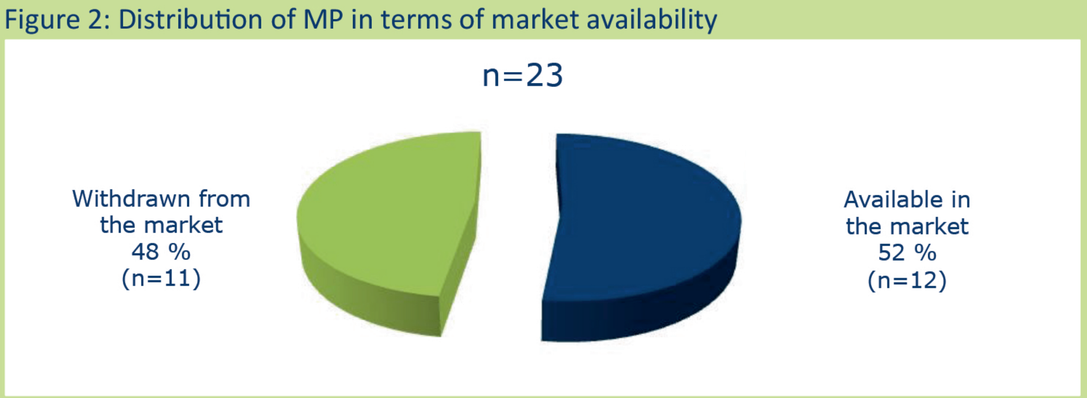
Figure 1: Distribution of EBA in terms of PG with no or any AB



AB: Additional benefit; EBA: Early benefit assessment; n: Number of PG; PG: Patient group

- An AB vs. the appropriate comparator could not be proven for 91 % (71 of 78) of PG for antidiabetics, whereas for 3 PG the lack of proof was caused by no submission of a dossier.
- A minor AB could only be proven for 9 % (7 of 78) of PG for antidiabetics, exclusively on the basis of less side effects.

Figure 2: Distribution of MP in terms of market availability



EBA: Early benefit assessment; MP: Medicinal product; n: Number of medicinal products that underwent EBA

- A considerable or a major AB could not be proven in the 27 EBA for antidiabetics finalized until 31 May 2016.
- 48 % (11 of 23) of analyzed MP belonging to above EBA were withdrawn from the market (vildagliptin n=3, linagliptin n=2, canagliflozin n=2, lixisenatide n=1, insulin degludec n=3).

Specific obstacles for antidiabetics during EBA

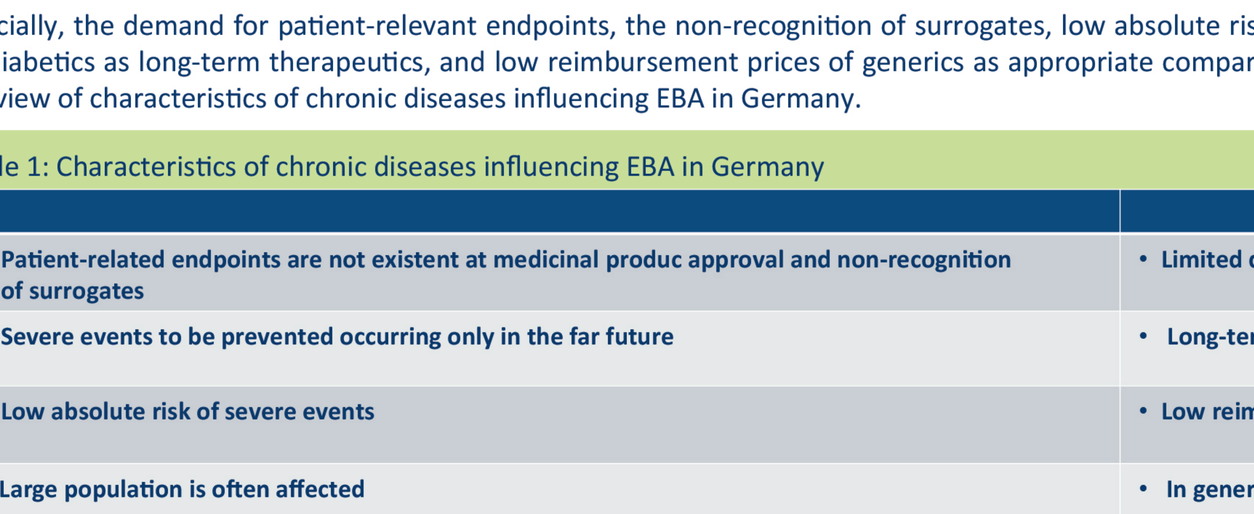
Especially, the demand for patient-relevant endpoints, the non-recognition of surrogates, low absolute risks of severe events occurring only in the far future, limited duration of studies for antidiabetics as long-term therapeutics, and low reimbursement prices of generics as appropriate comparators were identified as obstacles for antidiabetics in EBA. Table 1 presents a brief overview of characteristics of chronic diseases influencing EBA in Germany.

Table 1: Characteristics of chronic diseases influencing EBA in Germany

• **Patient-related endpoints are not existent at medicinal produc approval and non-recognition of surrogates**	• **Limited duration of studies**
• **Severe events to be prevented occurring only in the far future**	• **Long-term therapy is necessary**
• **Low absolute risk of severe events**	• **Low reimbursement prices of generics as appropriate comparators**
• **Large population is often affected**	• **In general, established therapeutic options are available**
• **Meaningful impact for SHI on budget impact**	• **Frequency of controllable disease events influences EBA**
Clearly increased risk of market withdrawals of medicinal products for chronic diseases	

Insulin consumption at the expense of the SHI increased by 149% from 1997 to 2014[2,3]

Figure 3: Insulin consumption at the expense of the SHI



DDD: defined daily dose; p.a.: per annum; SHI: statutory health insurance

Conclusions

- The higher insulin consumption might be a consequence of the uncertainty of physicians concerning the medical prescription of new antidiabetics due to EBA in addition to previous control tools, and associated market withdrawals.
- Thus, a reliable consensus on the potential importance of new antidiabetics under consideration of restricted possibilities for the proof of required evidence, the notably high need for efficient antidiabetic therapy just as the necessity of economic actions is indispensable.

References

1. Gemeinsamer Bundesausschuss (2016). *(Frühe) Nutzenbewertung nach § 35a SGB V.* https://www.g-ba.de/informationen/nutzenbewertung/.
2. Häussler B, Höer A, Hempel E (eds.) (2015). *Arzneimittel-Atlas 2015.* http://www.arzneimittel-atlas.de/.
3. Schwabe U, Paffrath D (eds.) (2016). *Arzneiverordnungs-Report 2015.* Berlin: Springer.