

AMNOG EARLY BENEFIT ASSESSMENT (EBA) AND MARKET PENETRATION OF NEW DRUGS FOR MELANOMA, MULTIPLE SCLEROSIS AND DIABETES MELLITUS IN GERMANY

J Mathes¹, A Höer²

¹ IGES Institut GmbH, Nuremberg, Germany. ² IGES Institut GmbH, Berlin, Germany

Objectives

The EBA of new drugs was implemented in Germany in 2011 in order to slow the increasing expenditure for expensive drugs for special indications. This research aims to analyze the market penetration of new drugs for melanoma, multiple sclerosis and diabetes mellitus considering their EBA results.

Methods

Drugs with the first EBA from January 2011 until December 2016 in the three indications were considered.¹ Market penetration was evaluated by comparing the observed consumption with the expected consumption derived from the target population of the EBA. The target population is defined as the maximally treatable number of statutory health insurance (GKV) patients based on epidemiologic data (upper limit of patient number). Observed consumption is derived from defined daily doses (DDD) for outpatient market of the GKV for each year from 2011 until 2016.² Moreover, the impact of an additional benefit vs. the appropriate comparator in the EBA on market penetration was analyzed.

Results

Melanoma

Market characteristics

- Until 2011 hardly any drugs available for patients with advanced melanoma

Results

- 6/7 drugs show additional benefit for melanoma patients
- Observed consumption of new drugs for melanoma is lower than the expected consumption
- Observed consumption is overestimated as 3 drugs are also licensed for other indications

Figure 1: Number of treatable patients

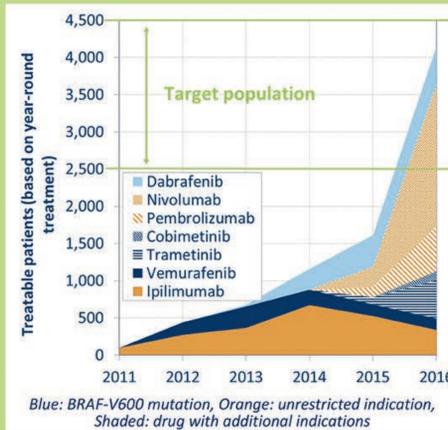


Table 1: New drugs launched for melanoma between 2011 and 2016

Active substance	Launch	Type of melanoma	Further indications	Add. benefit	Max. treatable patients	Patients treated in 2016
Ipilimumab	2011	Advanced	-	Sign.	3,100	338
Vemurafenib	2012	BRAF-V600 adv.	-	Sign.	1,400	154
Nivolumab	2015	Advanced	Hodgkin-lymphoma; head & neck, renal cell and urothelial cancer	Sign. NP	270-810, 2,230-3,690	1,889
Pembrolizumab	2015	Advanced	Hodgkin-lymphoma, NSCLC, urothelial cancer	Sign. NP	2,270-3,810, 230-690	616
Trametinib	2015	BRAF-V600 adv.	NSCLC	Sign.	1,400	516
Cobimetinib	2015	BRAF-V600 adv.	-	Sign.	1,400	116
Dabrafenib	2014	BRAF-V600 adv.	-	NP	1,400	517

Add.: Additional, Max.: Maximally, adv.: advanced, Sign.: Significant, NP: No Proof

Multiple Sclerosis

Market characteristics

- 124,000 - 200,000 patients in Germany³
- Standard of care: interferon beta and glatiramer acetate (both parenteral)
- Fampiridine and *cannabis sativa* extract excluded from analysis as they are solely approved to treat symptoms

Results

- 1/3 drugs show add. benefit for multiple sclerosis patients
- Observed consumption of teriflunomide and dimethyl fumarate is lower than the expected consumption, however still significantly high (probably due to oral application)
- Observed consumption of fingolimod is higher than the expected consumption

Figure 2: Number of treatable patients

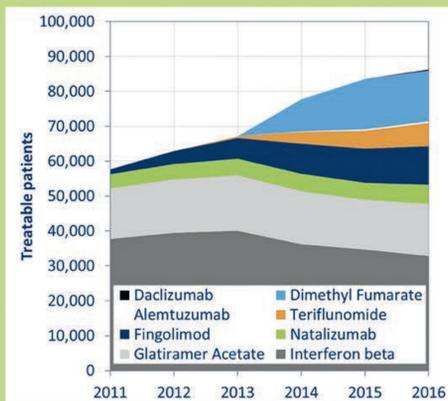


Table 2: New drugs launched for multiple sclerosis between 2011 and 2016

Active substance	Launch	Type of multiple sclerosis	Add. benefit	Max. treatable patients	Patients treated in 2016
Fingolimod	2011	RRMS highly active or rapidly progressing	NP Marg.	8,000, 1,500	10,973
Teriflunomide	2013	RRMS	NP	85,000-105,000	6,648
Dimethyl Fumarate	2014	RRMS	NP	85,000-105,000	14,593

Add.: Additional, Max.: Maximally, Marg.: Marginal, NP: No Proof, RRMS: Relapsing Remitting MS

Diabetes Mellitus

Market characteristics

- ~ 5 million patients in Germany⁴

Results

- 6/18 drugs show additional benefit for diabetes mellitus patients
- 9 assessed drugs withdrawn from market (opt out)
- Observed consumption of assessed anti-diabetics < 4% of all anti-diabetics

Figure 3: Consumption of antidiabetics

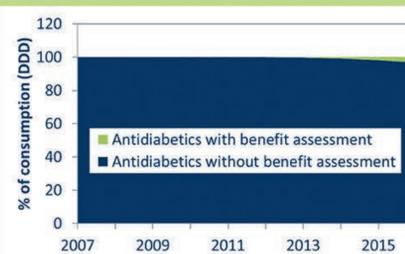


Table 3: New antidiabetics with the first EBA between 2011 and 2016

Active substance	Launch	Sum of max. treatable patients	Add. benefit	Max. treatable patients	Opt out ⁵	Active substance	Launch	Sum of max. treatable patients	Add. benefit	Max. treatable patients	Opt out ⁵
Linagliptin	2011	1,219,500	NP	1,219,500	Yes	Vildagliptin/Metformin	2007	792,050-810,850	NP	792,050-810,850	Yes
Saxagliptin/Metformin	2011	729,650-748,450	Marg.	615,800-634,600	-	Dapagliflozin/Metformin	2014	615,300	NP	615,300	-
			NP	113,850	-	Canagliflozin	2014	1,253,400-1,453,400	NP	1,253,400-1,453,400	Yes
Dapagliflozin	2012	896,100	NP	896,100	-	Insulin degludec	2014	1,095,950	NP	1,095,950	Yes
Saxagliptin	2009	1,182,900-1,382,900	Marg. NP	634,600-548,300-748,300	-	Insulin degludec/Liraglutide	2015	752,000-903,000	NP	752,000-903,000	Yes
Sitagliptin	2007	1,704,800-1,904,800	Marg. NP	1,156,500-548,300-748,300	-	Empagliflozin	2014	1,253,400-1,453,400	NP	1,253,400-1,453,400	-
Sitagliptin/Metformin	2008	792,050-810,850	Marg. NP	615,800-634,600-176,250	-	Canagliflozin/Metformin	2014	615,300	NP	615,300	Yes
Lixisenatide	2012	903,000	NP	903,000	Yes	Albiglutide	2014	1,253,400-1,453,400	Marg. NP	468,700-784,700-984,700	-
Vildagliptin	2007	1,705,400-1,905,400	NP	1,705,400-1,905,400	Yes	Dulaglutide	2015	1,705,500-1,905,500	Marg. NP	450,000-650,000-1,255,500	-
Empagliflozin/Metformin	2016	615,300	NP	615,300	Yes						

Add.: Additional, Max.: Maximally, Marg.: Marginal, NP: No Proof

Conclusions

The market penetration depends on the specific characteristics of the market. Based on our analysis the results of the EBA do not have a relevant impact of the market penetration of new drugs in melanoma, multiple sclerosis and diabetes mellitus.

References

1. Gemeinsamer Bundesausschuss: Verfahren der Nutzenbewertung nach § 35a SGB V, <https://www.g-ba.de/informationen/nutzenbewertung/> (depending on respective EBA)
2. Arzneimittel-Atlas 2018: in preparation. IGES Institut GmbH, Berlin.
3. Arzneimittel-Atlas 2017: Versorgungssituation bei Mitteln zur Anregung des Immunsystems. IGES Institut GmbH, Berlin. <https://www.arzneimittel-atlas.de/arzneimittel/103-immunstimulanzien/bedarf-amp-versorgung/> (accessed 01 Oct 2018)
4. Arzneimittel-Atlas 2017: Versorgungssituation mit Diabetesmitteln. IGES Institut GmbH, Berlin. <https://www.arzneimittel-atlas.de/arzneimittel/a10-antidiabetika/bedarf-und-versorgung/> (accessed 01 Oct 2018)
5. GKV-Spitzenverband: Übersicht zu den Verhandlungen der Erstattungsbeträge nach §130b SGB V, https://www.gkv-spitzenverband.de/krankenversicherung/arzneimittel/verhandlungen_nach_amnog/ebv_130b/ebv_nach_130b.jsp (depending on drug)