**IMPACT OF THE EARLY BENEFIT ASSESSMENT ON A PHARMACEUTICAL’S REAL CONSUMPTION IN GERMANY**

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**Objectives**

The Act on the Reform of the Market for Medicinal Products ("AMNOG") introduced an early benefit assessment (EBA) of pharmaceuticals in Germany in 2011. According to this law, all pharmaceuticals with a new active agent made available on the market for the first time have to go through a benefit assessment process. A benefit assessment dossier has to be submitted at the time of the market entry of the new pharmaceutical. In this benefit assessment dossier, the pharmaceutical company has to prove the additional benefit of the pharmaceutical compared to a given appropriate comparator. Since the impact of the EBA results on a pharmaceutical’s consumption is unclear, those effects were quantitatively analyzed.

**Methods**

All pharmaceuticals which were assessed by an EBA in 2011 or 2012 have reached a share in 2012 and 2013 of 2% or higher in at least one subpopulation (%). The aim of this analysis is to identify pharmaceuticals with a substantially higher share in 2013 compared to 2012, and to explore the reasons for this increase.

**Results**

**Pharmaceuticals with a low share (<10%) in 2013**

Pharmaceuticals with a low share (<10%) in 2013 were cabazitaxel (0.3%), saigalixin/metformin (1.4%), bempedoic acid (1.9%), erbulin (3.3%), tadalafil (3.5%), vandetanib (5.5%), naxibemib (5.5%), saigalixin (5.9%) and rilpivirine (7.9%) (Table 1).

**Pharmaceuticals with a midsize share (10-50%) in 2013**

Pharmaceuticals with a midsize share (10-50%) in 2013 were pirfenidone (11.0%), ipilimumab (11.2%), pasireotide (13.7%), ticagrelor (16.7%), vemurafenib (21.0%), sitaglitin (21.0%), celecoxib (25.7%), brentuximab vedotin (28.6%), crizotinib (31.4%) and tafamidis (49.7%) (Table 2).

**Pharmaceuticals with a large share (>50%) in 2013**

Pharmaceuticals with a large share (>50%) in 2013 were ivacaftor (53.4%), abiraterone (77.9%), emtricitabine/rilpivirine/tenofovir (195.2%), apixaban (261.4%) and fingolimod (397.8%) (Table 3).

**Conclusions**

The shares of pharmaceuticals considered in this analysis vary between 0.2% and 398%. No correlation between share and extent of AB could be identified. It is assumed that label restrictions regarding the use of a pharmaceutical competing alternatives in the same therapeutic indication, a pharmaceutical’s life-cycle or an overestimation of the EC influence a pharmaceutical’s share. Further research is needed to confirm these assumptions.

**References**