

Introduction

The advent of digital healthcare is rapidly gaining momentum, with countries worldwide actively seeking ways to assess and harness its benefits. Germany has established itself as a leader by enacting the 2019 German Digital Healthcare Act¹, a pivotal legislation that paved the way for the fast-track reimbursement and accessibility of digital health applications (Digitalen Gesundheitsanwendungen, i.e., DiGAs). However, DiGAs that have secured a permanent listing in the DiGA directory experience substantial price reductions following the initial year of free pricing, even though there is no transparent framework for establishing DiGA prices². This research aims to identify factors that are correlated with the pricing of DiGAs indicated for psychiatric disorders.

Methodology

Prices and HTA outcomes up to June 2023 for permanently listed DiGAs indicated for psychiatric disorders were extracted from the DiGA directory. The relationship between prices and domains were evaluated. These domains are part of the listing requirements outlined by BfArM.

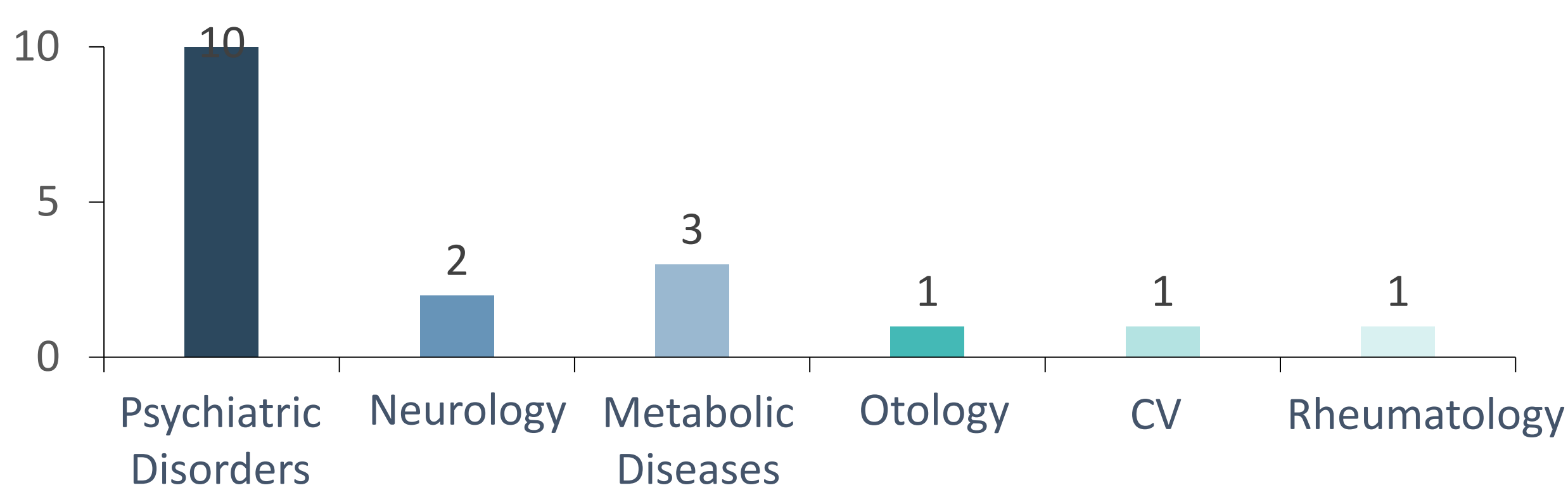
Table 1: Key Domains for Comparing DiGA Pricing

Domains	Factors
1 Study Design	Study Length, Sample Size
2 Price Setting Pathway	Negotiation with GKV-SV or the arbitration Board
3 Incremental Claimed Medical Benefit	Clinical outcome comparison between intervention and comparator

Results

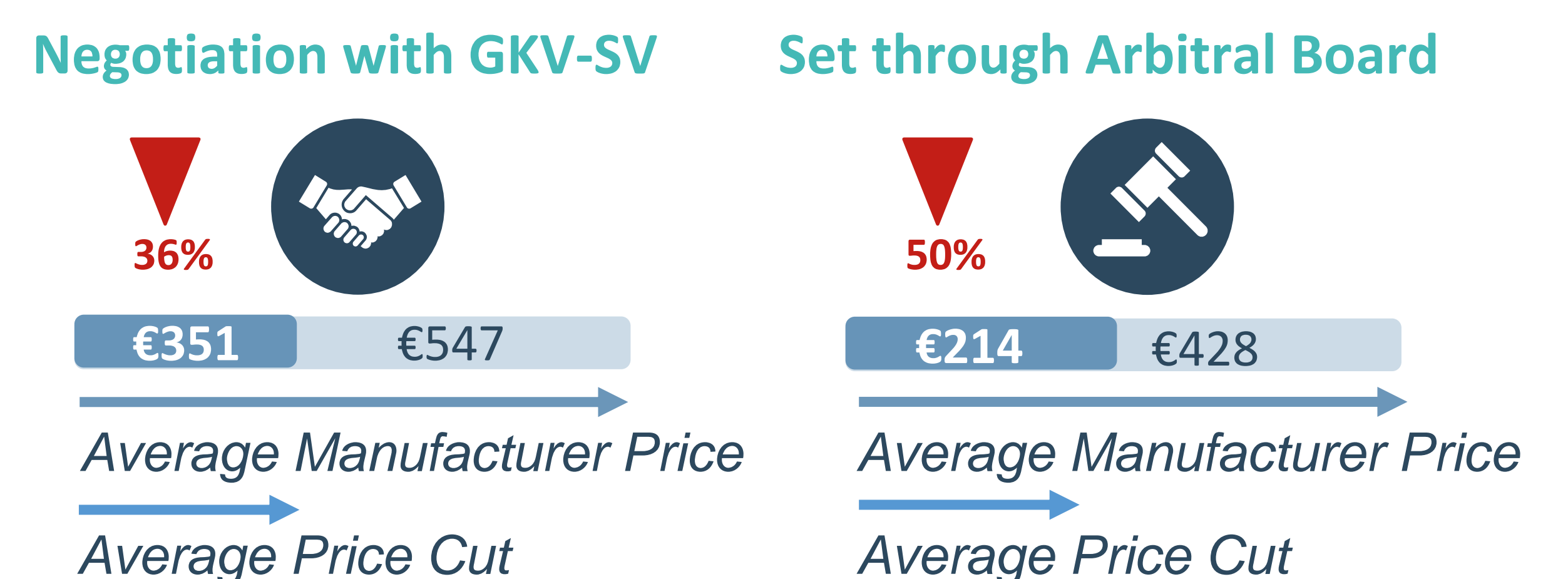
As of the data extraction cut-off date in June 2023, a total of 53 DiGAs have obtained approval for inclusion in the directory. Of these, 18 (34%) were permanently recorded, 29 (55%) were provisionally recorded*, and 6 (11%) were removed from the directory due to failure to demonstrate a health benefit. Of the permanently listed DiGAs, the most frequently listed therapy area was psychiatric disorders, followed by neurology, metabolic diseases and subsequently otology, cardiovascular diseases (CV) and rheumatology (Figure 1).

Figure 1: Disease Areas of all Permanently Listed DiGAs in the Directory



Consequently, these four were priced through the arbitration board, resulting in a comparatively higher price reduction of 50% (Figure 2).

Figure 2: Schematic of Price Cuts Based on Price Setting Pathway



Relationship between Pricing and Study Design

Of the permanently listed DiGAs, 100% (n=18) demonstrated medical benefits through randomised-controlled trials (RCTs). DiGAs indicated for psychiatric disorders had an average trial length of 5.3 months, ranging from 6 to 12 months. For these trials, the average patient population size was 222 patients, with patient numbers ranging from 56 to 608. A statistical analysis revealed that there was no significant relationship ($P > 0.05$) between DiGA prices and number of patients ($R^2=0.01 \pm 0.33$) in the RCTs, nor length of the RCTs ($R^2=0.04 \pm 19.34$).

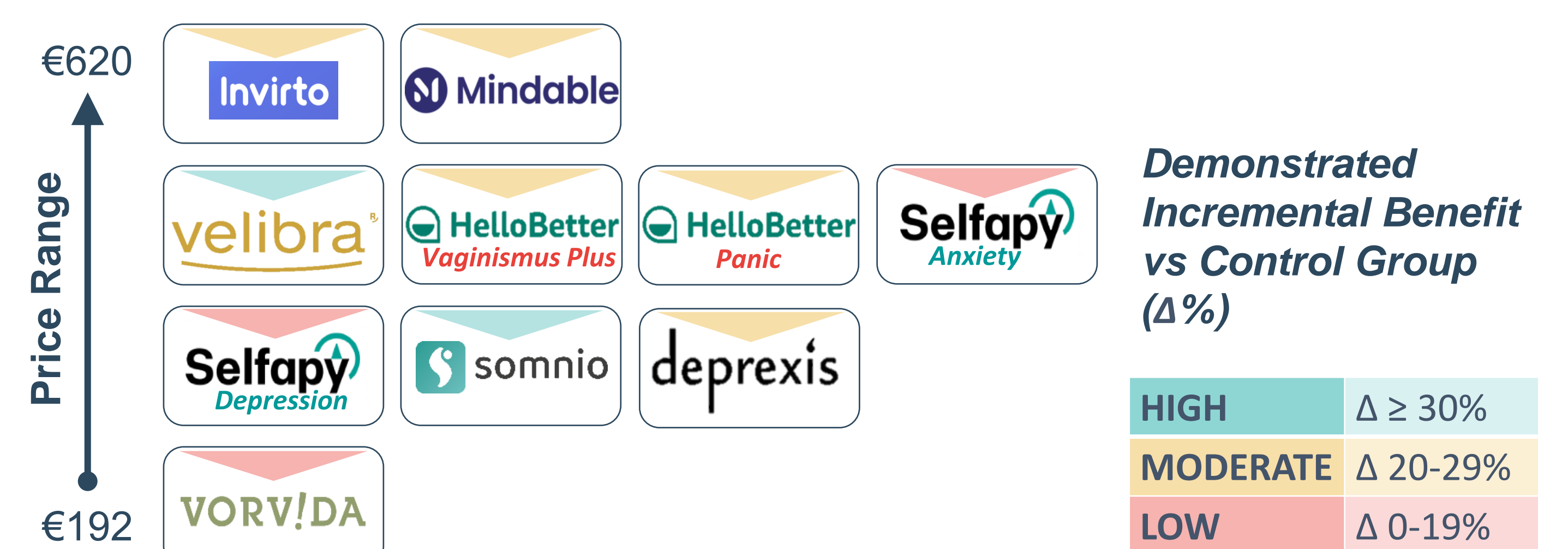
Relationship between Pricing and Price Setting Pathway

Of the 10 currently available reimbursed prices for psychiatric DiGAs, 6 were priced through negotiation with the GKV-SV, resulting in an average price reduction of 36% from the initial free price. As for the remaining four DiGAs, the manufacturers and GKV-SV were unable to reach a mutual agreement on pricing.

Relationship between Pricing and Claimed Medical Benefit

All DiGAs indicated for psychiatric disorders demonstrated their positive care effect through improvement in health status, with 3 applications also demonstrating an enhancement in patient-relevant endpoints (i.e., enhanced patient autonomy and reduction in caregiver burden). On average, these DiGAs demonstrated an incremental clinical improvement of 24.7% in their clinical trials when compared to their respective control groups. Further analysis revealed that there was no significant relationship ($P > 0.05$) between DiGA prices and the claimed incremental medical benefits ($R^2=0.03 \pm 4.11$) vs control groups (Figure 3).

Figure 3: Schematic of DiGA Prices and Incremental Medical Benefit as Compared to Control Group



Conclusion

DiGA prices did not differ significantly in the study design and claimed incremental benefit domains. However, the average price reduction across the price-setting pathways differed and the trend indicated that it may play a more significant role in the pricing of DiGAs indicated for psychiatric disorders. The list prices for permanently listed DiGAs suggest that the GKV-SV views provisionally listed DiGA prices as high, while manufacturers argue that these prices are justified by the strength of the evidence³. Further research with a larger sample size is needed to uncover the granularity of the current pricing framework in terms of how clinical value and evidence robustness are rewarded.

References

¹Bundesgesundheitsministerium (BMG), Accessed on: 30/05/23
²Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Accessed on: 01/06/23
³GKV-Spitzenverband Report, Accessed On: 05/06/23

Footnotes

*Provisional listing is the temporary inclusion of a DiGA in the directory, for initial evaluation, pending full approval