

1. Department of Pharmaceutical Sciences, University of Milan, Milan, Italy
2. INDICON Srl SB, Milan, Italy

Acceptance Code: MT3

OBJECTIVES

Germany leads the adoption of Digital Health Technologies (DHTs) in Europe thanks to the **2019 Digital Health Applications Ordinance (DiGAsV)**, which allows market access for applications lacking complete clinical data, granting **12 months of reimbursement (TEMPORARY LIST)** at the manufacturer's price. Afterward, price is negotiated with Statutory Health Insurance (SHI) for **permanent reimbursement (PERMANENT LIST)**.

This study analyzes DiGA prices, highlighting:



1) the DiGA price **variation** between **temporary and permanent list reimbursement**



2) the **reimbursement trends** from **2020** to September **2024**



3) the potential **correlation** between **price and therapeutic areas**.

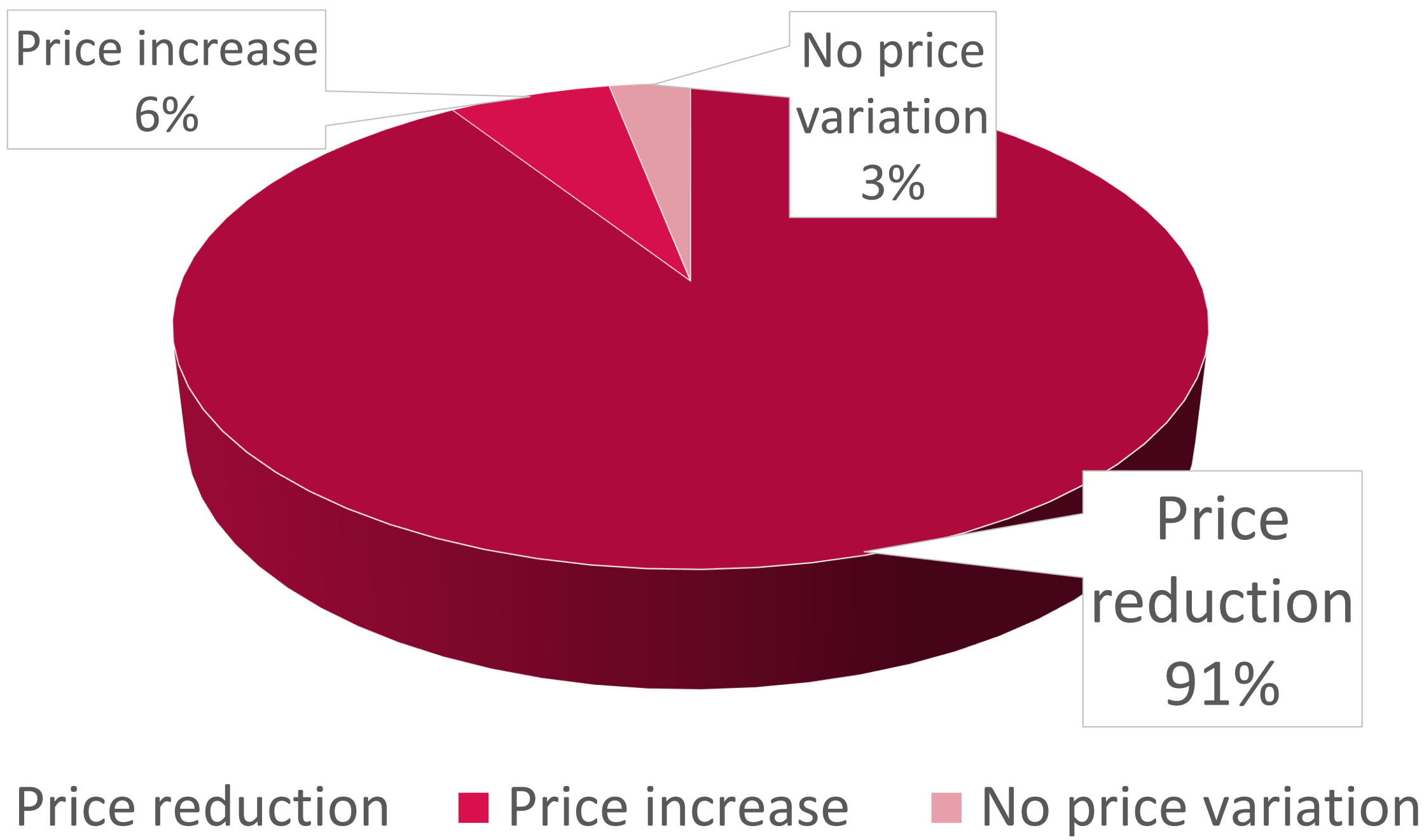
METHODS

The analysis was conducted by accessing the **DiGA Directory** available on the website of the German Federal Institute for Drugs and Medical Devices (**BfArM**)¹. The **33 DiGAs on the permanent list** were downloaded into an Excel platform focusing on following criteria: name, temporary list price, permanent list price, and therapeutic area. The price variation following negotiation, the price trend during the analysis period, and the correlation between the price and the therapeutic areas addressed by the DiGAs were then calculated.

RESULTS

1. PRICE VARIATION BETWEEN TEMPORARY AND PERMANENT LIST REIMBURSEMENT:

- **91%** (n=30) of DiGAs had a **price reduction** following negotiations, averaging -47%
- **3%** (n=1) maintained the **same price**
- **6%** (n=2) saw a **price increase of 33%**



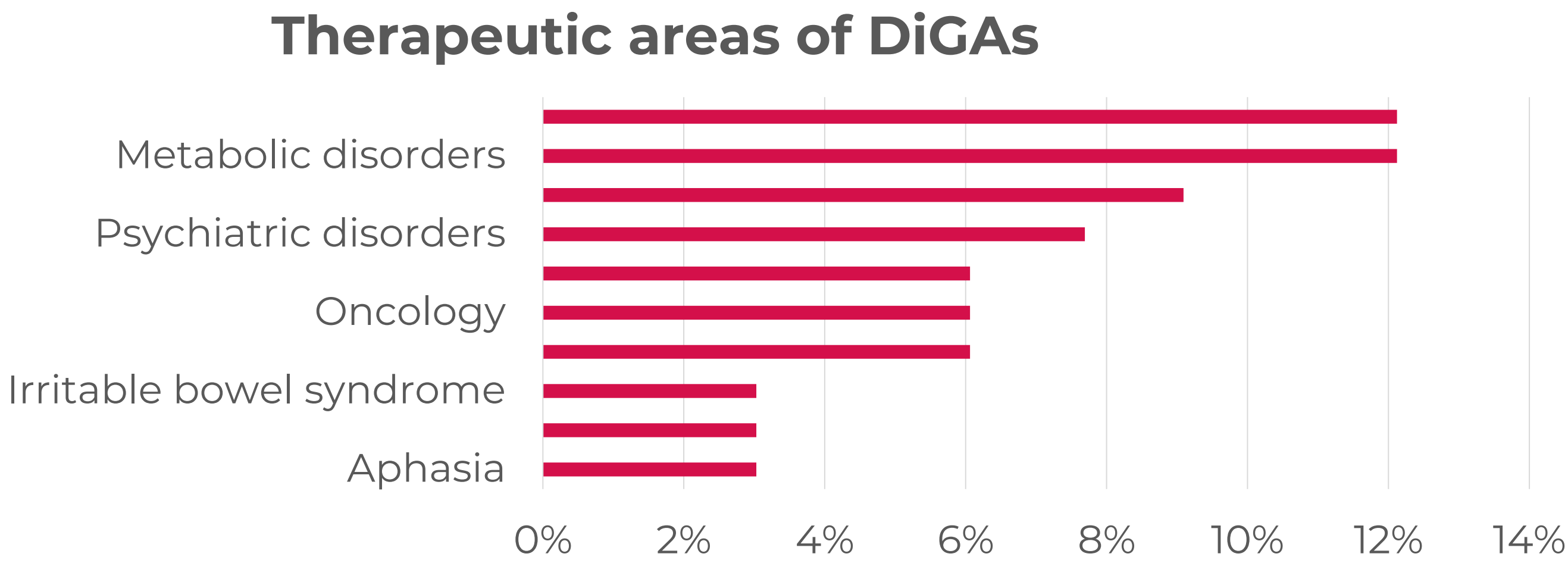
2. REIMBURSEMENT TRENDS FROM 2020 TO SEPTEMBER 2024:

The price analysis of 33 **permanently listed** DiGAs shows an **average DiGAs price of €222**, with an average permanent list price ranging from €220 in 2021 to €235 in 2024, while the **average price on the temporary list** remained stable at **€460**.

Year of entry into the permanent list	Number of DiGA entered in the permanent list	Average prices in the temporary list (€)	Average prices in the permanent list (€)	Average price variation
2020	0			
2021	5	468,1	220,8	-34%
2022	8	460,0	216,7	-49%
2023	16	462,6	221,7	-46%
2024	4	459,2	235,7	-42%

3. CORRELATION BETWEEN PRICE AND THERAPEUTIC AREAS

The most significant **price reduction (-67%)** occurred with a DiGA for the treatment of **neurological disorders**. **The only two DiGAs that experienced a price increase are used for the treatment of tinnitus**. No further correlation was found between the two parameters.



CONCLUSION

The analysis shows that **negotiations** between **manufacturers and statutory health Insurance** generally lead to a **reduction in DiGA prices**. Despite some variations, DiGA prices have **remained relatively stable over time**. Furthermore, the study suggests that price variation is **not correlated with the therapeutic area**.

This analysis can serve as a useful benchmark for European countries looking to implement the adoption and reimbursement of DHTs.

REFERENCES

[1] DiGA Directory, BfArM [available online at: <https://diga.bfarm.de/de/verzeichnis>]



SCAN THE QR CODE TO ACCESS THE «DTx MONITORING REPORT»