

CONTEXT

In France, the concept of hybrid medicines has been officially introduced in the French Social Security Finance Act for 2019. It is defined as medicines that don't meet the definition of generics, as they differ from the reference medicine in terms of therapeutic indication, dosage, pharmaceutical form, route of administration, or bioavailability. To date, no text addresses the evaluation procedures by the French National Authority for Health (HAS) or the pricing policy of the Economic Committee for Health Products (CEPS) for these medicines.

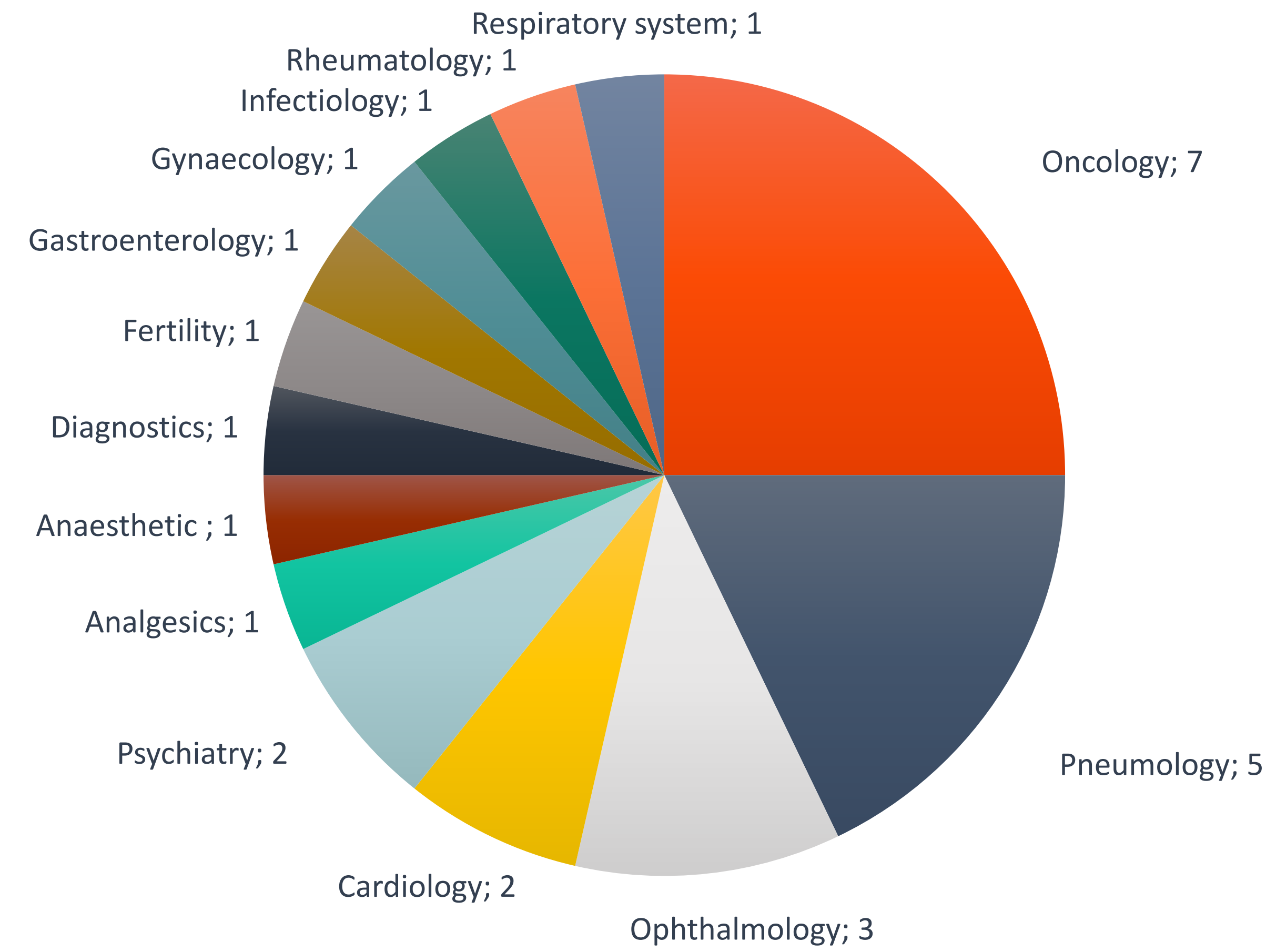
OBJECTIVES

Our study consisted of a descriptive analysis of hybrid evaluations in France.

RESULTS

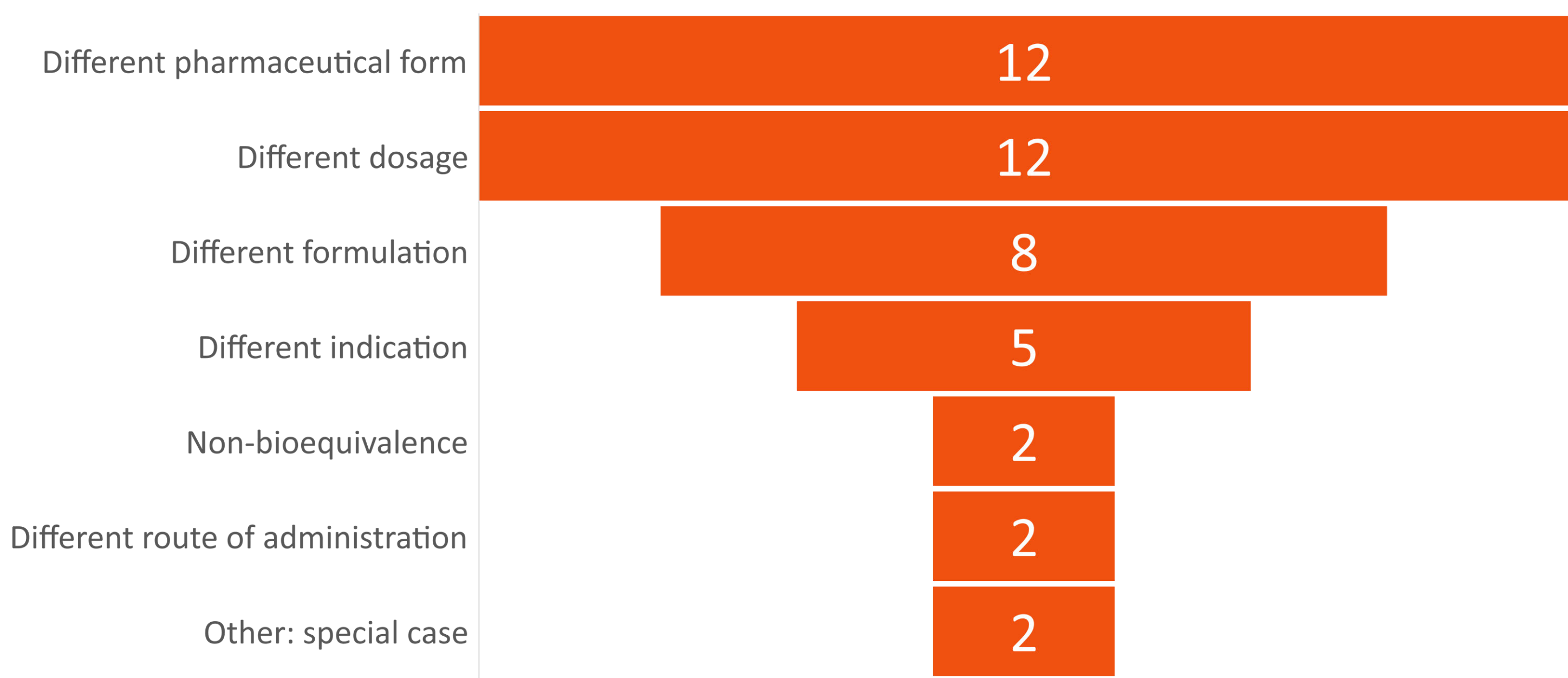
- In 2022, 28 hybrid medicines were evaluated.
- There was a wide range of therapeutic areas with most products indicated in oncology (25%) and pneumology (18%).

FIGURE 1. THERAPEUTICS AREAS OF HYBRID MEDICINES EVALUATED IN 2022



- The most common reasons for hybrid status were a different pharmaceutical form and a different dosage (43% each).
- The same hybrid could have several designations and some had none.

FIGURE 2. REASON FOR HYBRID STATUS OF HYBRID MEDICINES EVALUATED IN 2022



CONCLUSION

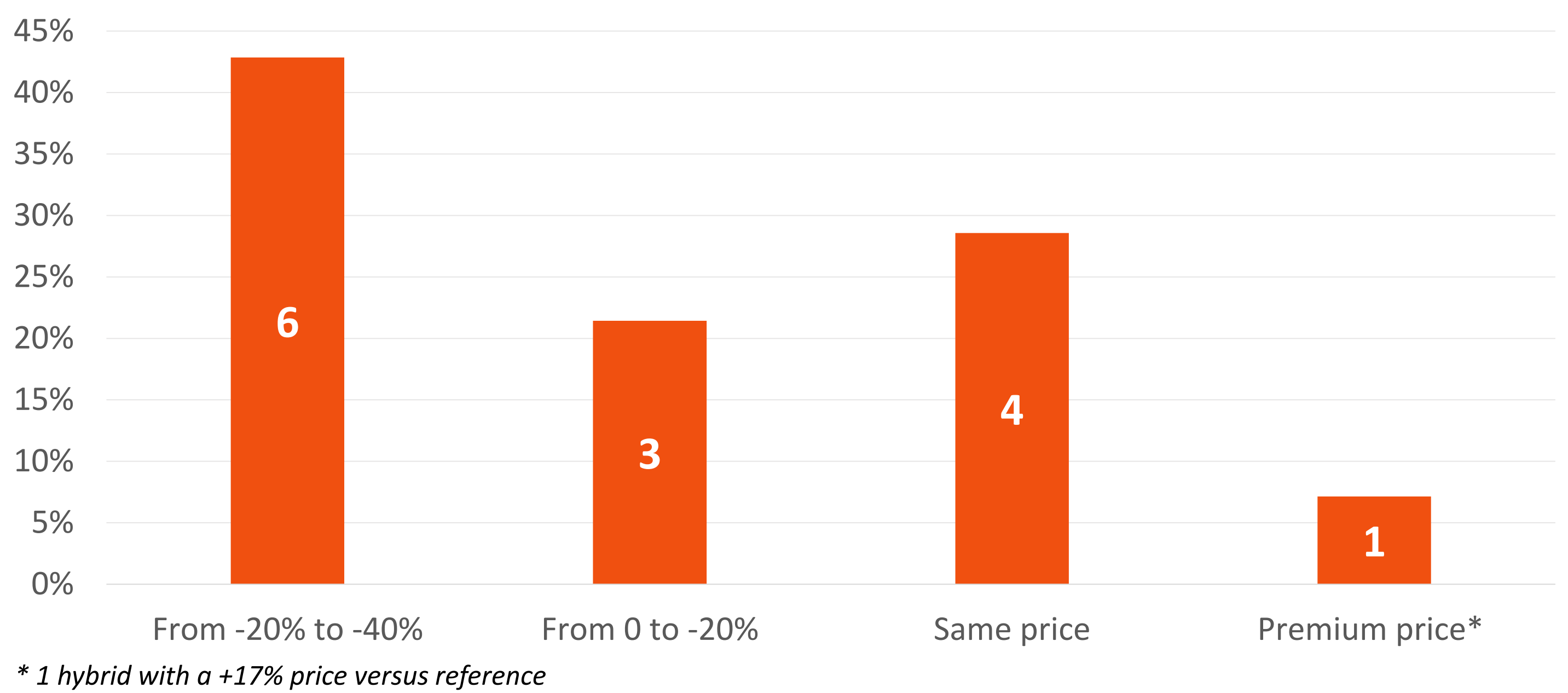
Hybrid medicines appear to be consistently reimbursed by obtaining a SMR in line with the one of their reference medicine. Nevertheless, in most cases no ASMR is granted resulting in lower prices than the reference medicine. Additionally, achieving an ASMR superior to V doesn't necessarily result in a systematic price increase.

METHODS

We conducted (1) a systematic analysis of hybrid medicines evaluated in 2022 and (2) an analysis of hybrid medicines having achieved a clinical added benefit (AMSR) superior to V from 2014 to the end of 2022.

- All identified hybrids evaluated in 2022 have obtained :
 - a clinical benefit (SMR) in line with the one of their reference medicine (sufficient)
 - no clinical added benefit (ASMR) compared to their reference medicine.
- Of the 14 hybrid medicines with a negotiated published price, this price was on average 18% lower than the reference medicine.

FIGURE 3. PRICE DIFFERENCE (HYBRID VS REFERENCE)



- Hybrid medicines achieving ASMR superior to V are very rare, with a total of 6 medicines identified between 2014 and the end of 2022 (all ASMR IV).

TABLE 1. CASES OF HYBRIDS ACHIEVING ASMR IV SINCE 2014

Name of hybrid medicine	PHEBURANE®	PROCYSBI®	NEOFORDEX®	AMGLIDIA®	NYXOID®	BAQSIMI®
Date of HAS assessment	22/01/2014	23/09/2015*	19/10/2016	06/02/2019	05/02/2020	24/03/2021

* Reassessment on 19/10/2016 : ASMR IV maintained

- Of the 4 hybrid medicines with an ASMR IV and a negotiated published price, this price was on average 35% lower than the reference medicine and only one had a premium price (+3%).

