

New AIFA innovation algorithm – 2 year report card

Background

- The Italian Medicines Agency (AIFA), is responsible for setting the reimbursement status and pricing of pharmaceutical products in Italy
- Since 2007, AIFA established a new designation, which granted more favorable reimbursement conditions for therapies deemed “innovative”
- In April 2018, a new methodology algorithm was established to evaluate these alongside new innovation funds for their reimbursement. Therapies can be designated:
 - “conditionally innovative” and gain immediate formulary inclusion
 - “innovative” which also benefit from funding through the innovation funds (worth a total of €1 billion/year) with exemptions from excess expenditure paybacks
- This research evaluates how many and what types of therapies have been granted AIFA innovative designation under this

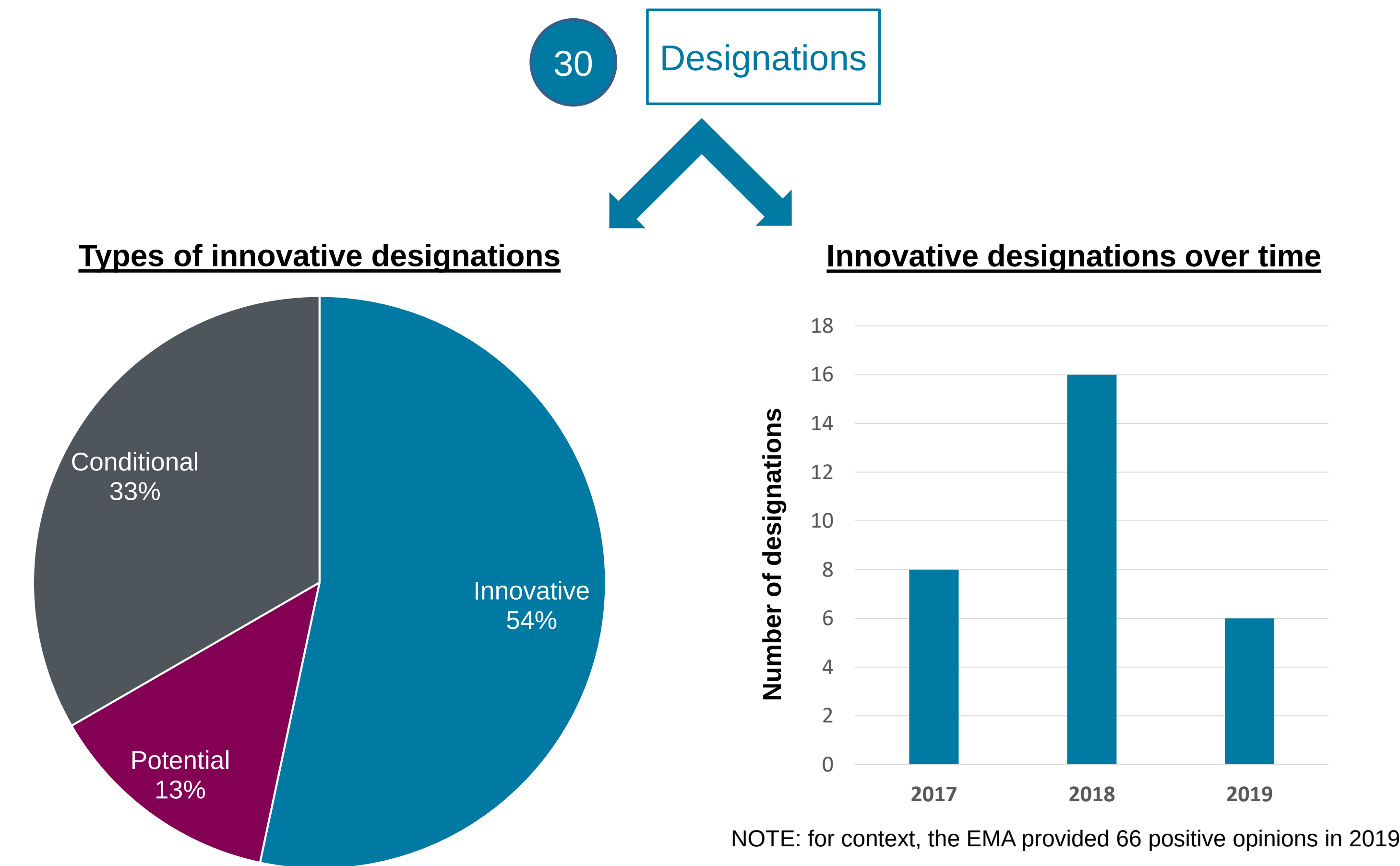
Methods

- Therapies with an AIFA innovative designation were identified from the AIFA website and key information extracted (up to 14/01/2020)

Results

Number of innovative, conditionally innovative, and potentially innovative designations

- 30 drug:indication pairings had innovative, conditionally innovative, and potentially innovative designations



Features of innovative designation, by type

	Innovative	Potential	Conditional
Number designated	16	4	10
Mean duration (yrs)	2.7	3.0	1.5
Class H	75%	75%	90%
Oncology	50%	75%	80%
Orphan	69%	75%	50%

Conclusion

- AIFA is only applying innovative status to a minority of new therapies, most of which are either for oncology indications and/or EMA-designated orphan indications. This may reflect stringency in application of the new criteria
- However, it may also reflect companies not applying for this designation. The limited scope of benefits (for example, the lack of pricing incentives) may contribute towards this