MAProvider
MARKET ACCESS PROVIDER

ISPOR
Improving healthcare decisions

ISPOR Europe 2019 | 2-6 November 2019 | Copenhagen - Denmark

FIFTY SHADES OF… INNOVATIVENESS IN ITALY

Giorgio Casilli, Virginia Ronco, Dario Lidonnici, Elena Paola Lanati

MA Provider, Milan, Italy

Background

Since 2017, AIFA recognizes innovative status to single therapeutic indication based on the evaluation of three criteria: therapeutic unmet need, added therapeutic value and quality of the evidences (by GRADE methodology)[1].

Objectives

The aim of the study was to track and evaluate AIFA Technical Scientific Committee approach on innovative status assessment, based on recently approved new criteria .

Methods

CTS outcomes on drugs innovative status, published on AIFA website between April 2017 and February 2019[2], were collected and categorized according to: i) kind of innovativeness: full, conditional or non innovative; ii) orphan designation[3]; iii) therapeutic area: oncological vs non-oncological drugs. For each single indication assessed for innovative status, the ranking of the three criteria (therapeutic unmet need maximum to absent, added therapeutic value maximum to absent, and quality of evidences high to very low) was analyzed. Sub-analyses according to the three categories were also run.

Figure 1. *Outcomes of AIFA innovative status assessment from April 2017 to February 2019 (n=41).*

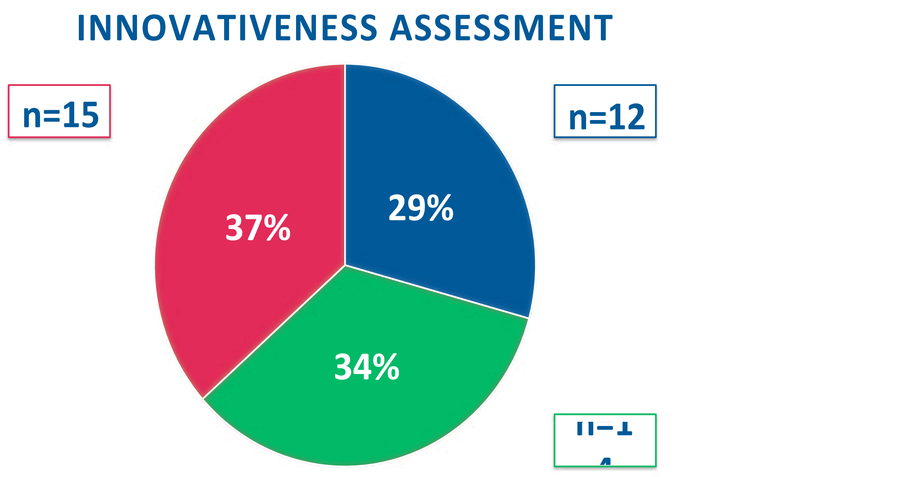
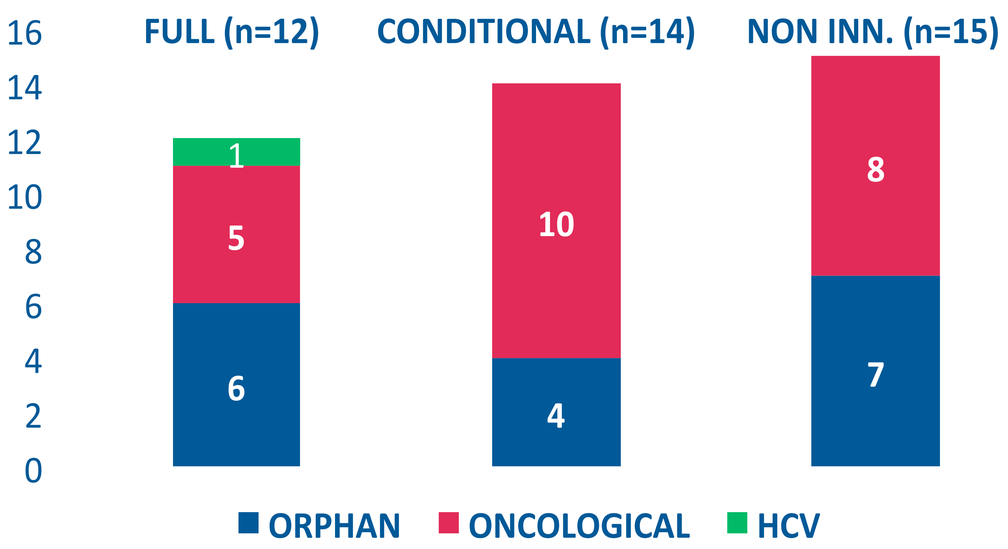


Figure 2. *Outcomes of AIFA innovative status assessment from April 2017 to February 2019: focus on therapeutic area and orphan designation.*



Results

Out of fourty-one indications (corresponding to 30 drugs) assessed by AIFA for innovative status recognition *(Figure 1)*, 12 (29%) were granted full innovative status, 14 (34%) obtained the conditional innovative status and the remaining 15 (37%) were assessed as non innovative (7 orphan and 8 oncological indications). 50% of full innovative indications were related to orphan drugs (6/12), 42% to oncological diseases (5/12) and one indication referred to HCV (*Figure 2*). Regarding conditionally innovative indications, 29% were for orphan drugs (4/14) and 79% (10/14) for oncological indications *(Figure 2)*. Analysing criteria application, AIFA has never recognized the maximum grading for added therapeutic value so far. Focusing on fully innovative indications, 9 out of 12 (75%) did not meet all the three criteria thresholds stated by AIFA decree *(Table 1)*: moderate grade in unmet medical need and therapeutic added value was not an impediment for granting full innovative status.

Table 1. *Fully innovative indications: AIFA outcomes by criteria.*

DRUG	ODD	UNMET NEED	ADDED VALUE	GRADE
1. MAVIRET		IMPORTANT	IMPORTANT	MODERATE
2. SPINRAZA	✔	MAXIMUM	IMPORTANT	LOW
3. OXERVATE	✔	IMPORTANT	IMPORTANT	LOW
4. DARZALEX	✔	MODERATE	IMPORTANT	MODERATE
5. VOSEVI		IMPORTANT	IMPORTANT	MODERATE
6. TECENTRIQ		IMPORTANT	MODERATE	HIGH
7. QARZIBA	✔	MAXIMUM	IMPORTANT	MODERATE
8. ALECENSA		MODERATE	MODERATE	MODERATE
9. RYDAPT	✔	MODERATE	IMPORTANT	MODERATE
10. DUPIXENT		IMPORTANT	MODERATE	HIGH
11. PREVYMIS	✔	MODERATE	IMPORTANT	HIGH
12. HEMLIBRA*		MODERATE	IMPORTANT	LOW

*ODD= Orphan Drug Designation * rare diseases*

Note: In case of rare diseases, also low quality of evidence is sufficient to grant full innovative status. Shaded items highlight levels that should not allow the recognition of the fully innovative status as per AIFA decree.

Conclusions

This analysis highlighted that there is no strict matching between AIFA criteria (as reported by AIFA decree) and the granting of innovative status. In fact, most of the analysed cases are borderline situations (full vs. conditional innovativeness) and have been assessed case-by-case, leaving a shade of subjectivity that gives innovative status decision-making process a margin of flexibility. The limited sample does not let us draw conclusions on the impact of orphan status or oncological setting.

References

1. https://www.aifa.gov.it/documents/20142/241044/Allegato_1_1.pdf/66558a13-543c-9643-e67b-85be01547465
2. http://www.agenziafarmaco.gov.it/content/elenco-aggiornato-farmaci-innovativi-0
3. ec.europa.eu/health/documents/community-register/html/reg_od_act.htm?sort=n

POSTER CODE: PMU44

via Vincenzo Monti 3
20123 Milan - Italy
tel +39 02 89096682
fax +39 02 89098927
e-mail | info@maprovider.com

piazza San Salvatore in Lauro 10
00186 Rome - Italy
tel | fax +39 06 68806614
e-mail | info.roma@maprovider.com