THE IMPACT OF THE NEW INNOVATIVE ALGORITHM IN ITALY

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Rova A[1], Cioni L[1], Urbinati D[1]

[1] IQVIA, RWI, Milan, Italy

INTRODUCTION

Since 2007 the Pharmaceutical Companies in Italy have the possibility to request the innovativeness status for their drugs in order to ease access and have some economic advantages. On April 6th 2017, the Italian Medicine Agency (AIFA) released a new algorithm in order to better characterize and define the recognition of therapeutic innovation and to facilitate and accelerate the access to market of these drugs.[1] The new algorithm is characterized by a multidimensional approach and takes into account three criteria: the unmet therapeutic need, the added therapeutic value and the quality of evidences. The first two criteria are assessed following a 5-score scale, from "maximum" to "absent", while the quality of evidences is evaluated by using GRADE method, from "high" to "very low". As regards the assessment of quality of evidences for rare diseases' drugs, AIFA takes into account the difficulty to conduct gold standard studies. The evaluation process determines a new drug to achieve one of the following designations: innovative, not innovative or conditionally innovative. (Figure 1) Every evaluation is related to a single indication. The achievement of the innovative designation leads to economic advantages (inclusion in the fund for innovative - or innovative and oncologic - drugs and exemption from the payback) and to faster access to market (with the automatic inclusion in all regional formularies). The achievement of the conditionally innovative designation leads only to immediate inclusion in the regional formularies. Since January 2018, AIFA has been publishing on its institutional website the innovativeness assessment reports of drugs subjected to this peculiar evaluation. The main purpose of this research was to analyze the assessments performed by AIFA and to assess AIFA's perception and perspective on innovativeness designation.

METHODS

A desk research gathered the innovativeness assessment reports published on AIFA institutional website since January 2018. The 18 reports analyzed corresponded to 16 drugs as every evaluation was necessarily linked to one single indication; two drugs were evaluated twice: once for each indication. Drugs in scope belonged to different therapeutic areas and categories: oncology (#8), virology (#2), rheumatology (#1) and other diseases. Every AIFA's assessment has been in-depth analyzed applying the following approach: a score from 1 to 5 to each criteria was assigned (1= "absent" or "very low" and 5= "maximum" or "high"), resulting in a final score representative the sum of the three criteria. Furthermore, a research on EMA website allowed to identify drugs with the orphan designation.

RESULTS

Results from the analysis showed that, out of 18 evaluations, 6 drugs/indications obtained the innovative designation (33%). Among the 6 innovative indications, 3 were associated to orphan drugs and their quality of evidences were considered low or moderate, whilst the added therapeutic value and the unmet therapeutic need ranged from maximum to moderate. Two out of 6 innovative drugs were oncologic, thus they have been included in the innovative and oncologic fund.

Two drugs, daratumumab and palbociclib, were evaluated twice because of two indications. Daratumumab, for both indications, obtained a moderate and an important score for the unmet therapeutic need and the added therapeutic value. Only the indication which obtained the innovative designation was assessed as moderate in the quality of evidences. On the contrary, the indication which did not obtain the innovative designation was evaluated as low in the same criteria.

Daratumumab, in the indication which obtained the innovativeness, and atezolizumab stood out due to the presence of a moderate score in the unmet therapeutic need and the added therapeutic value criteria, respectively. (Table 1)

The analysis of the results, as represented in Figure 2, showed that the key element to achieve the innovative designation was not linked to the highest total score: adalimumab obtained a total score higher than cenegermin and daratumumab, but it was evaluated as conditionally innovative. Atezolizumab achieved the highest total score among all drugs/indications, having received the highest score for the quality of evidences and the important evaluation for the unmet therapeutic need and, as mentioned above, it was evaluated moderate for the added therapeutic value. (Figure 2) The achievement of the innovative designation was linked to the combination of all the three criteria. Among the 6 innovative drugs/indications, the three lowest total scores belonged to orphan drugs, characteristic which AIFA can take into account during the quality of evidences evaluation.

CONCLUSION

The new algorithm, released by AIFA to guide the evaluation of the innovative designation, has improved on previous version by minimizing the technical requirements, allowing medical discretion for the assessment.

It ensures a balance between objectivity and flexibility, enhancing the level of evidence-based dialogue between the pharmaceutical Companies and AIFA.

The new algorithm and the subsequent publications have represented an important step forward in AIFA's transparency.

In those evaluations where the innovation is in-between, namely where the score is moderate, the new innovativeness algorithm appears more interpretative.

Hence, it is difficult to predict AIFA final decision since every evaluation has its own peculiarities. In short, the new method looks less "algorithm" and more "guideline".

FIGURE 1

Scores and outcomes in AIFA innovative evaluation[2]

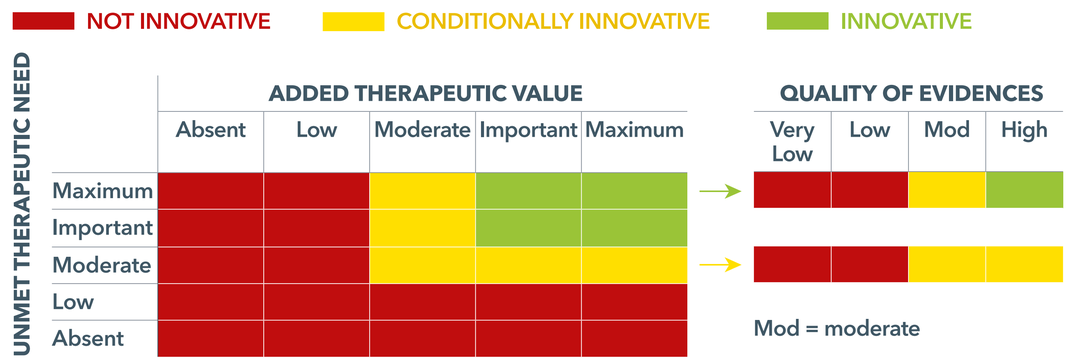


TABLE 1

Results of the innovativeness assessment for each criteria

NOT INNOVATIVE | CONDITIONALLY INNOVATIVE | INNOVATIVE

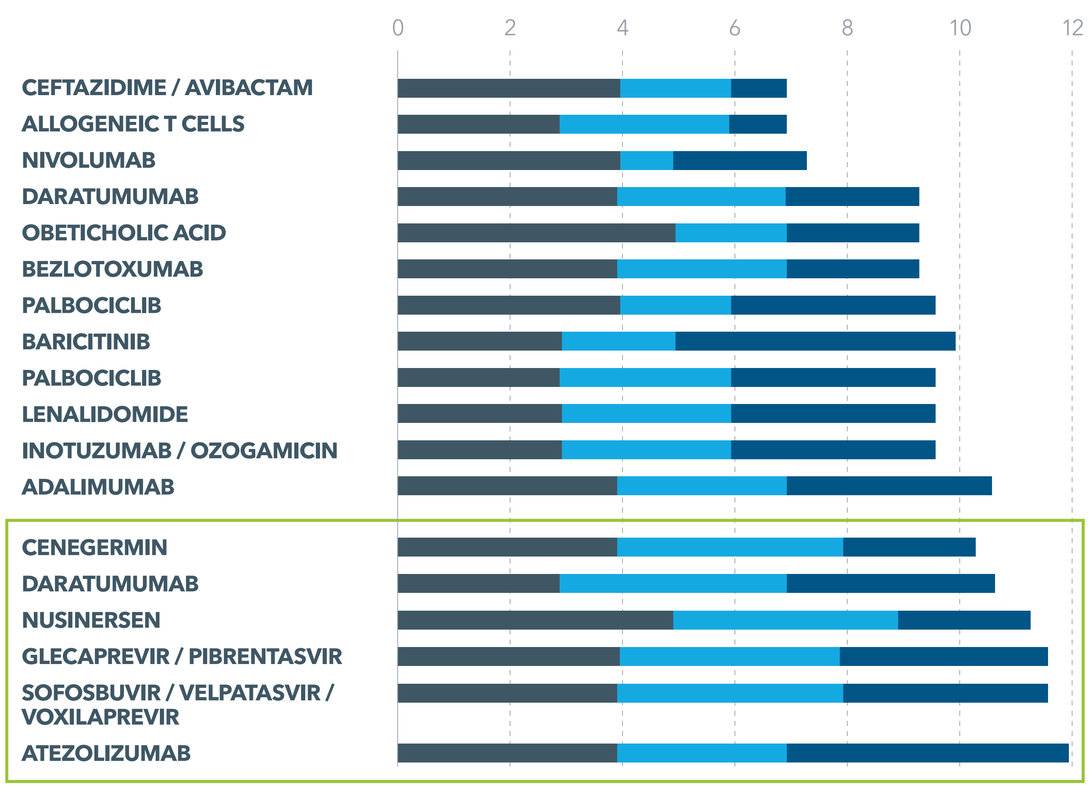
ACTIVE SUBSTANCES	ORPHAN	ONCO	UNMET THER. NEED	ADDED THER. VALUE	QUALITY OF EVIDENCES
CEFTAZIDIME / AVIBACTAM*			Imp	Poor	Mod-Low-Vlow
ALLOGENEIC T CELLS	✓		Mod	Mod	Vlow
NIVOLUMAB		✓	Imp	Ne	Low
DARATUMUMAB	✓	✓	Imp	Mod	Low
OBETICHOLIC ACID	✓		Max	Poor	Low
BEZLOTOXUMAB			Imp	Mod	Low
PALBOCICLIB		✓	Imp	Poor	Mod
BARICITINIB			Mod	Poor	High
PALBOCICLIB		✓	Mod	Mod	Mod
LENALIDOMIDE	✓	✓	Mod	Mod	Mod
INOTUZUMAB / OZOGAMICIN	✓	✓	Mod	Mod	Mod
ADALIMUMAB			Imp	Mod	Mod
CENEGERMIN	✓		Imp	Imp	Low
DARATUMUMAB	✓	✓	Mod	Imp	Mod
NUSINERSEN	✓		Max	Imp	Low
GLECAPREVIR / PIBRENTASVIR			Imp	Imp	Mod
SOFOSBUVIR / VELPATASVIR/ VOXILAPREVIR		✓	Imp	Imp	Mod
ATEZOLIZUMAB			**Imp**	**Mod**	**High**

Max = maximum; Imp = important; Mod = moderate; Vlow = very low; Ne = Not evaluable; Onco = Oncologic

(*) Ceftazidime/avibactam represented a particular case as regards the quality of evidences criteria: it obtained different evaluations resulting from different clinical trials conducted for three sub-populations (depending on the site of infection)

FIGURE 2

Results of the innovativeness assessment for each criteria



1. Agenzia Italiana del Farmaco (AIFA). Criteri per la classificazione dei farmaci innovativi e dei farmaci oncologici innovative. Decree 1535/2017
2. Pinto C et al. Schema per la preparazione del dossier di richiesta di innovatività dei farmaci. Economia politica del farmaco e delle tecnologie sanitarie. 2018

FOR FURTHER INFORMATION: Please contact - Duccio Urbinati, duccio.urbinati@iqvia.com - IQVIA Via Fabio Filzi 29, 20124, Milan (Italy)

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