

POSITIVE IMPACT OF INNOVATIVE STATUS IN P&R PROCESS TIMING IN ITALY

Andrea Enrici, Dario Lidonnici, Martina Isernia, Elena Paola Lanati

MA Provider, Milan, Italy

Background

In Italy, the possibility to request for the innovative status recognition to new indications, in order to have a faster access to the Italian market and economic advantages, exists since 2007.

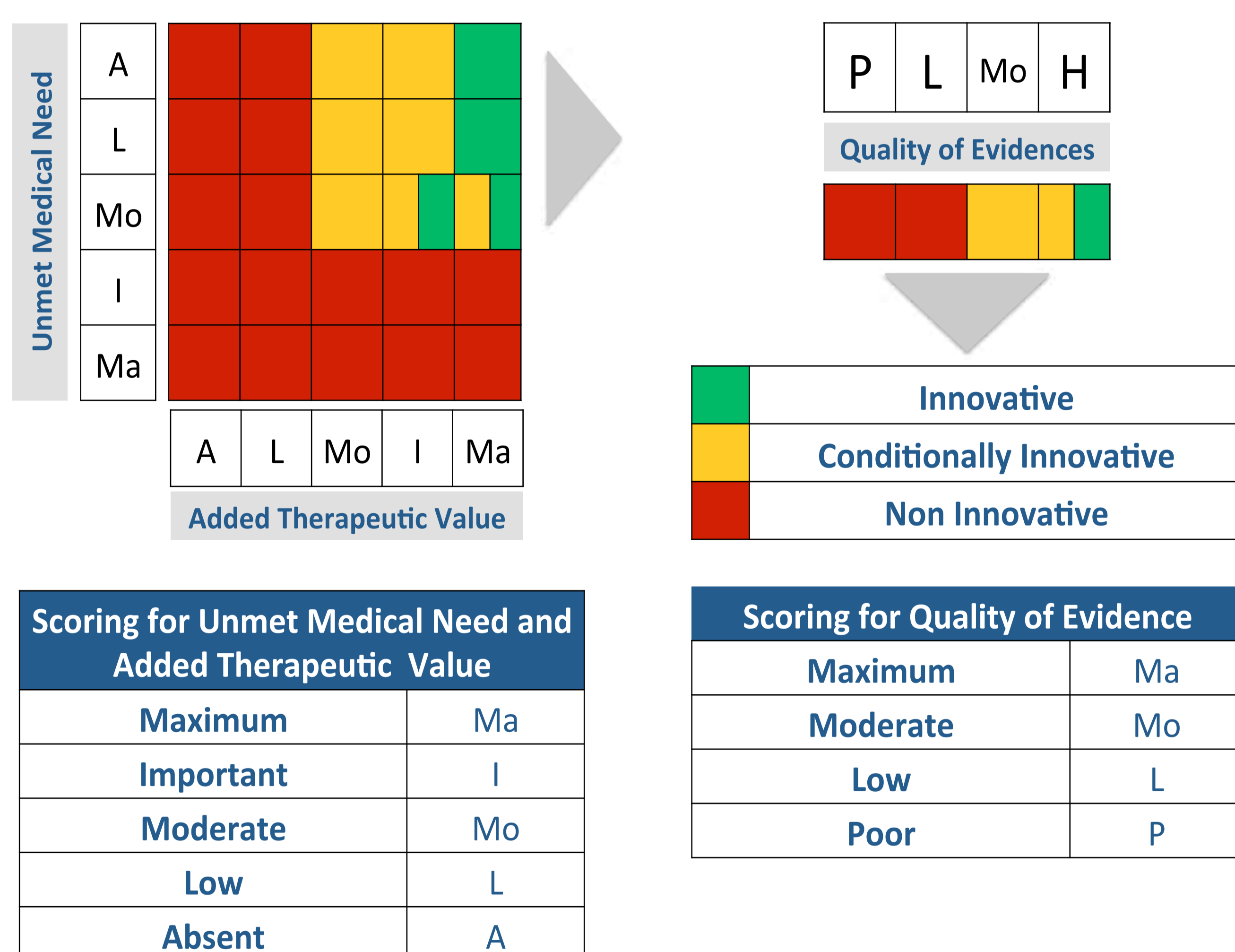
This aims to provide a fast access to actual innovation, while encouraging innovative drug development and ensuring sustainability and efficiency to the healthcare system.

On April 5th 2017, the Italian Medicines Agency (AIFA) released a new algorithm in order to better characterize and define clear and reported rules for the recognition of the innovative status. The three new criteria issued by AIFA let the Technical Scientific Committee (CTS) assess the level of innovation according to the "Unmet Medical Need" of the disease, the "Added Therapeutic Value" of the drug in the specific indication and the "Quality of Evidences" based on the GRADE methodology (Figure 1).

Objective

The main purpose of this analysis was to quantify the time to market (TTM) of innovative drugs and analyse the differences between innovative vs non-innovative drugs to understand if the innovative status recognition has an influence on the P&R process.

Figure 1. Graphic representation of the new 2017 criteria for assessment of the innovative status recognition.



Methods

Monthly reports of AIFA committees meeting, AIFA list of innovative drugs and Official Gazettes were screened for the period before and after the release of AIFA new criteria (April 2017).

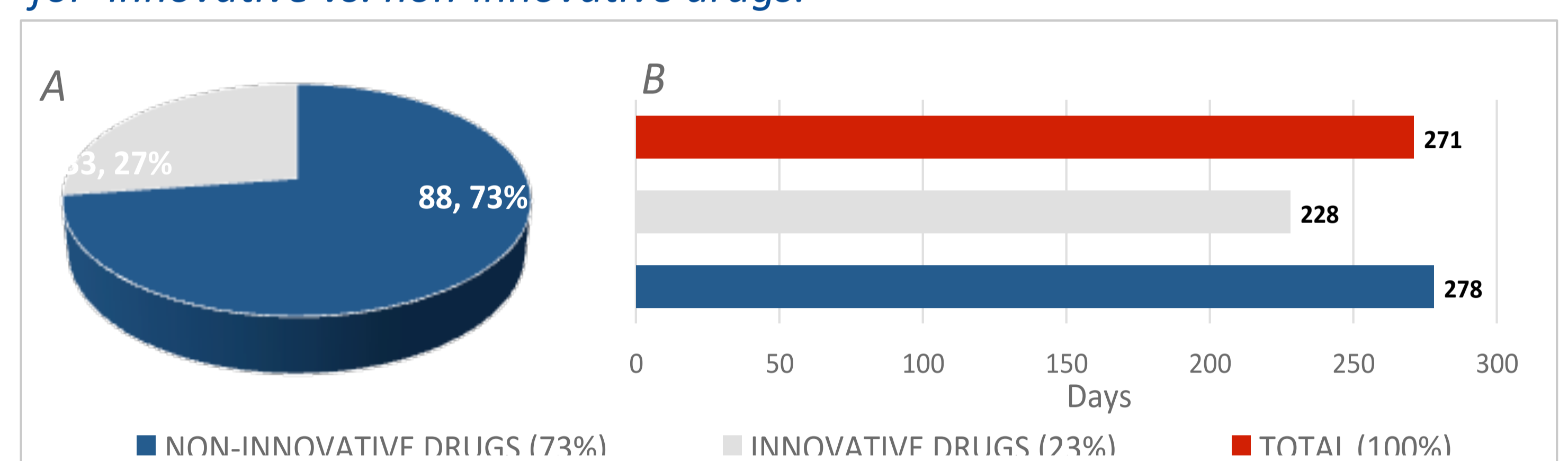
All reimbursed medicines of the period between January 2015 and May 2019 were tracked: 33 were granted innovative status linked to the specific indication and were analysed in terms of timing according to different categorizations (full vs conditional innovative status; pre- vs post-2017 criteria; oncological vs non oncological indications).

Results

The sample analysed included all reimbursed drugs (n=121) from January 2015 till May 2019 and the average approval timing resulted in 271 days from CTS opening to Official Gazette publication.

A sub-analysis was run to point out the difference in terms of approval timing between innovative drugs (33 out of 121, 27%) and non-innovative (88 out of 121; 73%) (Figure 2A): while non-innovative drugs had an average approval process of 287 days, innovative drugs were assessed and reimbursed in 228 days (Figure 2B).

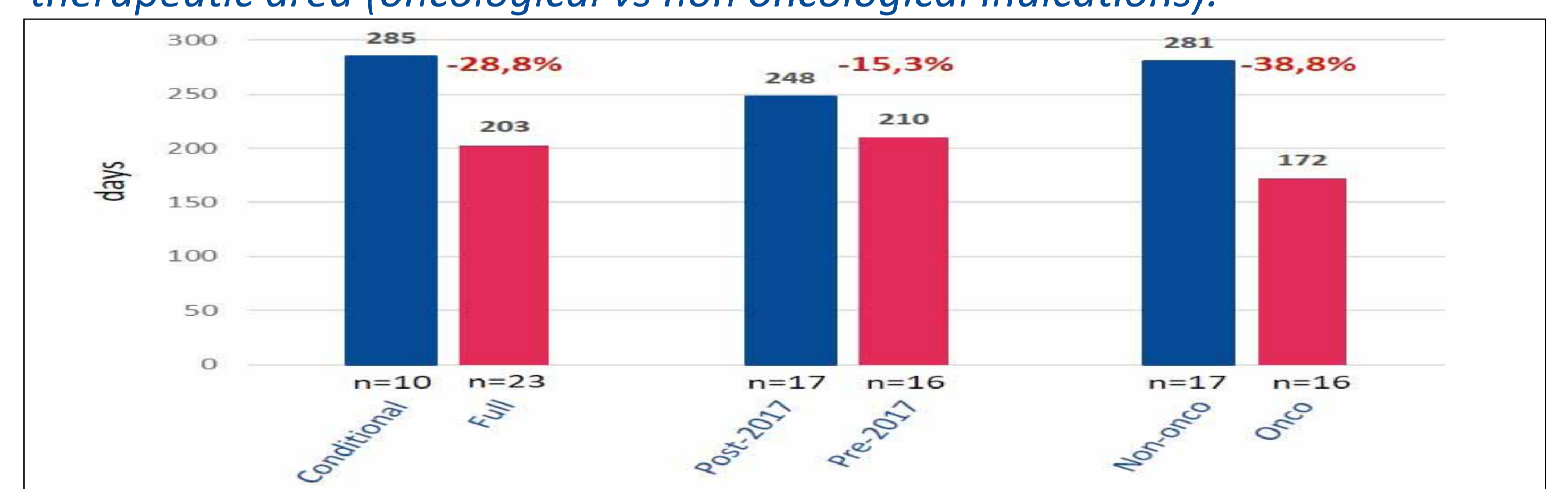
Figure 2. Sample considered for analysis (A) and average approval timing (B) for innovative vs. non-innovative drugs.



Innovative status was assessed "full" for 23 drugs/indications (19%) and "conditional" for 10 drugs/indications (8%): the average time to reimbursement was 203 vs 285 days respectively.

A gap of 38 days (210 vs 248 days) was detected comparing old (pre-2017) vs new innovative criteria (post-2017). Categorizing by therapeutic area, innovative-oncological drugs (17, 14%) had a longer approval process (281 days) compared to innovative-non oncological drugs (172 days) (16, 13%) (Table 1). All these differences in timing were due to active committees (CTS and CPR: 121 day pre criteria vs 162 post criteria) assessment, while post-assessment (bureaucratic/administrative) phase remained almost stable (about 90 days: pre criteria 92 days vs post criteria 82).

Figure 3. Timing and number of innovative drugs stratified by full and conditional innovative status recognition, pre- vs post-2017 criteria and therapeutic area (oncological vs non oncological indications).



Conclusions

The analysis showed a faster P&R process for innovative compared to non-innovative drugs, given the clinical need of patients affected by diseases with lack or poor alternative treatments recognised by AIFA committees according to the first innovation criteria.

Full vs conditional innovative status had an important impact on timing, with shorter assessment for full innovative drugs. Also therapeutic area influences the timing of approval process, maybe due to the need for deeper analysis in the assessment of oncological drugs. New criteria seems to have a negative impact on approval timing vs old criteria, but this may also be due to the necessary lead time to bring the new algorithm into the drug evaluation.

References

1. <http://www.agenziafarmaco.gov.it/content/aifa-criteri-la-classificazione-dei-farmaci-innovativi-e-dei-farmaci-oncologici-innovativi>
2. <https://www.gazzettaufficiale.it/eli/gu/2017/04/05/80/sg/pdf>
3. <http://www.agenziafarmaco.gov.it/content/archivio-elenco-farmaci-innovativi-legge-di-bilancio-2017>
4. 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

POSTER CODE: PMU46