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UPDATED NEW DRUGS APPROVAL TIMING IN ITALY (2015-2017)

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INTRODUCTION

A rapid access to new and effective treatments is a major priority of the Italian Medicines Agency (AIFA) and an important goal for pharmaceutical companies to guarantee drugs access equity to patients.

OBJECTIVES

The objective of the present work is to describe the time length taken by the Italian Medicine's Agency to formulate pricing and reimbursement decisions for drugs approved via European centralized procedures and to evaluate possible differences among specific categories of drugs (e.g. innovative, not innovative, orphan and oncological drugs).

METHODS

Monthly meeting reports of the AIFA Technical Scientific Committee (CTS) and Price and Reimbursement Committee (CPR), as well Official Journals (OJ) were scrutinized from January 2015 to December 2017. Analysed drugs, divided into categories, included the ones with completed P&R process and fully reimbursed. These drugs are part of a monthly updated database built in MS Excel (2010) (182 drugs at the time of analysis) aiming to track the process over years. For each analysed drug standard checkpoints were identified in order to measure timings of each single approval steps.

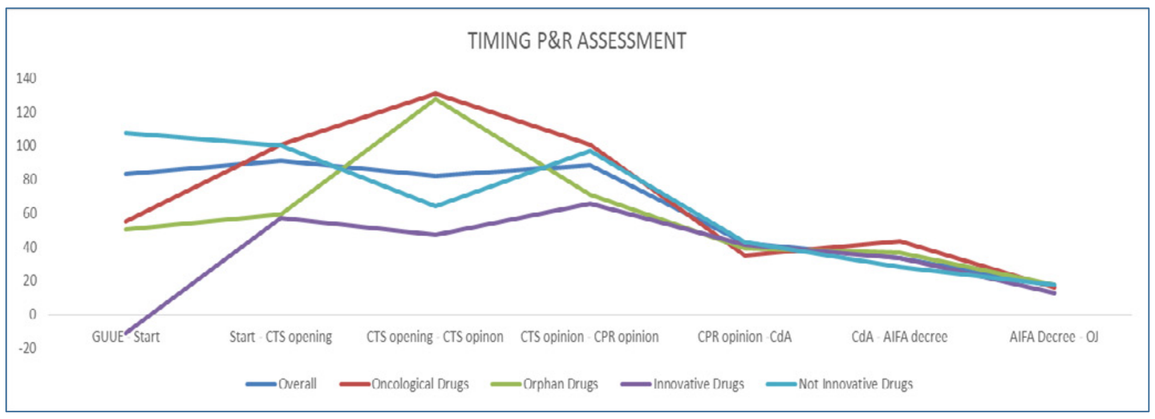

FIGURE 3.
Timing analysis of AIFA assessment and approval for P&R procedure: overall, innovative, not innovative, orphan and oncological drugs.

P&R TIMING ASSESSMENT FOR REIMBURSED DRUGS (N=82)					
STEP	**AVERAGE**	**MIN**	**MAX**	**DS**	**N**
2-7	355				
3-7	262	75	847	144	81
1	83	-82	504	127	51
2	91	0	197	47	51
3	82	0	723	124	81
4	89	-22	231	61	80
5	42	8	171	26	80
6	33	1	86	16	82
7	17	2	55	8	

TABLE 1.
Average, minimum (Min) e maximum (Max) time for each analysed step of all drugs. SD: standard deviation, N: number of analysed drugs. Steps detail: 1. GUUE – START; 2. START – CTS opening; 3. CTS opening – CTS opinion; 4. CTS opinion – CPR opinion; 5. CPR opinion – CdA; 6. CdA – AIFA's determination of P&R; 7. AIFA's determination of P&R – OJ.

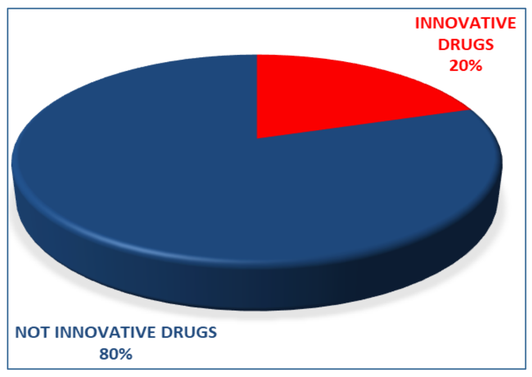

FIGURE 1.
Reimbursed drugs by AIFA: innovative drugs (16 out of 82, 20%) vs. not innovative drugs (66 out of 82, 80%).

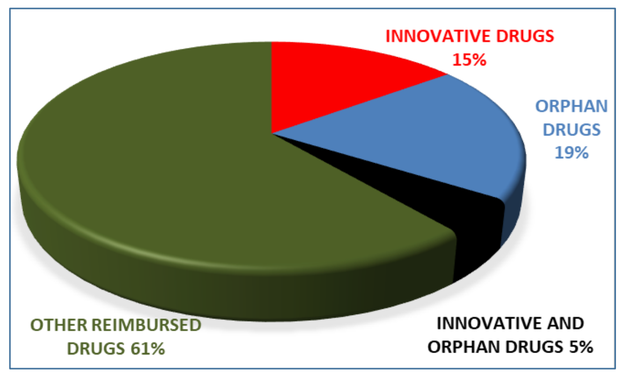

FIGURE 2.
Categories of reimbursed drugs (N=82 out of 182) in the observed period. In details: innovative (N=12), orphan (N=16), innovative and orphan (N=4) and other reimbursed drugs (N=50).

RESULTS

During the analysed period, 82 drugs out of 182 obtained reimbursement and were included in the analysis (***Figure 1*** and ***Figure 2***). Overall, time-to-market (CTS assessment opening to OJ: STEP 3 – 7) was 262 days (min 75, max 847, DS ±144, n=81). Timing was shorter for innovative drugs (201 days) and longer for other categories. About half of the whole procedure was dedicated to administrative steps (pre- and post-assessment period ≈ 184 days, 52% of the P&R procedure) without great differences among categories.

The median time length of the procedures is reported in ***Figure 3*** and ***Table 1***.

In detail:

- STEP 1 (GUUE – START) → ≈ 83 days (min -82, max 504, DS ±127, n=51)
- STEP 2 (Pre-assessment period: START – CTS opening) → ≈ 91 days (min 0, max 197, DS ±47, n=51)
- STEP 3 – 4 (CTS and CPR assessment) → ≈ 171 days
  - STEP 3 (CTS opening – CTS opinion) → 82 days (min 0, max 723, DS ±124, n=81)
  - STEP 4 (CTS opinion – CPR opinion) 89 days (min -22, max 231, DS 61, n=80)
- STEP 5 – 7 (Post-assessment period) → ≈ 92 days
  - STEP 5 (CPR opinion – CdA) → ≈ 42 (min 8, max 171, DS 26, n=80)
  - STEP 6 (CdA – AIFA's determination of P&R) → ≈ 33 (min 1, max 86, DS 16, n=82)
  - STEP 7 (AIFA's determination of P&R – OJ) → ≈ 17 days (min 2, max 55, DS ±8, n=82)

In ***Table 2*** the differences of P&R timing for each drug category are illustrated. In detail: STEP 2-7 (START – OJ) and STEP 3-7 (CTS opening – OJ).

DIFFERENCES IN P&R TIMING FOR DRUG CATEGORY					
P&R PROCEDURE	**OVERALL (N=82)**	**INNOVATIVE (N=16)**	**NOT INNOVATIVE (N=41)**	**ORPHAN (N=20)**	**ONCOLOGICAL (N=20)**
STEP 2-7	355	258	351	351	426
STEP 3-7	262	201	251	292	325

TABLE 2.
Differences in timing of P&R assessment for each specific category of drugs.

CONCLUSIONS

Compared to previous studies, our analysis suggests that the P&R process in Italy is shortening. Nonetheless, administrative procedures may still be optimized to allow a faster access to cures for patients. In general, the P&R procedure timing is not influenced by orphan designation or therapeutic area, with the exception for innovative drugs for which the time is much shorter.