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NEW DRUGS APPROVAL TIMING IN ITALY (2015-2017)

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INTRODUCTION

A rapid access to new and effective treatment 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 length of time taken by the Italian Medicines 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 May 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 (currently 149 drugs) aiming to track the process over the time. For each analysed drug standard checkpoints were identified in order to measure timings of each single approval steps.

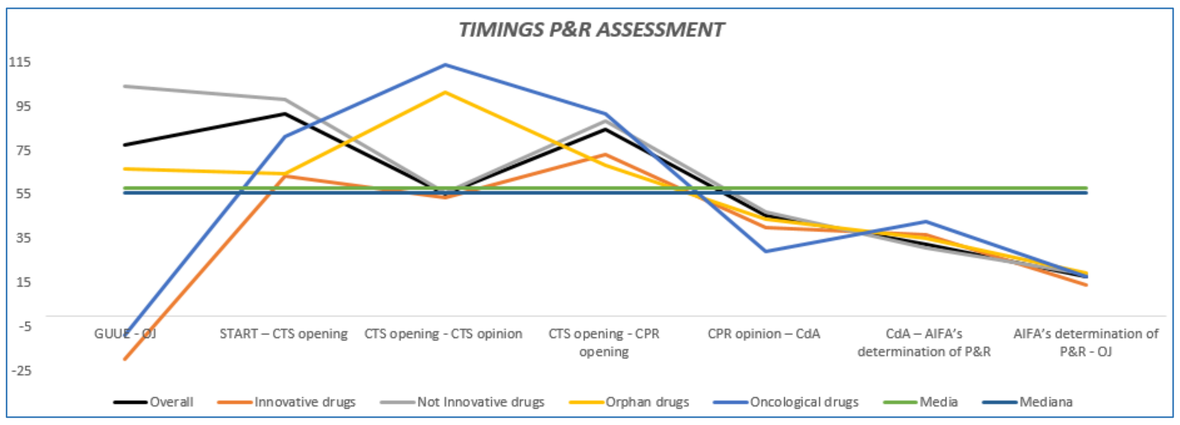

FIGURE 3.
Timing analysis of AIFA assessment and approval for P&R procedure: overall, innovative, not innovative, orphan and oncological drugs.

P&R TIMING ASSESSMENT FOR REIMBURSED DRUGS (N=53)					
STEP	**AVERAGE**	**MIN**	**MAX**	**DS**	**N**
2-7	328				
3-7	236	89	435	91	52
1	78	-45	401	129	23
2	92	23	197	45	25
3	56	0	239	65	52
4	85	6	231	57	51
5	45	8	171	28	51
6	33	1	85	17	53
7	18	4	55	8	53

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.

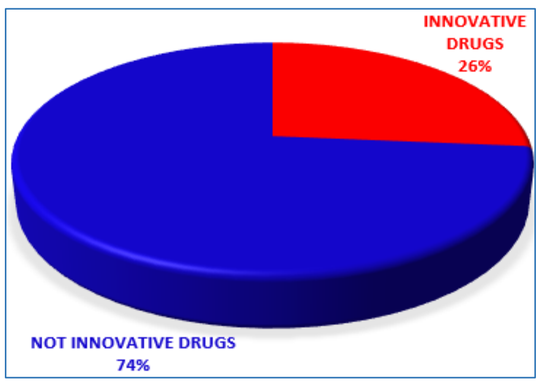

FIGURE 1.
Reimbursed drugs by AIFA: innovative drugs (14 out of 53, 26%) vs. not innovative drugs (39 out of 53, 74%).

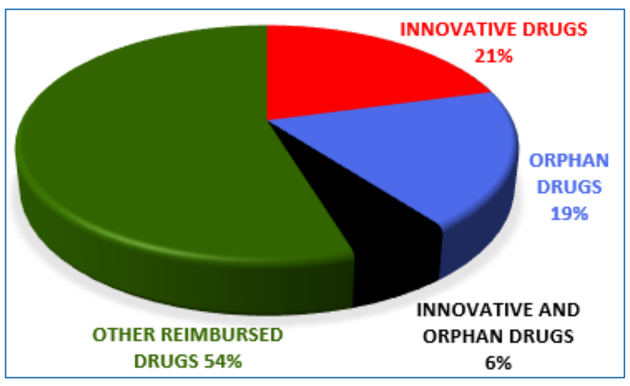

FIGURE 2.
Categories of reimbursed drugs (N=53 out of 149) in the observed period. In details: innovative (N=11), orphan (N=10), innovative and orphan (N=3) and other reimbursed drugs (N=29).

RESULTS

During the analysed period, 53 drugs out of 149 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 236 days (min 89, max 435, DS ±91, n=52). Timing was shorter for innovative drugs (214 days) and longer for other categories. About half of the whole procedure was dedicated to administrative steps (pre- and post-assessment period ≈ 188 days, 57% of the P&R procedure) without great differences among categories.

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

In detail:

- STEP 1 (GUUE – START) → ≈ 78 days (min -45, max 401, DS ±129, n=23)
- STEP 2 (Pre-assessment period: START – CTS opening) → ≈ 92 days (min 23, max 197, DS ±45, n=25)
- STEP 3 – 4 (CTS and CPR assessment) → ≈ 140 days
  - STEP 3 (CTS opening – CTS opinion) → 56 days (min 0, max 239, DS ±65, n=52)
  - STEP 4 (CTS opinion – CPR opinion) 85 days (min 6, max 231, DS 57, n=51)
- STEP 5 – 7 (Post-assessment period) → ≈ 96 days
  - STEP 5 (CPR opinion – CdA) → ≈ 45 (min 8, max 171, DS 28, n=51)
  - STEP 6 (CdA – AIFA's determination of P&R) → ≈ 33 (min 1, max 86, DS 17, n=53)
  - STEP 7 (AIFA's determination of P&R – OJ) → ≈ 18 days (min 4, max 56, DS ±8, n=53)

In ***Table 2*** are illustrated difference of P&R timing for each drug category. 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=53)**	**INNOVATIVE (N=14)**	**NOT INNOVATIVE (N=39)**	**ORPHAN (N=13)**	**ONCOLOGICAL (N=11)**
STEP 2-7	328	283	341	334	378
STEP 3-7	236	214	245	261	297

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 of patients. In general, the P&R procedure timing is not influenced by orphan designation or therapeutic area, with the exception of innovative drugs for which the time was shorter.