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NEW DRUGS APPROVAL IN ITALY: ANALYSIS OF THE APPLIED NEGOTIATION CONDITIONS 2015-2017

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INTRODUCTION

This study aims to track and analyse, using Official Journal publications, the negotiation conditions (Managed Entry Agreements [MEAs], monitoring registries, discounts) of novel drugs reimbursed in Italy.

OBJECTIVES

The objective of the present work is to describe the different type of MEAs, confidential discounts and AIFA monitoring registry applied and to define the timings in P&R procedure among specific categories of drugs, that have negotiation conditions (***Figure 1*** and ***Table 1***).

METHODS

Publicly available Official Journal (OJ) of 53 new active principles approved through European centralised procedure were screened since January 2015 to May 2017. 53 drugs out of 149 completed the P&R process and were reimbursed. Drugs were categorized by type and by therapeutic area (focus on oncological and oncohematological drugs). For each analysed drug, the kind of negotiated MEAs (Outcome Based and Not Outcome Based MEAs), the application of confidential discounts and monitoring registries were tracked.

	REIMBURSED DRUGS (N=53)									
	MEAs (N=19)					NO MEAs (N=34)				
STEP	AVERAGE	MIN	MAX	DS	N	AVERAGE	MIN	MAX	DS	N
START – OJ	329					329				
CTS opening – OJ	258	89	420	99	19	224	101	435	85	33
START – CTS opening	71	23	105	29	10	105	35	197	49	15
CTS opening – CTS opinion	67	0	196	61	19	49	0	239	67	33
CTS opinion – CPR opinion	95	7	223	61	19	79	6	231	54	32
CPR opinion – CdA	43	8	171	34	19	47	9	120	25	32
CdA – AIFA's determination of P&R	37	1	86	21	19	30	14	79	14	34
AIFA's determination of P&R – OJ	16	5	35	8	19	19	4	55	9	34

TABLE 1.
Timing to P&R assessment for analysed drugs.

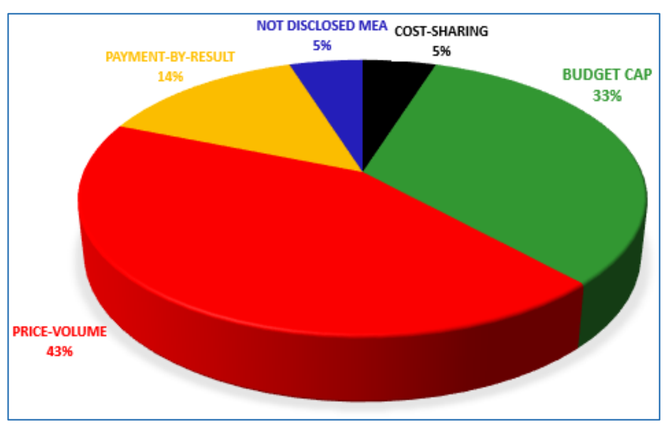

FIGURE 2.
Focus on reimbursed drugs with applied MEAs, categorized in: Outcome-based, Not Outcome-based and Not disclosed MEAs.

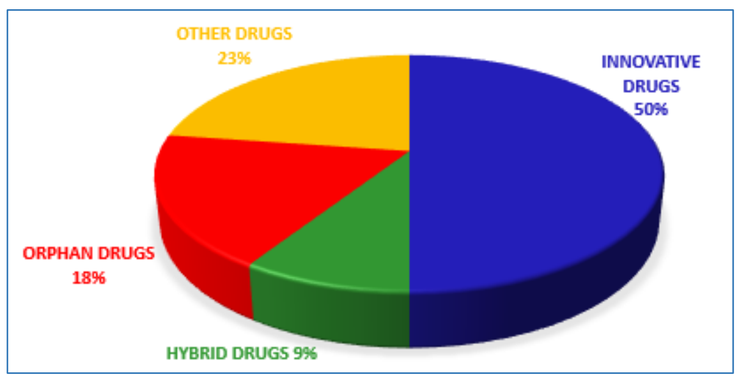

FIGURE 3.
Drugs with applied AIFA monitoring registry (N=22 out of 53) categorized in: innovative, orphan, hybrid (both with innovative and orphan designation) and other drugs.

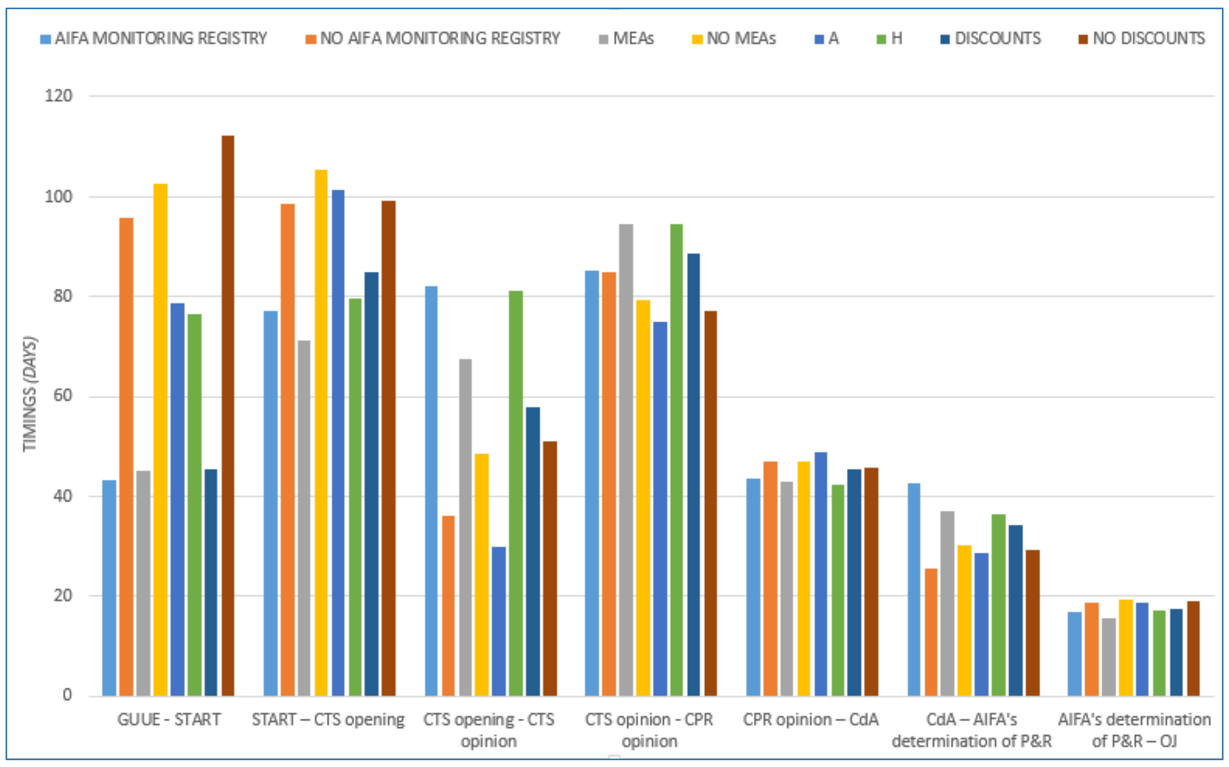

FIGURE 1
Differences in P&R assessment timing of reimbursed drugs with negotiation conditions (MEAs, AIFA monitoring registry, reimbursement class, discounts).

RESULTS

Based on these criteria, 53 out of 149 new drugs were reimbursed in Italy and of these the 21% were assessed as innovative, the 19% as orphan and the 6% as hybrid (both with innovative and orphan designation). The 11% (N=6) were oncological drugs and the 9% (N=5) oncohematological. The 32% (N=17) of the total (N=53) sample had a MEA (***Figure 2***) as approval condition agreed between the Marketing Authorisation Holder and AIFA. Two drugs (4%) out of 53 analysed had 2 simultaneously applied MEAs (1 payment-by-results + budget cap and 1 price-volume + budget cap). One drug had a MEA applied but not disclosed in the OJ (5%). Analysing the 21 tracked MEAs, 81% were non-outcome based and 14% were outcome-based. The only outcome-based applied MEA was the payment-by-results (14%).

In detail, the Not Outcome Based tracked MEAs were:

- cost-sharing (5%),
- budget cap (33%),
- price-volume agreement (43%).

Twenty-two (42%) out of 53 reimbursed drugs had an applied AIFA monitoring registry (***Figure 3***). Thirty-five (66%) out of 53 scrutinized drugs had an applied confidential discount. Reimbursement Class A included 27 (51%) out of 53 analysed drugs, the remaining 26 (49%) were assigned to Class H.

CONCLUSIONS

During observed period a broader use of non-outcome based (financial) MEAs emerged, highlighting the increasing focus of the Italian Medicines Agency to economic issues, due to a growth of the budget expenditure. Price-volume agreements appear as the mostly applied MEA, with a monitoring registry as measure to track prescription appropriateness. Publicly available analyses of these tools would be of great help in understanding the real value of their application.