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

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## INTRODUCTION

Italy has been among the first countries in introducing MEAs since July 2006 and the tracking of MEAs over the time is a mean by which to understand the Italian NHS behaviour in specific historical moments of tight budget constraints.

## OBJECTIVES

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

## METHODS

Publicly available Official Journal (OJ) of new active principles, approved through European centralised procedure, were screened since January 2015 to December 2017. 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.

Simple descriptive statistical analyses were conducted using MS Excel software (2010) to P&R procedure timing and analyse the negotiation conditions (Managed Entry Agreements [MEAs], monitoring registries, discounts) of novel drugs reimbursed in Italy.

| REIMBURSED DRUGS (N=82) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | MEAs (N=27) | | | | | NO MEAs (N=54) | | | | |
| STEP | AVERAGE | MIN | MAX | DS | N | AVERAGE | MIN | MAX | DS | N |
| START-OJ | 429 | 112 | 788 | 179 | 17 | 347 | 132 | 920 | 165 | 34 |
| CTS opening - OJ | 313 | 89 | 649 | 148 | 26 | 246 | 97 | 847 | 137 | 50 |
| START - CTS opening | 79 | 0 | 175 | 45 | 18 | 90 | 0 | 197 | 53 | 36 |
| CTS opening - CTS opinion | 108 | 0 | 434 | 116 | 26 | 72 | 0 | 723 | 130 | 50 |
| CTS opinion - CPR opinion | 104 | 7 | 225 | 65 | 27 | 82 | -22 | 231 | 57 | 52 |
| CPR opinion - CdA | 43 | 8 | 171 | 31 | 27 | 42 | 9 | 120 | 23 | 52 |
| CdA - AIFA's determination of P&R | 40 | 1 | 86 | 20 | 27 | 30 | 11 | 79 | 14 | 54 |
| AIFA's determination of P&R- OJ | 14 | 2 | 35 | 8 | 27 | 17 | 2 | 30 | 6 | 54 |

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

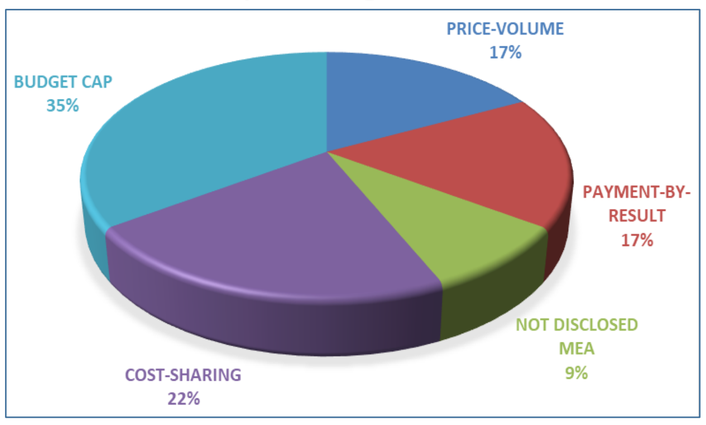


***FIGURE 2.***
Focus on reimbursed drugs with applied MEAs, categorized in: Outcome-based, Not Outcome-based and Not disclosed MEAs.

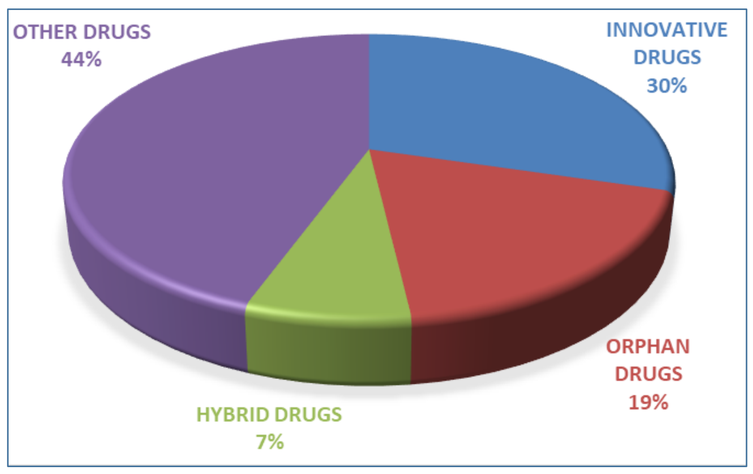


***FIGURE 3.***
Drugs with applied AIFA monitoring registry (N=27 out of 82) categorized in: innovative, orphan, hybrid (both with innovative and orphan designation) and other drugs.

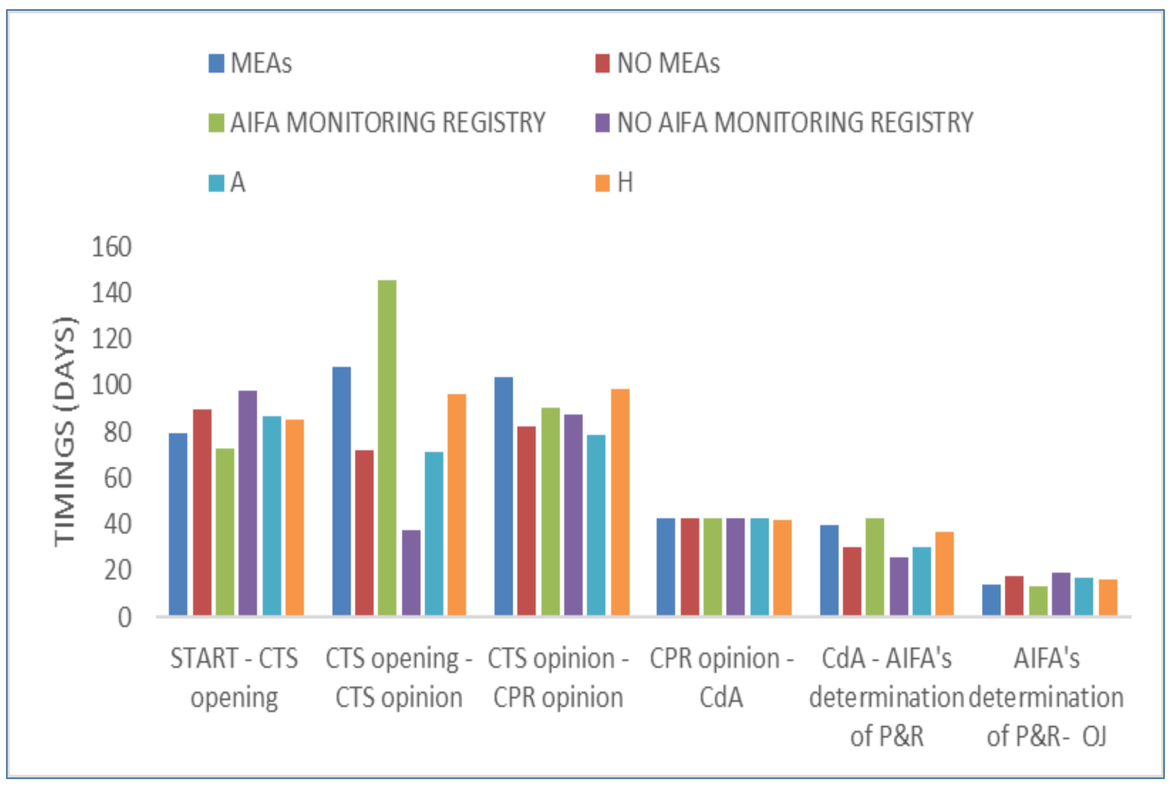


***FIGURE 1***
Differences in P&R assessment timing of reimbursed drugs with negotiation conditions (MEAs, AIFA monitoring registry, reimbursement class, discounts).

## RESULTS

Based on these criteria, 82 out of 182 new drugs (Table 1, Figure 1) were reimbursed in Italy in the analysed period. Of these, 15% received the innovative status, 18% the orphan designation and 5% the hybrid (both innovative and orphan); moreover, 13% (N=11) were oncological drugs while 11% (N=9) oncohematological. The 32% (N=26) of the total (N=82) sample had a conditional approval with a MEA agreed between the Marketing Authorisation Holder and AIFA (***Figure 2***). Three drugs (9%) had two simultaneously applied MEAs: a payment-by-results + budget cap for one drug and two had a price-volume + budget cap. One drug had a MEA applied but not disclosed in the OJ. Of the 29 tracked MEAs, 86% were non-outcome based and 14% were outcome-based. The only outcome-based applied MEA was the payment-by-results.

In detail, the Not Outcome Based tracked MEAs were:

- cost-sharing (20%),
- budget cap (36%),
- price-volume agreement (40%).

Thirty-six drugs (43%) out of the total sample had an applied AIFA monitoring registry (***Figure 3***). Forty-four (54%) had an applied confidential discount. Reimbursement Class A (drugs dispensed through community pharmacies) included 41 (50%) out of 82 analysed drugs, the remaining 41 (50%) were assigned to Class H (drugs dispensed only in the hospital setting).

## CONCLUSIONS

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