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P&R PROCESS IN ITALY: A FOCUS ON NEGOTIATION OUTCOMES OF INNOVATIVE DRUGS

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Background

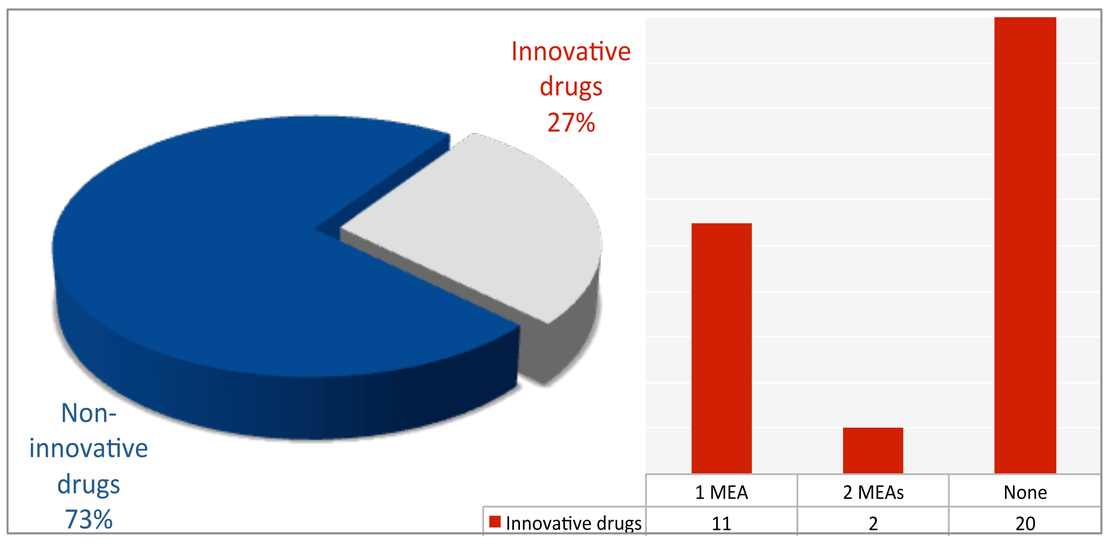
Managed Entry Agreements (MEAs), monitored by AIFA through the use of specific Monitoring Registries, have been introduced in June 2005. Italy is recognised as one of the pioneers in developing access schemes for new medicines.

Managed Entry Agreements between AIFA and Pharma Companies could be "financial/non-outcome-based" (cost sharing and capping, payback schemes and price-volume mechanism) or "performance/ outcome-based" (payment by results, risk sharing, success fee). Registries are also implemented to monitor appropriateness of drug prescription.

Objective

The objective of the present work is to analyse the negotiated conditions (Managed Entry Agreement, discount and monitoring registry) of drugs assessed as innovative by AIFA and reimbursed in Italy from January 2015 to May 2019.

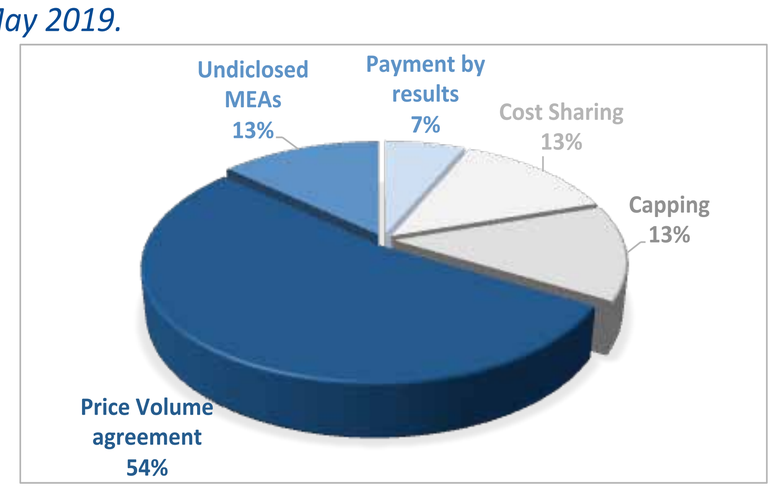
Figure 1. *Reimbursed drugs by AIFA: non innovative drugs (88 out of 121, 73%) vs innovative drugs (33 out of 121, 27%) and number of MEAs negotiated for innovative drugs (13 out of 33).*



Methods

The analysis was conducted starting from monthly reports of AIFA committees meeting and AIFA list of innovative drugs. P&R process of new medicinal products was tracked in internal database and a sub-analysis by therapeutic area was run. Published Official Gazettes were used to source the presence of monitoring registries, confidential hidden discounts and MEAs as negotiation outcomes.

Figure 2. *MEAs applied by AIFA for all the innovative drugs from January 2015 to May 2019.*

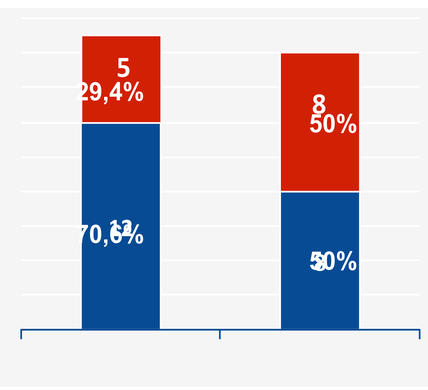


Results

During the analysed period, 33 out of 121 (27%) reimbursed new medicinal products were granted innovative status *(Figure 1).* The analysis first assessed the number of MEAs were applied for the innovative vs non-innovative: the results show 13 out of 33 (39.4%) innovative drugs vs 21 out of 88 (23.9%) non-innovative drugs had MEAs as negotiated condition. Focusing on innovative drugs, 11 (33.3%) had one single MEA and 2 drugs (6.1%) had two MEAs; the remaining 20 drugs (60.6%) had none. Analysing the 15 MEAs applied we tracked: 1 (6.7%) payment by results, 2 (13.3%) cost-sharing agreements, 2 (13.3%) capping, 8 (53.3%) price-volume agreements and 2 (13.3%) undisclosed MEAs (*Figure 2*). Categorization by therapeutic area yielded 5/17 (29.4%) innovative oncological drugs and 8/16 (50%) innovative-non oncological drugs with MEAs *(Figure 3).*

Figure 3. *Innovative oncological drugs vs innovative non-oncological drugs with and w/o MEAs.*

INNOVATIVE DRUG	With MEAs	W/O MEAs	TOT
ONCO	5	12	**17**
NON-ONCO	8	8	**16**
TOT	**13**	**20**	**33**



26 out of 33 (78.8%) innovative drugs had confidential discounts (*Figure 4*), while all innovative drugs, as a requirement by law, had monitoring registries.

Figure 4. *Hidden/Confidential discount applied by AIFA for all innovative drug reimbursed from January 2015 to May 2019.*

Conclusions

This analysis showed that innovative drugs were likely to have a negotiated MEA vs non-innovative drugs.

Price-volume agreement was the most commonly negotiated MEA, also in line with Ministry of Health guidelines on pharmaceutical governance issued at the end of 2018.

An unbalance between outcome-based vs financial MEAs was highlighted, basically mirroring the attention of AIFA and its primary role in pharma budget management, and particularly in the management of the two funds (500 million € each) dedicated to innovative and innovative-oncological drugs.

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