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# **OUTCOME OF NEW DRUG NEGOTIATION PROCESS IN ITALY: APPROVAL CONDITIONS (2015-2018)**

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# 1. Objective

Track and analyse the economic negotiated conditions of novel drugs reimbursed in Italy through Official Journal publications.

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## 2. Methods

### Database setup

A database containing all new drug registrations (**first indication of new chemical entities**) listed in the outcomes of the European Assessment Office of AIFA from May 2015 to May 2018 was set up.

### Checkpoints identification

**Standard Checkpoints** were identified and evaluated through CTS and CPR agendas and outcomes and through CHMP opinion and the Official Journal of the European Union.

### Sample selection and categorization

**Out of 207 drugs tracked, 88 drugs** were granted EU approval between May 2015 and May 2018 and had completed the P&R process in Italy; these drugs were tracked and categorized by type and therapeutic area.

### Analysis

**Negotiated MEAs, confidential discounts and monitoring registries** application were evaluated through Official Journal publications.

## 2. Methods - Checkpoints



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

CHMP  
opinion → EC decision



**7.OJ  
publication** → Efficacy

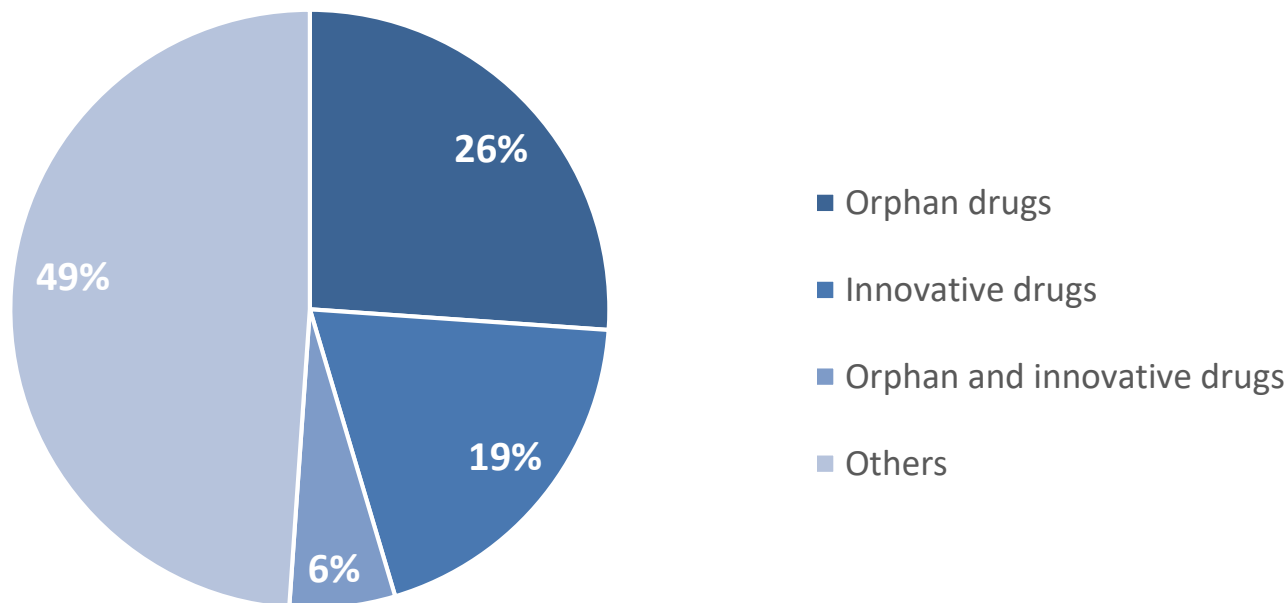
\* P&R dossier filing date available from March 2016

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## 2. Results - Sample description/categorization

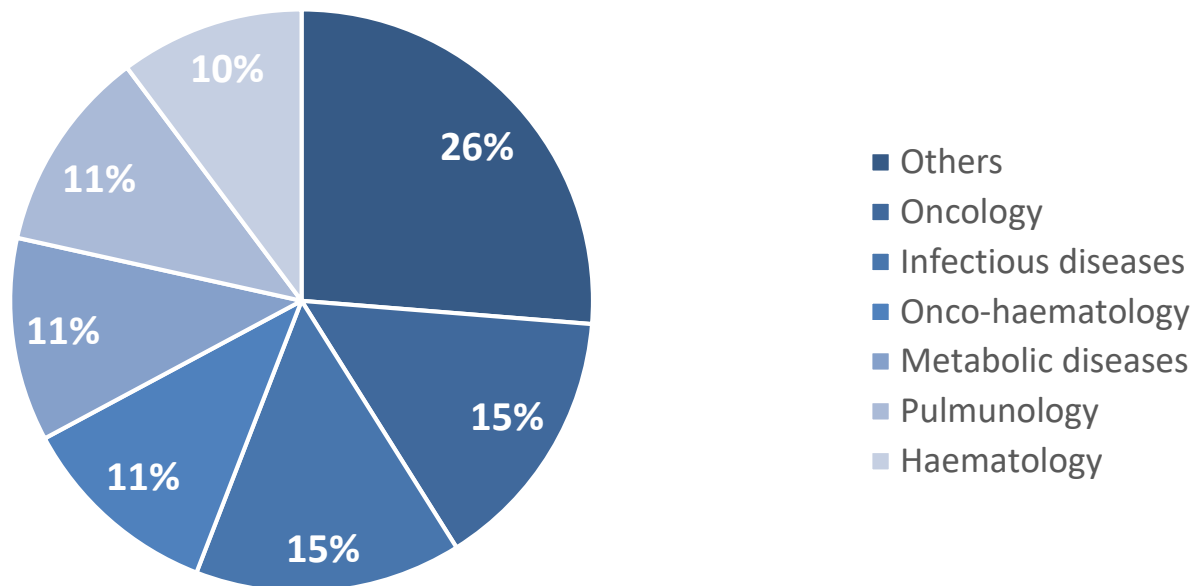
Category	%	N
Orphan drugs	26%	23
Innovative drugs	19%	17
Orphan and innovative drugs	6%	5
Others	49%	43
<b>TOTAL</b>	<b>100%</b>	<b>88</b>





## 2. Results - Therapeutic areas

Therapeutic area	%	N
Oncology	15%	13
Infectious diseases	15%	13
Onco-haematology	11%	10
Metabolic diseases	11%	10
Pulmunology	11%	10
Haematology	10%	9
Others	26%	23
<b>TOTAL</b>	<b>100%</b>	<b>88</b>

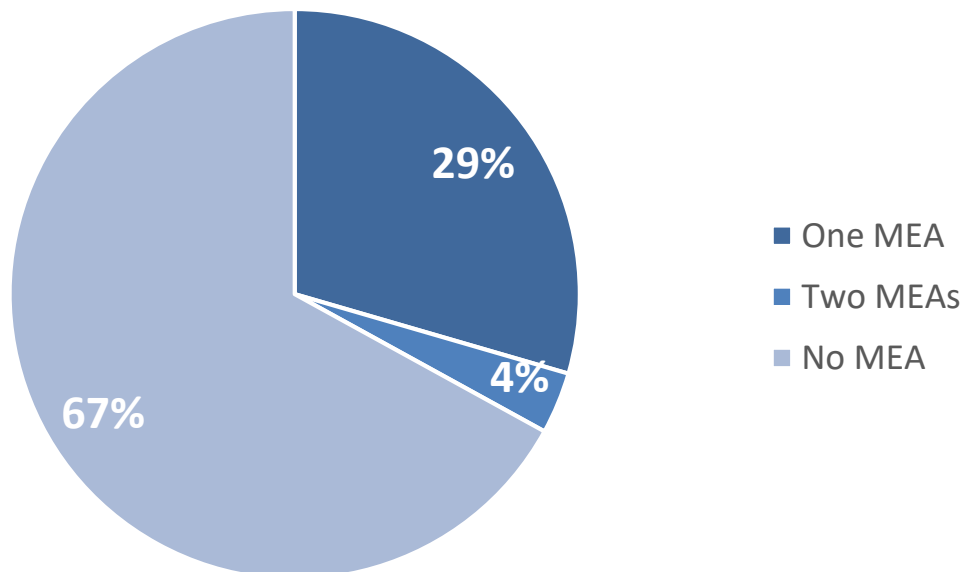


## 2. Results - MEA application (n)

N. of MEAs	%	N
One MEA	30%	26
Two MEAs	4%	3
No MEA	67%	59
<b>TOTAL</b>	<b>100%</b>	<b>88</b>



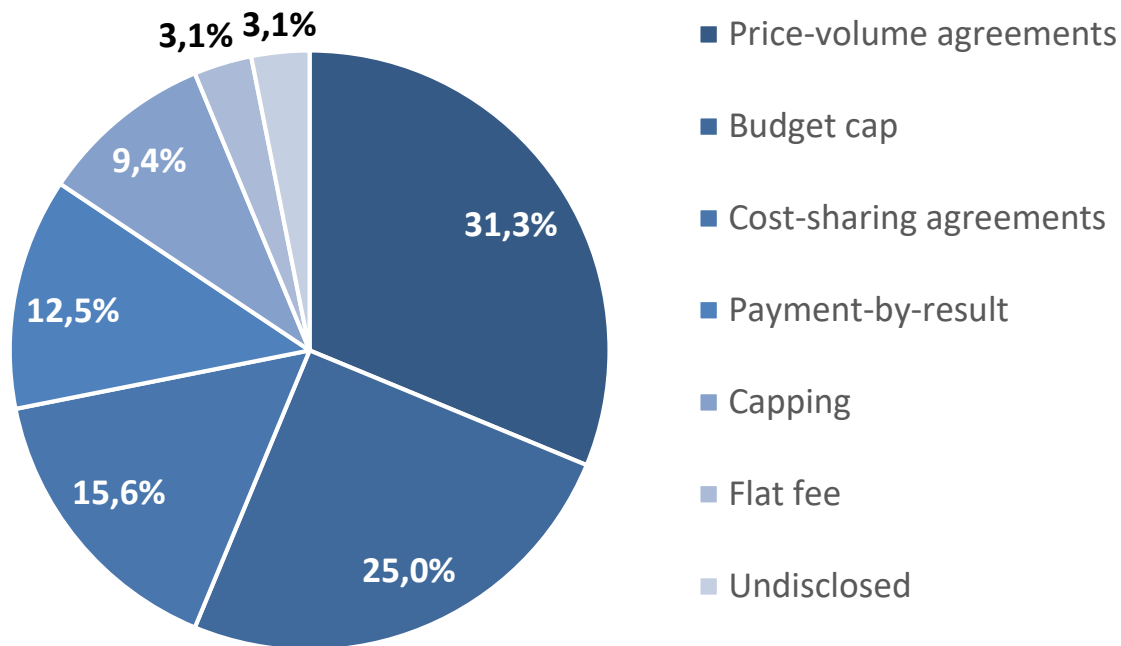
**29 drugs = 32 MEAs**



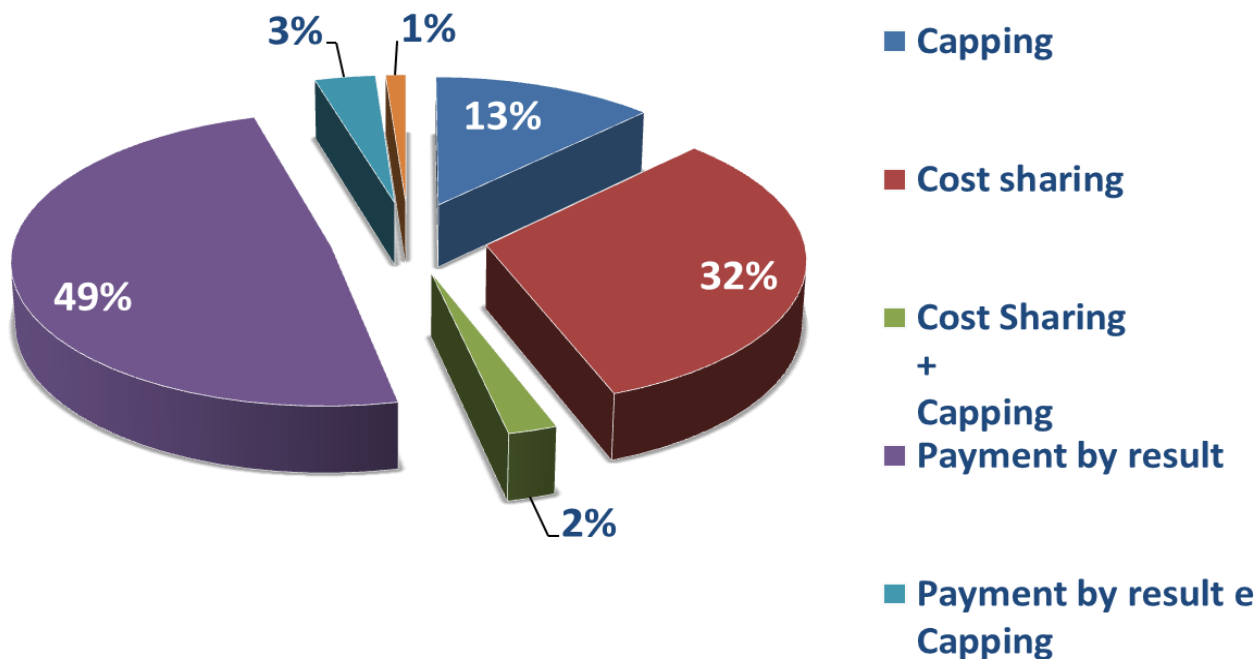
## 2. Results - MEA application (type)

MEA	%	N
Price/volume	31,3%	10
Budget cap	25,0%	8
Cost-sharing	15,6%	5
Payment-by-result	12,5%	4
Capping	9,4%	3
Flat fee	3,1%	1
Undisclosed	3,1%	1
<b>TOTAL</b>	<b>100%</b>	<b>32</b>

**84,4% financial MEAs**



## Distribuzione (%) delle tipologie di accordo di condivisione del rischio



MEAs	Rimborsi (2017)
Financial based (Cost sharing; Capping)	454.983.215,19
Outcome based (Payment by result; Risk sharing)	41.260.441,11

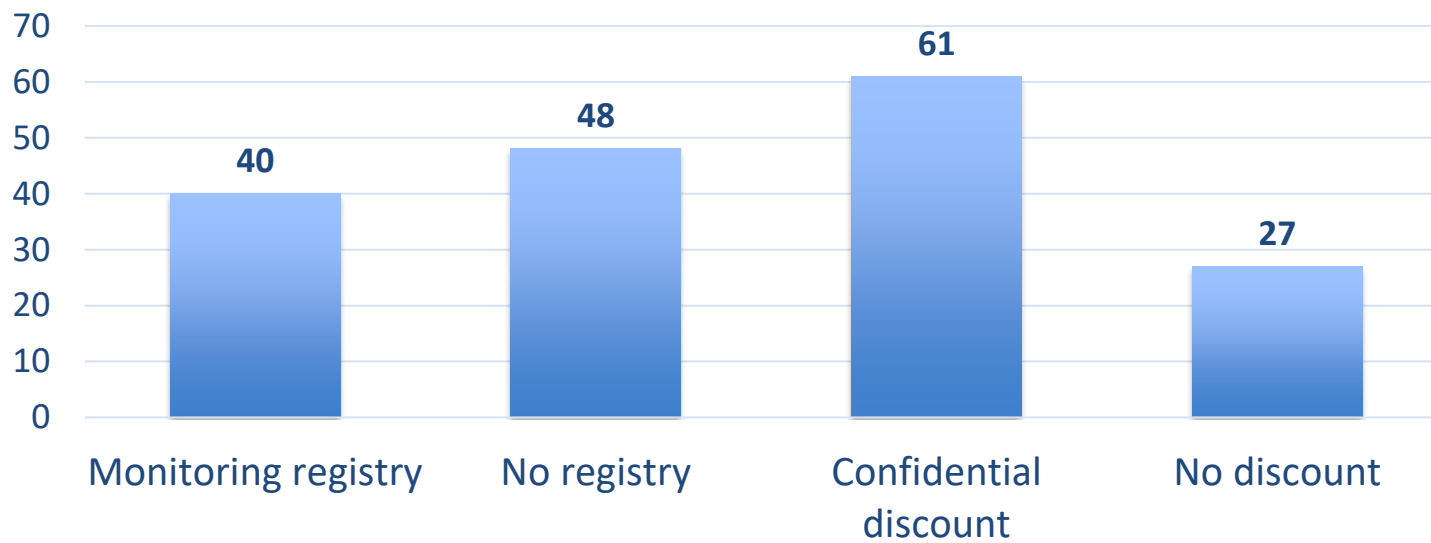


**91,7% financial MEAs**

*\*aggiornamento febbraio 2018*

## 2. Results - Registries and discounts

	%	N
Monitoring registry	45,5%	40
No registry	54,5%	48
<b>TOTAL</b>	<b>100%</b>	<b>88</b>
Confidential discount	69,3%	61
No discount	30,7%	27
<b>TOTAL</b>	<b>100%</b>	<b>88</b>



## 2. CTS assessment vs. registry negotiation

		Registry				No registry				
		media	min	max	n	media	min	max	n	
EU	CHMP - GUUE	62	40	133	39	63	53	110	46	0,12
C <sub>NN</sub>	GUUE- GU Cnn	161	26	503	23	106	62	182	40	<b>0,02*</b>
1	GUUE - START	50	-45	370	21	108	-86	504	32	<b>0,02*</b>
2	START - apertura CTS	83	23	175	21	102	29	237	32	0,32
3	Apertura CTS - parere CTS	108	0	434	39	43	0	313	45	<b>0,0007*</b>
4	Parere CTS - ParereCPR	93	7	225	38	94	6	250	45	0,94
5	Parere CPR - CdA	40	6	171	38	44	9	98	45	0,1
6	CdA - determina AIFA	42	1	86	39	25	11	49	46	<b>&lt;0,0001*</b>
7	Determina AIFA P&R - GU	14	2	55	39	20	5	35	46	<b>0,0001*</b>
3-7	Apertura CTS-GU P&R	295	75	655	39	226	97	513	45	<b>0,03*</b>

DS: deviazione standard; N: numero farmaci analizzati. \*Livello di significatività statistica a  $p < 0.05$ , Mann-Whitney U test.

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## 4. Conclusions

- **Unbalance** between outcome based and non-outcome based (financial) MEAs.
- **Budget cap** and **price-volume agreements** are the most commonly negotiated MEAs.
- **Negotiation driver** of last committees (2015-2018) was the **economic impact of new drugs** due to the historical overspending vs budget.
- **Confidential discounts** are also one of the main measures AIFA applies.
- **Large number of monitoring registries**, to track appropriate prescription behaviors.
- **Innovative MEAs**, such as **the flat fee per patient**, and AIFA commitment on possible alternative approaches for ATMPs.





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