THE EVOLUTION OF STANDARD MONITORING REGISTRIES IN THE ITALIAN MARKET

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INTRODUCTION

The Italian Standard Monitoring Registries (SMRs) are an important regulatory instrument introduced by the Italian Medicines Agency (AIFA) in 2005.[1,2] The primary aims of SMRs were to ease the access of innovative therapies, to guarantee the sustainability and affordability of therapies, to collect epidemiological data and to monitor the appropriate usage of several therapeutic treatments. Initially, registries were applied to medicines belonging to a limited number of therapeutic areas. Today, SMRs involve dozens of therapeutic areas; moreover, various regulatory, clinical and administrative figures are engaged in the decision making and managerial processes: AIFA, Regions, pharmaceutical companies, physicians and pharmacists.[1,3] The practical application of registries regards: the monitoring of appropriate use of medicinal products; the application of Managed Entry Agreements (MEAs), defined as negotiation agreements established between AIFA and the single pharmaceutical company.

MEAs have been widely implemented in Italy to foster access to new medicines with a high level of uncertainty at launch.[3] MEAs are divided into:

» Outcome based agreements (risk-sharing, payment by results and success fee);
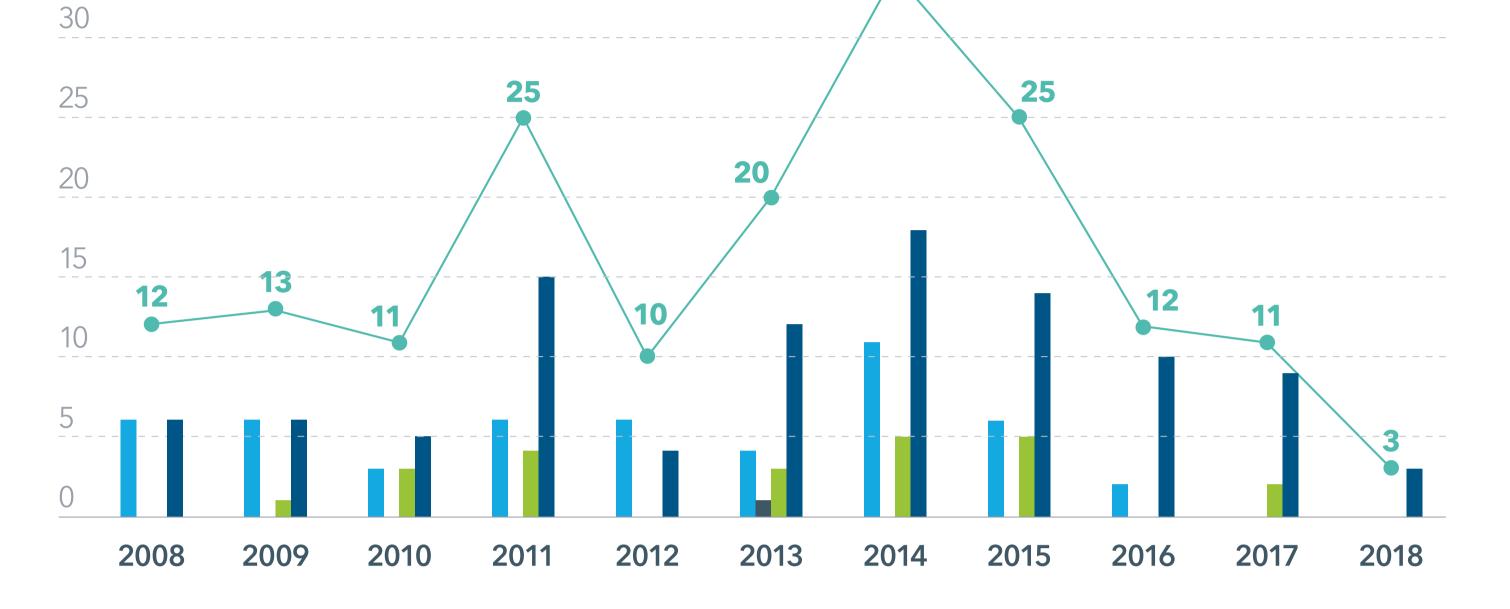» Non-outcome based agreements (cost-sharing, expenditure cap/payback);

This analysis aimed to investigate the adoption of SMRs, as well as the evolution of MEAs in Italy, in the last 10 years.

METHODS

A desk research on AIFA website was performed to identify products/indications with a monitoring registry from January 2008 to June 2018. Data were gathered for a total of 176 products/indications which have been or were monitored by AIFA. For products/indications with SMRs, further information was extrapolated from EMA website and from the Italian Official Journals (Gazzette Ufficiali), with the aim of investigating the Anatomical Therapeutic Chemical (ATC) Classification and the therapeutic area or disease. Moreover, for products/indications with SMRs related to MEAs, further information was gathered, focusing on the MEAs typology (outcome or non-outcome based).
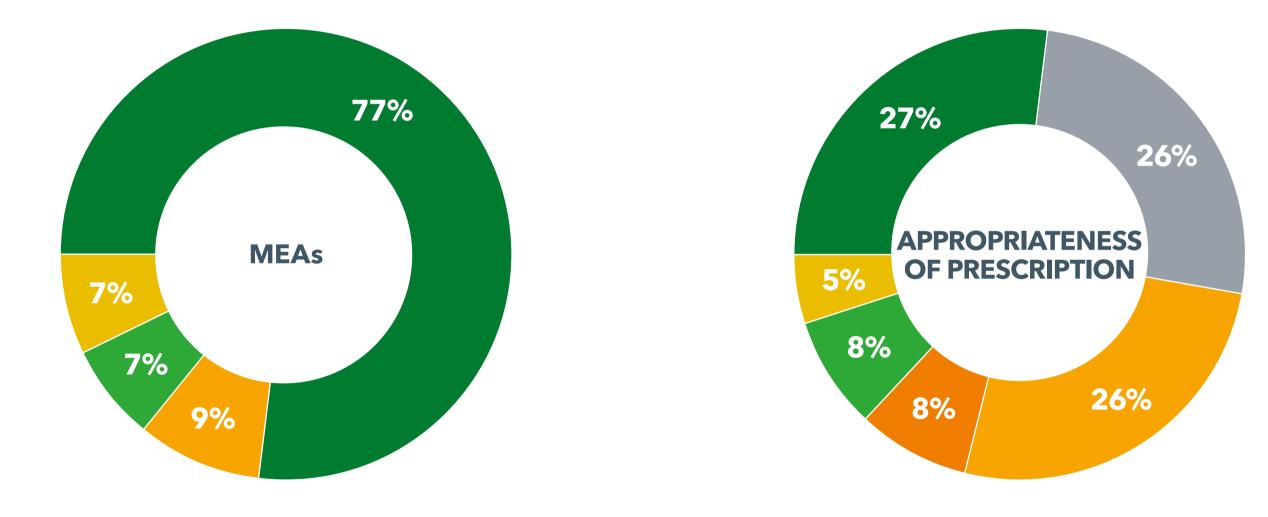
RESULTS

The analysis performed showed that, from 2008 to 2014, the number of drugs approved and inserted, each year, in a SMR had an increase, with 34 new drugs being monitored only in 2014. From 2015 onwards, however, there was a considerable reduction of new drugs monitored through SMRs; in 2017 (the last year with complete data available) only 11 new products/indications having a SMR were recorded (Figure 1). Regarding SMRs related to MEAs, it has been seen that, through the 10 years analyzed, the type of MEAs adopted remained stable, with the majority being outcome based MEAs. In fact, out of 74 products/indications having a MEA, 50 (68%) had an outcome based MEA vs 23 (31%) had a non-outcome based MEA. The combination of both outcome and non-outcome based agreements was found only in 2013 (Figure 1). A specific analysis investigated the distribution of the typology of SMRs by ATC-2 code. It highlighted that:

» the majority of products/indications with MEAs belonged to antineoplastic agents (L01), which represented 77%, followed by antivirals for systemic use (J05) and ophthalmologicals (S01), both representing 7%;
» the products/indications under "appropriateness of prescription" referred to various ATC-2 codes; 27% were antineoplastic agents (L01), 26% immunosuppressants (L04) and 8% antithrombotic agents (B01) (Figure 2).

Grouping all the SMRs by therapeutic area or disease (Figure 3) resulted that:
» SMRs for "appropriateness of prescription" were common for all therapeutic indications;
» cardiovascular and immunosuppressive areas presented only SMRs related to "appropriateness of prescription";
» antiviral drugs (all for the treatment of Hepatitis C) had non-outcome based MEAs;
» ophthalmic diseases showed outcome based agreements;
» medicine for multiple sclerosis had a combination of outcome and non-outcome based MEAs;
» the majority of anticancer drugs presented outcome based MEAs.

CONCLUSION

The objective of SMRs and the adoption of MEAs arose from the need to identify and guarantee a balance between innovation and economic sustainability. AIFA's monitoring registries contribute not only to ease timely access to new technologies, but also to collect data for research purposes and to gather information about clinical outcomes. Consequently, SMRs can be interpreted as generators of evidence from real world practice, encouraging strategic interactions between actors involved. Although until 2014 there has been a constant increase in the activation of new registries, in order to monitor both the appropriate use of medicinal products and MEAs, in recent years there has been a marked reduction in the number of new registries and accordingly of MEAs. This negative trend could be due to practical difficulties in accessing and using collected data and clearly defining and measuring clinical outcomes. In the future, it is expected that AIFA's SMRs will become a clearer reference system for the evaluation of drugs' effectiveness in the real world, facilitating the alignment between regulatory and pricing and reimbursement activities and improving patients access to therapeutics.

1. Carollo A. I registri di monitoraggio AIFA
2. Magro L et al. Expert Opin Drug Saf. 2016 Dec;15(sup2):69-75
3. Montilla S et al. Int J Technol Assess Health Care. 2015 Jan;31(4):210-3

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FIGURE 1
Number of products/indications related to a SMR from 2008 to 2018

- OUTCOME BASED AGREEMENTS
- BOTH OUTCOME AND NON-OUTCOME BASED AGREEMENTS
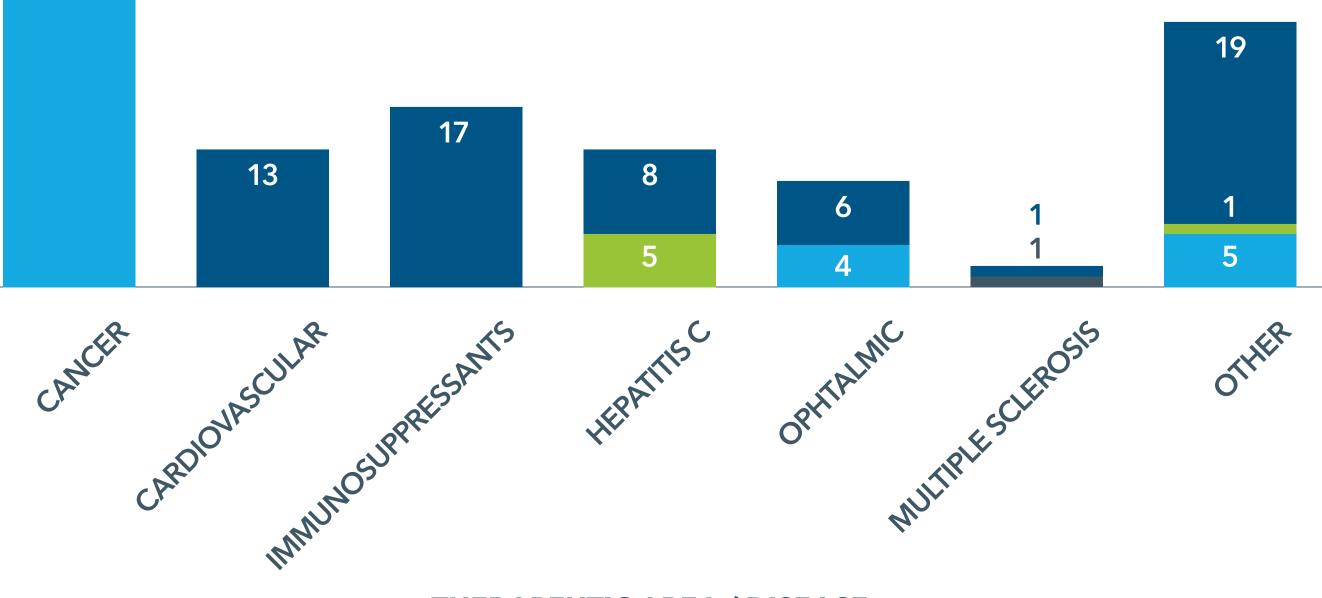- NON-OUTCOME BASED AGREEMENTS
- APPROPRIATENESS OF PRESCRIPTION
- TOTAL NUMBER OF SMRs

FIGURE 2
SMRs related to MEAs and to appropriateness of prescription split by ATC-2 code

- ANTINEOPLASTIC AGENTS (L01)
- ANTIVIRALS FOR SYSTEMIC USE (J05)
- IMMUNOSUPPRESSANTS (L04)
- OTHERS*
- OPHTALMOLOGICALS (S01)
- ANTITHROMBOTIC AGENTS (B01)

(*) the ATC-2 classes with ≤ 3 products / indications have been grouped into "others"

FIGURE 3
Overview of the type of SMRs grouped by therapeutic area/disease

- OUTCOME BASED AGREEMENTS
- BOTH OUTCOME AND NON-OUTCOME BASED AGREEMENTS
- NON-OUTCOME BASED AGREEMENTS
- APPROPRIATENESS OF PRESCRIPTION