

More and earlier data from AIFA: do they impact on the regional policies? Results from an exploratory analysis

Riccardo Novaro¹, Mattia Altini², Francesca Futura Bernardi³, Francesco Brunetti⁴, Pasquale Carulli⁴, Florapia Giustiniani³, Roberta Joppi⁵, Anna Martini⁵, Elisa Sangiorgi⁶, Giovanna Scroccaro⁵, Paolo Stella⁴, Julia Gabriela Szyszko⁶, Ugo Trama³, Rosy Amodeo⁷, Mauro Patroncini⁷, Giuliano Buzzetti⁷, Claudio Jommi¹

¹Department of Pharmaceutical Sciences, Università del Piemonte Orientale, Novara - Italy

²Azienda USL Modena, Regione Emilia Romagna - Italy

³UOS Politiche del farmaco e dei dispositivi medici – HTA, Regione Campania - Italy

⁴Sezione farmaci, dispositivi medici ed assistenza integrativa, Regione Puglia - Italy

⁵Direzione Farmaceutico, protesica, dispositivi medici, Regione Veneto - Italy

⁶Area Governo del farmaco e dei dispositivi medici, Regione Emilia Romagna - Italy

⁷Dephaforum Srl, Milano - Italy

ABSTRACT

Introduction: In Italy, drug prices and reimbursement are managed by the Italian Medicines Agency (AIFA), but regions actually enable patient access to medicines. Our aim is to provide evidence on (i) the current management of regional pharmaceutical policies, the use of resources and time to policy completion (TPC-procurement awarding), (ii) the potential impact on resources used and TPC of an earlier-enhanced access of regions to AIFA's data.

Methods: Four regions (Veneto, Emilia-Romagna, Campania, Puglia) were selected on a purposive basis. Data on policies and resources used were retrieved from a literature review and interviews with regional officers. TPC was tracked for medicines approved for reimbursement in Italy from January 2023 to June 2024. The potential impact of an earlier-enhanced access to AIFA's data was detected through perceptual questionnaires self-compiled by regional officers.

Results: To manage regional access, the regions employ a staff of 21 Full-Time-Equivalent (FTE) persons on average, ranging from 11 to 29. The mean TPC ranges from 135 to 361. The average score of perceived impact of an earlier-enhanced AIFA's data equals 3.3 within a range of 1-4 for both FTE and TPC. An earlier access to public information (e.g., innovativeness appraisal) is perceived as impactful on TPC. Availability of data that are currently not shared with regions may have a greater potential impact on FTE.

Conclusions: A great consensus emerged on the importance of timely access to revised P&R data. Systematic early disclosure by AIFA could help to improve efficiency in resource utilization and to expedite patient access to innovative medicines.

Keywords: AIFA, Data, Efficiency, Pharmaceutical policy, Regions