HTA/Payer Real World Data Context to support Outcomes Based Managed Entry Agreements (OBMEA)/ Conditional Reimbursement with Data Collection

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Date of completion	28/10/2022
Health System Organisation	AIFA (the Italian Medicines Agency) is the national public body that regulates medicines for human use in Italy; it governs pharmaceutical expenditure and follows the life cycle of the medicine to ensure its effectiveness, safety and appropriateness as well as access to the national territory. AIFA is supported by two scientific technical committees [the Scientific Technical advisory Committee (CTS) and the Price and Reimbursement Committee (CPR)]. The Monitoring Registries Office is part of the Pharmaceutical Economics and Strategy Division and manages the technical, regulatory and scientific aspects preparatory to the online implementation of each registry.
Health System Funding	Relating to Monitoring Registries: Law No. 135 of 7 August 2012 recognised the Monitoring Registries as a service of the Information System of the NHS, they are part of AIFA budget. Moreover, according to the Deliberation n. 37/2014 of the Management Board of AIFA and the Memorandum of Understanding between AIFA and Farmindustria the costs of development and maintenance of each registry and the relative business intelligence are covered by the Marketing Authorisation Holder.

1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes Relating to the AIFA monitoring registries Platform, an ID code is generated for each patient registered.
2. Can the prescribing record be linked with the indication?	Yes AIFA monitoring registries are technical tools used to control the appropriate use of a drug in a certain therapeutic indication and to apply eventual managed entry agreement (financial- or outcome-based) negotiated during the pricing and reimbursement process. Each registry has a specific section which has the aim to record prescriptions.
3. What sources and types of data could be used in your health system for conditional reimbursement purposes or OBMEA (e.g. to determine clinical effectiveness or inform economic evaluations)?	
AIFA Registries are ex-novo administrative data created ad hoc for pricing and reimbursement proposes. The monitoring registries are structured in a way that at a given time allows to clearly define therapeutic failures and successes for both the payer and the pharmaceutical companies. The users are physicians, pharmacists, regional representatives, hospital health managers and market authorization holders. A list of all manuals is available at the following link: https://www.aifa.gov.it/en/accesso- al-sistema	
4. Do data catalogues exist that include descriptions of the content (meta-data) of distributed data sources, which could support discoverability of data for HTA/Payer purposes?	
No data catalogues exist. The AIFA Monitoring Registry is the tool used to collect data for the application of a MEA. A list of all registries and MEAs is available at the following link: https://www.aifa.gov.it/en/web/guest/registri-e-piani-terapeutici1	
5. Are there any standards or systems in place to judge data quality?	
All data are collected and stored complying with national and community law about privacy and data protection. Furthermore, there is a set of technical and operational procedures which contributes to maintain data quality, such as an internal consistency both in the structure of each registry and among registries of medicinal products sharing the same therapeutic indication. Moreover, Marketing Authorization Holders and regional representatives play an important role in data quality management. AIFA monitoring registries are dynamic tools which need constant updating and maintenance, therefore improvement in the field of data quality management is one of the most important aspects in order to keep a high standard.	

6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
There are no tools or processes. AIFA Monitoring Registries System is a web based Platform which allows all stakeholders (medical doctors, pharmacists, representatives of region and pharmaceutical companies) to manage conditional reimbursement agreements. The selection of the indicator and its measurement with respect to the outcome of the treatment is a process carried out within AIFA Committees (CTS and CPR), together with the assessments of the economic implications related to the authorisation of the medicinal product carried on by AIFA Offices.
7. Describe "Secure Operating Environments" or "Trusted Research Environments" that exist within clear governance processes to enable access for approved purposes to one or more data sources that could potentially be used for HTA/Payer purposes.
Information not available.
8. How is access to data governed (e.g. legislation, data permits, register of uses)? Are there differences in governance between national and regional datasets?
AIFA Monitoring Registries Platform is a national network connecting national governance and local structures. Regional representatives can manage habilitation of structures and medical doctors of its region. Each region has the duty to perform an administrative control on the right utilization of the Platform by medical doctors and pharmacists of the territory. Community and national laws strictly detect different levels of access to data with different granularity.
9. What other information do we need to know about data governance and accessibility in your health system?
The AIFA Monitoring Registries web platform allows access to treatment in a homogeneous manner throughout the country. Monitoring Registries have a variety of functions but are essentially an administrative tool that cannot interfere with patient care. Other information is available at the following link: https://www.aifa.gov.it/en/web/guest/registri-farmaci-sottoposti-a-monitoraggio

10. Is there a precedent for national health system data to be used in OBMEA/conditional reimbursement? If yes, describe any supporting legislation or processes. If no, identify key challenges.
Law No. 135 of 7 August 2012 recognised the Monitoring Registries as an integral part of the Information System of the NHS (art.15, paragraph 10), while further subsequent regulations (Law 125/2015; Law 232/2016; Law 205/2017) have assigned to the registries functions of evaluating the effectiveness of the medicinal product for the purpose of renegotiation, and of controlling expenditure for innovative medicines and for avoidable costs in health care.
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
None
12. Any other comments?
None
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
The Monitoring Registries Office manages the entire regulatory and scientific part preparatory to the online implementation of the registries. Furthermore, there is a continuous updating of the AIFA Platform, with particular attention of improving specific functionalities for healthcare professionals or for the administration and the application of MEAs. The procedure of acquisition of technical and IT requirements for a new Platform is now ongoing. The two main features of the new platform should be 1) building a smarter tool in order to minimize the working burden of final users 2) creating a platform which might simplify linkage with other national databases.