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

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Role	Coordinator Expertise Pharmaceuticals
Country	Belgium
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Health System Organisation	National and regional health systems. Medicines: national, with exception of vaccines regionally (although there are exceptions on this exception)
Health System Funding	Public Health Care system Medicines nationally: yearly allocated budget of the Social Security.
1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes The unique number is used throughout the Social Security.
2. Can the prescribing record be linked with the indication?	No as to the prescribing as such. Yes. The prescribing of several medicines is done within reimbursement criteria (called Chapter IV or Chapter VIII medicines) because patients don't pay these medicines by themselves. In these cases the reimbursement criterion links to the indication for which the prescribing is done.

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)?
- Claims database of the conditional reimbursement (see above Chapter IV/VIII medicines): digitally assembled in the Intermutualistisch Agentschap (NL)/Agence Intermutualiste (FR) Brussels. This is an agency of all the public health care payers. - Various possibilities exist to couple hospital data records with a national agency called Sciensano. E.g. mucoviscidosis. - The National Belgian Cancer Registry gathers all the histological diagnoses of cancer at the moment of diagnosis.
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?
Not that we know. Possibly Sciensano and its spin-off Healthdata have these catalogues.
5. Are there any standards or systems in place to judge data quality?
Sciensano and Healthdata have their own standards for data quality control.
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
- Occasional links with processes at EMA, see: Eichler et al Exploring the opportunities for alignment of regulatory post-authorization requirements and data required for performance-based managed entry agreements. International Journal Of Technology Assessment In Health Care, 37 (e83), 1-11 - EUnetHTA REQueST tool is not used.
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.
National Committee for Protection of Privacy / Section Health Care data
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?
Case by case governed according to the decision of the National Committee for Protection of Privacy

9. What other information do we need to know about data governance and accessibility in your health system?
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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.
Claims database of the Nationaal Intermutualisch Agentschap/Agence Intermutualiste is regularly used.
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
None as to health data access across borders.
12. Any other comments?
- Beneluxa Initiative: minimal clinical data sets are discussed. - Contact person RIZIV - INAMI for national registries: Marleen Louagie
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
- *Running business* by Healthdata.be: To facilitate and standardize the recording of health data to increase research effectiveness. This is a department of Sciensano, the Belgian Health Scientific Institute. Website: https://www.sciensano.be/en/about-sciensano/sciensanos-organogram/healthdatabe#other-websites-selected-for-you - *To be launched*: Health Data Authority, as announced in the Belgian's Federal Gouvernement Planning (page 14 last §). https://www.belgium.be/sites/default/files/Accord_de_gouvernement_2020.pdf - Data integration, data governance and health data use by the RIZIV-INAMI will be one of the pilars of public service, to be agreed on by the Federal Gouvernement for the years 2022-2024 to come.