# Mapping the Article 57 Database from the European Medicines Agency containing all medicines authorized in the European Economic Area

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## Background

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

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The European Health data and Evidence Network (EHDEN) project was launched as a public private partnership under the framework of the Innovative Medicines Initiative (IMI) running from November 2018 until April 2024.

The EHDEN project aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care. Its mission is to provide a new paradigm for the discovery and analysis of health data in Europe, by building a large-scale, federated network of data sources standardized to the OMOP common data model.

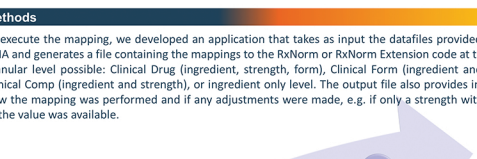
### Article 57 database of the European Medicines Agency

The Article 57 database is a comprehensive repository of structured information on all medicines authorized in the European Economic Area. Marketing authorization holders must submit and maintain this information in accordance with European Union legislation. A public version of this database is made available by the EMA (link) and contains information such as the product name, active substance, route of administration, country of authorization, marketing authorization holder (company), etc.

This database is of great value to the EHDEN project because it allows us to **extend the RxNorm Extension vocabulary to cover all the authorized drugs in Europe** and the mapping of all local drug coding systems without loss of information. The EMA made available a recent copy of the database that contains additional fields and will provide frequent updates in the future.

## Methods

To execute the mapping, we developed an application that takes as input the datafiles provided by the EMA and generates a file containing the mappings to the RxNorm or RxNorm Extension code at the most granular level possible: Clinical Drug (ingredient, strength, form), Clinical Form (ingredient and form), Clinical Comp (ingredient and strength), or ingredient only level. The output file also provides insight in how the mapping was performed and if any adjustments were made, e.g. if only a strength within 10% of the value was available.




| Drug Level | % Mapped |
|---|---|
| Clinical Drug | 86.96 |
| Clinical Drug Form | 4.60 |
| Clinical Drug Comp | 3.72 |
| Clinical Drug Comp & Ingredient | 1.31 |
| Ingredient | 1.09 |
| Unmapped | 2.32 |

## Conclusions

- 86.96 % of Article57 drugs can be mapped to clinical drug level
- Remaining can be used to add RxNorm Extensions
- Once added, the standard vocabulary should cover all drugs used in the European Economic Area

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 806968. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

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