



To better enable cross-border healthcare delivery, particularly the exchange of ePrescriptions and safe dispensation of prescribed medicinal products, this global undertaking advances the unique identification of medicinal products (MPs) and thereby patient safety in cross-border settings. Major stakeholders harmonise their respective efforts to deliver

- common data models for prescribed MPs
- a common vocabulary for unambiguous definition, description, and identification of MPs
- rules to harmonise practices of therapeutic and economic substitution
- a global roadmap for post-project actions and implementation

Based on earlier activities of standard development organisations (SDOs), use case scenarios are developed, where the identification of an MP is an issue, including pharmacological and pharmacokinetic attributes, clinical indications, and risks to be considered. Next, the univocal identification of MPs is addressed, for standard pre-packed ones as well as for special cases like MPs with multi-components, biologics, or special packaging. Impacts will be considerable for global healthcare services and systems as well as – through simplifying and speeding up the registration of new products and afterwards pharmacovigilance - for national and international regulatory agencies, healthcare providers, the MPs industry, and, in particular, patients.

Keywords. Medicine, medicinal product, pharmaceutical product, univocal identification, bioinformatics, ePrescription, eHealth interoperability, therapeutic and economic substitution, cross-border healthcare, standard development organisations