Fact sheet on Up-scaling the global univocal identification of medicines (UNICOM) project

Overarching Goal	Improving **patient safety** and facilitating **better healthcare** through ► ISO IDMP (IDentification of Medicinal & pharmaceutical Products) standards-based free flow of semantically interoperable Medicinal Product [MP] information ► across Europe and trans-Atlantic
Concrete objectives	► Support implementation of IDMP at EU level & in Member States (For submission of Marketing Authorisation Applications [MAA] by industry; at National Competent Authorities [NCAs]; by Medicinal Products Dictionary providers; in electronic prescribing systems, etc.) ► Facilitate mobility of European patients by cross-border ePrescription services adapted to IDMP for reliable dispensation
Action lines	I. Further development of IDMP and implementation support (ISO, other Standards Development Organisations) II. Adaptation and implementation of IDMP at EU/NCA level (Substance Data Bases; Common European Submission Portal [CESP] for marketing authorization applications; implementation by NCAs; training of implementers; links to European Medicines Agency [EMA] and its Substances, Products, Organisations & Referentials Management Systems [SPOR]) III. Adaptation of Member States cross-border digital health services (ePrescription; Patient Summary) to IDMP, testing, piloting and implementation IV. Exploration and implementation of IDMP for pharmacovigilance, Medicinal Product Dictionaries (MPDs), digital healthcare support services, patient empowerment, Big Data V. Analysis of socio-economic impact; investigation of exploration & sustainability, legal and governance/data protection, and ethics issues; promoting dissemination of project results and cross-Atlantic cooperation (including with USA Food & Drug Administration [FDA])
Benefits	► Improved cross-border patient services: substantially enhanced probability of successful identification of an MP in a foreign ePrescription and dispensation ► Enhanced patient empowerment: better personalised information on medicines, also when abroad ► Better healthcare: reliable semantic harmonisation of records of medicinal products dispensed to a patient (e.g. across electronic patient records) ► More effective pharmacovigilance: more efficient processes, faster identification and results integration of medicines mentioned in adverse event reports ► Availability of interoperable, high-quality data on medicines: for Big Data analyses; Public Health policy making and data exchange across Europe, trans-Atlantic and globally; clinical & pharmaco-economic research ► More efficient regulatory processes: reliable input & consistent exchange of electronic data over the life cycle of a medicine between industry, NCAs, EMA ► Digital health industry & SME competitiveness: via open APIs access to univocally identified, reliable EU-wide medicinal products data for smart apps, medicine dictionaries, software systems and clinical applications
Stakeholder participation	► 39 Core actors participate as consortium members ► Other stakeholders are involved via their associations or as experts (Advisory Board, workshops, etc.) ► IDMP data value chain stakeholders are: pharmaceutical industry; national medicinal products & national eHealth agencies; EC & national cross-border digital health services; providers of medicinal product dictionaries; healthcare software producers; healthcare professionals (incl. pharmacists); patients; start-ups developing intelligent apps for patients; medical research; Public Health
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