

Project full title: Up-scaling the global univocal identification of medicines

# Report

## IDMP in the clinical world

Version: 2

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## TABLE OF CONTENTS

Summary.....	3
1 Workshop introduction .....	4
1.1 Context of the workshop.....	4
1.2 Overview of IDMP.....	4
2 electronic Prescription .....	6
2.1 Setting the scene .....	6
2.2 Discussion .....	6
3 Adverse Event Reporting .....	7
3.1 Setting the scene .....	7
3.2 Discussion .....	8
4 Shortages .....	9
4.1 Setting the scene .....	9
4.2 Discussion .....	9
5 Conclusion.....	10
5.1 Consensus.....	10
5.2 Closure .....	10

## Summary

UNICOM organised a workshop dedicated to the use of IDMP in the clinical domains. That workshop grouped about 24 participants, coming from various horizons to cover all the views pertaining for the clinical domains. Number of participants were not engaged in UNICOM, and some of them even knew only little about IDMP.

Beside a short introduction, the day was articulated in 3 use cases: electronic prescription, adverse event reporting and shortages; these use cases are of accurate relevance, and enabled showing the different expectations participants have for IDMP.

## 1 Workshop introduction

### 1.1 Context of the workshop

UNICOM hosted a workshop that aimed to engage stakeholders in discussions about the advantages, challenges, obstacles, and timelines related to the implementation and utilisation of IDMP in the clinical realm. This exclusive, one-day event, accessible by invitation only, was designed to showcase the advancements achieved within the UNICOM project and underscore the ongoing efforts to unlock the benefits of IDMP.

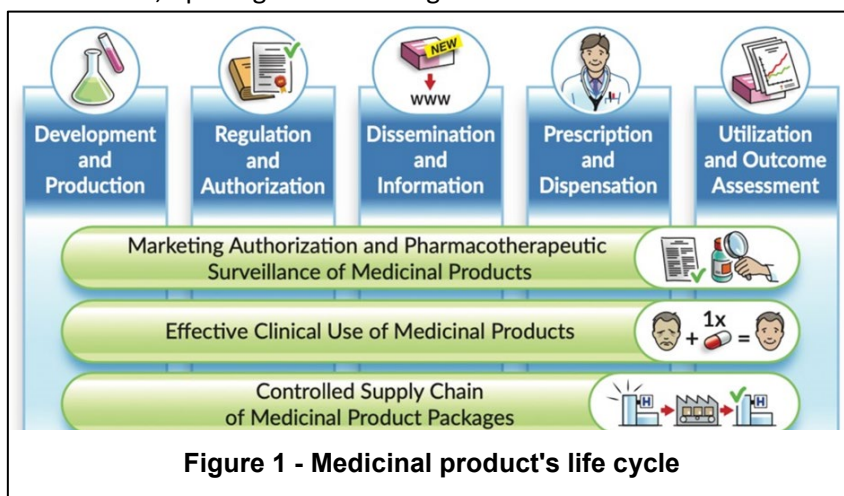
Invited stakeholders included:

- National Competent Authorities
- eHealth national organisations
- Medicinal Product Dictionaries providers
- EHR vendors
- Pharmacovigilance specialists
- SDO representatives (ePrescription, SNOMED CT, etc...)
- Hospital Pharmacists
- University representatives (MD)

The workshop served as an opportunity to involve participants who were not all actively part of the UNICOM project discussions. It enabled open discussions under the Chatham House Rule<sup>1</sup>, which were appreciated by participants.

### 1.2 Overview of IDMP

IDMP comprises a set of five standards, often depicted graphically as a “wedding cake” to illustrate its layers. Four of these standards include technical specifications. IDMP goes beyond regulatory affairs and is intended to serve those working across the entire lifecycle of medicinal products. IDMP is not yet completely implemented but significant progress has been made thanks to UNICOM, for the global identification of substances, opening the doors to global Pharmaceutical Product Identifier.



<sup>1</sup> <https://www.chathamhouse.org/about-us/chatham-house-rule>

IDMP application spans various aspects of the clinical realm, including e-prescription, dispensation, electronic health records (EHR), adverse event reporting, shortages; these are supported by medicinal product dictionaries (MPD), which in turn are supported by National Competent Authorities (NCAs).

Achieving global interoperability necessitates the establishment of global Pharmaceutical Product Identifiers (PhPIDs), which should ideally be generated and maintained in a single place. The WHO-UMC has the capacity, and is ideally suited, to develop PhPIDs that can serve as basis for generating universal interoperability. These global PhPIDs will be accessible for national or regional Medicinal Product Dictionaries. The standard allows the possibility of local or regional calculation, potentially by regulators, although this approach has limitations in terms of global interoperability.

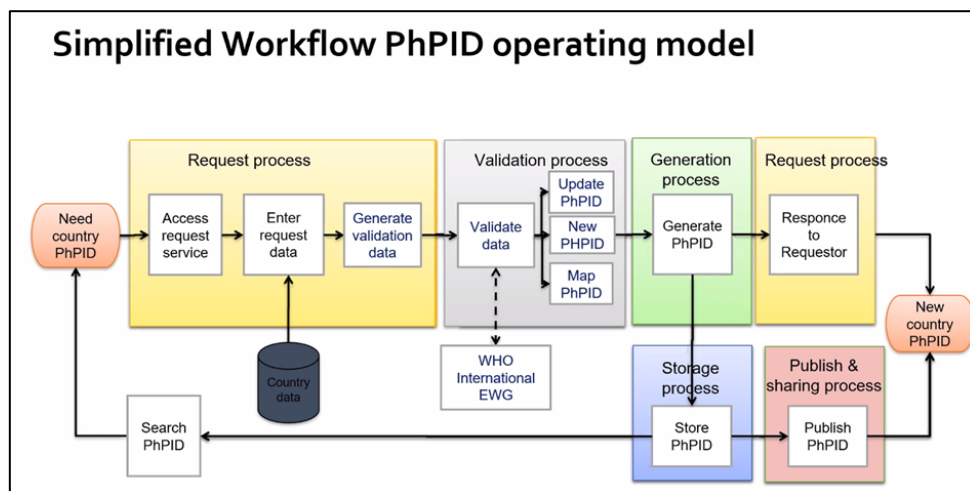


Figure 2 - WHO-UMC workflow for PhPID generation

Global PhPID is required for global interoperability and shall be considered as fully reliable grouper.

The identification of medicinal products within each country requires assigning a unique Medicinal Product Identifier (MPID); at the package level, data carrier identifier in a barcode or 2D carrier enable scanning and linkage to the Medicinal Product Dictionary (MPD). This connection facilitates access to the other IDMP identifiers, such as the global (or local) Pharmaceutical Product Identifier (PhPID).

Beside regulatory requirements, IDMP is increasingly referred to in the clinical domain as exemplified by this joint statement of European Academy of Paediatrics and European Confederation of Primary Care Paediatricians: “Over 85% of all European children are vaccinated and monitored by the WHO. The WHO classification system Anatomical Therapeutic Chemical (ATC) registers vaccines and medicines. A more detailed International Organization for Standardization (ISO) suite of IDMP (Identification of Medicinal Products) standards is coming. These standards provide an international framework to uniquely identify and describe medicinal products with consistent documentation and terminologies and to ensure the exchange of product information”<sup>2</sup>.

<sup>2</sup> Digital child health: opportunities and obstacles REVIEW article Front. Pediatr., 22 December 2023 Sec. Children and Health Volume 11 - 2023 | <https://doi.org/10.3389/fped.2023.1264829>

## 2 electronic Prescription

### 2.1 Setting the scene

Requirements for e-prescription are outlined in ISO 17523, which specifies the electronic prescription of medicinal products. This standard contains specifications for its logical model, detailing the concepts underlying e-prescription. The logical model encompasses one patient, one prescriber, ideally only one medication, along with usage instructions and a dispense request. The workshop concentrated on medication, determining what should be incorporated into this segment. It is noted that the requirements may vary across regions and countries, with different approaches or customs being deployed. Consequently, addressing cross-border prescription becomes a pertinent issue, making it difficult to avoid consideration about generic-level prescriptions. Prescriptions are further influenced by the prescriber (based on their prescription preferences), dispenser (considering available options), insurers/payers (following policies like dispensing the cheapest alternatives), or producers (availability in the country/region).

### 2.2 Discussion

Some e-prescription systems currently force prescribers to opt for generic prescriptions using active substance (INN); others make use of ATC (see former epSOS project) or VMP from SNOMED. In a near future, PhPID and/or GSID could be added, increasing prescription's precision.

The group noticed that some prescription using the existing solutions might need additions (which are not provided by the PhPID). As example, the released delivery of pharmaceutical products might not always be defined precisely if the pharmaceutical dose form does not include that duration. This example has been used to explore the ways prescribers or prescribing systems need to complete the existing coding.

Some MPD providers propose additions to the PhPID (or its current equivalent) such as release rate (for Infusion pump or transdermal plaster). Others suggest the use of the current structure of PhPPID as the basis and add additional characteristics in a narrative text. Afterall PhPID does cover the needs in perhaps 99% of the cases.

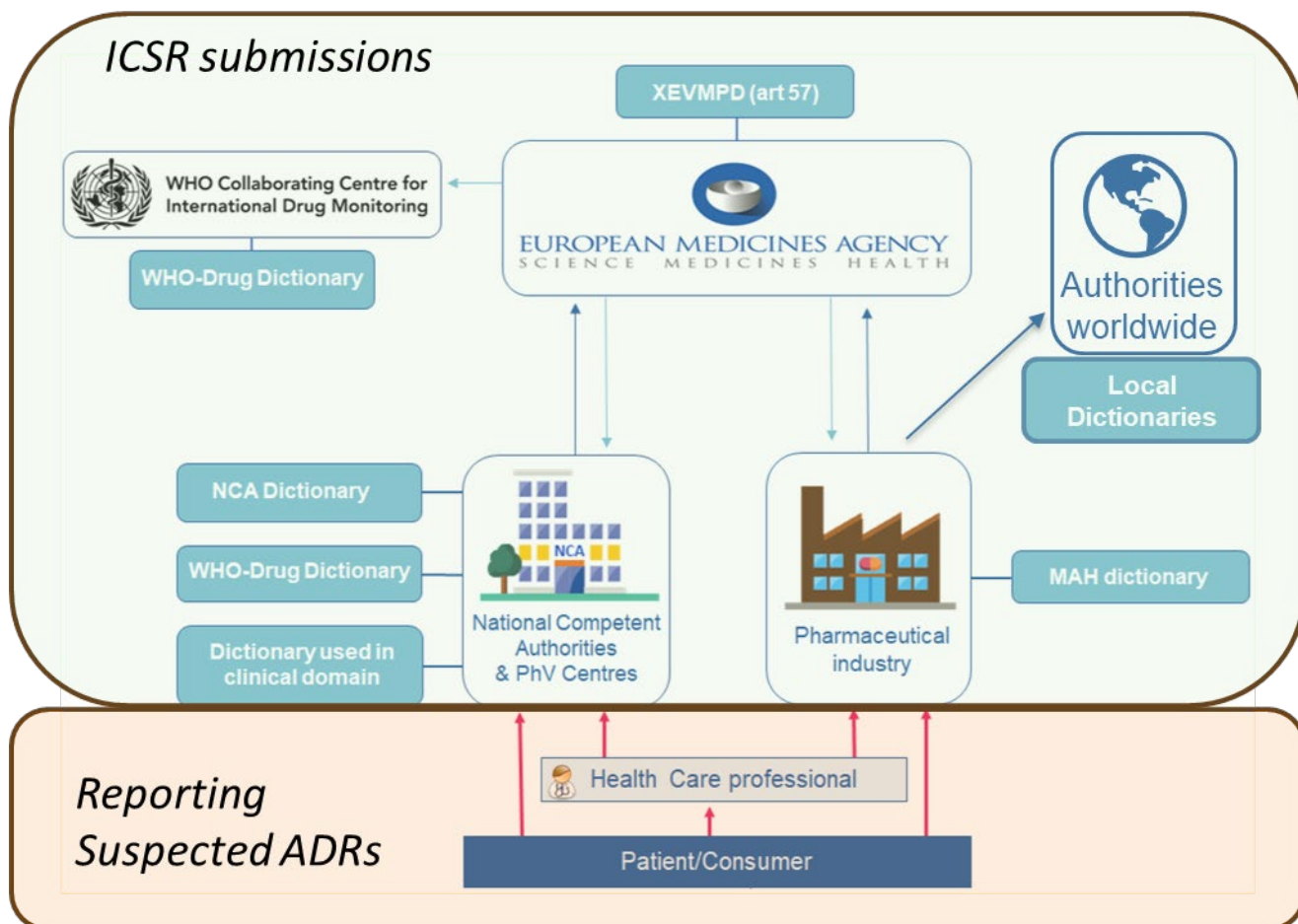
It is recognised that data should flow unchanged along the information chain -from industry, regulatory authority, MPD, prescribing and dispensing systems and EHR to host patient specific information. Along that chain, data might be enriched with hospital formulary, drug/drug interactions, allergies, etc to feed Clinical Decision Support Systems, and ultimately patient's dossier.

The need to adapt and/or improve prescribers' as well as EHR, CDSS, prescription systems vendors training, is recognised. In general from a very diverse way of prescribing, the potential IDMP offers shall streamline prescription usages, contributing to safer medication.

### 3 Adverse Event Reporting

#### 3.1 Setting the scene

Suspected adverse drug reactions/events shall be reported along some steps which currently require expertise to complete, verify, validate information. In addition, there is a change of standards along that information chain.



**Figure 3 - Adverse event reporting from patient to global use**

Illustration above demonstrates the number of potential steps where experts exchange, process and analyse information and make decisions. Purpose of IDMP is to support these processes with high quality data, standardised – meaning made available to each stakeholder in the process.

On the clinical level (in the red framed box) standards in use are mostly HL7 FHIR and SNOMED. Messages issued from the clinical level might be electronic, paper, phone or a combination. In the blue framed box the ISO ICSR (Individual Case Safety Report) standard (based on HL7 version 3) is used for message exchange and has placeholders for using IDMP identifiers. MedDRA is used as terminology for adverse events/reactions, indications and lab test results. EDQM is used as terminology for dose forms and routes of administration.

Often imprecise or incomplete drug information is provided by the initial reporter; this impacts which level of IDMP identifier can be used within the ICSR. IDMP Name Parts can aid to achieve more precise drug information in ICSR. Historic identifiers are important as there is often 'retrospective' reporting of reactions/events.

## 3.2 Discussion

Discussion was articulated on the following points:

- a. All adverse events shall be reported. All? Only in clinical trials the investigator needs to report all adverse events to the clinical trial sponsor. This is in contrast to spontaneous reporting systems, which are not designed to capture every event that happened to each patient taking a medicine. Thus, in a normal clinical setting not all events need to be reported; only those with a suspected causal relationship. Mostly those which are not already described in the SmPC, those which (might) bring new information are of interest. Healthcare providers such as hospitals may have a local committee whose role is to analyse all data (intolerance, adverse effects etc..) and then decide if an ADR report needs to be issued. Even if side effects have already been identified in the SmPC, their frequency or severity can also be considered as a new knowledge.
- b. Difference between intolerance and adverse event is sometimes not easy to recognise. A clinician's focus when recording an adverse event in a patient's record is towards improving the care of the individual patient rather than on the public health aspect of pharmacovigilance. There is a risk to generate "noise" by passing without further care, any suspected adverse event, which needs to be balanced with the need (and obligation) to announce all of them.
- c. Definition of suspected adverse event might be different in some context. For example, a "near miss" is sometimes considered a suspected adverse event, whereas there was no consequence for the patient, and some other context would consider this as part of the risk management.
- d. SNOMED is used in the clinical space to provide adverse event terminology, whereas the regulatory domain requires its own terminology (MedDRA). Luckily a relevant subset of both terminologies is cross mapped in both directions. But it is recognised that the maintenance of these mappings is all but not easy. In some places, projects to implement MedDRA in the clinical domain are announced or in place. In the Netherlands, NICTIZ provides a public webservice to facilitate the transition from one terminology to another in local language.
- e. IDMP has been initiated to address the challenges of free text interpretations in the ICSR data-elements used to describe medicines. Accordingly, it is expected that IDMP implementation across medicinal product's life cycle will improve the analysis processes at each step of the information supply chain (within the healthcare provider, at regulatory level, industry level and at the stage of information aggregation such as EMA and WHO-UMC).
- f. Overall, the use of IDMP identifiers may significantly improve the efficiency, accuracy, and effectiveness of pharmacovigilance activities related to reporting, communicating, and managing adverse drug reactions. This ultimately contributes to the continuous monitoring and improvement of drug safety and patient care.



## 4 Shortages

### 4.1 Setting the scene

The issue of shortages has become increasingly accurate. Some actions to get more intelligence about medicinal product availability or anticipating shortages are driven in a “top-down” method. By setting the scene in the workshop, a hospital initiative has been reported, where stock levels, regular supplies, are matched with electronic prescriptions for the short term (3 days) and mid-term (few weeks). This project enables anticipation of possible problems and take action for substitution. The project has been brought at the level of the country and is in progressive large-scale implementation. It complements actions taken by the authorities, both being to be interlinked.

The situation reported highlights the need for common identifiers, such as the GTIN in logistics (automatic stock management reports), and an identifier at medicinal product (ideally at pharmaceutical product) level.

### 4.2 Discussion

There is currently no formal definition of what a “shortage” is, hence the need to work with the concept in a very agile way as many different constraints exist. The discussion revealed that the differences (also towards the introduction report) between countries, where:

- In France, shortage is defined at package level. MPDs integrate information from the national authority and sends it to the EHR systems.
- In Belgium, a compulsory daily data collection on shortages is implemented with a feed by all actors who have a stock. There is also an obligation for all Marketing Authorisation Holders to notify shortage. A national multi-stakeholder’s task force keeps accurate analysis of the market and may adopt decisions for possible substitutions.
- The coming new shortage platform developed by EMA reveals importance of using common identifiers, such as those managed by EMA in the SPOR programme. If not using such a common denominator, the mapping task becomes resource demanding, slow and error prone.
- Once a shortage identified comes the need for substitution. This is where IDMP plays a role, primarily the PhPID and its levels 1 to 4. This is followed by the identification of packages and their integration in MPD, hospital formularies, and EHR systems.

## **5 Conclusion**

### **5.1 Consensus**

The discussions did not lead to any vote or kind of decisions. They enabled understanding how participants' minds were converging.

Certainly, many regret that although considerable progresses have been made thank to the UNICOM project, IDMP is neither available locally, regionally or globally. There was a consensus that the most important objective is to dispose of a global IDMP implementation, which implies availability of global substance identification and global pharmaceutical product identification. The sooner, the better!

It is noted that recommendations for ePrescriptions and individual case safety reports already dispose of placeholders for IDMP identifiers. That seems not to be the case for all MPD or EHR systems. Although IDMP is increasingly known by stakeholders, dissemination, education, conviction still need considerable efforts.

Awareness was raised about the "portfolio of identifiers" which might be part of MPDs to enable linkage of products from packaging level to PhPID level, and vice-versa.

### **5.2 Closure**

Participants expressed their satisfaction to have joined this workshop. Some regrets have been expressed that such a workshop did not take place earlier during UNICOM -which the pandemic knowingly prevented.