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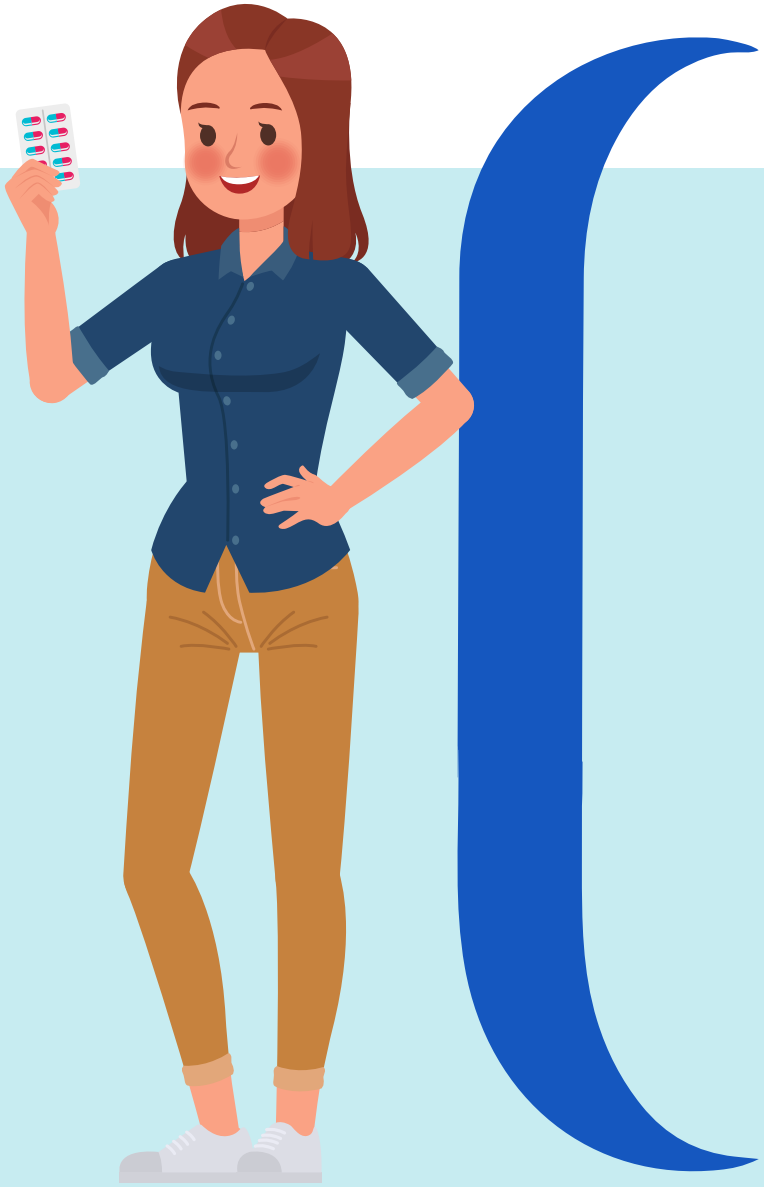

IDMP in a capsule

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About this document

This document is one of the UNICOM deliverables. It provides a simplified vision on how IDMP could support safer processes in the medication business. This vision does not imply an endorsement of UNICOM or any of its stakeholders. It has been written in an informative way and thus has no normative character.

Click here for the list of abbreviations

Click here for the list of definitions

IDMP in a capsule helps promote greater understanding about how IDMP standards could "work" throughout the life-cycle stages of a medicinal product. In each stage - from the initial stage of *Development and Production* through the final stage of *Utilisation and Outcome Assessment* - IDMP standards' concepts and theory are explained as part of two stories: SweetDreams, a medicinal product, and Ingrid, its user. Readers will find this handbook offers a straight-forward approach and explanation of IDMP standards, and their impact in real-world situations.

Should you have any questions or comments about this document, please send us an email at unicom@nictiz.nl

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1 Introduction

1.1 Ingrid experiences an adverse drug event

Ingrid and her family are taking a long-awaited holiday in sunny Greece. Their days are full of activities, in the city and at the beach. Each night Ingrid returns to the hotel exhausted; each night she can't sleep. "I suffer from insomnia," explains Ingrid. "When I'm away from home, it's especially hard for me to sleep. Unfortunately, while on this holiday, I ran out of my sleeping tablets - SweetDreams."

Desperate for rest, Ingrid visits a local drug store. She shows the drug store assistant her empty SweetDreams' package. Since the SweetDreams' brand is not available in Greece, he reaches for Sweet Dreaming, assuming that this drug is the same medicinal product, with a different brand name in Greece.

That night, Ingrid experiences severe side effects - a migraine headache, dizziness and blurriness of vision. Ingrid and her family rush home to Sweden the next day where she is admitted to the hospital that evening. Her distressed husband asks the doctor, "Why was the wrong medicine dispensed? How could it have been avoided?"

1.2 Identification of medicinal products

The identification of medicinal products is a global problem - one that is typically resolved by the use of medicinal product dictionaries (MPDs) and clinical decision support (CDS) system for medication. The providers of MPDs and CDSs use valuable resources to re-identify medicinal product information received from pharmaceutical companies, with the aim to provide some level of patient safety within hospital and ambulatory environments. This approach has proven to produce a fragmented network of processes and information across jurisdictions and domains, with limited or no interoperability between stakeholders.

Today's situations that call for the identification of medicinal products include:

- **Providing healthcare providers with appropriate, complete and understandable medicinal product information when prescribing medications, regardless of brand name**

Consider the increasingly mobile population that receives medical services and medicinal products from different healthcare providers that could be located in different countries, jurisdictions or simply in different healthcare systems.

With the use of IDMP standards, ADEs can be prevented or, at least, dramatically minimised.

- **Reducing risks of falsified medicines**

Measures to protect markets against falsified medicinal products include linkages to IDMP standards. The connection between product identifiers - from a pharmaceutical product's PhPID as a common denominator to medicinal products in supply chains - increases the ability to detect and react when falsified medicinal products enter the legitimate supply chain.

- **Making safe substitutions when branded, prescribed medicinal products are unavailable**

There is a vast number of medicinal products in today's global market - prescription and over-the-counter products - that are dispensed in hospitals, pharmacies and retail drug stores. And, a medicinal product can be packaged in different ways, with different brand names and different strengths from country-to-country.

- **Reporting and analysing adverse drug events (ADEs) and medication errors**

The World Health Organization estimates that adverse drug reactions are the fourth to sixth largest cause for mortality in some countries. The percentage of hospital admissions due to such reactions is 10-20%. And, there is a concomitant high economic impact on healthcare services. Some countries spend up to 15-20% of their healthcare budgets on drug-related problems.[3]

These needs can be addressed with the use of the Identification of Medicinal Products suite of standards. IDMP standards help provide complete and accurate data about a medicinal product throughout its life cycle - to all healthcare stakeholders across different jurisdictions and countries. While IDMP standards are not yet fully implemented, the following provides a view of how IDMP standards would benefit all stakeholders, especially patients, throughout global healthcare.

3 World Health Organization. Aide Memoire: For a national strategy for safe drugs and their appropriate use. https://www.who-umc.org/media/1211/aide-memoire-en.pdf

1.3 IDMP standards and two stories

Let's consider how IDMP standards address the need for the global identification of medicinal products - how they give healthcare providers trusted information about a medicinal product, regardless of brand name, and help them safely prescribe, identify equivalents and ensure the safe use of medicinal products by patients to avoid ADEs and medication errors.

To do this, we'll explore the concepts and theory behind IDMP standards as part of two stories - SweetDreams, a medicinal product, and Ingrid, its user.

We'll follow the stories of Ingrid and SweetDreams throughout the medicinal product's life-cycle stages:

QUIZ

Q1-1 What is IDMP? *(Tick what is RIGHT)*

- ◯ **a)** A set of ISO standards to improve the quality of medicinal products
- ◯ **b)** A project to support the global trade of medicinal products
- ◯ **c)** A set of ISO standards for the identification of medicinal products
- ◯ **d)** A regulation to prevent the illegal trade in falsified medicinal products

Q1-2 What does IDMP aim to provide? *(Tick what is RIGHT)*

- ◯ **a)** A set of identifiers to uniquely identify medicinal products across the globe
- ◯ **b)** A European classification of related groups of medicinal products
- ◯ **c)** A global (worldwide) medicinal product dictionary
- ◯ **d)** A global (worldwide) authorisation for medicinal products

Q1-3 What does IDMP stand for? *(Tick what is RIGHT)*

- ◯ **a)** International Definition of Medicinal Products
- ◯ **b)** ISO Drug and Medication Profiles
- ◯ **c)** Identification of Medicinal Products
- ◯ **d)** Interoperability of Data in Medication and Pharmacy

Q1-4 Which real-life situation will be addressed by IDMP? *(Tick what is RIGHT)*

- ◯ **a)** Facilitating reimbursement of medicinal product
- ◯ **b)** Making it easier to detect falsified medicines entering the legitimate supply chain of medicinal products
- ◯ **c)** Strengthening global pharmacovigilance: learning quickly from adverse drug events worldwide
- ◯ **d)** Reducing the number of variants (names, strengths, packages) of medicinal products that are authorized for use across the globe

Click here for the answers

Please provide us with feedback on these questions by sending an email at unicom@nictiz.nl

2 Development and Production

2.1 Ingrid hears about a new medicine

Let's reconsider Ingrid's story with IDMP standards in place.

Ingrid has suffered for many years from insomnia. She finds it very difficult to sleep. Over the years, she has tried countless medicines, but none have worked well and many have negative side effects. During her annual examination, Ingrid's doctor, Karina, tells her about a new medicine currently under development by M&P Company. A new substance in the pharmaceutical product is expected to offer an effective treatment for those with insomnia, and promises to have very few and minor side effects.

2.2 IDMP standards in Development and Production

Based on emerging health needs and innovative research, a pharmaceutical company develops new pharmaceutical products that address targeted diseases, bringing to the market new methodologies, substances and technological advances.

When doing so, it must make multiple decisions about how each pharmaceutical product's substances will be combined; about its strength, dose form and packaging; and how the new product will ultimately be produced, marketed and dispensed.

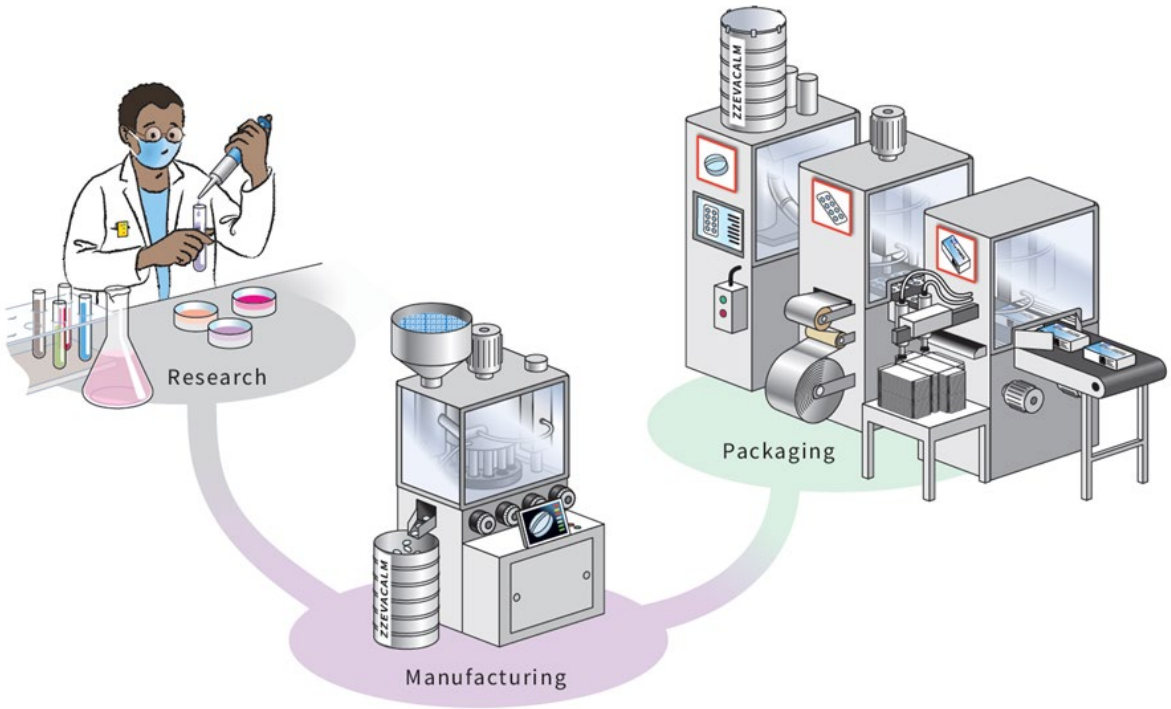

Figure 2 As a pharmaceutical product is developed, the pharmaceutical company or its representative prepares the product's dossier for submission to the local national competent authority to secure the NCA's marketing authorisation to market and sell the medicinal product in the local market.

As a pharmaceutical product is developed, the pharmaceutical company or its representative prepares the product's dossier for submission to the local national competent authority (NCA). This is to secure the NCA's marketing authorisation (MA) to market and sell the medicinal product in the local market.

As part of the dossier, the pharmaceutical company provides information, to include the medicinal product's:

- **Substance, including one or more active ingredients**
- **Dose form, whether a powder, coated tablet, injection, capsule or other**
- **Strength per dosage**

The substances can each be assigned a global identifier by the World Health Organization's Uppsala Monitoring Centre (WHO-UMC). The product's dose form is identified by the European Directorate for the Quality of Medicines (EDQM) organisation, and its strength is defined based on the Universal Code for Units of Measure (UCUM) by the Regenstrief Institute. All are IDMP compliant. With this information, the WHO-UMC can calculate a global PhPID. The NCAs and EMA are responsible for assigning a Medicinal Product Identifier (MPID) and Medicinal Product Package Identifier (PCID) to identify how the medicinal product will be packaged in the local market.

A pharmaceutical company must receive marketing authorisation from the national competent authority in each country where it plans to market and sell a medicinal product.

To market and sell a medicinal product in other markets or countries, the pharmaceutical company must receive marketing authorisation from the NCA in each country.

Once the medicinal product's MA is approved, the pharmaceutical company uniquely identifies the medicinal product globally by assigning GS1 Global Trade item Numbers (GTINs), encoded in two-dimensional (2D) GS1 DataMatrix barcodes and applied to its primary and secondary packages.

The pharmaceutical company will communicate this information to stakeholders such as the NCA, European Medicines Verification Organisation (EMVO) and local medicinal product dictionary.

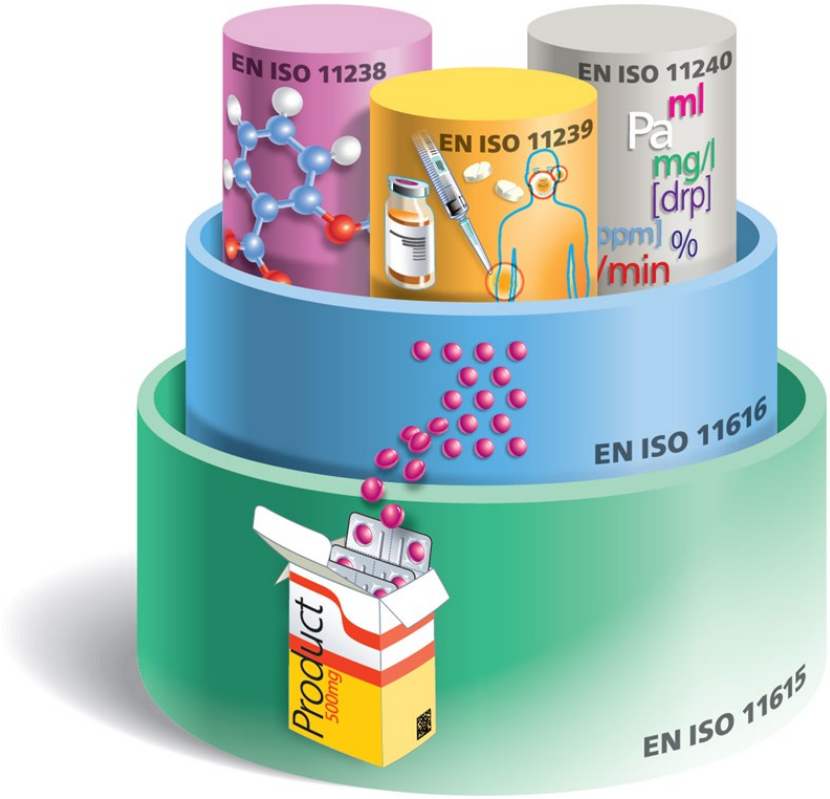

Figure 3 IDMP identifiers are assigned by the local national competent authority for a medicinal product as well as by other NCAs in countries where the medicinal product is marketed and sold.

2.3 Pharmaceutical company applies for marketing authorisation

M&P Company specialises in creating new, innovative medicinal products that offer relief to millions of insomniacs worldwide. SweetDreams is conceived and developed in the pharmaceutical company's research labs in Sweden.

SweetDreams is based on a new substance, ZZevacalm, that has proven to be very effective with few side effects. During SweetDreams' development, M&P conducts multiple clinical trials of the medicinal product's concept, which are overseen by Sweden's NCA and others.

As M&P prepares for the new product's production and marketing in Sweden, the company presents its dossier to the country's NCA to secure marketing authorisation.

After some exchanges between M&P and the NCA, marketing authorisation is granted to market the new medicinal product in Sweden under the brand name of SweetDreams.

ZZevacalm is assigned a global IDMP substance identifier, ABC123, by the WHO-UMC.

As production and distribution plans are put in place, M&P assigns and applies GTINs encoded in DataMatrix barcodes on SweetDreams' primary and secondary packages for the Swedish market.

M&P also plans to offer the new medicinal product in four other countries under different brand names. The product will be marketed as Doux Rêves in Belgium and France, SüsseTräume in Germany and Όνειρα Γλυκά in Greece. In each of these countries, M&P presents its dossier to the NCA to request approval of marketing authorisation.

Additional unique GTINs are assigned for each country, under the different brand name, encoded in DataMatrix barcodes and applied on primary and secondary packages.

QUIZ

Q2-1 **Which of the following elements is relevant for the unique identification of a pharmaceutical product using a PhPID?**
(Tick what is WRONG)

- ◯ **a)** Substances (including one or more active ingredients)
- ◯ **b)** Dose form
- ◯ **c)** Strength
- ◯ **d)** Packaging

Q2-2 **Which of the following IDMP compliant identifiers can only be assigned ONCE to a medicinal product on a global level?**
(Tick what is RIGHT)

- ◯ **a)** Medicinal Product Identification (MPID)
- ◯ **b)** Medicinal Product Package Identification (PCID)
- ◯ **c)** Global Trade Item Number (GTIN)
- ◯ **d)** Pharmaceutical Product Identifier (PhPID)

Click here for the answers

Please provide us with feedback on these questions by sending an email at unicom@nictiz.nl

3 Regulation and Authorisation

3.1 Ingrid learns SweetDreams will soon be available

Ingrid is excited to hear about the new medicinal product. Karina promises to advise her when it is available so that she can be one of the first patients to use it.

Karina explains how M&P is currently seeking marketing authorisation from Sweden's national competent authority to prescribe and dispense the new medicinal product under the brand name, SweetDreams.

After months of waiting, Karina contacts Ingrid to advise her that Sweet-Dreams has been approved and will soon be available for prescribing and dispensing in Sweden.

3.2 IDMP standards in the regulatory environment

When an NCA receives a new pharmaceutical product's dossier, it will assess the pharmaceutical dose form, as well as the administrable dose form. The NCA will analyse the diverse amount of information provided by the pharmaceutical company or the pharmaceutical company's representative requesting marketing authorisation.

The administrable dose form is used in calculating the medicinal product's PhPID - an IDMP standard that is used in both regulatory and clinical processes.

Note that different levels of PhPIDs can be calculated. For example, a PhPID can consist of:

- **Level 1:**
  Substance(s) only
  (e.g., PhPID # 155)
- **Level 2:**
  Substance(s) + strength
  (e.g., PhPID # 15522)
- **Level 3:**
  Substance(s) + dose form
  (e.g., PhPID # 155ABC)
- **Level 4:**
  Substance(s) + dose form + strength
  (e.g., PhPID # 15522ABC)

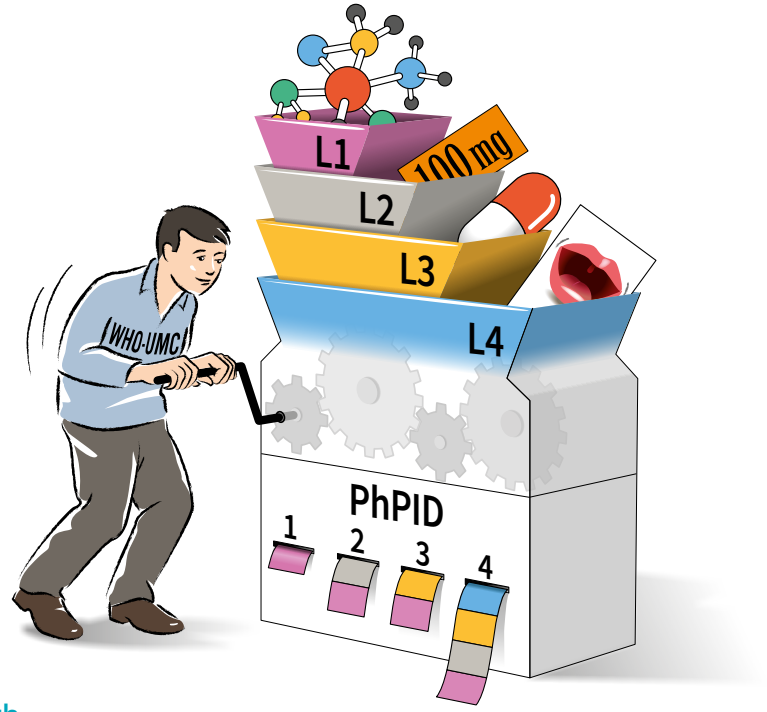

Figure 4 The global PhPID is calculated by the WHO-UMC.

The PhPID globally and uniquely identifies a pharmaceutical product's substances, dose form and strength. It's the medicinal product's "common denominator" from country-to-country regardless of where it is prescribed, dispensed and used.

The local NCA in each country where the medicinal product is marketed will use the PhPID and assign the MPID and PCID, which are based on the size of packaging for that particular country.

For example, in one country the medicinal product may have 50 tablets in its package where in another country, the package may contain 100 tablets. Even though the MPIDs and PCIDs will differ from country-to-country, the PhPID will remain the same for all countries.

The NCA approves the MA and makes the medicinal product's information available to medicinal product dictionaries and other stakeholders in the country where it is offered. The MA also impacts information provided as part of a medicinal product's leaflet for consumers.

The PhPID globally and uniquely identifies a pharmaceutical product's substances, dose form and strength. It's the medicinal product's "common denominator" from country-to-country regardless of where it is prescribed, dispensed and used.

3.3 SweetDreams gets a PhPID

Following MA approval by Sweden's NCA, a global PhPID from WHO-UMC can be made available. This will enable idenfication of the related medicinal products when authorised for marketing as Doux Rêves in Belgium and France, SüsseTräume in Germany and Όνειρα Γλυκά in Greece.

The PhPID is calculated based on information about the medicinal product's:

- **Substance: ZZevacalm**
- **Dose form: Tablet**
- **Strength: 20 mg/tablet**

As noted earlier, ZZevacalm is assigned a global IDMP substance identifier, ABC123, by the WHO-UMC. When approving the medicinal product for the market, two additional IDMP standards - the MPID and PCID - are assigned by the Swedish NCA for SweetDreams. These two standards provide information about how SweetDreams will be marketed in Sweden, such as the size of the package. In Sweden, each SweetDreams' package will consist of 2 blisters of 10 tablets each.

When applying for marketing authorisation in each country, M&P Company shares the PhPID (#155) assigned by WHO-UMC for Sweden's NCA, with the other NCAs.

Since the medicinal product will be marketed under different brand names and will be packaged differently in other countries, it must receive marketing authorisation in each. The NCA assigns a unique MPID and PCID to provide information about the medicinal product and its package in each country.

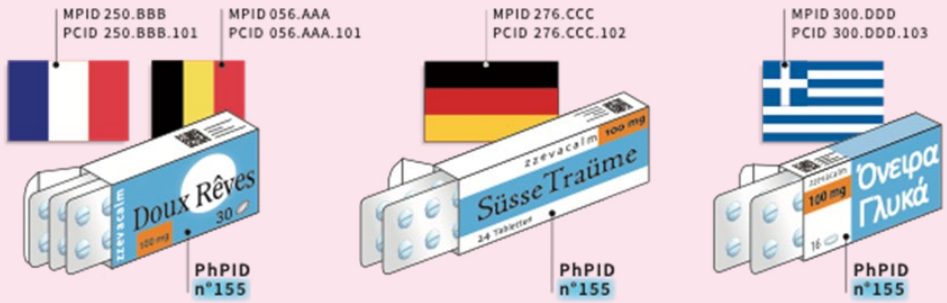

Figure 5 SweetDreams in Sweden is marketed under different brand names in other markets, yet the PhPID remains the same.

QUIZ

Q3-1 What is the difference between a Pharmaceutical Product (PhP) and a Medicinal Product (MP)? *(Tick what is WRONG)*

- ◯ **a)** MP is specific to one jurisdiction (country), whereas a PhP may be the same in several countries
- ◯ **b)** Apart from having different identifiers, PhP and MP are synonyms
- ◯ **c)** PhP can refer to multiple medicinal products as found on the global market, whereas MP only refers to one specific medicinal product on the global market
- ◯ **d)** MPs are identified by national competent authorities and imply a marketing authorisation has been granted, whereas PhPs do not imply marketing authorisation

Q3-2 When is a new PhPID required, i.e. will it change when changes are made to a medicinal product? *(Tick what is RIGHT)*

- ◯ **a)** When the brand name is changed
- ◯ **b)** When the packaging of the product is changed
- ◯ **c)** When an ingredient is changed
- ◯ **d)** When it is marketed in another country

Q3-3 Which level of the PhPID should be identical for it to be safe to interchange two medicinal products without changing the prescription? *(Tick what is RIGHT)*

- ◯ **a)** PhPID Level 1 – substance(s) only
- ◯ **b)** PhPID Level 2 – substance(s) and dose form
- ◯ **c)** PhPID Level 3 – substance(s) and strength
- ◯ **d)** PhPID Level 4 – substance(s), dose form and strength

Q3-4 Which of these IDMP identifiers is assigned by the pharmaceutical company and not by the national competent authority? *(Tick what is RIGHT)*

- ◯ **a)** Medicinal Product Identification (MPID)
- ◯ **b)** Medicinal Product Package Identification (PCID)
- ◯ **c)** Global Trade Item Number (GTIN)
- ◯ **d)** Pharmaceutical Product Identifier (PhPID)

Click here for the answers

Please provide us with feedback on these questions by sending an email at unicom@nictiz.nl

4 Dissemination and Information

4.1 Ingrid has peace of mind since the MPD stores vital medicinal product information

With the approval of SweetDreams' MA, Ingrid can be confident that information about the new medicinal product has been captured and registered, and is now part of Sweden's medicinal product dictionary.

IDMP identifiers have also been assigned - the PhPID that is the same across Sweden and all other markets in which the medicinal product is offered, and the medicinal product's MPID and PCID for its use in Sweden. In addition, the GS1 Global Trade Item Number (GTIN), encoded in the DataMatrix barcode on the product's package, is part of Sweden's portfolio of identifiers in the MPD.

4.2 IDMP standards provide complete and accurate information

The medicinal product dictionary plays a central role in storing and disseminating information about medicinal products for prescription and dispensation in a country.

The MPD is sourced with different types of information from the NCA's marketing authorisation process, from regulated files and other (scientific) documentation, to include IDMP identifiers, preferred medication substitutions, pricing information and more.

The MPD provides a structured repository of information from these sources and makes them available to multiple types of users such as clinicians (via supporting software and systems), patients (via online queries), e-Health authorities and others. The MPD provides the clinical user of the medicinal product (e.g., doctors and pharmacists) with a source of information for clinical decision support, clinical dose calculations or recommendations, access to peer reviews and references, and much more.

Using smartphone apps, consumers can scan a medicinal product's barcode on its package to access information about the product's substances and other valuable information in consumer-friendly language.

The MPD is also a key player in the legitimate supply chain. Consumers can be assured that medicinal products are authorised and safe when documented in the MPD, helping doctors to prescribe and pharmacists to dispense medicinal products. All information contained in the MPD and accessible by patients is integral in building consumer trust and confidence in medicinal products.
The global PhPID calculated by the WHO-UMC, may reside in all countries' medicinal product dictionaries where the medicinal product is prescribed and dispensed in the respective jurisdiction.

The global PhPID calculated by the WHO-UMC, may reside in countries' medicinal product dictionaries where the medicinal product is prescribed and dispensed in the respective jurisdiction.

4.3 MPD provides needed medicinal product information

Information about SweetDreams - including the PhPID, MPID and PCID - is available in Sweden's medicinal product dictionary, which is sourced from Sweden's NCA and other validated sources. The NCA also approves the information to be provided in SweetDreams' (electronic) product leaflet for consumers.

The MPD makes available other types of information pertaining to SweetDreams like pricing, insurance reimbursement policies and the product's GTIN packaging hierarchy. SweetDreams' GTINs belong to the Swedish portfolio of identifiers in which the PhPID is linked to the other countries' medicinal dictionaries where the medicinal product is marketed.

- **As M&P distributes the medicinal product throughout Belgium, France, Germany and Greece, it provides the product's information like the PhPID and other useful information to each country's NCA.**
- **Once marketing authorisation is granted, each country's NCA allocates the MPID and PCID and makes this information - including the PhPID calculated for Sweden's NCA - accessible via the local medicinal product dictionary.**
- **The national portfolio of identifiers that contains the common, global PhPID and the country-specific MPID, PCID and GTIN shall be published by the local / regional medicinal product dictionary.**

With IDMP identification standards in place in all countries' national MPDs, solution providers can develop an API to search for this information. This will give healthcare providers the tools needed to efficiently access the information and make informed decisions when prescribing and dispensing medicinal products.

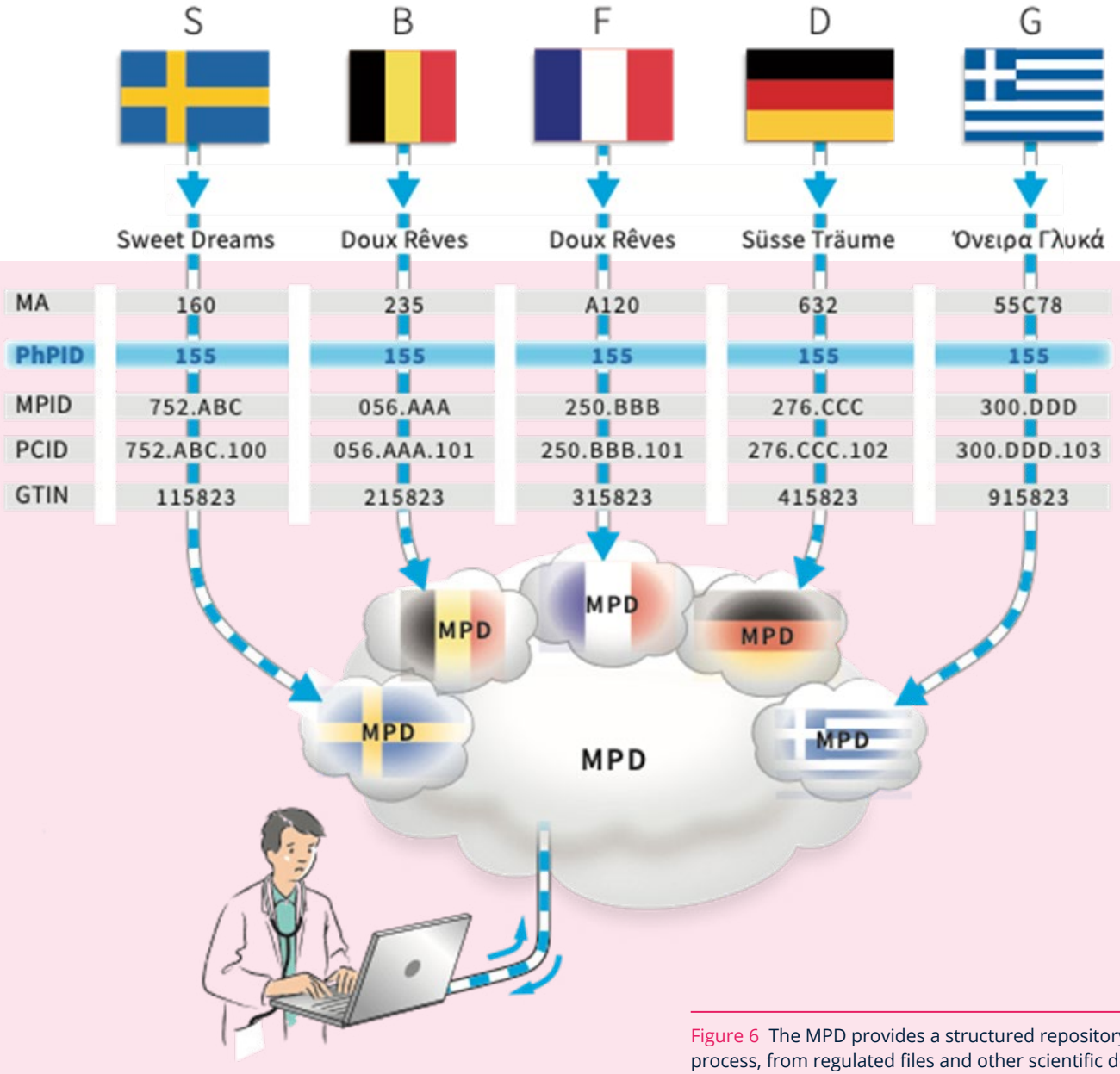

Figure 6 The MPD provides a structured repository of information from the NCA' marketing authorisation process, from regulated files and other scientific documentation, to include IDMP identifiers, preferred medication substitutions, pricing information and more. The MPD makes this information available to multiple types of users: clinicians, patients, e-Health authorities and others.

QUIZ

Q4-1 What does the abbreviation MPD stand for? *(Tick what is RIGHT)*

- ◯ **a)** Medicinal Product Definition
- ◯ **b)** Marketing Pharmaceutical Database
- ◯ **c)** Medicinal Product Dictionary
- ◯ **d)** Medical Product Directory

Q4-2 What information is contained in an MPD? *(Tick what is WRONG)*

- ◯ **a)** The portfolio of identifiers for a medicinal product
- ◯ **b)** The prescription and dispensation record for a medicinal product
- ◯ **c)** The regulated product information for a medicinal product
- ◯ **d)** Recommendations on the dose calculation for prescription

Q4-3 At what level will an MPD be maintained? *(Tick what is RIGHT)*

- ◯ **a)** At the local level of a hospital or pharmacy
- ◯ **b)** At the level of the region or jurisdiction of the healthcare system
- ◯ **c)** At the level of the pharmaceutical company
- ◯ **d)** At the level of a health insurance company

Click here for the answers

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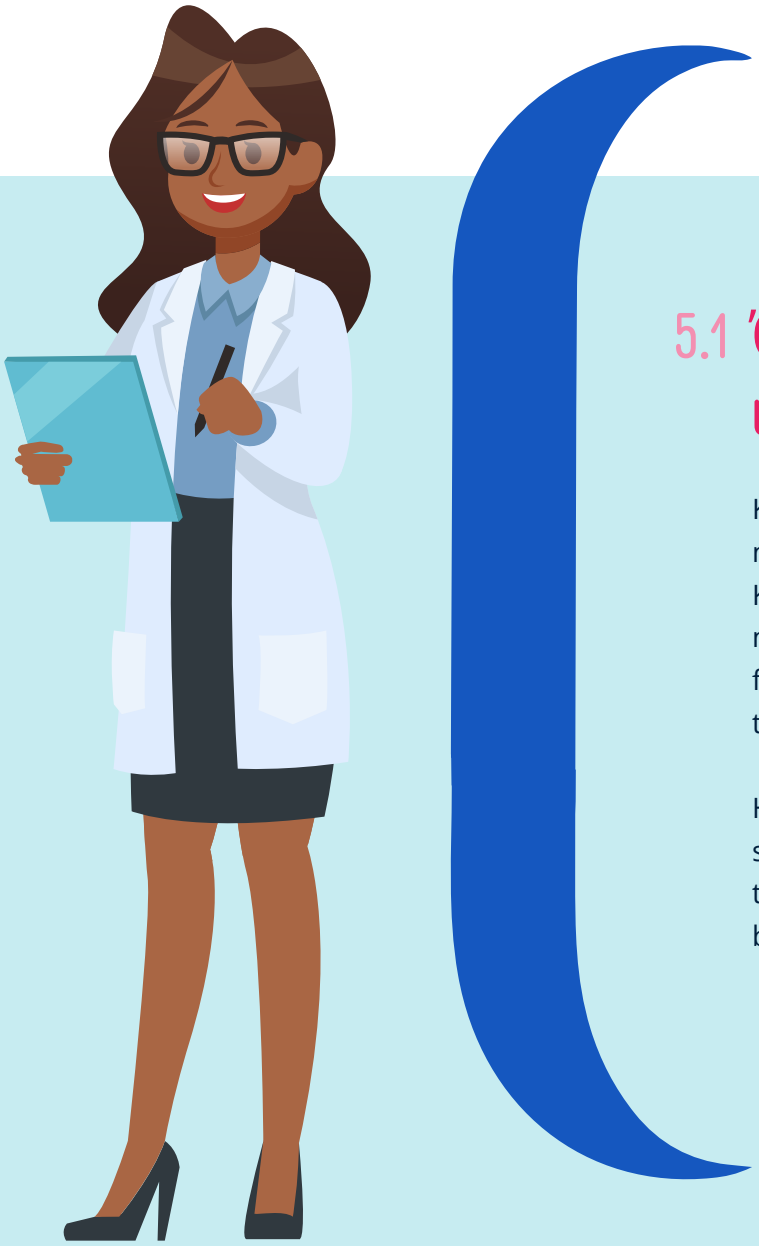
5 Prescription and Dispensation



5.1 Όνειρα Γλυκά is prescribed for Ingrid while on holiday

Karina reviews information about SweetDreams in Sweden's MPD and prescribes the new medicine for Ingrid during her visit. Based on the wealth of information available, Karina feels confident that SweetDreams and its main substance, ZZevacalm, will have no negative side effects for Ingrid. As expected, SweetDreams is a "dream come true" for Ingrid since it helps her better manage insomnia and eliminates drowsiness during the day.

However, Ingrid fails to plan well for her upcoming holiday. While in Greece, she realises she needs more SweetDreams tablets. She visits the local pharmacy and shows Monica, the pharmacist, the SweetDreams package who scans the package's DataMatrix barcode to read SweetDreams' GTIN, serial number and other information.

Monica recognises the medicinal product is from Sweden and accesses Sweden's MPD via Greece's MPD and its portfolio of identifiers, using a common IDMP interface on her pharmacy system. She is able to identify the same medicinal product that is marketed in Greece as Όνειρα Γλυκά, thanks to her confirmation of the common PhPID in Sweden's portfolio of identifiers as well as other attributes (e.g., ATC, package size) from the Swedish MPD.

When dispensing the medicine, Monica explains to Ingrid that SweetDreams is called Όνειρα Γλυκά in Greece. She shows Ingrid that each package of Όνειρα Γλυκά contains only 16 tablets where, in Sweden, a package includes 20 tablets. Ingrid purchases Όνειρα Γλυκά since a package will provide enough tablets for the remainder of her time in Greece. Ingrid can now sleep and is well-rested for her family's holiday!

5.2 IDMP standards help clinicians safely prescribe and dispense

During the Prescription and Dispensation stage, a doctor consults with her patient, analyses his symptoms, refers to the local MPD and makes decisions about how to treat the patient's conditions with a preferred medicinal product, its strength and dosage. To guide these decisions, the doctor consults the clinical decision support system that contains information about the patient's characteristics and the prescribed medicinal product - information provided by the MPD.

The pharmacist can avoid negative drug-drug interactions with help from information in his pharmacy support system, also sourced from the MPD. The pharmacy system provides him with access to information about other medications being taken by the patient and verifies that the new medicinal product, based on information from the MPD, will not produce a negative drug-drug effect for the patient. When inventory is not available, he may also consult with the doctor when making an alternative prescription for the preferred medication.

The MPD provides the main source of detailed medicinal product information, including IDMP identifiers, for systems used by doctors and pharmacists in all types of environments (e.g., hospitals, private practices, retail pharmacies and others).

IT systems play a significant role as information "concentrators," leveraging the MPD to make information usable. Since MPDs are different in different countries, each country will have a landscape of medicinal product database providers.

The MPD provides the main source of detailed medicinal product information, including IDMP identifiers, for systems used by doctors and pharmacists in all types of environments.

Solution providers develop IT systems that provide decision-making support for doctors, pharmacists and nurses when prescribing, dispensing and administering closed-loop medication. These systems support patients whether in the hospital or in out-patient clinics and offices. Relevant information from the patient electronic health record is also integrated into these systems to help inform doctors and pharmacists when prescribing and dispensing medicines.

5.3 PhPID: Όνειρα Γλυκά & SweetDreams identified as same pharmaceutical product

With its approved marketing authorisation, SweetDreams' information from the NCA and additional validated sources (e.g., paediatric dose calculations) is documented in Sweden's MPD. This MPD is used by Karina, Ingrid's Swedish doctor, as well as Jasmine, the Swedish pharmacist, via their respective prescription and dispensation systems.

According to EU legislation on safety features on medicinal products, Jasmine verifies the authenticity of the medicinal product based on information encoded in the DataMatrix barcode on the package. When dispensing SweetDreams, the pharmacy provides an invoice based on its insurance information in the MPD.

In Greece, Όνειρα Γλυκά information - sourced from the Greek NCA and other appropriate validated sources - is accessible in Greece's MPD. The Greek MPD is consistently used by Monica, the pharmacist in Greece, and is queried when Ingrid presents the SweetDreams package for refill.

When Monica scans the DataMatrix barcode, the SweetDreams GTIN is not recognised; in response, the Greek MPD will query the GS1 infrastructure, specifically the GS1 Global Registry, to locate the origin of the GTIN, and will ultimately find the SweetDreams PhPID in the Swedish MPD.

With the common PhPID, Monica identifies Όνειρα Γλυκά as the equivalent medicinal product marketed in Greece. She can then confidently dispense Όνειρα Γλυκά for Ingrid, explaining the difference in the medicinal product's packaging, and assuring Ingrid of its safety since it is the same medicine.

QUIZ

Q5-1 What information does a healthcare professional need when prescribing medication? *(Tick what is WRONG)*

- ◯ **a)** The PhPID for the medicinal product
- ◯ **b)** The EDQM Standard Term for the dose form of the product
- ◯ **c)** The GTIN as visible in the DataMatrix on the secondary packaging of the product
- ◯ **d)** Coded allergy information from the Electronic Health Record of the patient

Q5-2 What information does the medicinal product dictionary provide to the prescriber? *(Tick what is RIGHT)*

- ◯ **a)** The condition the patient presents, for which the medication is to be prescribed
- ◯ **b)** The recommended dose calculation for the medicinal product
- ◯ **c)** Prior adverse drug events the patient has experienced when taking medication
- ◯ **d)** The list of current medication the patient is taking that may cause interactions with the medicinal product to be prescribed

Q5-3 Which IDMP identifier bridges medicinal products on a local market to the medicinal product taken by a foreign visitor? *(Tick what is RIGHT)*

- ◯ **a)** Medicinal Product Identification (MPID)
- ◯ **b)** Medicinal Product Package Identification (PCID)
- ◯ **c)** Global Trade Item Number (GTIN)
- ◯ **d)** Pharmaceutical Product Identifier (PhPID)

Click here for the answers

Please provide us with feedback on these questions by sending an email at unicom@nictiz.nl

6 Utilisation and Outcome Assessment

6.1 When Ingrid experiences an adverse drug event

In this version of Ingrid's story, it ends happily with help from IDMP standards.

Yet, what if (as portrayed in the initial scenario) Ingrid had suffered an adverse drug event from taking the wrong medicine with a substance that produced negative side effects?

When the drug store assistant dispensed Sweet Dreaming instead of Όνειρα Γλυκά, the following steps would be taken. Ingrid's ADE and the impact of Sweet Dreaming on Ingrid's health would be reported by Karina, Ingrid's Swedish doctor, to Sweden's NCA, other appropriate regulatory authorities and WHO-UMC.

Due to the power of IDMP standards, intelligence about Ingrid's ADE would not be an isolated event. Rather, it would be used by the WHO-UMC and the WHO Programme for International Drug Monitoring members to understand its applicability to others like Ingrid and how to avoid ADEs, making medicinal products safer for everyone.

6.2 IDMP standards enable aggregation of medicinal product information

During the *Utilisation and Outcome Assessment* stage, IDMP standards enable the aggregation and verification of medicinal product information to:

- **Identify appropriate substitutions**

When facing shortages, local and regional authorities can use the PhPID to identify medicinal products as substitutions for the originally prescribed medicine.

- **Validate authenticity when falsification is suspected**

IDMP identifiers (e.g., substance, PhPID) support the analysis of suspect medicinal product samples. The unique identifier, according to the European Union's Falsified Medicines Directive (EU-FMD) such as the serialised GTIN, enables authenticity verification.[5]

- **Analyse and prevent ADEs**

When an adverse drug event occurs, the doctor or hospital is required to inform the NCA that, in turn, will contact the medicinal product's MA holder. Documenting an ADE requires the use of the medicinal product's GTIN, lot/batch number and IDMP identifiers like the PhPID and MPID. Additional information is also required like the patient's characteristics, description of the processes that led to this ADE, other medications taken by the patient, co-morbidity conditions and more.

Due to the power of IDMP standards, intelligence about Ingrid's ADE would not be an isolated event. Rather, it would be used by the WHO-UMC and the WHO Programme for International Drug Monitoring members to understand its applicability to others like Ingrid and how to avoid ADEs, making medicinal products safer for everyone.

All information about the ADE is aggregated and forwarded to the European Medicines Agency (EMA) and WHO-UMC.

- **Recall a medicinal product**

If an issue is detected with a medicinal product based on an analysis of an ADE (or for other reasons), the PhPID and substance identifiers provide the needed IDMP standards for a global recall.

5 Directive 2011/62/EU

The recall is issued by the NCA and pharmaceutical company to stop the use of the targeted medicinal products.

- **Understand the impact of medicinal products on public health**

The comprehensive collection and aggregation of information at different levels of a medicinal product's life cycle is integral to the successful implementation of public health initiatives. Information can be aggregated at national and international levels to understand a population's condition and behaviour. At the macro level, health authorities can use this information to better understand and take action regarding the use of medicinal products - informing the public about the overuse of medicinal products and substances, and changing the behaviour of doctors in prescribing alternatives.

Consider the prolific use of antibiotics. Ongoing studies of antibiotic consumption have enabled the transition from the use of broad spectrum antibiotics to the use of more focused antibiotics. Using IDMP standards enable authorities to understand the evolution of infections and the use of antibiotics beyond their approved applications.

Another notable example is using COVID-19 vaccines' PhPIDs in the aggregation of vaccination data across regions around the world. There is high interest regarding the percentages of populations vaccinated with each available vaccine, and their associated results over time. With the increased proliferation of different vaccines and modified vaccines (e.g., to address coronavirus mutations), the need for precise IDMP identification will become more important than ever.

Clearly, with IDMP standards in place, adverse drug events, recalls and public health initiatives like today's COVID-19 vaccination efforts can be implemented much more efficiently by sharing data enabled by these global standards. The time required to react and take life-saving action will be significantly reduced with a high degree of accuracy when IDMP standards - especially the PhPID, substance identifier and GTIN - are fully implemented and used across countries and jurisdictions.

6.3 SweetDreams' IDMP standards help authorities take action

During the course of analysing the ADE, a prominent label is printed on the Sweet Dreaming package along with changes to the Sweet Dreaming information leaflet, warning consumers with particular pre-existing conditions about the potential side effects. This is enforced by the Greek NCA and communicated to additional NCAs that have provided marketing authorisations for Sweet Dreaming, based on its PhPID.

Without IDMP identifiers in place, the WHO-UMC would need to spend valuable time researching the difference between Sweet Dreaming and SweetDreams. IDMP standards enable the aggregation of information to make it useful and actionable by the WHO-UMC.

QUIZ

Q6-1 Which of the following objectives is within scope for IDMP? ***(Tick what is WRONG)***

- ◯ **a)** To enable safe substitutions in case of medication shortages in the local market
- ◯ **b)** To enable easier and more precise global analysis of adverse drug events
- ◯ **c)** To reduce the cost of medication in the local market
- ◯ **d)** To fight the distribution of falsified medicinal products

Q6-2 What is the key primary use of IDMP in public health? ***(Tick what is RIGHT)***

- ◯ **a)** To better understand and monitor the use of medicinal products in the local jurisdiction
- ◯ **b)** To easily share data on the effectiveness and use of medicinal products across jurisdictions
- ◯ **c)** To address pharmacovigilance issues in the most efficient and fast manner
- ◯ **d)** To assist healthcare professionals in prescribing the appropriate medicinal products in the optimal dose to individual patients

Q6-3 Consider the situation in which a serious contamination has been detected in the raw materials used for the manufacturing of one pharmaceutical product. Upon verification, the competent authorities determine that an urgent recall of all contaminated medicinal products is required (including different pack sizes and batches). Which identifier(s) is/are used to request the supply chain actors to block the use of this pharmaceutical product? ***(Tick what is RIGHT)***

- ◯ **a)** Medicinal Product Identification (MPID) in combination with the substance identifier
- ◯ **b)** Medicinal Product Package Identification (PCID) in combination with the marketing authorization number
- ◯ **c)** Global Trade Item Number (GTIN) for each packaging size, in combination with the lot number(s) or serial number(s) of the specific medicinal products
- ◯ **d)** Pharmaceutical Product Identifier (PhPID) in combination with the identification of the marketing authorisation holder

Click here for the answers

Please provide us with feedback on these questions by sending an email at unicom@nictiz.nl

7 Impact of IDMP standards

IDMP standards and accurate medicinal product information can deliver multiple benefits for pharmaceutical companies, regulators, healthcare providers, and especially patients in all the countries where a medicinal product is prescribed, dispensed and used.

Following are projected benefits for each of the stakeholders:

7.1 Pharmaceutical Company/ Manufacturer

IDMP standards enable a consistent information structure for a pharmaceutical company's medicinal products regardless of where they are marketed. The granularity and reliability of medicinal product data increases with IDMP standards, allowing pharmaceutical companies to be highly efficient in their production and distribution processes. By using a single, standards-based vocabulary, pharmaceutical companies can benefit from mass data management systems that allow them to use information about their medicinal products across every market.

7.2 Medicines regulatory agency

With IDMP standards in place, regulators benefit with improved and increased mass product data, bringing the quality of information to a standardised, interoperable, high level. This, in turn, helps regulators in different countries more easily compare and exchange medicinal product information.

7.3 Healthcare provider

IDMP standards provide healthcare providers access to information in their local language about medicinal products that are not directly marketed in their country. With access to standardised information in local MPDs, doctors and pharmacists can safely and more easily prescribe and dispense medicinal products to patients - not only their existing, local patients, but also patients who are away from home.

7.4 Public health

In case of shortages or unexpected ADEs, public health authorities benefit from IDMP standards in place with easier and safer ways to identify substitutions, take action to avoid ADEs, and potentially recall harmful products and substances, and not just specific brands. Further, IDMP standards facilitate pharmaco-epidemiology and other research activities.

7.5 Patient

Even with language differences, patients can access and understand safe levels of a medicinal product's strength from country-to-country. Perhaps the most important benefit of using IDMP standards is the health, well-being and safety of patients and consumers worldwide.

8 Call to action

To realise the benefits for all stakeholders, pharmaceutical companies and regulators shall take action to fully implement IDMP standards for medicinal products.

IDMP standards-enabled information shall then be collected and stored in medicinal product dictionaries for easy access by doctors and pharmacists.

With the link between IDMP standards and the MPD, IT solution providers shall integrate this medicinal product information in their solutions. Only then, healthcare providers will be able to safely prescribe and dispense the right medicinal products to the right patients, regardless of where they are.

Public health organisations can more easily and quickly aggregate worldwide information to address ADEs, recalls and important public health initiatives to ensure the world is a safer place for everyone.

9 Learn more

UNICOM

- **unicom-project.eu**

The UNICOM project is working to ensure that any medicine and what it contains can be accurately identified anywhere in the world.

UNICOM webinars

- **youtube.com/channel/UCBsNj4B33Q7-50XTXdqAGIg**

Besides its website, UNICOM has published a large number of recordings from the "community of expertise" about subjects related to IDMP implementation.

CTADHL

- **ctadhl.org**

CTADHL is part of Call to Action Inc, a 501c3 non-profit organisation. It delivers data and health literacy through global collaboration and partnerships. See IDMP training courses offered by CTADHL.

List of abbreviations

ABBREVIATION	COMPLETE FORM
ADE	adverse drug event
ATC	anatomical therapeutic chemical classification
API	application programming interface
EDQM	European Directorate for the Quality of Medicines & HealthCare
EMA	European Medicines Agency
EMVO	European Medicines Verification Organisation
EU-FMD	European Union falsified medicines directive
GTIN	global trade item number
IDMP	identification of medicinal products
ISO	international organisation for standardisation

ABBREVIATION	COMPLETE FORM
MA	marketing authorisation
MAH	marketing authorisation holder
MPD	medicinal product dictionary
MPID	medicinal product identifier
PCID	medicinal product package identifier
NCA	national competent authority
PhPID	pharmaceutical product identifier
UCUM	unified code for units of measure
WHO-UMC	Uppsala Monitoring Centre
WHO	World Health Organization

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List of definitions

TERMS	DEFINITION
administrable dose form	pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured items and their corresponding manufactured dose forms has been carried out
anatomical therapeutic chemical classification	classification of medicines that is controlled by WHO. It is used for statistical purposes for drug utilisation research in order to improve quality of medicine use
European Union falsified medicines directive	this directive introduces harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled
global trade item number	number that is used for the unique identification of trade items worldwide
GS1	neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain standards system in the world.
healthcare professional	person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care
healthcare provider	organisation that has been commissioned or contracted to deliver what the respective authority considers is health care services and / or support
manufacturer	organisation or establishment undertaking the manufacturing and other associated operations related to a medicinal product in a region

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TERMS	DEFINITION
marketing authorisation	authorisation issued from a medicines regulatory agency (NCA) that allows a medicinal product to be placed on the market
marketing authorisation holder	organisation that holds the authorisation for marketing a medicinal product in a region
medicinal product	any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct, or modify physiological functions
medicinal product dictionary	system that is specifically designed to support the prescription, dispensing and administration of medications in healthcare based on an accurate listing, description and identification of medicinal products
medicinal product identifier	unique identifier allocated to a medicinal product supplementary to any existing authorisation number as ascribed by a medicines regulatory agency (NCA) in a region
medicinal product package identifier	unique identifier allocated to a packaged medicinal product supplementary to any existing authorisation number as ascribed by a medicines regulatory agency (NCA) in a region
medicines regulatory agency	institutional body that, according to the legal system under which it has been established, is responsible for the granting of marketing authorisations, clinical trial authorisations and manufacturing authorisations for medicinal products
national competent authority	medicines regulatory agency (NCA) in a European Union member state

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TERMS	DEFINITION
patient	person in receipt of healthcare
pharmaceutical product	qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information
pharmaceutical product identifier	globally unique identifier assigned to the pharmaceutical product(s)
primary package	container or other form of packaging directly in contact with the medicinal product
public health	the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society
secondary package	packaging designed to contain one or more primary packages together with any protective materials where required
unified code for units of measure	code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units
Uppsala Monitoring Centre	independent centre for drug safety and scientific research working for a world where the safe and effective use of medicines is commonplace. UMC serves as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring. UMC operates the technical and scientific aspects of the WHO's worldwide pharmacovigilance network

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About the authors

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The authors wish to thank the reviewers within and outside the UNICOM project for their valuable input.

ANSWERS

Q1-1 What is IDMP? *(Tick what is RIGHT)*

- a) A set of ISO standards to improve the quality of medicinal products
- b) A project to support the global trade of medicinal products
- ✓ c) A set of ISO standards for the identification of medicinal products
- d) A regulation to prevent the illegal trade in falsified medicinal products

Q1-2 What does IDMP aim to provide? *(Tick what is RIGHT)*

- ✓ a) A set of identifiers to uniquely identify medicinal products across the globe
- b) A European classification of related groups of medicinal products
- c) A global (worldwide) medicinal product dictionary
- d) A global (worldwide) authorisation for medicinal products

Q1-3 What does IDMP stand for? *(Tick what is RIGHT)*

- a) International Definition of Medicinal Products
- b) ISO Drug and Medication Profiles
- ✓ c) Identification of Medicinal Products
- d) Interoperability of Data in Medication and Pharmacy

Q1-4 Which real-life situation will be addressed by IDMP? *(Tick what is RIGHT)*

- a) Facilitating reimbursement of medicinal product
- b) Making it easier to detect falsified medicines entering the legitimate supply chain of medicinal products
- ✓ c) Strengthening global pharmacovigilance: learning quickly from adverse drug events worldwide
- d) Reducing the number of variants (names, strengths, packages) of medicinal products that are authorized for use across the globe

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ANSWERS

Q2-1 Which of the following elements is relevant for the unique identification of a pharmaceutical product using a PhPID?
(Tick what is WRONG)

- a) Substances (including one or more active ingredients)
- b) Dose form
- c) Strength
- ✓ d) Packaging

Q2-2 Which of the following IDMP compliant identifiers can only be assigned ONCE to a medicinal product on a global level?
(Tick what is RIGHT)

- a) Medicinal Product Identification (MPID)
- b) Medicinal Product Package Identification (PCID)
- c) Global Trade Item Number (GTIN)
- ✓ d) Pharmaceutical Product Identifier (PhPID)

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ANSWERS

Q3-1 What is the difference between a Pharmaceutical Product (PhP) and a Medicinal Product (MP)? *(Tick what is WRONG)*

a) MP is specific to one jurisdiction (country), whereas a PhP may be the same in several countries

✓ b) Apart from having different identifiers, PhP and MP are synonyms

c) PhP can refer to multiple medicinal products as found on the global market, whereas MP only refers to one specific medicinal product on the global market

d) MPs are identified by national competent authorities and imply a marketing authorisation has been granted, whereas PhPs do not imply marketing authorisation

Q3-2 When is a new PhPID required, i.e. will it change when changes are made to a medicinal product? *(Tick what is RIGHT)*

a) When the brand name is changed

b) When the packaging of the product is changed

✓ c) When an ingredient is changed

d) When it is marketed in another country

Q3-3 Which level of the PhPID should be identical for it to be safe to interchange two medicinal products without changing the prescription? *(Tick what is RIGHT)*

a) PhPID Level 1 – substance(s) only

b) PhPID Level 2 – substance(s) and dose form

c) PhPID Level 3 – substance(s) and strength

✓ d) PhPID Level 4 – substance(s), dose form and strength

Q3-4 Which of these IDMP identifiers is assigned by the pharmaceutical company and not by the national competent authority? *(Tick what is RIGHT)*

a) Medicinal Product Identification (MPID)

b) Medicinal Product Package Identification (PCID)

✓ c) Global Trade Item Number (GTIN)

d) Pharmaceutical Product Identifier (PhPID)

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ANSWERS

Q4-1 What does the abbreviation MPD stand for? *(Tick what is RIGHT)*

a) Medicinal Product Definition

b) Marketing Pharmaceutical Database

✓ c) Medicinal Product Dictionary

d) Medical Product Directory

Q4-2 What information is contained in an MPD? *(Tick what is WRONG)*

a) The portfolio of identifiers for a medicinal product

✓ b) The prescription and dispensation record for a medicinal product

c) The regulated product information for a medicinal product

d) Recommendations on the dose calculation for prescription

Q4-3 At what level will an MPD be maintained? *(Tick what is RIGHT)*

a) At the local level of a hospital or pharmacy

✓ b) At the level of the region or jurisdiction of the healthcare system

c) At the level of the pharmaceutical company

d) At the level of a health insurance company

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ANSWERS

Q5-1 What information does a healthcare professional need when prescribing medication? *(Tick what is WRONG)*

a) The PhPID for the medicinal product
b) The EDQM Standard Term for the dose form of the product
✓ c) The GTIN as visible in the DataMatrix on the secondary packaging of the product
d) Coded allergy information from the Electronic Health Record of the patient

Q5-2 What information does the medicinal product dictionary provide to the prescriber? *(Tick what is RIGHT)*

a) The condition the patient presents, for which the medication is to be prescribed
✓ b) The recommended dose calculation for the medicinal product
c) Prior adverse drug events the patient has experienced when taking medication
d) The list of current medication the patient is taking that may cause interactions with the medicinal product to be prescribed

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ANSWERS

Q6-1 Which of the following objectives is within scope for IDMP? ***(Tick what is WRONG)***

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- **d)** Pharmaceutical Product Identifier (PhPID) in combination with the identification of the marketing authorisation holder

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