



Norwegian Medical
Products Agency

PhPID and IDMP/EMA SPOR in EHDS – Safe exchange of patient medication data

The value of ISO IDMP PhPID in clinical healthcare – within a country, cross border and in-hospital use

HL7 Europe Working Group Meeting Cologne, Germany, 1-5 December 2025
Bernd Moeske and Elin May Merry, NOMA, Norway

The Norwegian Medical product Agency (NOMA) and IDMP implementation



- NOMA has provided electronic medicinal product data to Norway's health sector since 2008.
- Since 2021, the SAFEST project has been transforming legacy medicinal-product data and referentials into ISO IDMP / FHIR, aligned with the EU implementation guide.
- National PhPID design complete and UMC/NOMA pilot (API) used to compare national and global PhPIDs
- Full IDMP & PhPID production rollout planned for 2026.

Presenters:

Representing clinical requirements for IDMP at NOMA and
Testing the UMC PhPID pilot (API)



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Information architect

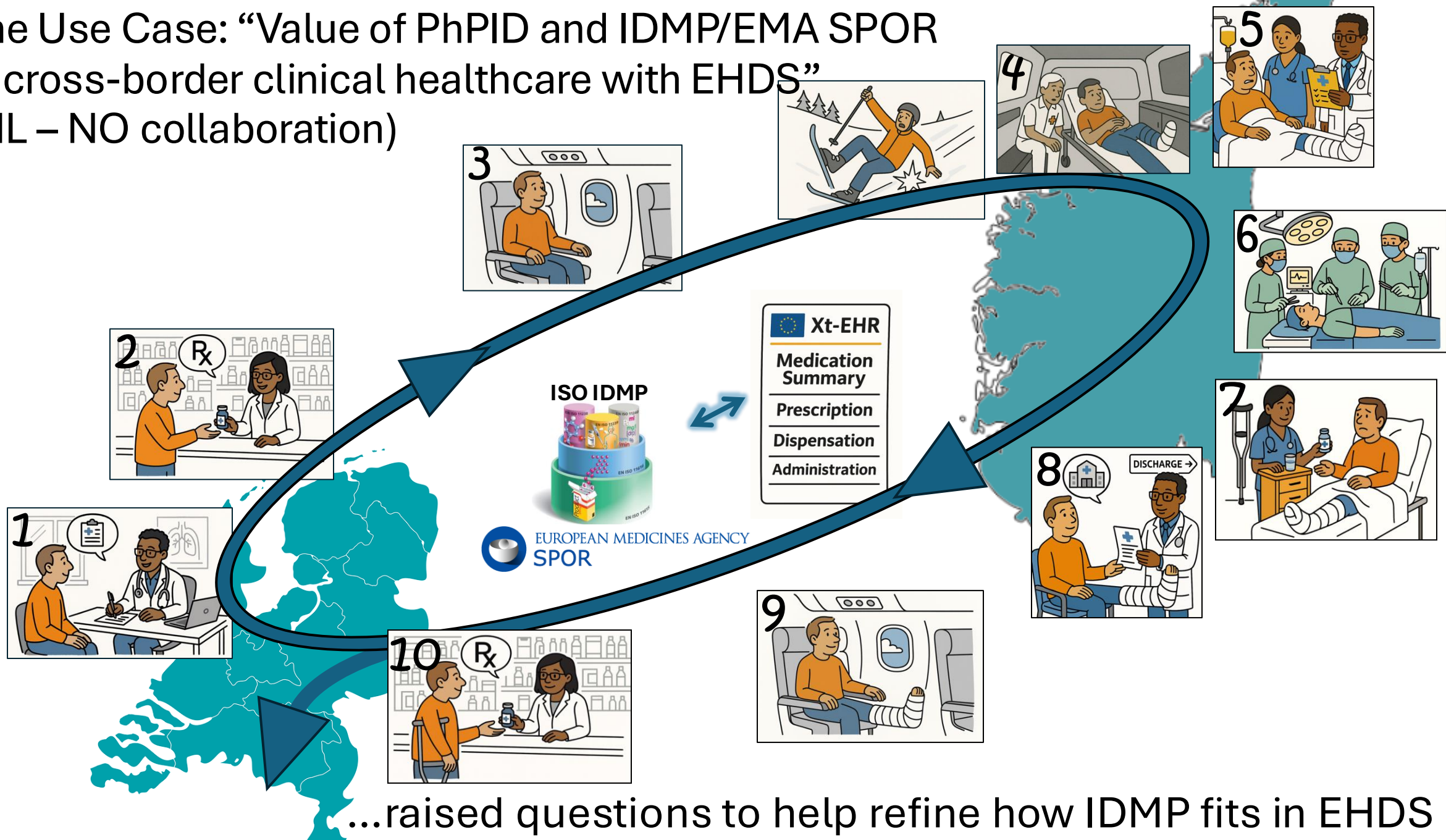
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The Use Case: “Value of PhPID and IDMP/EMA SPOR in cross-border clinical healthcare with EHDS” (NL – NO collaboration)



The challenge: To safely identify medication in clinical use cases using PhPID and IDMP/EMA SPOR

The purpose of EHDSMedication is to enable safe and unambiguous identification of medicinal products in clinical use cases across the EU/EEA

EU eHealth Network guidelines, Article 11 on Terminology and data

“ISO IDMP suites of standards should be used for medicinal product identification. The identifiers for pharmaceutical product, PhPID, as identifier, once it has become available by the EMA and NCAs joint SPOR systems”

Assumption in this presentation

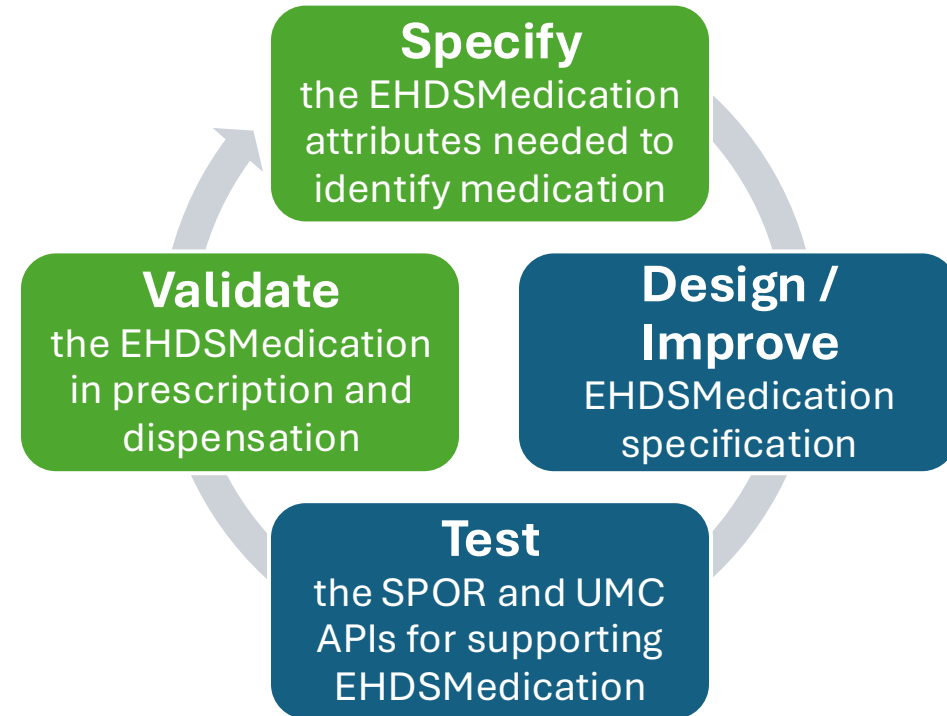
EHDSMedication should support the use of PhPID and IDMP/EMA SPOR identifiers and attributes for cross-border health care

Objective of the presentation

Move toward a common EU specification / implementation guide on how PhPID and IDMP/EMA SPOR data should be used in the EHDSMedication profile

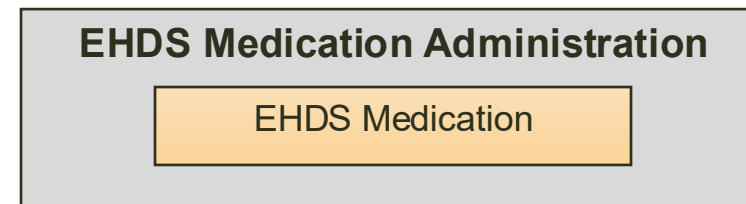
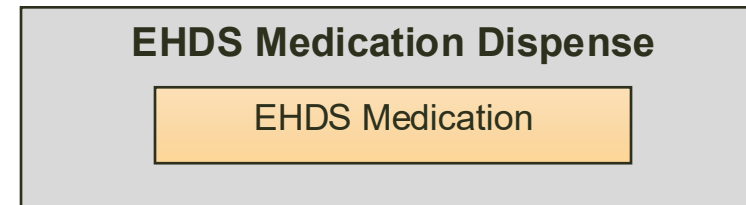
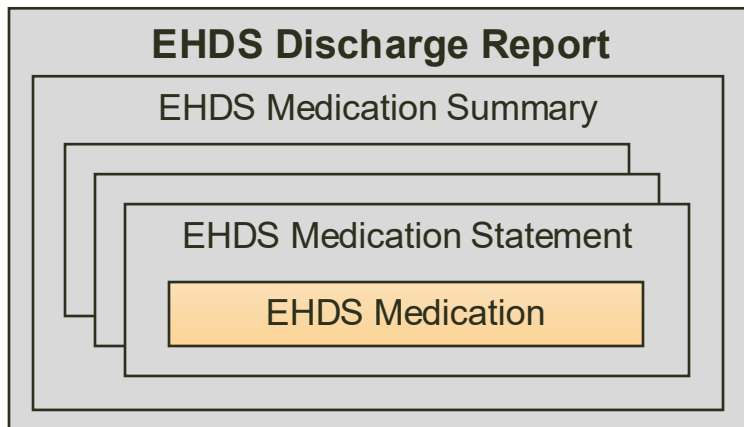
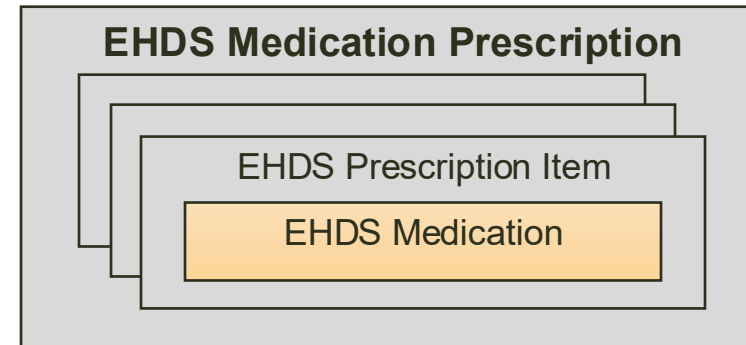
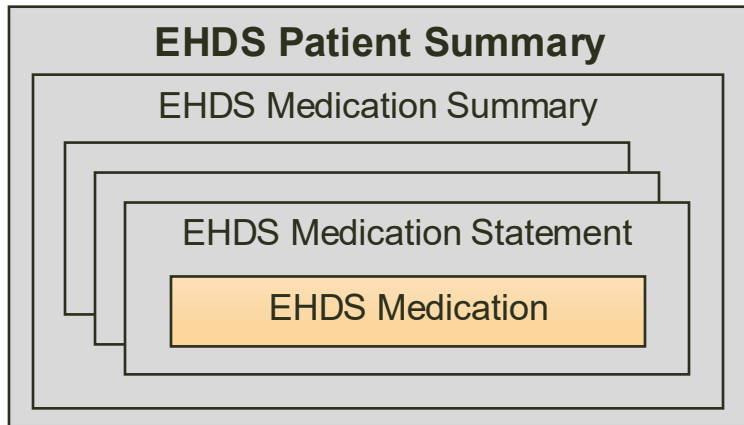
Specifying and identifying medication: Focus on the clinical needs

- We use clinical use cases combined with real medication data to **validate** the existing model (v0.2.1.) and to ask questions aiming at improving the **requirements** and **specification**
- This presentation focuses on how SPOR/PhPID data can be used to satisfy clinical needs by deciding on:
 - How to use UMC PhPID and SPOR data to ensure successful implementation of EHDS
 - How to ensure common implementations across jurisdictions
 - How to enable validation and certification for EHDS implementations
- Supporting the iterative process of specifying, implementing, testing and validating



EHDS: Medication-Related FHIR Profiles

The EHDS Medication resource is pivotal for identifying medicinal products in clinical use cases. Cross-border and within a country; in hospitals, pharmacies and primary healthcare



Name	Card.	Type
EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
deviceQuantity	1..1	Quantity
device[x]	1..1	
characteristic	0..*	Base
batch	0..1	Base
lotNumber	0..1	string
expirationDate	0..1	dateTime

Product / package identifiers (PMS ID, MPID, PCID),
Product grouping / virtual product identifiers (PhPID)

Classifications such as ATC, orphan drug etc

Item: Can be used to identify the medicinal product / package when the identifiers are unknown or not related to any products
May be multiple items, e.g. for combination- or multi-strength packages

Product attributes such as

- Name
- Dose Form – Authorised and Manufactured dose form
- Ingredient(s), each containing
 - Substance
 - Strength
 - Basis of Strength Substance (BoSS)
- Unit of Presentation

Can be used to **identify the product** instead of using MPID / PhPID

Packaging attributes such as

- PackSize, containedQuantity and amount
- Package Type
- Batch

Can be used to **identify the package** instead of using PCID

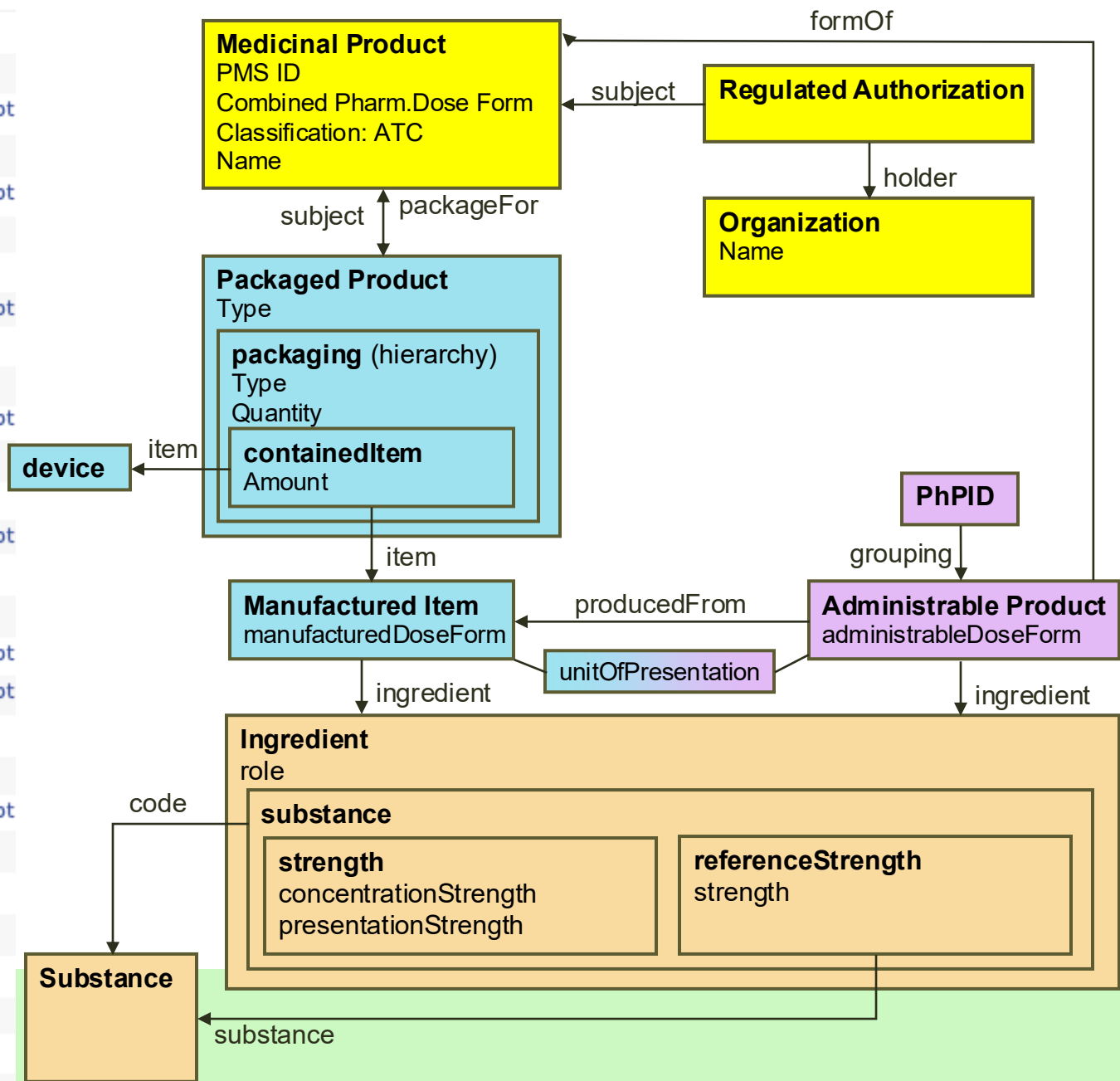
Medical device information

Can be used to **identify the medication / package** according to the device / container such as pen or syringe.

Product characteristics

Other features of the product. Identified by type of characteristic and value.

Name	Card.	Type
EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
deviceQuantity	1..1	Quantity
device[x]	1..1	
characteristic	0..*	Base
batch	0..1	Base
lotNumber	0..1	string
expirationDate	0..1	dateTime



Use Case 1: Prescribing a branded Product

1 Patient consultation in primary healthcare and medication reconciliation



E-PRESCRIPTION

Thomas

MEDICATION

Selokeen ZOC prolonged release tablet

1 tablet per day



PhPID

C

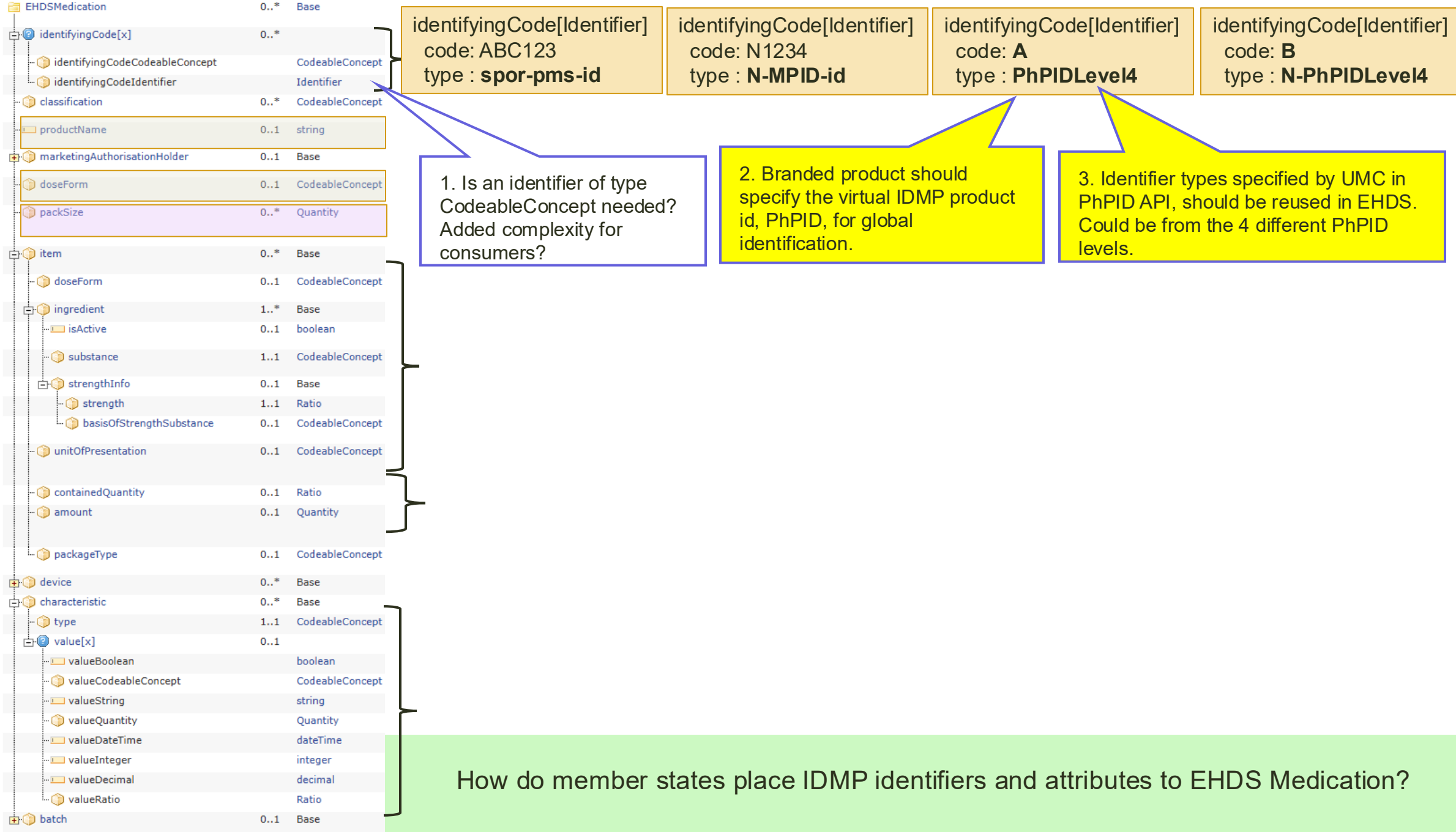
Global and National PhPID for Metoprolol

Products	Active Substance + strength	BOSS + strength	Active Moiety + strength	PhPID GLOBAL level 4	PhPID NOMA level 4	PhPID Netherlands Level 4
Metoprolol Sandoz prolonged release tabl 100 mg	Metoprolol suksinat 95 mg	Metoprolol tartrate 100 mg (BOSS)	Metoprolol 78,08 mg	A	B	C
Metoprolol Medical Valley prolonged release tabl 100 mg	Metoprolol suksinat 95 mg	Metoprolol tartrate 100 mg (BOSS)	Metoprolol 78,08 mg	A	B	C
Bloxazoc KRKA prolonged release tabl 100 mg	Metoprolol suksinat 95 mg	Metoprolol tartrate 100 mg (BOSS)	Metoprolol 78,08 mg	A	B	C
Selo-Zok Orifarm prolonged release tabl 100 mg	Metoprolol suksinat 95 mg	Metoprolol tartrate 100 mg (BOSS)	Metoprolol 78,08 mg	A	B	C
Selo-Zok Recordati prolonged release tabl 100 mg	Metoprolol suksinat 95 mg	Metoprolol tartrate 100 mg (BOSS)	Metoprolol 78,08 mg	A	B	C

Same product in the groups for national and global PhPID – for Metoprolol, 5 brands grouped by Active Substance globally and Active Moiety nationally, however the **groups are 1:1 and can be easily mapped**.

This is a “special case” Medication, since the authorized strength is referring to substance (BOSS) that is not part of the product ingredient. However, this medication is frequently used and common in many EU countries.

The global PhPID can easily be added to any prescription, dispensation, administration or medication summary and will refer to the same products in various countries



EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

ATC=«C07AB02, Metoprolol»

productName: Solokeen ZOC prolonged release tablet 100 mg
doseForm: «Prolonged release tablet» (SPOR RMS ID 100000073683)

Item
doseForm=«Prolonged release tablet» (SPOR RMS ID 100000073683)
ingredient.substance=“Metoprolol suksinat” (SPOR SMS ID XXXXXXXXAAAA)
ingredient.strength=«100 mg»
Ingredient.basisOfStrengthSubstance=“Metoprolol tartrate” (SPOR SMS ID XXXXXXXXAAAAAA)
unitOfPresentation=«Tablet»

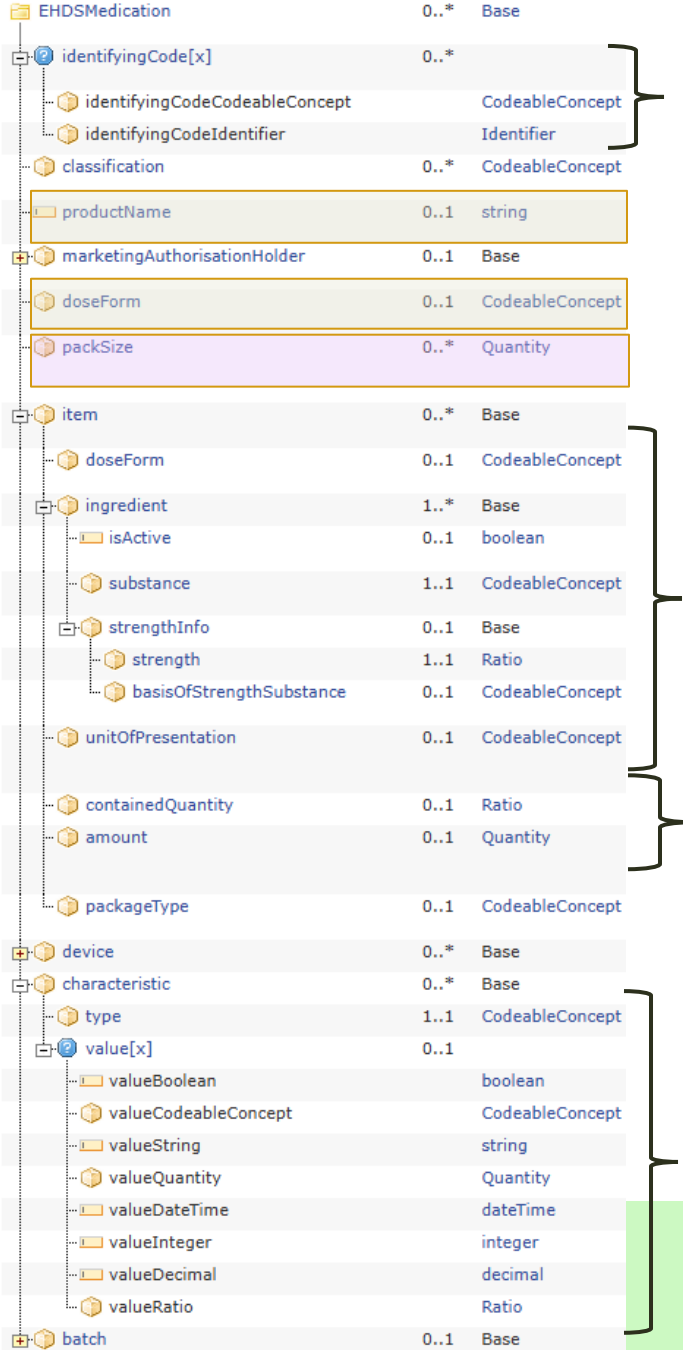
7. Strength of active substance or strength of BOSS (authorised strength) – which is required or preferred?

4. Authorised Dose Form? (Binding to all RMS Pharmaceutical Dose Form types: Pharmaceutical Dose Form, Combined Pharmaceutical Dose Form, Combination Pack, Combined Term)

5. Manufactured or Administrable Dose Form? (Binding RMS Type Pharmaceutical Dose Form)

6. Active Substance? Using the SPOR SMS ID?

How do member states place IDMP identifiers and attributes to EHDS Medication?



8. Where to place PhPID properties, dose form characteristics, substance and strength used for PhPID?

PhPID properties:

Administrable dose form characteristics

basicDoseForm: tablet

IntendedSite: oral

administrationMethod: swallowing

releaseCharacteristics: prolonged

Substance and strength:

substance: Metoprolol suksinat (GSID+SMSID)

strength: 95 mg

reference substance: Metoprolol

reference strength: 78.08 mg

9. UMC API will return GSID for the substance, however the EHDS ingredient uses SPOR SMS ID?

How do member states place IDMP identifiers and attributes to EHDS Medication?

Use Case 2: Prescribing a virtual Product, based on IDMP PhPID

1 Patient consultation in primary healthcare and medication reconciliation



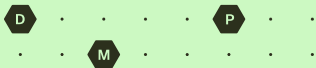
Variations in global and National PhPID for Prasugrel

Products	Active Substance + strength	Active Moiety + strength	PhPID GLOBAL level 4	PhPID NOMA level 4	PhPID Netherlands Level 4
Efient Orifarm tabl 10 mg	Prasugrel hydrochloride 10,98 mg	Prasugrel 10 mg (BOSS)	A	D	E
Efient Substipharm tabl 10 mg	Prasugrel hydrochloride 10.98 mg	Prasugrel 10 mg (BOSS)	A	D	E
Prasugrel Krka tabl 10 mg	Prasugrel 10 mg	Prasugrel 10 mg (BOSS)	B	D	E
Prasugrel Viatris tabl 10 mg	Prasugrel besilat 14,24 mg	Prasugrel 10 mg (BOSS)	C	D	E

Global Deviation – for Prasugrel , 1 brands grouped by Active Moiety, 2 grouped by the salt Prasugrel hydrochloride and 1 by salt Prasugrel besilat. All have Active Moiety as BOSS.

This is both due to actual difference in ingredients and variation in manufacturers details in SPC. They have the same clinical effect and are interchangeable.

Due to different Active Substance specified in SPC, they will get different Global PhPID, but national PhPID in Norway and in The Netherlands will be the same for all products (mapping n:1)



EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

identifyingCode[Identifier]
code: **A**
type : **PhPIDLevel4**

identifyingCode[Identifier]
code: **E**
type : **N-PhPIDLevel4**

10. The virtual product, represented by the IDMP PhPID, is specified as global identification of a product grouping, not as a classification.

Identifier types specified by UMC in PhPID API, reused in EHDS

11. Can there be multiple global PhPIDs, for example representing all variations of PhPID A, B and C? E.g. If a local PhPID is represented by several global PhPIDs
However, that requires also information on what is primary PhPID, used e.g. in PhPID properties?

How do member states place IDMP identifiers and attributes to EHDS Medication?

EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

ATC=«B01AC22, Prasugrel»

productName:
doseForm:

Item

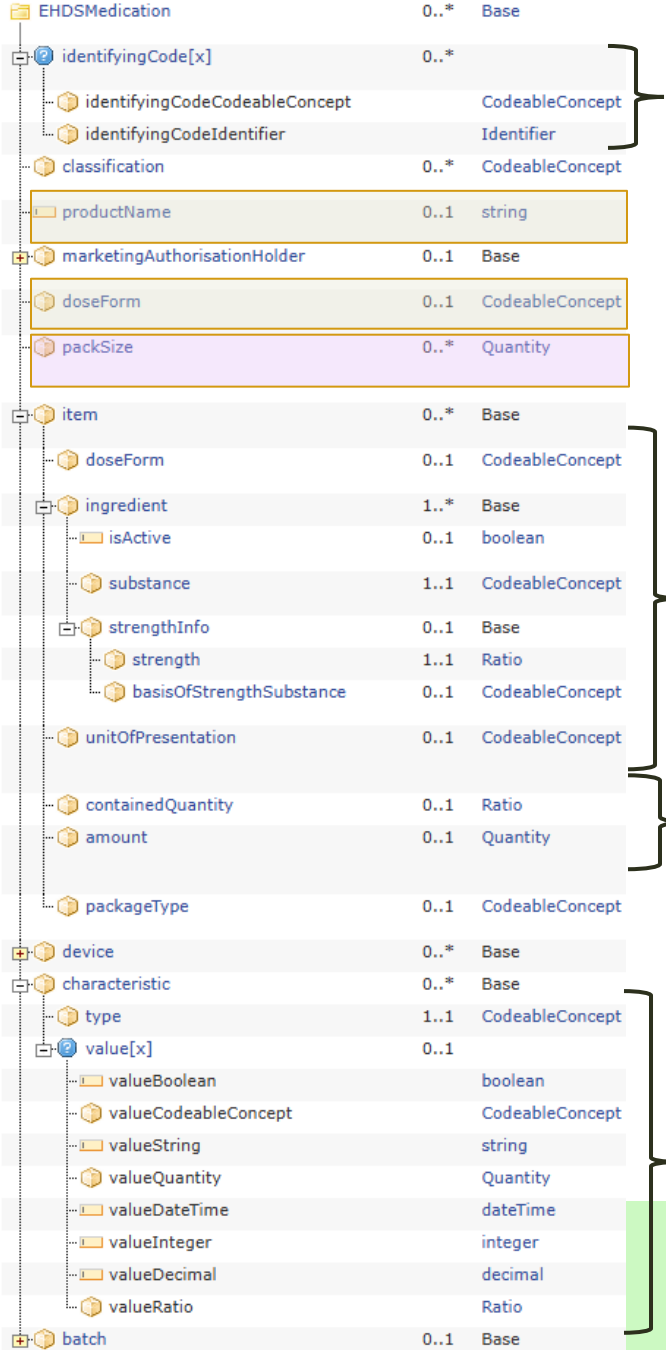
Packaging attributes – N/A

12. There is no global name for PhPID, but it could include a local name created by the subscriber of the prescription? For example, «Prasugrel tablet 10 mg», local language

13. The PhPID has no (pharmaceutical) dose form, only administrable dose form attributes: Administration Method, Basic Dose Form, Intended Site, Release Characteristics – the EHDSMedication does not provide attributes for these.

14. “Item” is related to real branded products and is not a good fit for the PhPID attributes. So assume empty for virtual product with PhPID?

How do member states place IDMP identifiers and attributes to EHDS Medication?



UMC API will return GSID for the substance, however the EHDS ingredient uses SPOR SMS ID?

16. It might be useful to align the structure for reference substance and strength according to ISO IDMP?

15. If multiple PhPID allowed, one property pr PhPID? dose form characteristics, substance and strength used for PhPID?

PhPID properties:
Administrable dose form characteristics
 basicDoseForm: tablet
 intendedSite: oral
 administrationMethod: swallowing
 releaseCharacteristics: conventional
Substance and strength:
 substance: Prasugrel hydrochloride (GSID+SMSID)
 strength: 10,98 mg
 reference substance: Prasugrel
 reference strength: 10 mg

How do member states place IDMP identifiers and attributes to EHDS Medication?

Use Case 3: dispense and administration of injection

4



The ambulance journey to the hospital takes a long time, and to help Thomas with the severe pain, he is **injected with**

Oxycodone 10 mg/ml, 10 mg (1 ml) dose, with MPID and PhPID A.

The administration is recorded and sent to the preregistered hospital journal to prepare for Thomas' admission. Thomas personal identification details are registered and sent along with the medicinal administration.

Injection and Infusion are assigned seperate national PhPIDs.

Product	Authorized doseform	Authorized strength	Active substance	Active Moiety	Administrable doseform	PhPID Strength	Global PhPID	NOMA PhPID	Nether lands PhPID
Oxycodone Hameln	solution for Injection and infusion	10 mg/ml	Oxycodone hydrochloride (BOSS)	Oxycodone	Solution for injection	8,96 mg/ml	C	A	D
					Solution for infusion	8,96 mg/ml		B	E

EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

identifyingCode[Identifier]
code: ABC345
type : **spor-pms-id**

identifyingCode[Identifier]
code: NOMA56678
type : **NOMA-MPID-id**

identifyingCode[Identifier]
code: **A**
type : **NOMA-PhPIDLevel4**

identifyingCode[Identifier]
code: **C**
type : **PhPIDLevel4**

identifyingCode[Identifier]
code: NOMA56678
type : **NOMA-PCID-id**

Identifier types specified by UMC in PhPID API, reused in EHDS

The virtual product, represented by the IDMP PhPID, is specified as global identification.

17. If the PCID is Identifying the product, the MPID and PhPID should also be included as Identifiers?

How do member states place IDMP identifiers and attributes to EHDS Medication?

EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

ATC=«N02AA05, Oxycodone»

Authorised Dose Form?
(Binding RMS Type Pharmaceutical Dose Forms)

productName: Oxycodone Hameln solution for inj./inf. 10 mg/ml
doseForm: «solution for infusion/injection» (SPOR RMS ID 100000074038)

Manufactured or
Administrable Dose Form?
(RMS Type Pharmaceutical
Dose Form)

Item
doseForm=«Solution for injection» (SPOR RMS ID 100000073863)
ingredient.substance=“Oxycodone hydrochloride” (SPOR SMS ID 100000078523)
ingredient.strength=«10 mg/ml»
Ingredient.basisOfStrengthSubstance=“Oxycodon” (SPOR SMS ID 100000078523)
unitOfPresentation=«Ampule»

Active Substance?
Using the SMS ID?

Strength of active substance or strength of
BOSS (authorised strength) (prefeered)?

How do member states place IDMP identifiers and attributes to EHDS Medication?

EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

18. Not precise enough specification of the requirement related to overall amount, e.g. 3 bottles of 100 ml, or 300 ml. Binding Description: EHDS to use Unit of Measure and Unit of presentation or UCUM for units of measure?
packSize is not part of the Packaged Product Definition in IDMP

packSize: The packSize is not supported by IDMP. It has been suggested part of Packaged Product, but not yet defined. NOMA supports the details in description «1 x 10 x 1 ml Ampulle of glass».

19. The naming of these terms are opposite of those in Packaged Product.
PackagedProduct.packaging.quantity is of type integer and is the number of package items of that packaging level.
PackagedProduct.packaging.containedItem.amount type Quantity "The number of this type of item within this packaging or for continuous items such as liquids it is the quantity, for example 25ml.

containedQuantity: «1 ml»
amount: «10 ampules»
packageType: «Ampule»

21. The mapping between EHDSMedication.packageType and the IDMP Packaged Product is ambiguous. Which package type should this refer to? Packaged Product or package.type? If latter, at which level of packaging?

batch: Batch information of a *medicinal product package*. Typically recorded during dispense or administration, rarely known or relevant for a prescription/request

20. Should only lotNumber and expiry date be part of transaction information? Clinical requirements for GTIN, production date, serialNumber?

How do member states place IDMP identifiers and attributes to EHDS Medication?

EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
characteristic	0..*	Base
type	1..1	CodeableConcept
value[x]	0..1	
valueBoolean		boolean
valueCodeableConcept		CodeableConcept
valueString		string
valueQuantity		Quantity
valueDateTime		dateTime
valueInteger		integer
valueDecimal		decimal
valueRatio		Ratio
batch	0..1	Base

UMC API will return GSID for the substance, however the EHDS ingredient uses SPOR SMS ID?

22. How and when should the device be specified? Doseform type combined term? To distinguish f ex between syringe and pen?

We might also need a structure for reference substance and strength according to ISO IDMP

If multiple PhPID allowed, one property pr PhPID? dose form characteristics, substance and strength used for PhPID?

PhPID properties:
Administrable dose form characteristics
 basicDoseForm: tablet
 intendedSite: oral
 administrationMethod: swallowing
 releaseCharacteristics: prolonged
Substance and strength:
 substance: Oxycodone hydrochloride (GSID+SMSID)
 strength: 8,96 mg
 reference substance: Oxycodone
 reference strength: 10 mg

How do member states place IDMP identifiers and attributes to EHDS Medication?



Norwegian Medical
Products Agency

Discussion

Identifier
Product attributes
PhPID properties
Packaging (batch, device)

Questions for discussion – Identifier

Qnr	Question	Use Case	Category
1 (OUT)	Is an identifier of type CodeableConcept needed? Added complexity for consumers?	1 Prescribing a branded Product	Identifier
2	Branded product should specify the virtual IDMP product id, PhPID, for global identification.	1 Prescribing a branded Product	Identifier
10	The virtual product, represented by the IDMP PhPID, is specified as global identification of a product grouping, not as a classification.	2 Prescribing a virtual product, PhPID	Identifier
17	If the PCID is Identifying the product, the MPID and PhPID should also be included as Identifiers?	3 Dispense and administration of injection	Identifier
3	Identifier types specified by UMC in PhPID API, should be reused in EHDS. Could be from the 4 different PhPID levels.	1 Prescribing a branded Product	Identifier
11	Can there be multiple global PhPIDs, for example representing all variations of PhPID A, B and C? E.g. If a local PhPID is represented by several global PhPIDs However, that requires also information on what is primary PhPID, used e.g. in PhPID properties?	2 Prescribing a virtual product, PhPID	Identifier

Questions for discussion – Product attributes / Item

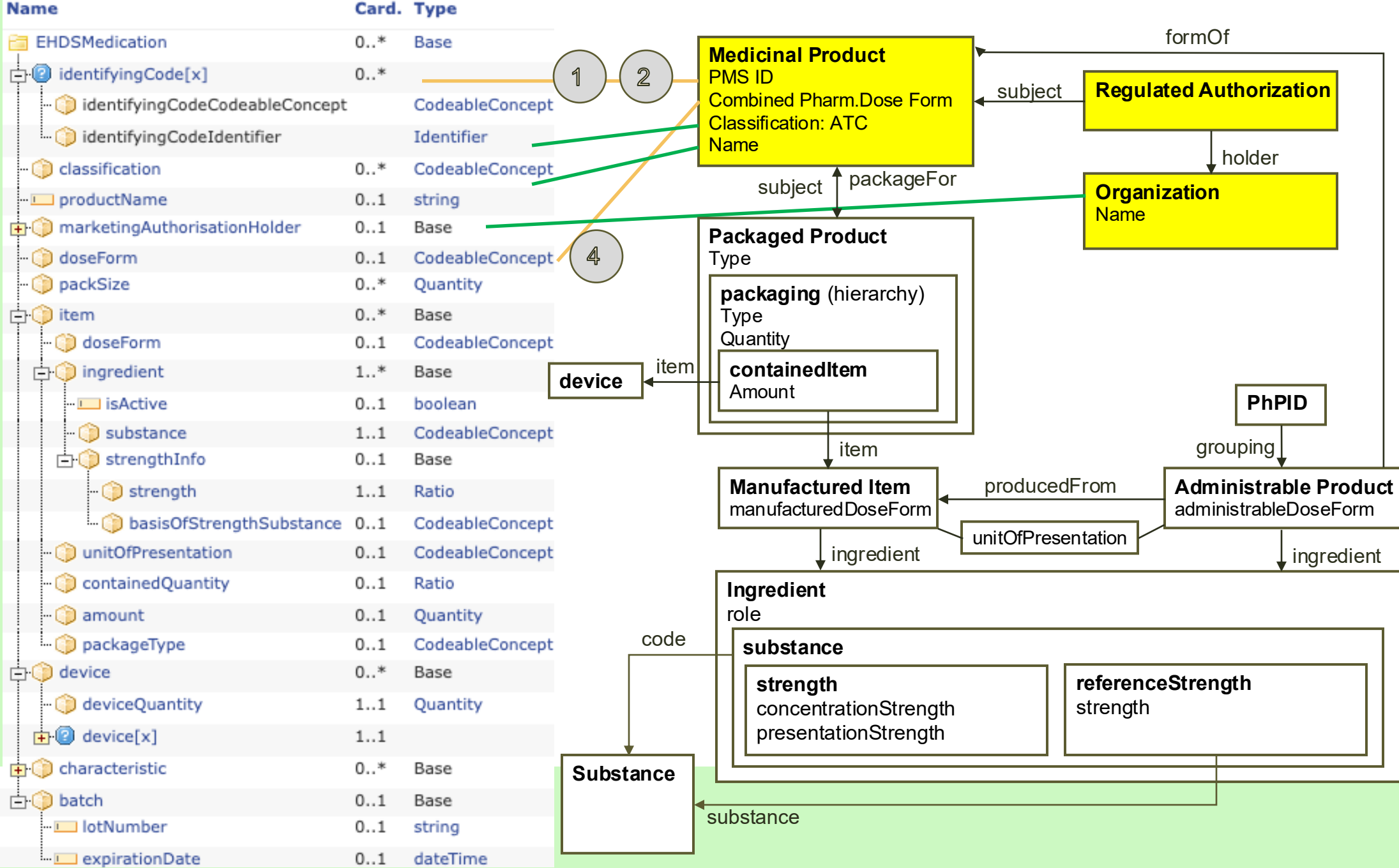
Qnr	Question	Use Case	Category
4	Authorised Dose Form? (Binding to all RMS Pharmaceutical Dose Form types: Pharmaceutical Dose Form, Combined Pharmaceutical Dose Form, Combination Pack, Combined Term)	1 Prescribing a branded Product	Product attribute
5	Manufactured or Administrable Dose Form? (Binding RMS Type Pharmaceutical Dose Form)	1 Prescribing a branded Product	Product attribute
6	Active Substance? <i>Using the SPOR SMS ID?</i>	1 Prescribing a branded Product	Product attribute
7	Strength of active substance or strength of BOSS (authorised strength) – which is required or preferred?	1 Prescribing a branded Product	Product attribute
12	There is no global name for PhPID, but it could include a local name created by the subscriber of the prescription? For example, «Prasugrel tablet 10 mg», local language	2 Prescribing a virtual product, PhPID	Product attribute
14	“Item” is related to real branded products and is not a good fit for the PhPID attributes. So assume empty for virtual product with PhPID?	2 Prescribing a virtual product, PhPID	Product attribute

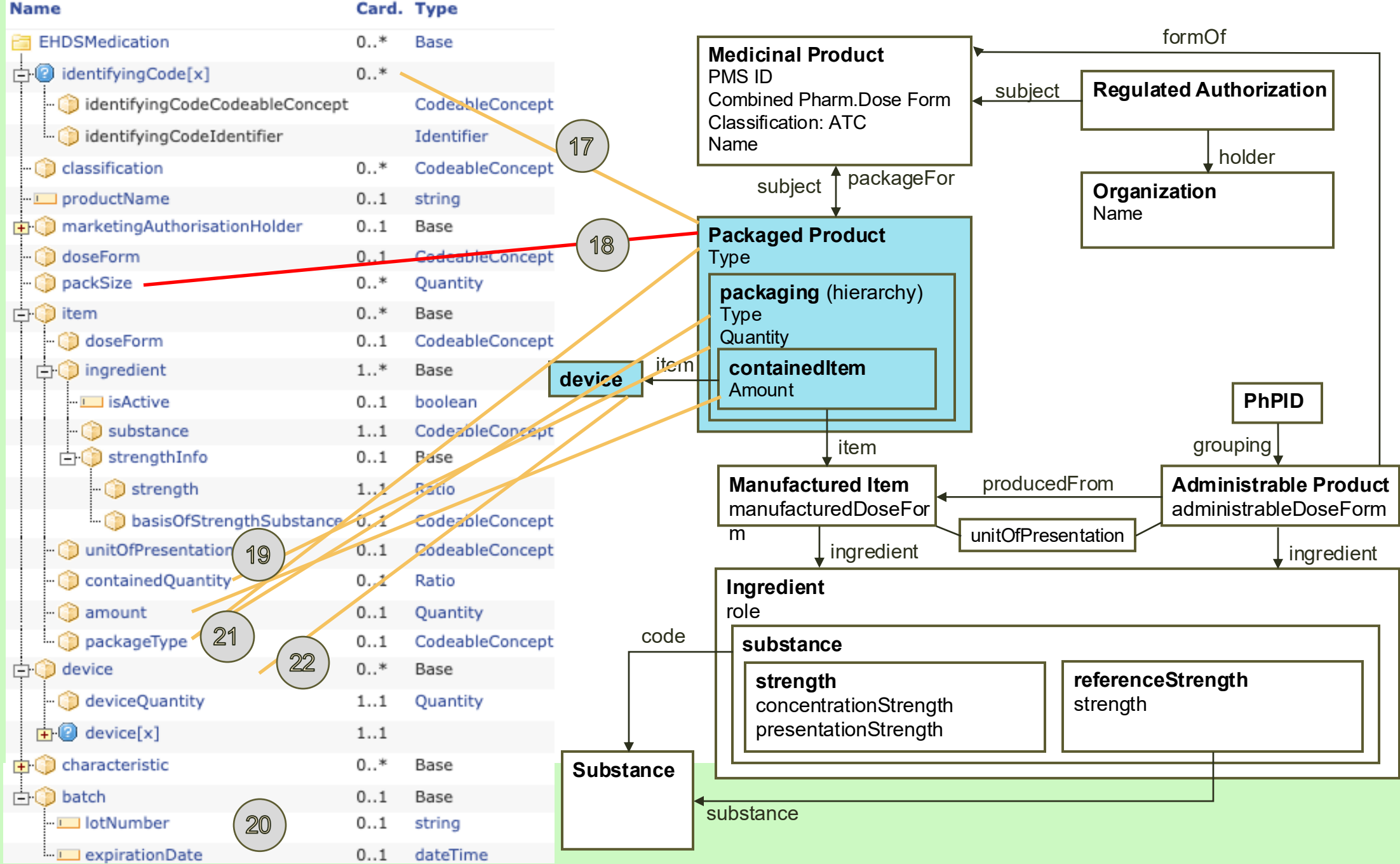
Questions for discussion – PhPID Properties

Qnr	Question	Use Case	Category
8	Where to place PhPID properties, dose form characteristics, substance and strength used for PhPID?	1 Prescribing a branded Product	PhPID properties
13	The PhPID has no (pharmaceutical) dose form, only administrable dose form attributes: Administration Method, Basic Dose Form, Intended Site, Release Characteristics – the EHDS Medication does not provide attributes for these.	2 Prescribing a virtual product, PhPID	Product attribute
9 (OUT)	UMC API will return GSID for the substance, however the EHDS ingredient uses SPOR SMS ID. UMC API will soon return also SMSID and can be used in EHDS.	1 Prescribing a branded Product	PhPID properties
15	If multiple PhPIDs are allowed, should there be one set of attributes per PhPID? Dose form characteristics, substance and strength used for PhPID?	2 Prescribing a virtual product, PhPID	PhPID properties
16	It might be useful to align the structure for reference substance and strength according to ISO IDMP?	2 Prescribing a virtual product, PhPID	PhPID properties

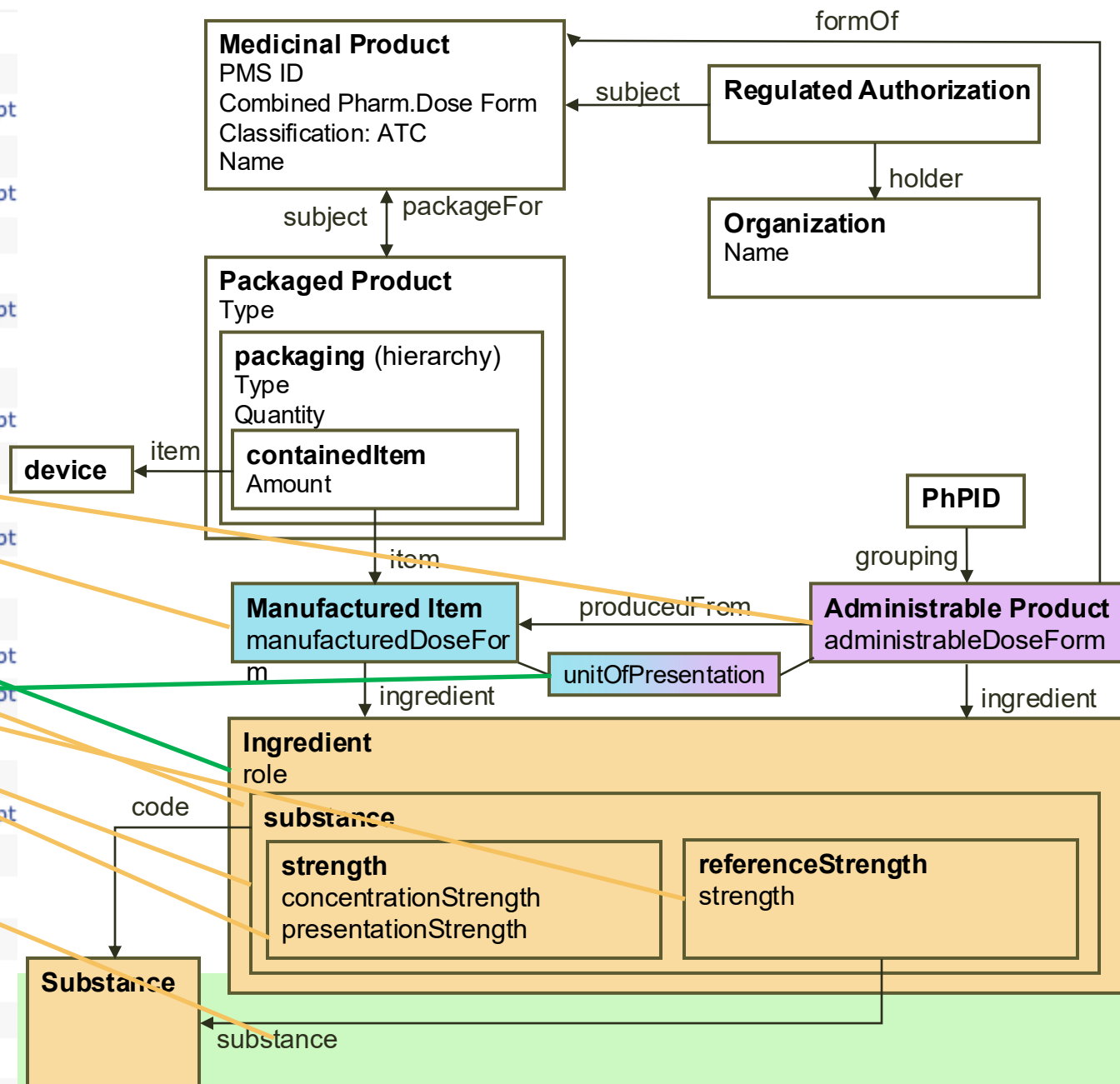
Questions for discussion – Packaging (Batch, Device)

Qnr	Question	Use Case	Category
18	Not precise enough specification of the requirement related to overall amount, e.g.. 3 bottles of 100 ml, or 300 ml. Binding Description: EHDS to use Unit of Measure and Unit of presentation or UCUM for units of measure? packSize is not part of the Packaged Product Definition in IDMP	3 Dispense and administration of injection	Packaging attributes
19	The naming of these terms are opposite of those in Packaged Product. PackagedProduct.packaging. quantity is of type integer and is the number of package items of that packaging level. PackagedProduct.packaging.containedItem. amount type Quantity “The number of this type of item within this packaging or for continuous items such as liquids it is the quantity, for example 25ml.	3 Dispense and administration of injection	Packaging attributes
20	Should only lotNumber and expiry date be part of transaction information? Clinical requirements for GTIN, production date, serialNumber?	3 Dispense and administration of injection	Packaging attributes
21	The mapping between EHDSMedication.packageType and the IDMP Packaged Product is ambiguous. Which package type should this refer to? Packaged Product or package.type? If latter, at which level of packaging?	3 Dispense and administration of injection	Packaging attributes
22	How and when should the device be specified? Doseform type combined term? To distinguish f ex between syringe and pen?	3 Dispense and administration of injection	Device





Name	Card.	Type
EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
deviceQuantity	1..1	Quantity
device[x]	1..1	
characteristic	0..*	Base
batch	0..1	Base
lotNumber	0..1	string
expirationDate	0..1	dateTime



Name	Card.	Type
EHDSMedication	0..*	Base
identifyingCode[x]	0..*	
identifyingCodeCodeableConcept		CodeableConcept
identifyingCodeIdentifier		Identifier
classification	0..*	CodeableConcept
productName	0..1	string
marketingAuthorisationHolder	0..1	Base
doseForm	0..1	CodeableConcept
packSize	0..*	Quantity
item	0..*	Base
doseForm	0..1	CodeableConcept
ingredient	1..*	Base
isActive	0..1	boolean
substance	1..1	CodeableConcept
strengthInfo	0..1	Base
strength	1..1	Ratio
basisOfStrengthSubstance	0..1	CodeableConcept
unitOfPresentation	0..1	CodeableConcept
containedQuantity	0..1	Ratio
amount	0..1	Quantity
packageType	0..1	CodeableConcept
device	0..*	Base
deviceQuantity	1..1	Quantity
device[x]	1..1	
characteristic	0..*	Base
batch	0..1	Base
lotNumber	0..1	string
expirationDate	0..1	dateTime

