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WP 1: Identifiers - Medicinal Product, Marketing Authorization, Pharmaceutical Product and Package Medicinal Product

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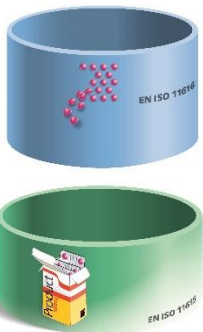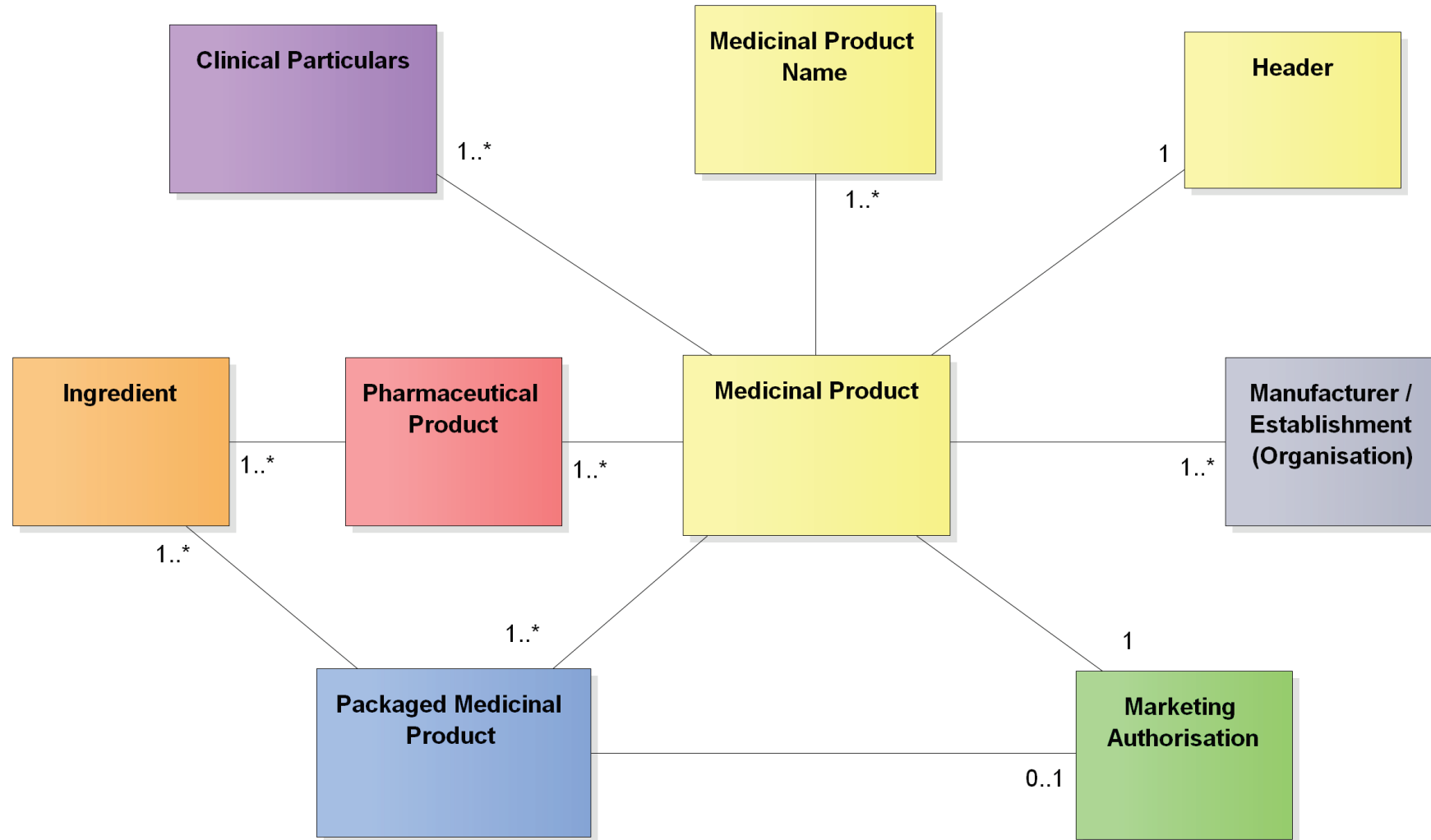jean-gonzague.x.fontaine@gsk.com
ISO TC 215 WG 6 « Pharmacy and Medicines Business » Expert

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► Opinions and positions expressed in these slides doesn't represent GSK official opinion or position, but only Jean-Gonzague Fontaine expertise.

► DB: Database

► DCID: Data Carrier Identifier

► EMVO: European Medicines Verification Organisation

► EMVS: European Medicines Verification System

► FMD: Falsified Medicine Directive

► GTIN: Global Trade Identifier Number

► IDMP: Identification of Medicinal Product

► MAH: Marketing Authorisation Holder

► MMP: Multi-Market Pack

► MP: Medicinal Product

► MPID: Medicinal Product Identifier

► NCA: National Competent Authority

► NMVS: National Medicines Verification System

► NTIN: National Trade Identifier Number

► OBP: On-boarding Partner

► PCID: Package Identifier

► PhPID: Pharmaceutical Product Identifier

► PIC: Package Item Container

► PMP: Package Medicinal Product

► RIMS: Regulatory Information Management System

► SC: Supply Chain

► SKU: Stock Keeping Unit

► SMP: Single-Market Pack

► SPOR: Substance, Product, Organisation and Referential

Medicinal Product, Marketing Authorization, Pharmaceutical Prod. & Package Medicinal Prod.

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Clinical Particulars

Medicinal Product Name

Header

1..*

1..*

1

Ingredient

Pharmaceutical Product

Medicinal Product

Manufacturer / Establishment (Organisation)

1..*

1..*

1..*

1..*

1..*

Packaged Medicinal Product

Marketing Authorisation

1

0..1

EN ISO 11616

EN ISO 11615

ISO 11615:2017

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

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Reconciliate data domains with independant lifecycle:

- regulatory
- manufacturing (down to SKU/SKU identification in the supply chain and Manufactured Item)
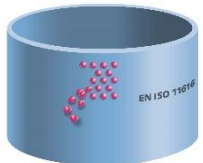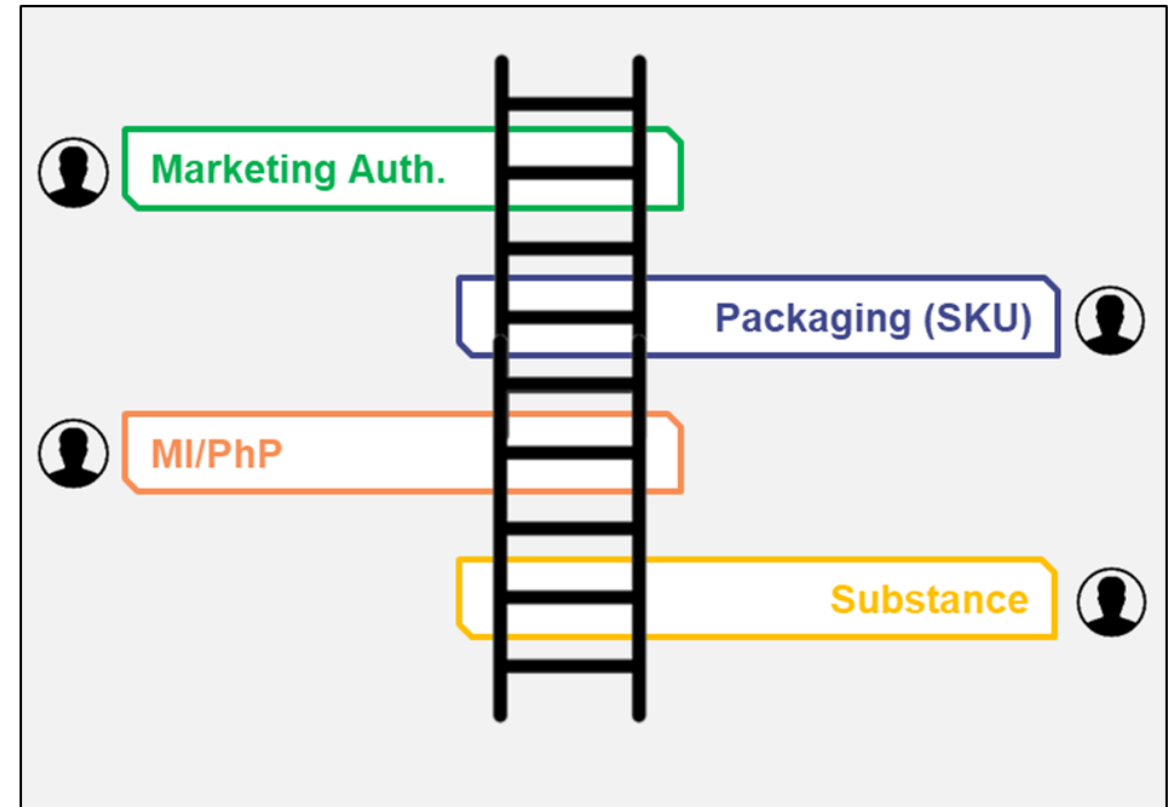- formulation and substance/CMC

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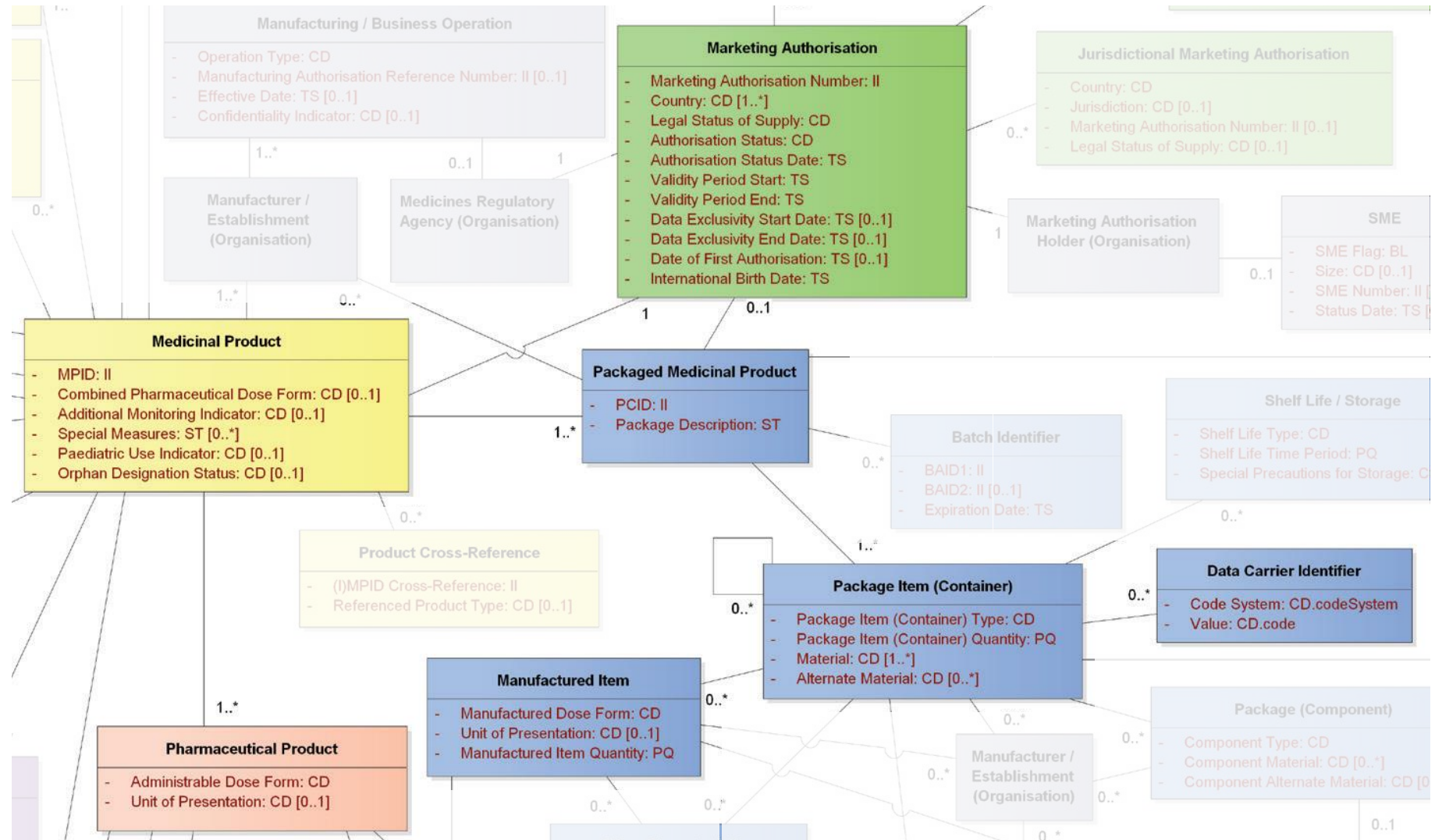
IDMP is:

– Providing a standardize backbone (ladder)

– Enabling an End-2-End connectivity

– Allowing each function to manage its own life-cycle.

Condition:

Each system/process which is involved share a dedicated amount of master data with the backbone.

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Marketing Auth.

Packaging (SKU)

MI/PhP

Substance

Medicinal Product
- MPID: II
- Combined Pharmaceutical Dose Form: CD [0..1]
- Additional Monitoring Indicator: CD [0..1]
- Special Measures: ST [0..*]
- Paediatric Use Indicator: CD [0..1]
- Orphan Designation Status: CD [0..1]

Pharmaceutical Product
- Administrable Dose Form: CD
- Unit of Presentation: CD [0..1]

PhPID Set
- PhPID Identifier Sets: II

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		MPID 123	MPID 234	MPID 345	MPID 456	MPID 567
Medicinal Product						
Pharmaceutical Product Administrable dose form:		Effervescent tbl.	Effervescent tbl.	Effervescent tbl.	Film-coated tbl.	Capsule, soft
	Unit of Presentation:	Tablet	Tablet	Tablet	Tablet	Capsule
	Active Ingredient:	Paracetamol	Paracetamol	Paracet./Cafeine	Paracetamol	Paracetamol
	Strength:	1 g	500 mg	500 mg	1 g	500 mg
PhPID_Sub: L1: Active Substance(s)		1	1	12	1	1
L2: Active Substance(s) + Strengths		1-1000	1-500	12-500	1-1000	1-500
L3: Active Substance(s) + Administrable Dose Form		1-A	1-A	12-A	1-B	1-C
L4: Active Substance(s) + Strengths + Administrable Dose Form		1-1000-A	1-500-A	12-500-A	1-1000-B	1-500-C

Why? Determination of equivalence in prescription, trans-border prescription, pharmacovigilance

The images are only used to illustrate the example and remain the property of their respective registered brand holders.

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► What are the relations between:

• MPID

• PhPID

• MA

• PCID (and then, DCID) ?

► What's the hierarchy between these IDs?

Manufacturing / Business Operation
- Operation Type: CD
- Manufacturing Authorisation Reference Number: II [0..1]
- Effective Date: TS [0..1]
- Confidentiality Indicator: CD [0..1]

Manufacturer / Establishment (Organisation)

Medicines Regulatory Agency (Organisation)

Marketing Authorisation
Marketing Authorisation Number: II
- Country: CD [1..*]
- Legal Status of Supply: CD
- Authorisation Status: CD
- Authorisation Status Date: TS
- Validity Period Start: TS
- Validity Period End: TS
- Data Exclusivity Start Date: TS [0..1]
- Data Exclusivity End Date: TS [0..1]
- Date of First Authorisation: TS [0..1]
- International Birth Date: TS

Jurisdictional Marketing Authorisation
- Country: CD
- Jurisdiction: CD [0..1]
- Marketing Authorisation Number: II [0..1]
- Legal Status of Supply: CD [0..1]

Marketing Authorisation Holder (Organisation)

SME
- SME Flag: BL
- Size: CD [0..1]
- SME Number: II
- Status Date: TS

Medicinal Product
MPID: II
- Combined Pharmaceutical Dose Form: CD [0..1]
- Additional Monitoring Indicator: CD [0..1]
- Special Measures: ST [0..*]
- Paediatric Use Indicator: CD [0..1]
- Orphan Designation Status: CD [0..1]

Packaged Medicinal Product
- PCID: II
- Package Description: ST

Batch Identifier
- BAID1: II
- BAID2: II [0..1]
- Expiration Date: TS

Shelf Life / Storage
- Shelf Life Type: CD
- Shelf Life Time Period: PQ
- Special Precautions for Storage: C

Product Cross-Reference
- (I)MPID Cross-Reference: II
- Referenced Product Type: CD [0..1]

Package Item (Container)
- Package Item (Container) Type: CD
- Package Item (Container) Quantity: PQ
- Material: CD [1..*]
- Alternate Material: CD [0..*]

Data Carrier Identifier
Code System: CD.codeSystem
- Value: CD.code

Manufactured Item
- Manufactured Dose Form: CD
- Unit of Presentation: CD [0..1]
- Manufactured Item Quantity: PQ

Manufacturer / Establishment (Organisation)

Package (Component)
- Component Type: CD
- Component Material: CD [0..*]
- Component Alternate Material: CD [0

Pharmaceutical Product
- Administrable Dose Form: CD
- Unit of Presentation: CD [0..1]

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Subs InnoMed 250mg
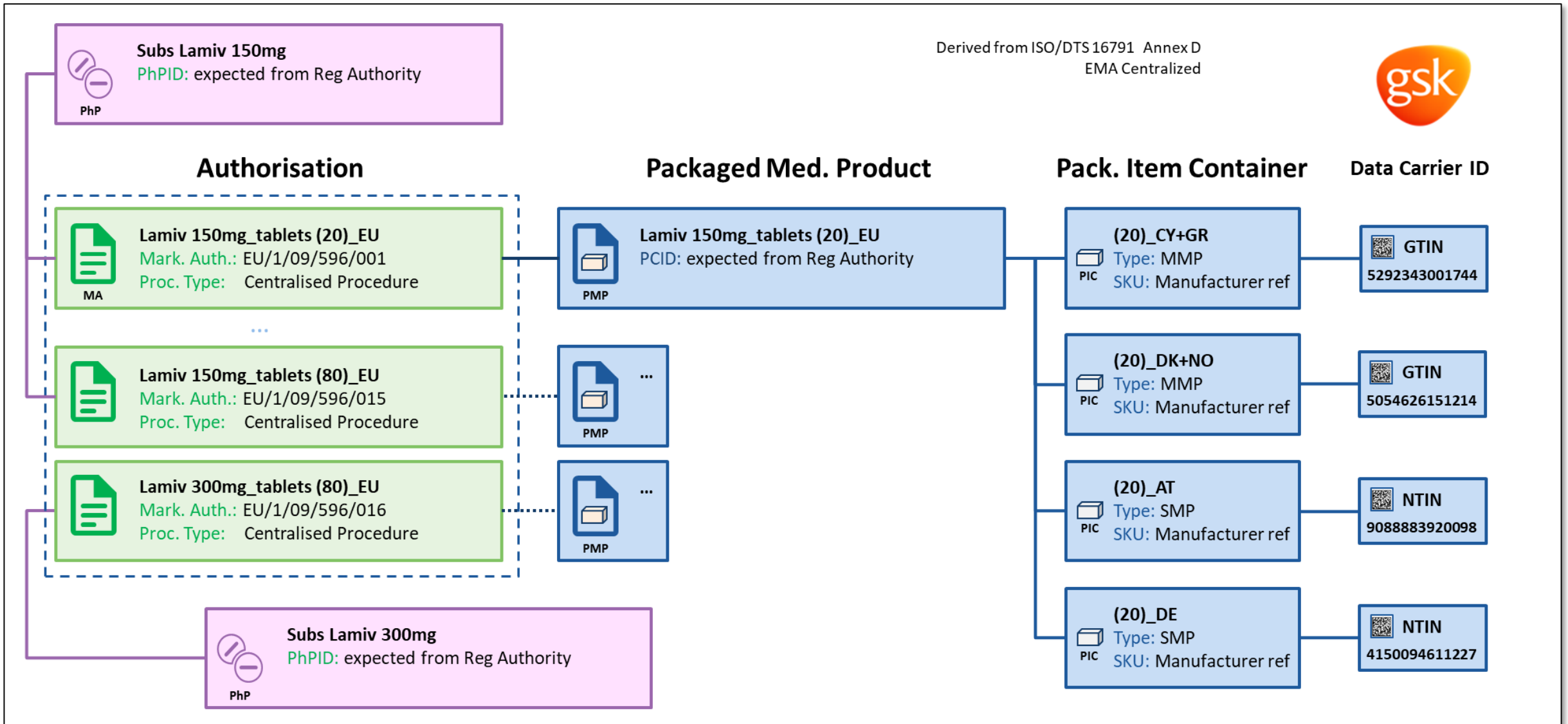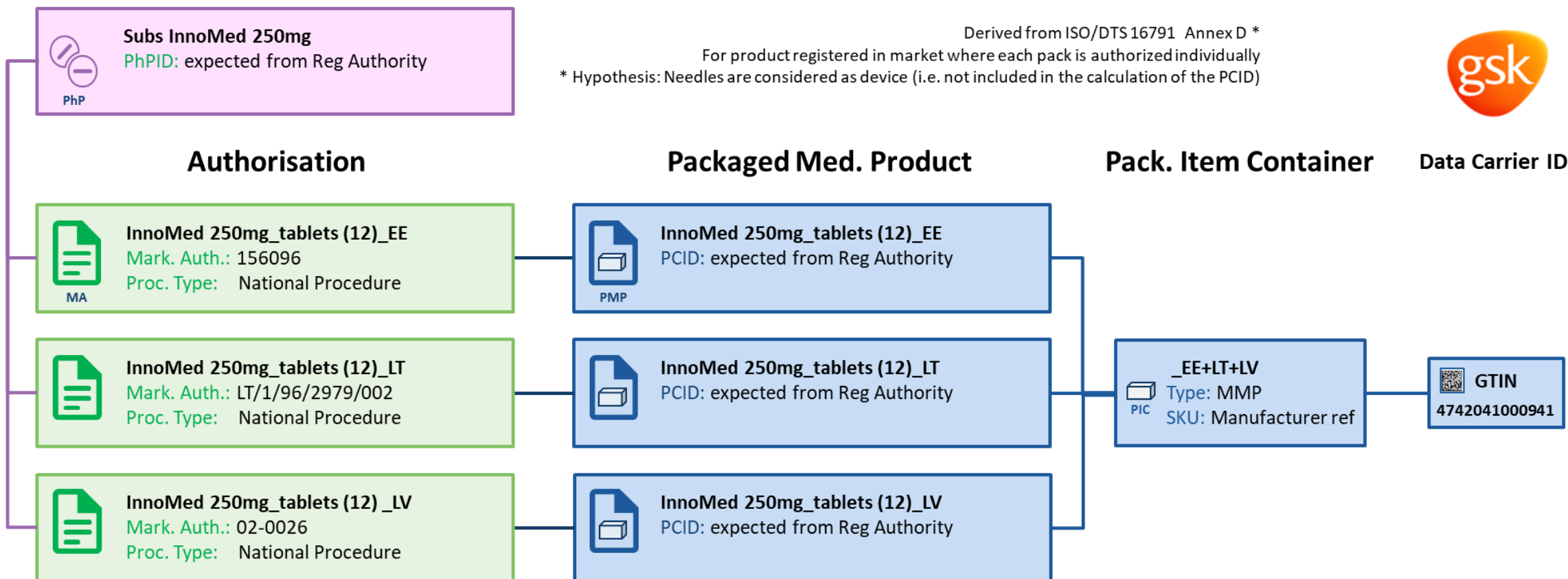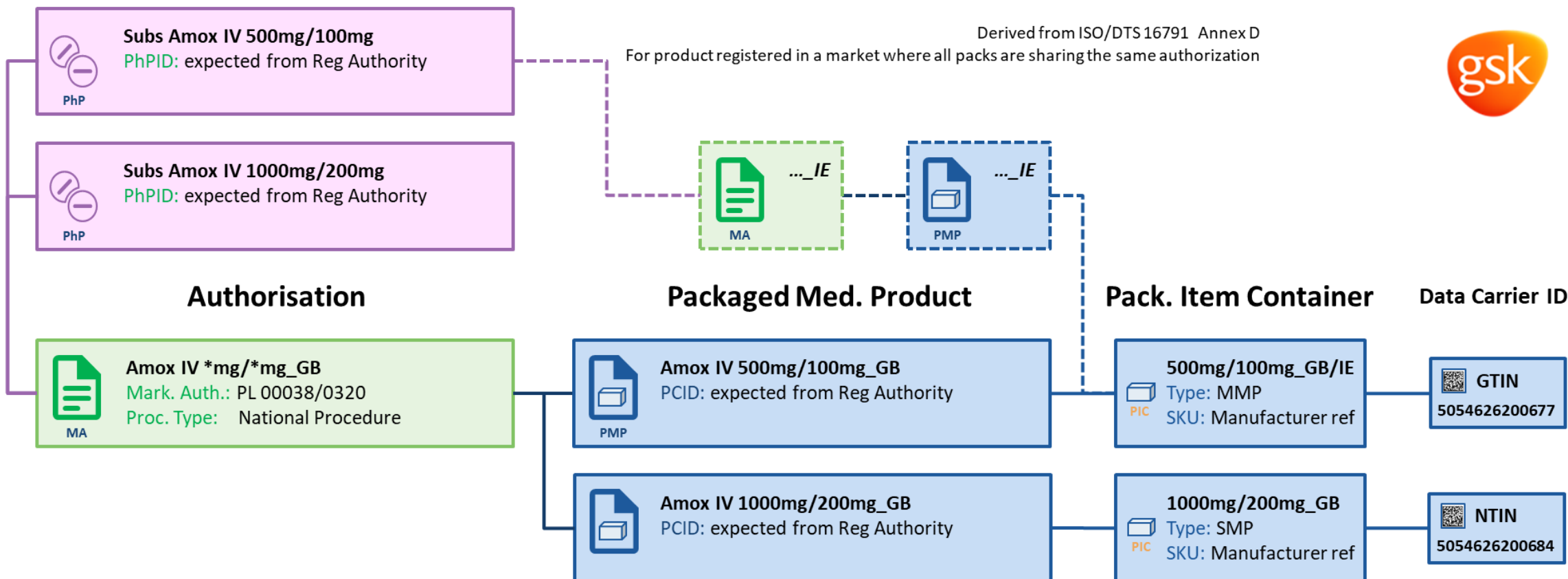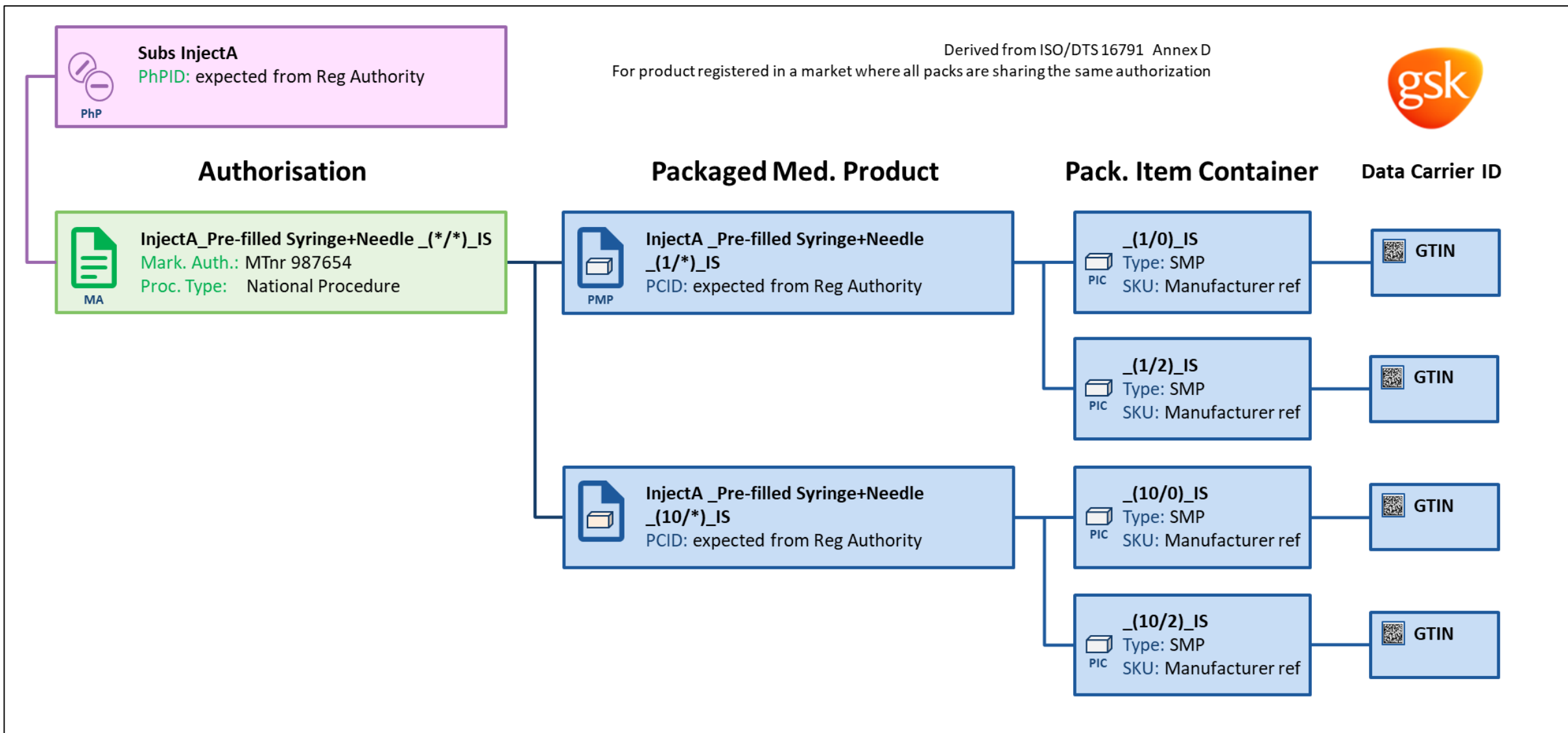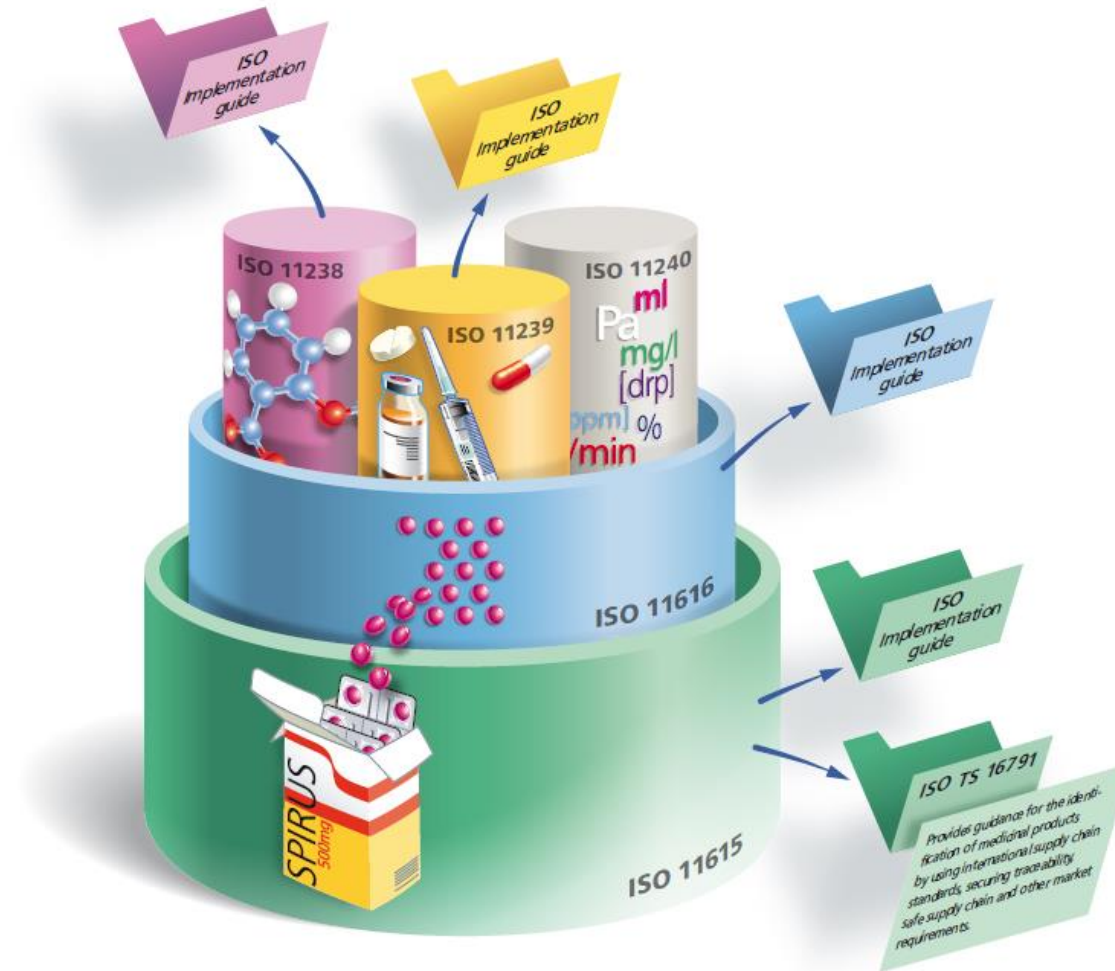PhPID: expected from Reg Authority
PhP

Derived from ISO/DTS 16791 Annex D *
For product registered in market where each pack is authorized individually
* Hypothesis: Needles are considered as device (i.e. not included in the calculation of the PCID)

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Authorisation   **Packaged Med. Product**   **Pack. Item Container**   **Data Carrier ID**

InnoMed 250mg_tablets (12)_EE
Mark. Auth.: 156096
Proc. Type: National Procedure
MA

InnoMed 250mg_tablets (12)_EE
PCID: expected from Reg Authority
PMP

InnoMed 250mg_tablets (12)_LT
Mark. Auth.: LT/1/96/2979/002
Proc. Type: National Procedure

InnoMed 250mg_tablets (12)_LT
PCID: expected from Reg Authority

_EE+LT+LV
Type: MMP
SKU: Manufacturer ref
PIC

GTIN
4742041000941

InnoMed 250mg_tablets (12) _LV
Mark. Auth.: 02-0026
Proc. Type: National Procedure

InnoMed 250mg_tablets (12)_LV
PCID: expected from Reg Authority

► PhPID set consists of 8 different IDs based on the following information:

► PhPID active substance stratum

  ▷ PhPID_SUB_L1 → Substance(s)

  ▷ PhPID_SUB_L2 → Substance(s) + strength + reference strength

  ▷ PhPID_SUB_L3 → Substance(s) + administrable dose form

  ▷ PhPID_SUB_L4 → Substance(s) + strength + reference strength + administrable dose form

► PhPID specified substance stratum

  ▷ PhPID_SpSUB_L1 → Specified substance(s)

  ▷ PhPID_SpSUB_L2 → Specified substance(s) + strength + reference strength

  ▷ PhPID_SpSUB_L3 → Specified substance(s) + administrable dose form

  ▷ PhPID_SpSUB_L4 → Specified substance(s) + strength + reference strength + administrable dose form

► Country code segment

► Marketing Authorization Holder (Organisation Identifier) code segment

► Medicinal Product code segment (Unique MP Identifier)

▷ Marketing authorization indicated in a region

▷ Legal status of supply as a value/attribute

▷ Medicinal Product name;

▷ Pharmaceutical dose form;

▷ Active ingredient(s)/active moieties and their corresponding strength;

▷ Device(s) where a Medicinal Product is combined with a medical device and where the pharmacological, immunological or metabolic action should be considered as the principal mode of action; the medical device is presented as part of the Medicinal Product;

▷ Therapeutic indication(s) as authorised for the Medicinal Product

► MPID

► Package description code segment

▷ Packaged item (container)(s) — the type, quantity (items per package), material(s) and alternate material(s);

▷ Package component(s) — type, material(s) and alternate material(s);

▷ Manufactured item(s) — manufactured dose form, unit of presentation, quantity (items per package).

► In this case, needles are considered as device, then not entering in the package description code segment.