EMVO-00122 - EMVS MASTER DATA GUIDE

Revision History

Version Date	Version	Author	Reason For Changes
13-Jun-2017	1.0	Paul Mills Stefan Artlich Grant Courtney Anci Kvarnström	Initial Document
14-Jun-2018	2.0	Paul Mills	Updated review copy to include SPOR mapping, feedback from reviews and EMVO Gateway element name mapping and to reflect appropriate feedback items received from FMD workshop team members.
28-Nov-2018	3.0	Paul Mills	Added NHRN rules for Portugal, amended rules for Germany. EFPIA and GIRP provided input for the enhanced Appendix 5 including sample documents for designated wholesaler appointment and delivery note details. Amended section 3 and 4 as now the Hub has been updated.
16-Oct-2019	4.0	Tiago Barrosa Anjos	Added Product Master Data versioning rules. Added the mandatory National Code rules in the Market Specific Master Data Elements as per Appendix 4. Update of table from Appendix 3: Member State ISO 3166 Code
02-Oct-2020	5.0	Tiago Barrosa Anjos	Deprecation of "Serialisation Flag" in the Master Data Upload and adaptation of emulated markets.
25-Nov-2021	6.0	Margarita Belichovska	Updated the Guidance for Entering National Code for the UK in Appendix 4.
24-Oct-2022	7.0	Athanasios Kantarelis	Updated section 5 with regards to MAH ID and Germany.
31-Oct-2024	8.0	Tracy Slosse	General update + preparation for the new mandatory fields. Added section 8: Glossary Updated sections: - Previous section 3 "SPOR" removed - New section 3: Data Overview - New section 4: Upload procedure to the EU Hub - New section 5: Product Master Data – Common Elements - New section 6: Product Master Data - Market Specific Elements - Section 7: Product Pack Data Element (Batch and Pack Data) - Appendix 4: Guidance for entering National Code - Appendix 7: Product Code Version Validation Rules
05-Nov-2024	9.0	Tracy Slosse	- Correction of typo in section 5 Product Master Data – Common Elements

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1. Purpose

The EMVS requires that OBPs upload both Product Master Data and Product Pack Data (hereafter referred also as "EMVS Master Data") in the EU Hub. This guide aims to clarify the EMVS Master Data to be uploaded in the EU Hub.

2. EMVS Master Data Requirements

These consist currently of two primary data collections.

- A common 'applies to all markets' collection of data and
- A market specific collection of data.

Master data elements are required by Article 33 of the COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015 [Linked Here] and the documents referred to therein.

Master data should therefore be in line with regulatory submission and the law in force at the time. The data listed in the Commission Delegated Regulation (EU) 2016/161 Article 33, Sections 2.c and 2.g, are to be sourced from the regulatory QRD data or SmPC information.

This document is a guide and is not intended to be used as the 'authority'. Ultimately it is the sole responsibility of each OBP to ensure that their data submissions meet the requirements of the law.

3. Data Overview

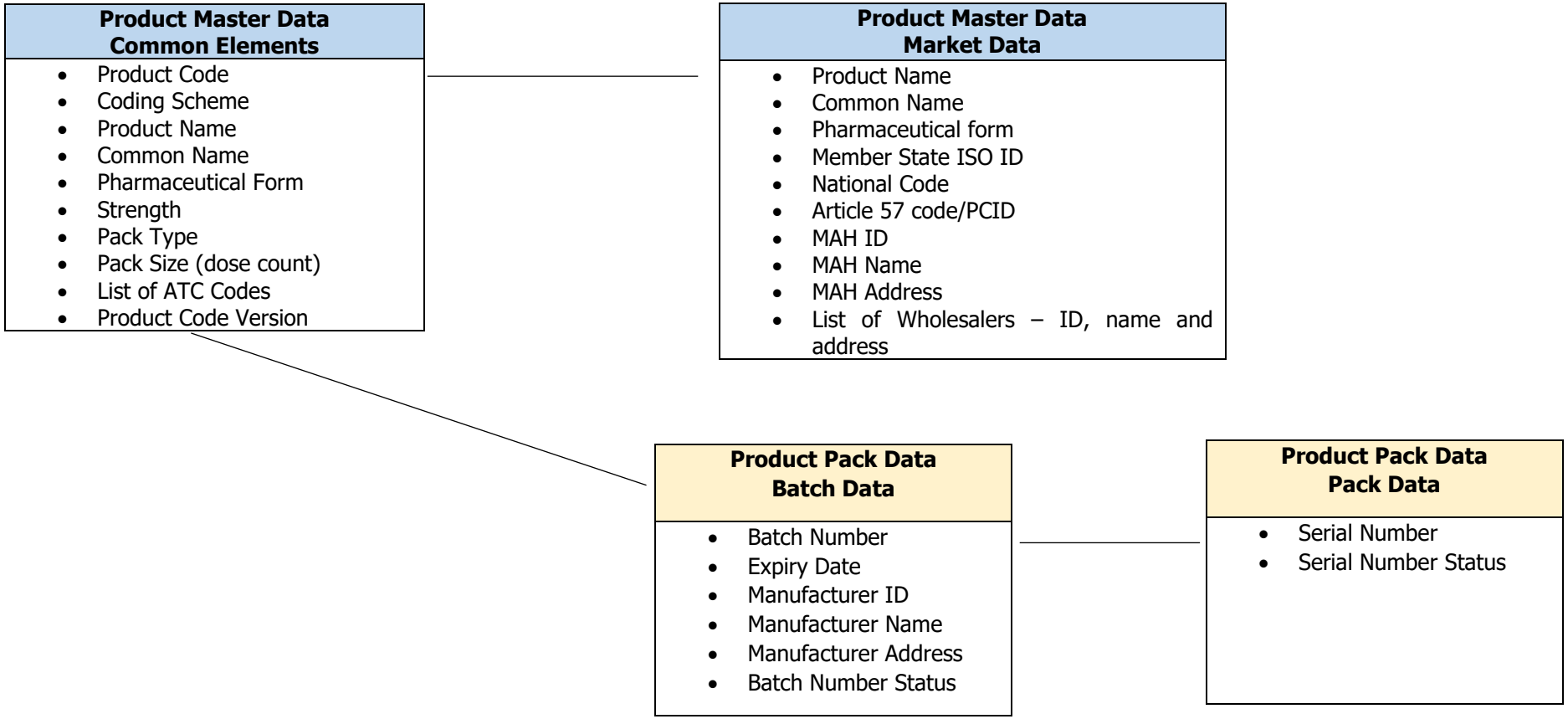
This section provides an overview of the EMVS Master Data[1] and how they are connected.

- For additional information on PMD Common Elements, please refer to section 5. Product Master Data – Common Elements;
- For additional information on PMD Market Data, please refer to section 6. Product Master Data - Market Specific Elements;
- For additional information on PPD Batch Data, please refer to section 7.1. Batch Data;
- For additional information on PPD Pack Data, please refer to section 7.2. Pack Data.

For the above mentioned master data; we recommend using the below sources as guidance on to fill in the data:

- Regulatory QRD data/dossier
- SmPC information
- EMA/OMS databases

[1] Exact name of the data field may vary depending on how the OBP chooses to connect to the EU Hub.



4. Upload Procedure to the EU Hub

4.1 Single Market Products

Upload to the European Hub the data from:

- Table 1 (see Section 5 Product Master Data – Common Elements)
- Table 2 (see Section 6 Product Master Data - Market Specific Elements)
- Table 3 (see section 7.1 - Batch Data)
- Table 4 (see section 7.2- Pack Data)

4.2 Multi-Market Products

Upload to the European Hub the data from:

- Table 1 (see Section 5 Product Master Data – Common Elements)

  Table 2 (see Section 6 Product Master Data - Market Specific Elements). Data described in Table 2 are to be uploaded for each market for which the Product is intended. If a Product is intended to be uploaded to the BE and the FR markets, data from Table 2 are to be uploaded twice. Once with the information related to the BE market and once with the information related to the FR market.
- Table 3 (see section 7.1 - Batch Data)
- Table 4 (see section 7.2- Pack Data)

If the OBP requires to add a new market to an existing PMD, a new PMD version must be created.

5. Product Master Data – Common Elements

In the common master data elements section, the following elements shall be uploaded in the EU Hub by each OBP.

How to read the table:

Element Name	**Description**	**Example**	**Reference Examples**	**Mandatory Input**
Field Name [FieldName in the EMVO Gateway]	Field content description	Example of field content	Reference for guidance on how to fill in the field	Specifies if it is mandatory to fill in the field in the system. Mandatory fields left blank will lead to the rejection of the PMD upload with an #A16 alert (data validation error).

If a [FieldName] is shown as [Not Accessible], this means that the OBP cannot set these values using the EMVO Gateway. The corresponding items are shown in *italics*.

Element Name	Description	Example		Reference Examples	Mandatory Input
Product Code [CodeValue]	The product code on the pack and contained within the Data Matrix code. Will only be either a 14-digit GTIN , 14-digit NTIN or 12-digit PPN.	05060141900015		• Logistics / Supply Chain Mgmt. • Appendix 1: Common Master Data Element References	Mandatory
Coding Scheme [CodingScheme]	Can only be either GTIN (where a GTIN or NTIN is used for the product code) or PPN	GTIN		• Simple choice GTIN/PPN • Appendix 1: Common Master Data Element References	Mandatory
Product Name[2] [Name]	The (invented) name + strength + pharmaceutical form.	Product Name *to be uploaded*	Amoxicillin Effective Medicines 500mg Capsules	• QRD, Annex 1, sec 1 • xEVMPD AP.13.1 productname • Regulatory dossier	Mandatory
		(Invented) Name	Amoxicillin Effective Medicines		
		Strength	500mg		
		Pharmaceutical form	Capsules		

[2] Language: For Single Market Products, use the national language for NAP/MRP/DCP as applicable in the context of the Marketing Authorisation; English is acceptable for CP. If SmPCs are valid for a specific product in more than one language (e.g., in Belgium), provide the name/common name from within one of the SmPCs. For Multi-Market Products, use the name/common name as it appears on the artwork or a concatenation of the name/common name in each language suitable for the pack.

Element Name	Description	Example	Reference Examples	Mandatory Input
Common Name[2] [CommonName]	• Recommended INN accompanied by its salt or hydrate form if relevant. • If no INN exists, the European Pharmacopoeia name if that name represents an established name in Europe. • If the substance is not in the pharmacopoeia, the usual common name should be used. • In the absence of a common name, the exact scientific designation should be given. • In case of several active substances, their names should be presented separated by a "/", following the order of the WHO classification. Substances not having an exact scientific designation should be described by a statement on how and from what they were prepared.	• Amoxicillin • Telmisartan/Hydrochlorothiazide	• QRD, Annex III A, sec. 1	Mandatory
Pharmaceutical Form [FormType]	• The single full Standard Term of the European Pharmacopeia, using the plural form if appropriate (https://standardterms.edqm.eu/) – only the English terms are supported. • For multi-component medicinal product use EDQM Combined Pharmaceutical Dose Form CV.	Capsule	• QRD, Annex 1, sec 3 • SPOR IDMP "Pharma Dose Form Name Part"	Mandatory

Element Name	Description	Example	Reference Examples	Mandatory Input
Strength [Strength]	The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	• Example for capsule: 500mg • Example for Powder for oral suspension: 250 mg/ml	Strength element of the Medicinal Product name in SPOR (IDMP), QRD, Annex 1, sec 1	Mandatory
Pack Type [PackType]	Refers to the packaging that carries the safety features (serial number and ATD), i.e., the sales pack, using a single Standard Term of the European Pharmacopeia. Only the English terms are supported.	Box, Bottle, Bag	EDQM 'Packaging' term list	Mandatory
Pack Size [PackSize]	• The number of re-packable doses in the pack. • Where the pack is not readily re-packable, the value should be set as '1'. E.g. a pack of tablets that can be readily re-packed and therefore this value will represent the number of tablets in the pack. • A powder or syrup cannot be readily re-packed and therefore, regardless of volume, the pack size will be set as '1'.	See Appendix 2: Guidance for Values to enter for Pack Size	• The pack size can be derived from QRD, Annex 1, sec 6.5 • See Appendix 2: Guidance for Values to enter for Pack Size	Mandatory

Element Name	Description	Example	Reference Examples	Mandatory Input
ATC Codes[3] *[Not Accessible]*	*List [0..10] of ATC code values in 5 or 7 character format.*	*ANNAANN*	N/A	N/A
Product Code Version[4] [ProductVersion Number]	• The Product Code Version is an optional field that shall be used by OBPs to associate the data to a specific version of the uploaded PMD.	1, 2, 3, 4	N/A	Not mandatory

Table 1 - Common Master Data (Market Agnostic)

Note: The Name, Common Name, Pack Type and Pharmaceutical Form entered by the OBP will be copied to the Market Specific Data level by the European Hub. These cannot be entered directly by the OBP.

[3] The EU Hub data model supports the inclusion of up to ten ATC codes per Product Master Data entry. However, these elements are not currently accessible by the OBP interface and, therefore, cannot be populated by OBPs.
[4] The rules applicable to Product Code Versions are described in *Appendix 7: Product Code Version Validation Rules*.

6. Product Master Data - Market Specific Elements

For each market within a Multi-Market Products, the following table should be completed. For Single Market Products, only one completed table is required.

How to read the table:

Element Name	Description	Example	Reference Examples	Mandatory Input
Field Name [FieldName in the EMVO Gateway]	Field description – what should be put in this field	Example of what to put in the field	Reference for guidance on how to fill in the field	Whether is it mandatory to fill in the field in the system. Mandatory fields left blank will lead to the rejection of the PMD upload with an #A16 alert (data validation error).

If [FieldName] is shown as [Not Accessible], this means that the OBP cannot set these values using the EMVO Gateway. Items shown in *italics* cannot be loaded directly by the OBP.

Element Name	Description	Example	Reference Examples	Mandatory Input
Member state ISO Code [Id]	Two-letter country code from ISO 3166-1 alpha-2 defining the local sales market(s) for the product. One ISO code per market table.	BE	Appendix 3: Member State ISO 3166 Code	Mandatory
National code [Nationalcode]	A national reimbursement number or other national number if requested by the Member state. If not requested by the Member State, it is recommended to insert the code (when it exists), however it is left to the discretion of the OBP to decide.	1234567	Appendix 4: Guidance for entering National Code	Mandatory if part of the countries listed in Appendix 4: Guidance for entering National Code
Article 57 code/PCID [Article57Code]	Article 57 code: xEVMPD EV Code which is assigned by EMA after successful transmission of Master Product Data to xEVMPD. Packaged Medicinal Product Identifier (PCID): ISO IDMP/SPOR identifier if already existing. If multiple codes exist for the market, only select one that matches the 'Name' and 'Common Name' supplied. For Switzerland and Parallel Distribution products, leave empty.	PRD115784	As assigned by EMA upon submission of a new record to EVMPD	Not mandatory
Product Name *[Not Accessible]*	*See common section for the description (this element is not directly accessible by the OBP)*	N/A	N/A	Automatically filled in with data input as seen in Table 1

Element Name	Description	Example		Reference Examples	Mandatory Input
Common Name *[Not Accessible]*	*See common section for the description (this element is not directly accessible by the OBP)*	N/A		N/A	Automatically filled in with data input as seen in Table 1
Pack Type *[Not Accessible]*	*See common section for the description (this element is not directly accessible by the OBP)*	N/A		N/A	Automatically filled in with data input as seen in Table 1
Pharmaceutical Form *[Not Accessible]*	*See common section for the description (this element is not directly accessible by the OBP)*	N/A		N/A	Automatically filled in with data input as seen in Table 1
MAH ID [Under element group MAH = Id]	Unique ID to identify the MAH	N/A		N/A	Not mandatory
MAH Name [Under element group MAH = Name]	The name as provided in the official business register of the company or other legal entity which holds the authorisation to market a medicine in one, several or all European Union Member States.	World Class Medicines Limited		QRD, Annex 1, sec 7	Mandatory
MAH Address [Under element group MAH = Street1, Street2, City, PostCode and CountryCode]	Postal address for the MAH detailed above.	*Street 1*	Neue Strasse 12	QRD, Annex 1, sec 7	Mandatory
		Street 2	Box 2	QRD, Annex 1, sec 7	Not mandatory
		City	Berlin	QRD, Annex 1, sec 7	Mandatory
		Postcode	10119	QRD, Annex 1, sec 7	Mandatory
		Country Code	DE	QRD, Annex 1, sec 7	Mandatory

Element Name	Description	Example		Reference Examples	Mandatory Input
List of designated wholesalers with ID, name and address [Under element group ContractedWholesalers = Id, Name, Street1, Street2, City, PostCode and CountryCode]	The list should contain the details of each designated wholesaler (or equivalent) contracted by, or **on behalf of**, the MAH detailed above (thus only pertinent to the stated local market) to handle the product represented by the product code in table 1 row 1.	*ID*	N/A	Appendix 5: Designated Wholesaler Definition/Guidance	Not mandatory
		Name	Better Wholesaling GmbH	Appendix 5: Designated Wholesaler Definition/Guidance	Mandatory if it is a designated wholesaler
		Street 1	Neue Strasse 12	Appendix 5: Designated Wholesaler Definition/Guidance	Mandatory if name provided
		Street 2	Box 2	Appendix 5: Designated Wholesaler Definition/Guidance	Not mandatory
		City	Berlin	Appendix 5: Designated Wholesaler Definition/Guidance	Mandatory if name provided
		Postcode	10119	Appendix 5: Designated Wholesaler Definition/Guidance	Mandatory if name provided
		Country code	DE	Appendix 5: Designated Wholesaler Definition/Guidance	Mandatory if name provided

Table 2 - Market Specific Master Data

As described in section 4.2 Multi-Market Products, for Multi-Market Products, the above *Table 2 – Market Specific Master Data* is to be repeated for each market the product is intended to be sold.

7. Product Pack Data Element (Batch and Pack Data)

The Delegated Regulation defines requirements for the data related to the batches and packs, which can be separated into two basic element groups:

1 The first defines the details of the batch being produced, see section 7.1 Batch Data;

2 The second defines the physical pack serial ID's associated with the batch, see section 7.2 Pack Data.

The following tables define the data elements in detail.

How to read the tables:

Element Name	**Description**	**Example**	**Mandatory Input**
Field Name [FieldName in the EMVO Gateway]	*Field description – what should be put in this field*	*Example of what to put in the field*	*Whether is it mandatory to fill in the field in the system. Mandatory fields left blank will lead to the rejection of the PMD upload with an #A16 alert (data validation error).*

If [FieldName] is shown as [Not Accessible], this means that the OBP cannot set these values using the EMVO Gateway. Items shown in *italics* cannot be loaded directly by the OBP.

7.1 Batch Data

Element Name	Description	Example		Mandatory Input
Batch number [BatchID]	• Batch number as printed on the serialized Pack • Use alphanumeric (case sensitive) values of up to 20 characters, limited to those characters defined in the GS1 General Specifications (GS1 AI Encodable Character Set 82)	• LOT123 • LOTXYZ3		Mandatory
Expiry date [BatchExpiry]	• Expiry date of the serialized batch represented by six (6) numeric digits in the form YYMMDD • Where the day element is not provided in the human-readable format, the value of DD must be set to the last day of the month (e.g. 02-2026 would be set to 260228) if not specified otherwise by the manufacturer.	190209		Mandatory
Manufacturer ID [Under element group Manufacturer = Id]	Unique ID to identify the Manufacturer	N/A		Not mandatory
Manufacturer Name [Under element group Manufacturer = Name]	Enter here the full name of the manufacturer placing the safety features.	Effective Medicines Limited		Mandatory
Manufacturer Address [Under element group Manufacturer Details = Name, Street1, Street2, City, PostCode and CountryCode]	Enter the Registered address of the manufacturer placing the safety features.	*Street 1*	Neue Strasse 12	Mandatory
		Street 2	Box 2	Not mandatory
		City	Berlin	Mandatory
		Postcode	10119	Mandatory
		Country code	DE	Mandatory
Batch Number Status [N/A]	Automatically maintained by the verification system. No data is to be uploaded.	N/A		N/A

Table 3: Batch Data

7.2 Pack Data

Element Name	Description	Example	Mandatory Input
Serial ID [Under element group SerialIds = Id]	Up to twenty (20) alpha-numeric characters or single case (i.e. upper or lower case not both) according to the GS1 Specifications from table 7.11-1. Serial number shall be randomised according to the Delegated Regulation requirements (Art 4(b)) and the pack coding guidelines. For clarity, serial ID's can be numeric only as long as they meet the given criteria.	ZT34012956345DLM	Mandatory
Serial ID Status [N/A accessed by update use case as either CurrentStatus or NewStatus]	Automatically maintained by the verification system. No data is to be uploaded.	N/A	N/A

Table 4: Pack data

Note: The pack serial ID status is set to 'Active' upon upload to the EMVS (European Hub). Future operations on the pack status require the invocation of dedicated use cases – the status cannot be declared at the point of upload and nor can pack status be changed by means of repeated pack data uploads. Some pack state manipulation use cases defined 'bulk' operations where many serial ID's for a given product batch can be changed in a single operation.

8. Glossary

Term	Abbreviation	Definition
Anatomical Therapeutic Chemical code	ATC Code	Unique code assigned to a medicine according to the organ or system it works on and how it works
Anti-Tempering Device	ATD	The safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with.
Centralised procedure	CP	The European Union-wide procedure for the authorisation of medicines, where there is a single application, a single evaluation and a single authorisation throughout the European Union. Only certain medicines are eligible for the centralised procedure.
Decentralised Procedure	DCP	Procedure for authorising medicines in more than one European Union Member State in parallel. It can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any Member State.
European Medicines Agency	EMA	A decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
European Medicines Verification Organisation	EMVO	A non-profit legal entity that is responsible to set up and manage a central information and data router ('hub') in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
European Medicines Verification System	EMVS	The system for medicines verification that has been set up and is managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems, and allows the End-Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
Global Trade Item Number	GTIN	The Global Trade Item Number is an identifier for trade items, developed by the international organization GS1. It is used to identify trade items uniquely and unambiguously (e.g. products sold online or in-store).

Term	Abbreviation	Definition
Identification of Medicinal Products	IDMP	A set of five standards developed by the International Organization for Standardization (ISO) to create a universal framework of structured, coded data that uniquely identify and describe all key aspects of medicinal products.
International Non-proprietary Name	INN	International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.
Multi-Market Pack	MMP	Product intended to be commercialised in more than one market.
Mutual Recognition Procedure	MRP	Procedure through which an authorisation of a medicine in one European Union Member State is recognised by another Member State.
Nationally authorised products	NAP	Medicine authorised in a Member State in accordance with its national authorisation procedure.
National Medicines Verification Organisation	NMVO	The non-profit legal entity (entities) that is (are) responsible to set up and manage a national and/or supranational repository(ies) in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
Nation Trade Item Number	NTIN	A coding scheme, administered in the healthcare sector by a national organisation for which a GS1 Prefix has been issued to permit its uniqueness within the GTIN pool but without assurance of full compatibility with GTIN functionality. The result is a product identification number assigned by a third party (not the brand owner or manufacturer).
On-Boarding Partner	OBP	Company or organisation which is the contracting party of EMVO in the Participation Agreement and represents the affiliated entities that hold marketing authorisations for products for which the OBP uploads product and pack data to the EU Hub to be transferred to the National Systems
Organisation Management Service	OMS	Organisation Management Service launched by the EMA to support regulatory activities throughout the European Union.

Term	Abbreviation	Definition
Product Master Data	PMD	Product Master Data are considered as the set of data elements associated with a specific product record and contain the elements of information about the product. The product code and the target market that OBPs need to upload when connecting to the EU Hub.
Product Pack Data	PPD	Transactional data associated with the upload of batches and serial numbers.
Quality Review of Documents	QRD	European Medicines Agency's (EMA) Working Group on Quality Review of Documents (QRD) develops, reviews and updates templates for product information for use by applicants and marketing authorisation holders for human medicines.
Single-Market Pack	SMP	Product intended to be commercialised in only one market.
Summary of Product Characteristics	SmPC	Document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively.
Substance, Product, Organisation and Referential	SPOR	SPOR data management services. Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.
eXtended EudraVigilance Medicinal Product Dictionary	xEVMPD	Reference source for the coding of substances and medicinal products reported in ICSRs based on the information provided by MAHs in line with Article 57(2), second subparagraph of Regulation (EC) No 726/2004.

Appendix 1: Common Master Data Element References

Element Name	Directive 2001/83/EC „Medicinal Products for Human Use“	QRD Template Version 10.4	Guideline on SmPC Revision 2 (September 2009)	xEVPMD Data Element
Name of Medicinal Product	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.	Annex I, sec. 1 “Name of Medicinal Product”	The (invented) name should be followed by both the strength and the pharmaceutical form.	AP.13.1 productname
Common Name of Medicinal product	The international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.	Annex III A, sec. 1	Product INN (International Non-Proprietary Name) / Common Name	N/A
Pharmaceutical Form	According to SmPC	Annex I, sec. 3 “Pharmaceutical Form”	The pharmaceutical form of a medicinal product should be described by a single full Standard Term of the European Pharmacopoeia using the plural form if appropriate (e.g. tablets)	Value will be consistent with the European Pharmacopeia until Hub V1.4 2018 interface when AP.13.6 productform should be referenced.
Strength	The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	Annex I, sec. 1 “Name of Medicinal Product”	The strength should be the relevant quantity for identification and use of the product and should be consistent with the quantity stated in the quantitative composition and in the posology.	AP.13.5 productstrength
Pack Type	According to the standard terms published by the European Pharmacopeia Commission (EU 520/2012, Art. 25 (1) (b))	Annex I, sec. 6.5	n/a	Value will be consistent with the European Pharmacopeia until Hub V1.4 2018 interface when AP.13.7 packagedesc should be referenced

Appendix 2: Guidance for Values to enter for Pack Size

Package description/size	**Master Data input**
Amber glass bottle, 84 tablets	84
Aluminium blister pack, 96 tablets	96
Packs containing 7, 14, 28 etc. film-coated tablets.	7, 14, 28 etc
Pack containing a specific number of tablets for a cure or to be taken in a certain order and thus cannot be split, e.g. 28 tablets of a contraceptive	1
Pack size of 1 vial of 10 ml	1
Pack size of 5 vials of 10 ml	5
Multipack of 5 packs of 1 x 10 ml vial	5
Pack size of 10 prefilled syringes of 0.1 ml of suspension	10
Pack of 10 prefilled syringes, 1 ml.	10
Glass bottle, 100 ml	1
Powder for oral suspension is in a 250 ml glass bottle	1
Pack containing 1 vial (of Powder) and 1.5 ml of Solvent.	1
Inhalator, 120 doses	1
Inhalator, 3 x 120 doses	3

Appendix 3: Member State ISO 3166 Code

Country	ISO Code[5]
Austria	AT
Belgium	BE
Bulgaria	BG
Croatia	HR
Cyprus	CY
Czech Republic	CZ
Denmark	DK
Estonia	EE
Finland	FI
France	FR
Germany	DE
Greece	GR
Hungary	HU
Iceland	IS
Ireland	IE
Italy	IT
Latvia	LV
Liechtenstein	LI
Lithuania	LT
Luxembourg	BE
Malta	MT
Netherlands	NL
Norway	NO
Poland	PL
Portugal	PT
Romania	RO
Slovakia	SK
Slovenia	SI
Spain	ES
Sweden	SE
Switzerland	CH
United Kingdom	GB

[5] Two emulated Markets ("XA" and "XB") are only available in ITE and IQE environments (not PRD). These emulated markets are not ISO 3166 codes but reserved special codes for the emulators only.

Appendix 4: Guidance for entering National Code

The National Code must be entered for the following markets for which the EMVS is used to verify the National Code.

- **Austria** (add the PZN for all product types) (format: 6 digits + 1 check digit without separator, example: 4474700)
- **Germany** (add the PZN for all product types)
- **Spain** (all product types) (format: 6 digits + 1 check digit without separator, example: 6068946)
- **Portugal** (all product types) (format: 7 digits, all numeric)

Appendix 5: Designated Wholesaler Definition/Guidance

Executive Summary

'Designated Wholesalers' are wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf. Likewise, the parallel importer / parallel distributor may designate a wholesaler, by means of a written contract, to store and distribute on his behalf the products covered by the parallel import authorisations/parallel distribution notices respectively.
Marketing authorization holders and parallel importers / parallel distributors are obliged to upload to the EMVS a list of 'Designated Wholesalers. The following rules apply:

Entity	Description	To Be Listed as 'Designated Wholesaler'?
Pre-wholesalers / 3PLs (3rd Party Logistics provider) / Distributors	Legal entity independent from MAHs that has been contracted for storage and distribution	Yes
Sales Affiliates	Representative of the MAH focusing on sales and controlled by the MAH or subject to control by the same legal entity as the MAH	No
Co-promoter	Representative of the MAH focusing on sales and **NOT** controlled by the MAH or subject to control by the same legal entity as the MAH	Yes
Co-marketer	Legal entity independent of the MAH that commercializes the product under a different trademark and holds an own marketing authorization	No
Transportation Company	Legal entity contracted to transport the products	No
Full-line Wholesaler	Legal entity **NOT** acting in pre-wholesale role as described above	No

Legal Background

According to Commission Delegated Regulation (EU) 2016/161, Art. 20 (b), a wholesaler shall at least verify the authenticity of the unique identifier for medicinal products he receives from a wholesaler who is

- neither the manufacturer
- nor the wholesaler holding the marketing authorisation (MAH)
- nor a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

Consequently, wholesalers are NOT obliged to verify the authenticity of the unique identifier for medicinal products they have received from the manufacturer or the marketing authorization holder or a 'Designated Wholesaler'.

With the introduction of the 'Designated Wholesaler', DR 2016/161 takes a view on the physical material flow in the supply chain rather than the financial flow between supply chain partners. From the definition in Art. 20 (b) it becomes clear that a 'Designated Wholesaler' is

- neither the manufacturer
- nor the Marketing Authorization Holder (MAH)
- nor a full-line wholesaler who is not operating on behalf of the MAH.

According to DR 2016/161, Art. 33 (2) (h),

- the marketing authorisation holder or,
- in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing those medicinal products on the market

is obliged to upload to the EMVS a list of 'Designated Wholesalers'.

Note: in Divestiture and Acquisition cases where the product code changes ownership, the acquirer is to ensure that the Designated Wholesaler information is updated accordingly in the Product Master Data.

Scenario 1: List of 'Designated Wholesalers' according to text of DR 2016/161

Figure 1 outlines the different roles that DR 2016/161 envisages together with the verification obligations. For clarification, the Figure considers the financial flow in addition to the material flow:

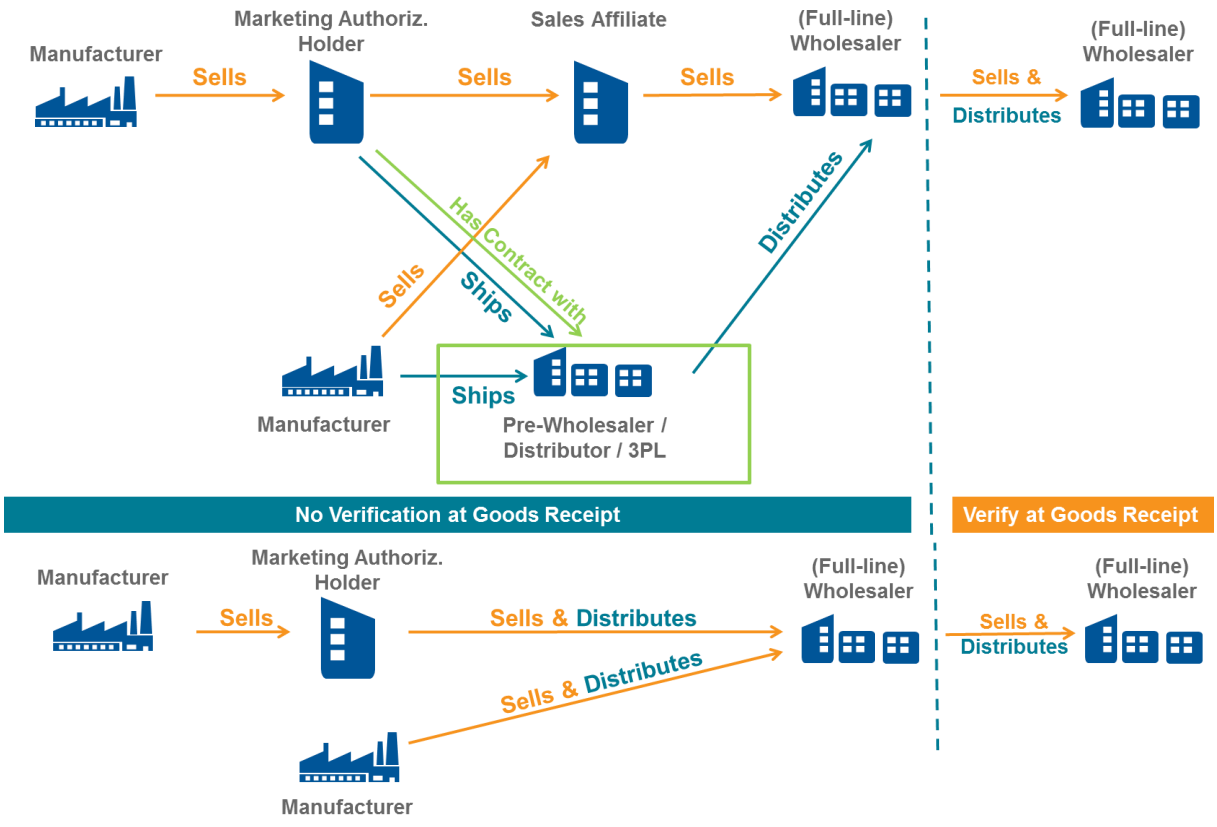


Figure 1: Supply chain setup as envisaged by Delegated Regulation DR 2016/161

Outsourcing of warehousing and distribution operations by the MAH requires that the outsourcing partner holds a wholesale distribution authorization. Common terminology for the outsourcing partners is pre-wholesaler, distributor, or 3PL (3rd Party Logistics provider). If such outsourcing partners are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf, then such entity **SHALL BE listed** as 'Designated Wholesalers'.

The Marketing Authorization Holder, the Manufacturer, and any of the (full-line) wholesalers in the figure above **SHALL NOT BE listed** as 'Designated Wholesalers'.

Scenario 2: Storage and Distribution Contract held by a Sales Affiliate

A 'sales affiliate of an MAH' means a company focussing on sales which is controlled by the MAH or which is subject to control by the same legal entity as the MAH. For purposes of EU pharma regulation, such sales affiliate and the MAH are considered to be one entity.

It is a common scenario that the contract with the warehouse and distribution partner is not held by the MAH himself but by a sales affiliate. Such scenario is depicted in Figure 2:

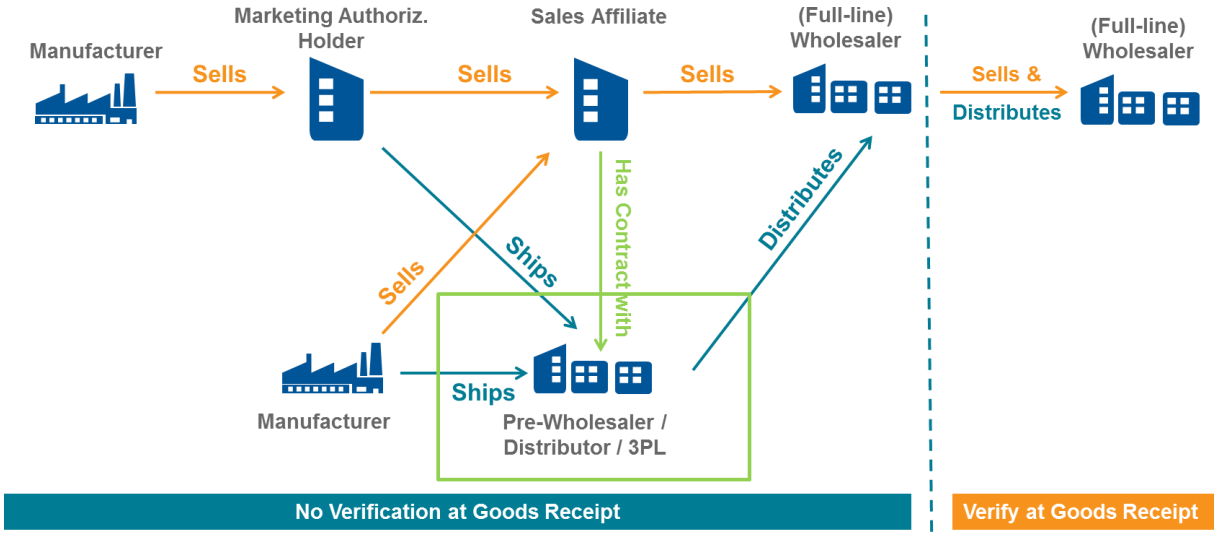


Figure 2: Supply chain setup where the contract for storage and distribution is held by a sales affiliate

Since the MAH and the sales affiliate are considered to be one entity, the sales affiliate **SHALL NOT BE** listed as 'Designated Wholesaler'. For all other parties depicted in the figure, the rules set forth in Scenario 1 apply.

Scenario 3: Storage and Distribution Involving Multiple Logistics Outsourcing Partners

Common supply chain designs involved more logistics partners than the one responsible for the distribution in the target country. Figure 3 outlines such example where the MAH or manufacturer ships its products to Country A where freight from different sites is consolidated. However, the affiliate in country A does not operate the warehouse himself but has outsourced activities to a 3PL. Products consolidated in the 3PL's warehouse are then shipped to the Pre-Wholesaler/Distributor/3PL in the target country B.

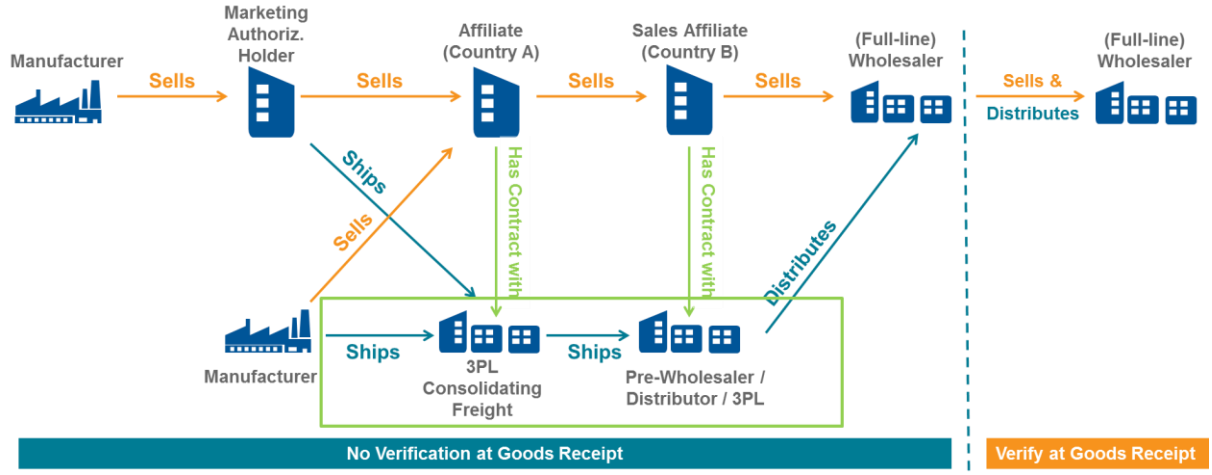


Figure 3: Supply chain setup that involves multiple outsourcing partners for logistics

In such a scenario, the logistics partner in country B **SHALL BE** listed as 'Designated Wholesaler' to avoid that the first (full-line) wholesaler in the supply chain needs to verify the products upon goods receipt.
Furthermore, the 3PL in country A **SHALL BE** listed as 'Designated Wholesaler' to avoid that the 'Designated Wholesaler' in country B needs to verify the products upon goods receipt.
For all other parties depicted in the figure, the rules set forth in Scenario 1 apply.

<u>Scenario 4: Commercialisation by a Co-Promoter</u>

Co-promoters operate under an agreement with the MAH or manufacturer and/or a license to commercialise the same medicinal product under the same trademark. The related distribution scenario is depicted in Figure 4:

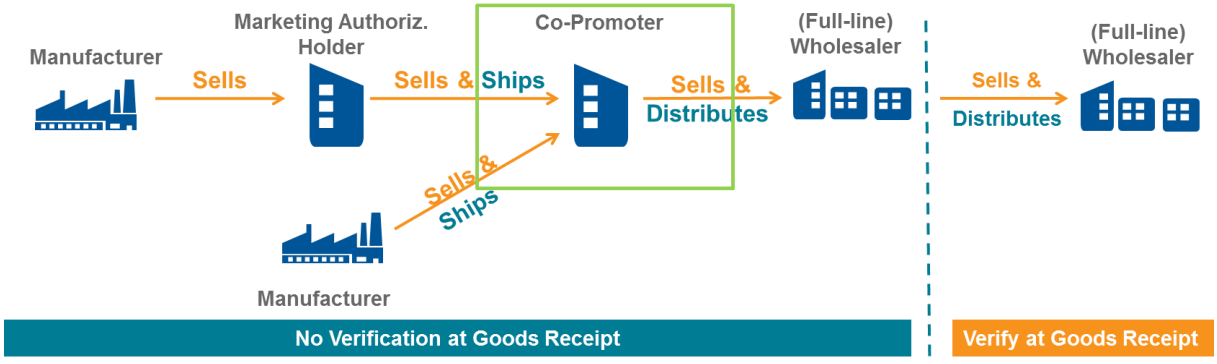


Figure 4: Supply chain setup where co-promoter has been contracted for commercialisation

By virtue of their co-promotion agreement the co-promoter has the right to market the medicinal product on behalf of the contract partner and/or licensor, including the right to store and distribute the medicinal product. They **SHALL BE** listed as 'Designated Wholesalers'. For all other parties depicted in the figure, the rules set forth in Scenario 1 apply.

Scenario 5: Commercialisation by a Co-Marketer

Co-marketing is a common commercialisation arrangement between originator companies. A co-marketing agreement is generally understood as an agreement between two parties to commercialise a specific medical product by each party under a different trademark. As co-marketers commercialise the product under a different trademark, they have their own marketing authorisation, different from that of the MAH (e.g. a duplicate or an independent marketing authorisation). They are thus MAHs in their own right.

In a co-marketing arrangement, the co-marketer holding his own marketing authorization has to fulfil himself the obligations for data upload according to DR 2016/161, Art. 33. This includes the list of 'Designated Wholesalers' that the co-marketer has chosen.

Scenario 6: Transportation Company

When a product is transported from location A to location B under a logistics contract and where for purposes of this transport the product is unloaded from an incoming semi-trailer truck or railroad car and loaded directly onto outbound trucks, trailers, or rail cars, with little or no storage in between, then the transportation company **SHALL NOT** be listed as 'Designated Wholesaler'.

Further Remarks and Recommendations

In practice, various supply chain designs beyond those outlined in the scenarios above exist. EMVO will not provide guidance on the proper determination of 'Designated Wholesalers' for any other scenarios. Marketing Authorization Holders (MAHs) and parallel distributors may wish to consider the following remarks when determining the appropriate list of 'Designated Wholesaler' for each country or product-country combination as well as documenting their decision:

- If an MAH has outsourced logistics operations to a 'Designated Wholesaler' operating a regional distribution centre, such 'Designated Wholesaler' **SHALL BE** listed for the products **IN EACH MARKET** it is distributing products to. The address provided for a designated wholesaler should correspond to the address from which the packs are physically sent.
- The marketing authorization holder can designate a representative (commonly known as local representative) to represent him in a EU Member State[6]. This includes rights for the representative such as to store and distribute the products.
- MAH's and parallel distributors should document in writing the delegation to sales affiliates or other legal representatives to appoint themselves 'Designated Wholesalers' for storage and distribution of the products covered by the MAH's marketing authorisation/s.

Best Practices

MAH's together with their Designated Wholesalers should collaborate with the MAH's wholesale customers regarding proper maintenance of the 'Designated Wholesaler' information in the product master data to ensure smooth operations for wholesale customers at goods receipt. Co-promoters should also communicate with the respective MAH so that they are listed as Designated Wholesalers by the MAH.

In the interest of increased operational and supply chain efficiencies MAH's and their wholesale customers may also work together to explore ways of adapting/upgrading the shipping documentation (i.e. delivery notes/invoices) to provide clarity for the wholesale customers regarding the entities involved in the delivery e.g. MAH, designated wholesaler, wholesale customer, delivery company etc. thus facilitating smooth operations at goods receipt.

[6] EU Directive 2001/83/EC on the Community Code relating to medicinal products for human use, Art. 1 (18a), Art. 6 (1a)

Template Delegation of Designated Wholesaler Appointment (Example)

[**Explanatory Note:** Article 20(b) DR obliges a wholesaler to verify the authenticity of the unique identifier except if the product was received from the manufacturer, a wholesaler with the marketing authorisation, or a wholesaler designated by the MAH.

This template delegation may be used by MAH to expressly delegate the appointment of designated wholesalers under Article 20(b) DR to sales affiliates or other legal representatives.]

DELEGATION OF DESIGNATED WHOLESALER APPOINTMENTS TO SALES AFFILIATE

Agreement by and between

[INSERT name and address of corporate entity]

"Marketing Authorisation Holder"

and

[INSERT name and address of corporate entity]

"Sales Affiliate" [or "Legal Representative"]

1. The Marketing Authorisation Holder ("MAH") delegates to the Sales Affiliate [Legal Representative] the appointment of designated wholesalers under Article 20(b) of the Delegated Regulation[7], meaning the appointment of wholesalers to store and distribute the products covered by the MAH's marketing authorisation/s [OPTIONAL: as listed in the Annex, which may be amended at the Market Authorisation Holder's discretion,] on the MAH's behalf.
2. Sales Affiliate [Legal Representative] accepts the delegation.
3. The delegation is effective as of [INSERT effective date].

[7] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, 2016 OJ L 32/1.

[INSERT place], on [INSERT date]

For the Marketing Authorisation Holder:

For the Sales Affiliate:

_____

(Signature)

[INSERT name, function]

_____

(Signature)

[INSERT name, function]

CONTRACT AMENDMENT/INSERT

DELEGATION OF DESIGNATED WHOLESALER APPOINTMENT TO SALES AFFILIATE

[INSERT number of new clause/section] **Delegation of Designated Wholesaler Appointment**

[INSERT DEFINED TERM for the Marketing Authorisation Holder] delegates to [INSERT DEFINED TERM for the Sales Affiliate/Legal Representative] effective as of [INSERT effective date of appointment/the effective date of the agreement/amendment] the appointment of designated wholesalers, i.e. wholesalers who store and distribute the products covered by his marketing authorisation/s [OPTIONAL: as listed in the Annex, which may be amended at the Market Authorisation Holder's discretion,] on his behalf ("Designated Wholesaler") pursuant to Article 20(b) of the Delegated Regulation[8]. [INSERT DEFINED TERM for the Sales Affiliate/Legal Representative] accepts the delegation.

[8] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, 2016 OJ L 32/1.

Template Delivery Note (Example)

1. Supplier (Name, Address, Country) Verkauefer (Name, Anschrift, Land) Fournisseur (Nom, Adresse, Pays) **MAH or its representative** **Name of the Company** **Address and Street Number** **City – Postcode** **Country**	2. Receiver (Name, Address, Country) Empfaenger (Name, Anschrift, Land) Destinataire (Nom, Adresse, Pays) **Full line Wholesaler** **Name of the Company** **Address and Street Number** **City - Postcode** **Country**
3. Sender (Name, Address, Country) Absender (Name, Anschrift, Land) Expediteur (Nom, Adresse, Pays) **Storage Unit** **Name of the Company** **Address and Street N°** **City – Postcode** Country	4. Freight Forwarder (Name, Address, Country) Frachtfuehrer (Name, Anschrift, Land) Transporteur (Nom, Adresse, Pays) **Transport company** **Name of the Company** **Address and Street N°** **City – Postcode** Country

- The objective is to identify the place and country where the manufacturer (1) is located and get an order from the Full line wholesaler (2).
- It is assumed that the supplier is operating under a Manufacturing License
- It is assumed that the sender (3) is not necessarily a "Designated Wholesaler" and therefore it is requested to have confirmation if we have to control or not the unique identifier.

Appendix 6: EMVO Gateway File Input Element Name Mapping

Common EMVS Master Data Element Names	**EMVO Gateway (file upload) Element Names**
Product Code	CodeValue
Coding Scheme	CodeScheme
Product Name	Name
Common Name	CommonName
Pharmaceutical Form	FormType
Strength	Strength
Pack Type	PackType
Pack Size	PackSize
Market-Based EMVS Master Data Element Names	**Market-Based EMVO Gateway (file upload) Element Names**
Member state ISO Code	Id
National code	NationalCode
Article 57 code/PCID	Article57Code
MAH	MAH
MAH ID	Id
MAH Name	Name
MAH Address (2 x Street, City, Postcode and Country Code)	Street1, Street2, City, PostCode and CountryCode
List of Wholesalers	ContractedWholesalers
Wholesalers ID	Id
Wholesalers Name	Name
Wholesalers Address(2 x Street, City, Postcode and Country Code)	Street1, Street2, City, PostCode and CountryCode

Appendix 7: Product Code Version Validation Rules

The European Hub will first validate that the Product Master Data (PMD) file containing the request is:

- not trying to add a market to an existing product record version
- not trying to remove a market from an existing product record version
- not trying to add a market unknown to the European Hub
- not one with an identical timestamp to an existing product version
- authorised to make the request

Failure to be successfully validated on any of the above points will result in the file containing the request being rejected.

Product Code Version Not Supplied[9]

For a first upload, the European Hub will create version 1; otherwise, the Product Master Data (PMD) file needs to be examined.

i. If the product material is the same as a version already stored, the European Hub will update the timestamp and continue the process (load and send it to the NMVSs).

ii. If there is no data which match that which is provided by the OBP, it will create a new version (incrementing the latest version number by 1) and the process continues.

Product Code Version Supplied

If the Product Code Version is supplied in the request, the European Hub will try to update the related PMD version.

[9] In case the OBP supplies the Product Code Version equals to 0 (zero), the EU Hub will behave as in the case that the Product Code Version is not supplied.