EMVS MASTER DATA GUIDE

Contents

1. Purpose

The EMVS (European Medicines Verification System) requires that OBP's (On-Boarding Partners) upload both product master data and product pack data. The aim of this guide is to clarify what data is expected to be used for the EMVS master data noting that the long-term goal is to source directly from the IDMP/SPOR system.

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 Eudralex 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 DR 2016/161 Article 33, Sections 2.c and 2.g are to be sourced, on a short-term basis, from the regulatory QRD data or SmPC (summary of product characteristics) information. The code listed in the DR 2016/161 Article 33, Section 2.e is to be sourced, from the Article 57(1) product database. Long-term all will be sourced from SPOR.
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. SPOR

The long-term aim for EMVS is to have the European Hub connected to the European Medicines Agency (EMA) SPOR data repository and to use this connection to provide a source of regulatory approved data that can be utilized by EMVS to provide a higher quality of data. An additional benefit is that it will allow each EMVS connected OBP to submit a lower payload of master data knowing that the bulk can be sourced from SPOR and will be populated automatically.

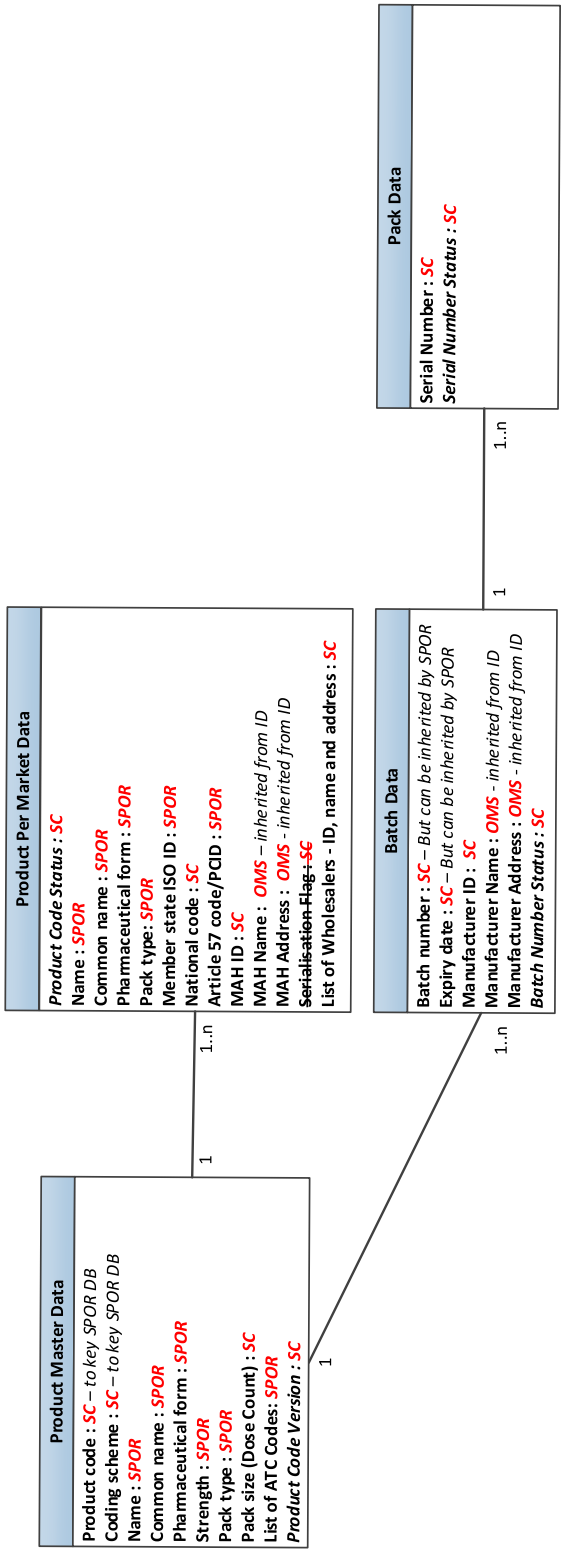
The key data fields that will enable this to function, for those parties who fall under the scope of SPOR, are:

- Product Code and Coding Scheme (in EMVS)
- Data Carrier Identifier (in SPOR) which is equivalent to the Product Code in EMVS.
- ISO Country Identifier for each market of intended sale

There will always be a requirement for each OBP to upload a partial set of master data to EMVS however, when SPOR is available, populated and connected, this overhead will reduce.

To better facilitate the connection with SPOR, the underlying data model within EMVS has been modified. The impact of this change on the OBP interface was minimal (zero) however there will be an enhancement required to the interface with each NMVS.

The update realised in Hub version 1.4 provides the necessary data element 'placeholders' which will be populated when the connection with SPOR is established. The following is provided as guidance to provide insight into the changes to the data model and to explain why the changes will occur and how they are able to better equip EMVS when SPOR is ready for connection.



SC = Sourced from the Supply Chain i.e. the OBP
SPOR = Sourced from SPOR (when active and connected)
OMS = Sourced from SPOR OMS system when active and connected.

The highlights of the data model are as follows:

- The Common Data Section has a new 'List of ATC Codes' added. Maximum number of codes per list is ten. ATC codes can be in the 5 character format or 7 character format and they apply to all markets for the given product code. (The ATC Code cannot be updated or set directly by the OBP).
- The Product Code Status (which is not accessible by the OBP) is moved to the Market Specific Data section to support the 'Product Withdrawal' capability.
- The Market Specific Data section has been upgraded to included:
    - Name
    - Common Name
    - Pack Type
    - Pharmaceutical Form

  This permits the future insertion from SPOR of the localised regulatory data for each market.
- The element 'Serialisation Flag' has been deprecated but left on the OBP interface. No logic is applicable to this element.

Currently SPOR is some way off being available to use in conjunction with EMVS and indeed, some OBP categories are not within the scope of SPOR.

Adding the Name, Common Name, Pack Type and Pharmaceutical Form to the Market Specific Data will allow localised regulatory approved data to be inserted and sent to each applicable market when SPOR in available.

Retaining the same data at the 'Common Data' level allows the existing OBP interface to remain consistent thus lowering the development risk for each OBP..

Rules will be inplace to ensure that these values are used appropriately and allow for SPOR to become the 'master source' when available.

ATC codes apply to all markets and thus have been added to the Common Data level and will be appended to the data sent to each market by the European Hub. This will be an updated interface version and NMVS will need to be updated to make use of the new data. These elements will not be accessible by the OBP interface and will only be populated when SPOR is connected. The ATC code data is required to fulfil one of the NCA reporting requirements.

4. Common Master Data Elements

In the common master data elements section, we have the following elements that are addressable by the OBP interface and that will be the responsibility of each OBP to upload.

Added to the table below in the 'Element Name' column is the mapping to the EMVO Gateway file format naming conventions. These are shown thus: [aaaaaaa] if 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[1]	Reference Examples
Product Code [CodeValue]	The logistics code on the pack and contained within the new Data Matrix code. Will be either a GTIN, NTIN or PPN only.	05060141900015	Logistics / Supply Chain Mgmt.
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
For the following 5 fields, please refer to the table in Appendix 1 for guidance or to the reference[1] below			
Name [Name]	e.g. the (invented) name + strength + pharmaceutical form. *For single market packs, 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 (Belgium), provide the name from within one of the SmPCs.* *For multi-market packs, use the name as it appears on the artwork or a concatenation of the name in each language suitable for the pack. Longer term aim for multi-market packs will be to have the name held in the market specific data not in the common data.*	Amoxicillin Effective Medicines 500mg Capsules WQX®"Plus" 80mg/25 mg Filmtablette	QRD, Annex 1, sec 1 Can be xEVMPD AP.13.1 productname) For multi-market packs this can be a concatenation of the values for AP 13.1 for all relevant markets

[1] For additional examples on Name, Common Name, Pharmaceutical Form, and Strength refer to "EMA splitting of the full presentation name of the medicinal product best practice", EMA/327516/2014 Rev. 3, 19 January 2016

Element Name	Description	Example[1]	Reference Examples
Common Name [CommonName]	International Non-proprietary name (INN) or the usual common name of the active substance(s), if part of the full name of the medicinal product. *For single market packs, use the national language for NAP/MRP/DCP. English is acceptable for CP. If SmPCs are valid for a specific product in more than one language (Belgium), provide the common name from within one of the SmPCs. For multi-market packs, use the common name as it appears on the artwork or a concatenation of the common name in each language suitable for the pack. Longer term aim for multi-market packs will be to have the common name held in the market specific data not in the common data.*	Amoxicillin Telmisartan/Hydrochlorotiazide	QRD, Annex 1, sec 1 (name element only) i.e. an extract from the 'Name of Medicinal Product'. This field is not validated against an external term. Note: this field may not always be present in regulatory submissions and therefore this field may legitimately be left empty in these circumstances.
Pharmaceutical Form [FormType]	The single full Standard Term of the European Pharmacopeia, using the plural form if appropriate (https://standardterms.edqm.eu/) – currently only the English terms are supported. For multi-component medicinal product use EDQM Combined Pharmaceutical Dose Form CV. *More flexibility will be permitted in the future by moving this element to the market specific data and removing the "English Only" restriction.*	Capsule	QRD, Annex 1, sec 3 SPOR IDMP "Pharma Dose Form Name Part"
Strength [Strength]	The pharmaceutical strength of the product. This should be consistent with the quantity stated in the quantitative composition and the posology. (Will be a repetition of what is entered as part of the full name)	500mg 80mg/25 mg	Strength element of the Medicinal Product name in SPOR (IDMP), QRD, Annex 1, sec 1

Element Name	Description	Example[1]	Reference Examples
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. *Currently only the English terms are supported. More flexibility will be permitted in the future by moving this element to the market specific data and removing the "English Only" restriction.*	Box, Bottle, Bag	EDQM 'Packaging' term list
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'. Please refer to the table in Appendix 2 for examples. *if the pack could not be split, e.g. a 28 day supply of contraceptive, the value is 1	28	The pack size can be derived from QRD, Annex 1, sec 6.5 but this is often not the same as the re-packable dose.
ATC Codes [Not Accessible]	*List [0..10] of ATC code values in 5 or 7 character format.*	*ANNAANN*	
Product Code Version[2] [ProductVersion Number]	The Product Code Version is an optional field that shall be used by OBPs to associate the Product Master Data with a specific version. This field may be used for any retrospective upload of Product Master Data. [3]	1, 2, 3, 4.	

Table 1 - Common Master Data (Market Agnostic)

[2] See Appendix 7: Product Code Version Validation Rules

[3] The retrospective upload of Master Data is used to upload packs to new countries that were not included in previous versions of Product Master Data

N.B. 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. When SPOR is connected, these values will be over-written by those obtained by SPOR. The internal data model also supports the inclusion of up to ten ATC codes per product master data entry. These cannot be entered directly by the OBP and will be extracted from SPOR when the connection is made.

5. Market Specific Master Data Elements

For each market within a multi-market pack the following table should be completed. For single market packs only one completed table is required.

Element Name	Description	Example	Reference Examples
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.	DE	List of ISO Codes (Appendix 3)
National code [Nationalcode]	It is required to insert the national code if requested by the NMVO (see Appendix 4). If not, it is recommended to insert the code (when it exists), however it is left to the discretion of the OBP to decide.[4]	1234567	Appendix 4
Article 57 code/PCID [Article57Code]	Article 57 code: xEVMPD EV Code which is assigned by EMA after successful transmission of MPD (Master Product Data) to xEVMPD. Packaged Medicinal Product Identifier (PCID): ISO IDMP/SPOR identifier if already existing. If multiple codes exists for the market, only select one that matches the 'Name' and 'Common Name' supplied. For Switzerland and Parallel Distribution products, leave empty.	PRD115784	Key as assigned by EMA upon submission of a new record to EVMPD
Name [Not Accessible]	*See common section for the description (this element is not directly accessible by the OBP)*		
Common Name [Not Accessible]	*See common section for the description (this element is not directly accessible by the OBP)*		
Pack Type [Not Accessible]	*See common section for the description (this element is not directly accessible by the OBP)*		
Pharmaceutical Form [Not Accessible]	*See common section for the description (this element is not directly accessible by the OBP)*		
MAH ID [Under element group MAH = Id]	Use the IDMP/SPOR OMS Organisational ID when available for the marketing authorization holder. This field is optional. Exception Germany: For interim period keep IFA registration number until further notice. For CAP/MRP, this represents the MAH obtaining the license. For NAP, this will be the local MAH.	48101	

[4] It is mandatory that this field is populated when Product Master Data is intended to be distributed to Portugal, Spain, Austria, Germany and the UK.

Element Name	Description	Example	Reference Examples
MAH Name [Under element group MAH = Name]	Registered name of the MAH responsible for the product in the market (stated in row 1). Only compulsory to enter when the MAH ID is not used.	World Class Medicines Limited	QRD, Annex 1, sec 7
MAH Address [Under element group MAH = Street1, Street2, City, PostCode and CountryCode]	Postal address for the MAH detailed above. Only compulsory to enter when the MAH ID is not used.	14 Harper Street, Lincoln, LN6 3PW, UK	QRD, Annex 1, sec 7
Serialisation Flag [N/A]	Fill in "True" Field will be deprecated and has no business function.[5]	**True**	n/a
List of Wholesalers with ID, name and address [Under element group ContractedWholesalers = Id, Name, Street1, Street2, City, PostCode and CountryCode] See Appendix 5 for guidance	This will be a list organised as <ID> (if available) <Name> <Address>. The list should contain the details of each wholesaler (eqv.) who is 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. The ID is optional and reserved for future inclusion when Wholesalers are identified as meticulously as MFR) and MAH's.	ID=N/A Name = 'Better Wholesaling GmbH' Address = 'Neue Strasse 12, 10119 Berlin, Germany'	n/a

Table 2 - Market Specific Master Data

For multi-market/shared-market packs, the above table 2 is repeated for each market the pack is destined to be sold. Note, that multi-market designation (i.e. multiple table 2) can be added in a stepwise manner as the EMVS system reach extends. Thus if only one of the markets for a specific product is connected and operating – only add the one table 2 for that market. When another of the markets comes on-line, amend the master data entry to add the new market table. Adding tables for markets that are not on-line will result in the master data submission being rejected.

[5] This field shall only be deprecated when the 2016.1 interface is decommissioned

6. Submission Procedure

6.1 Single Market Products.

Complete and send to the European Hub, one of each, Table 1 and Table 2 with the Table 2 Member state ISO Code set to the market required.

6.2 Multi-Market Products.

Complete and send to the European Hub, one of Table 1 and one of Table 2 for each market of intended sale (noting that a stepwise approach may be required during the ramp-up phase whilst all national systems are not fully operational).

7. Batch and Pack Data

Master data is essentially a one-off or occasionally uploaded function however the uploading of batch and pack data is more frequent.
The Delegated Regulation has defined some extra data requirements for this more frequently used operation.
This more frequently uploaded data consists of two basic element groups.

1 The first defines the details of the batch being produced
2 The second defines the physical pack serial ID's associated with the batch.

The following tables define the data elements more completely.

7.1 Batch Data

Element Name	Description	Example
Batch number [BatchID]	Batch number as printed on the serialized pack	LOT123/XYZ3
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 can be set to 00 (e.g. 190200 is February 2019). Market/Company rules apply.	190209
Manufacturer ID [Under element group Manufacturer = Id]	Use the IDMP/SPOR OMS Organisational ID when available for the manufacturer organisation that placed the safety features. Use of this field is optional for now.	1234567

Element Name	Description	Example
Manufacturer Name [Under element group Manufacturer = Name]	Enter here the full name of the manufacturer placing the safety features. Only compulsory to enter when the Manufacturer ID is not used.	Effective Medicines Limited.
Manufacturer Address [Under element group Manufacturer = Id, Name, Street1, Street2, City, PostCode and CountryCode]	Enter the Registered address of the manufacturer placing the safety features. Only compulsory to enter when the Manufacturer ID is not used.	12 Harper Street, Lincoln, LN6 3PW, UK
Batch Number Status [N/A]	Automatically maintained by the verification system so no requirement to upload.	N/A

7.2 Pack Data

Element Name	Description	Example
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 should be randomised according to the Delegated Regulation requirement (Art 4(b)) and the pack coding guidelines. For clarity, serial ID's can be numeric only so long as they meet the given criteria.	ZT34012956345DLM
Serial ID Status [N/A accessed by update use case as either CurrentStatus or NewStatus]	Automatically maintained by the verification system so no requirement to upload.	N/A

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.

Appendix 1: Common Master Data Element References

Element Name	**Directive 2001/83/EC „Medicinal Products for Human Use"**	**QRD Template Version 10**	**Guideline on SmPC[6] 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	AP.13.3 productgenericname
Pharmaceutical Form	according to summary of product characteristics (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) (see section 3).	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

[6] SmPC Summary of Product Characteristics

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

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
Emulation 1	XX
Emulation 2	XY
Emulation 3	XZ[7]
Emulation 4	XA
Emulation 5	XB[8]

N.B. Emulated Markets are only available in ITE and IQE (not PRD) and are not ISO 3166 codes but reserved special codes for the emulators only.

[7] Markets XX, XY and XZ emulated with the 2016.1 schema

[8] Markets XA and XB emulated with the 2018.1 schema

Appendix 4: Guidance for entering National Code

The National Code must be entered for the following countries that require, and have specifically requested, that the EMVS is used to look up the National Code.

Austria (add the PZN for all product types i.e. Multi-Market and Single Market)
Germany (add the PZN for all product types i.e. Multi-Market and Single Market)
Spain (all product types) (format: 6 digits + 1 check digit without separator, example: 6068946)
UK (AMPP required for all product types)
Portugal (all product types) (format: 7 digits, all numeric)

The list has initially been derived from the "Efpia Coding Requirement Tracker" and NMVOs should send a request to EMVO to be added to the list in this appendix if they want to national code to be entered.

For other countries it is recommended to enter the National Code when it exists, however the decision rests with the OBP.

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'

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:

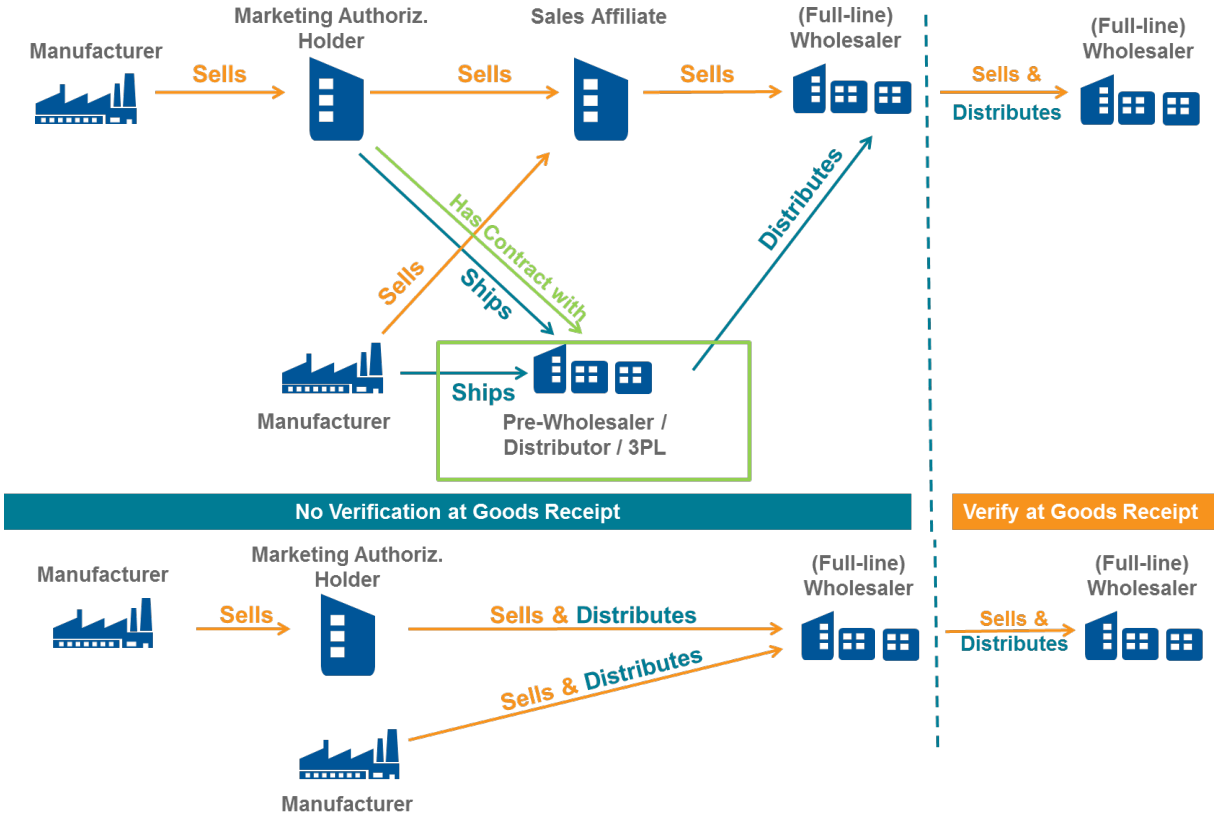


Figure 1: Supply chain setup as envisaged by Delegated Regulation DR 2016/161

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:

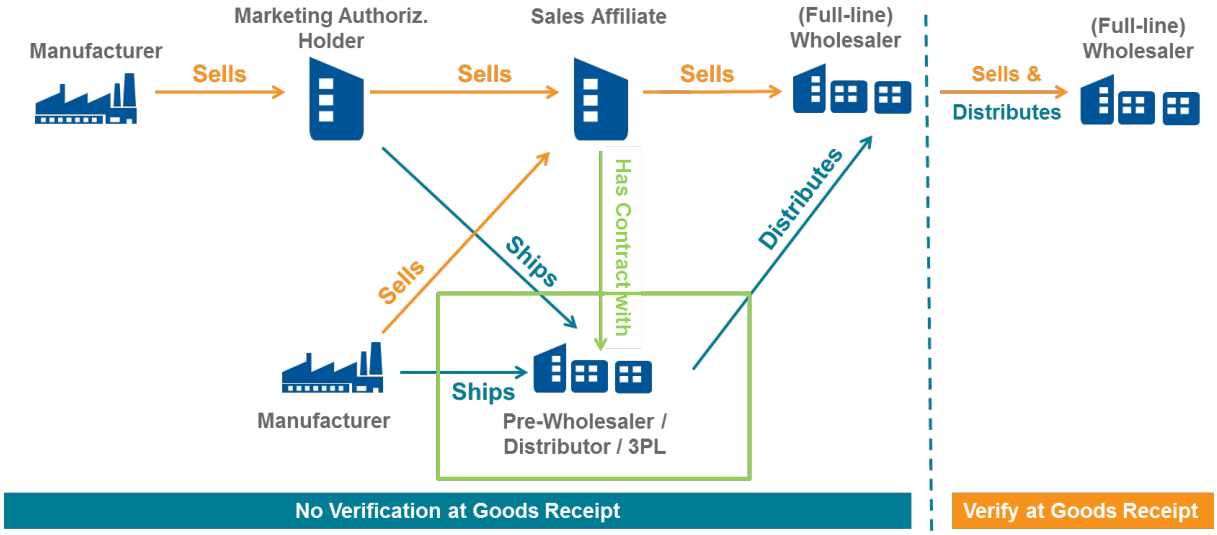


Figure 2: Supply chain setup where the contract for storage and distribution is held by a sales affiliate

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.

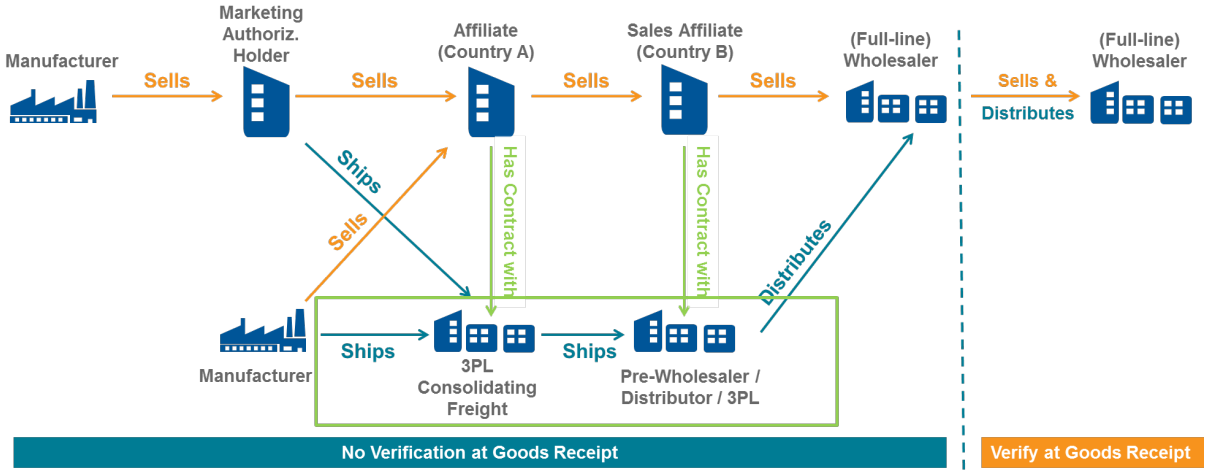


Figure 3: Supply chain setup that involves multiple outsourcing partners for logistics

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.

Scenario 4: Commercialisation by a Co-Promoter

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:

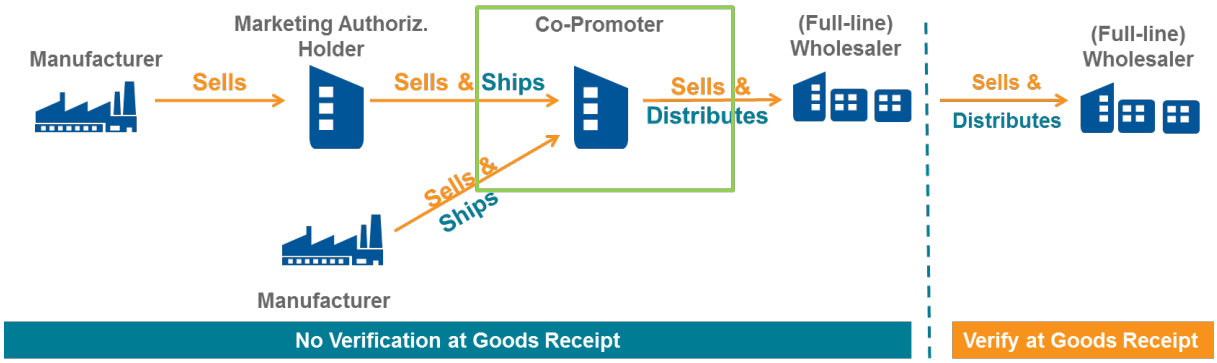


Figure 4: Supply chain setup where co-promoter has been contracted for commercialisation

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** he is distributing products to.
- The marketing authorization holder can designate a representative (commonly known as local representative) to represent him in a EU Member State[9]. This

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

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.

EMVO MD Guide
Appendix 5 - Design

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[10], 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].

[INSERT place], on [INSERT date]

[10] 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.

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[11]. [INSERT DEFINED TERM for the Sales Affiliate/Legal Representative] accepts the delegation.

[11] 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
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 ID	Id
MAH Name	Name
MAH Address (2 x Street, City, Postcode and Country Code)	Street1, Street2, City, PostCode and CountryCode
Serialisation Flag	N/A (automatically set to True)
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

Product Code Version Not Supplied [12]

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

The European Hub will first check if there is a PMD stored with an identical timestamp. If the timestamps are identical, it will assume that it should be linked with the same version. The European Hub will then do the following check:

i. If the data stored and the data requested match, there is no data change and the European Hub only updates the timestamp stored;

ii. If the data changes, the process will stop, and the European Hub sends back to the OBP an Data Validation Error and logs the exception;

If the timestamp provided does not match any timestamp of a version already stored, the European Hub will compare the data provided with that which is already stored.

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 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 it. A check between the data stored and that which just been uploaded will be done. If any target market is excluded for the updated version of Product Master Data, the request will be rejected by the European Hub.

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