SMVO
swiss medicines
verification organisation

Comments & Recommendations

on the EMVO_0122_EMVS Master Data Guide for

Switzerland and Liechtenstein

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This document includes Comments and Recommendations on how to utilize the EMVO_0122_EMVS Master Data Guide in the Swiss and Liechtenstein markets.

Should you have any questions or comments, please do not hesitate to contact us by e-mail or phone.

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1. Common Master Data Elements

Element Name	Description	Example[1]	Reference Examples	Recommendation Switzerland/Liechtenstein
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.	Swiss Packs use GTIN with Company Prefix or NTIN with national Prefix "7680 + Swissmedic-MA-Nr.+ Swissmedic Pack code + Check digit"
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	Only GTIN
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	Please refer to sai.refdata.ch

Element Name	Description	Example[1]	Reference Examples	Recommendation Switzerland/Liechtenstein
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.	Please refer to sai.refdata.ch

Element Name	Description	Example[1]	Reference Examples	Recommendation Switzerland/Liechtenstein
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"	Please refer to sai.refdata.ch
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	Please refer to sai.refdata.ch
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	Please refer to sai.refdata.ch

Element Name	Description	Example[1]	Reference Examples	Recommendation Switzerland/Liechtenstein
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.	Please refer to sai.refdata.ch
ATC Codes [Not Accessible]	*List [0..10] of ATC code values in 5 or 7 character format.*	*ANNAANN*		Please refer to sai.refdata.ch
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.		Optional

2. Market Specific Master Data Elements

Element Name	Description	Example	Reference Examples	Recommendation Switzerland/Liechtenstein
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)	The ISO Code for Switzerland AND Liechtenstein is "CH"
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	It is recommended to enter the 8-Digit Swissmedic MA-Number: 5-Digit MA-Number + 3 Digit Pack Code
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	NOT APPLICABLE
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)*			

Element Name	Description	Example	Reference Examples	Recommendation Switzerland/Liechtenstein
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		Swissmedic has not specified ID-Rule yet. Use IDMP/SPOR Org-ID https://spor.ema.europa.eu/omswi/#/
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	Please refer to sai.refdata.ch
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	Please refer to sai.refdata.ch

Element Name	Description	Example	Reference Examples	Recommendation Switzerland/Liechtenstein
List of Wholesalers with ID, name and address [Under element group ContractedWholesa lers = 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	

2.1 Batch Data

Element Name	Description	Example	Recommendation Switzerland/Liechtenstein
Batch number [BatchID]	Batch number as printed on the serialized pack	LOT123/XYZ3	Identic to EU description
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	Identic to EU description
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	Identic to EU description
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.	Identic to EU description

Element Name	Description	Example	Recommendation Switzerland/Liechtenstein
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	Identic to EU description
Batch Number Status [N/A]	Automatically maintained by the verification system so no requirement to upload.	N/A	

2.2 Pack Data

Element Name	Description	Example	Recommendation Switzerland/Liechtenstein
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.	ZT34012956345DL M	Identic to EU description
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	

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