EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Business Support

Outlines of amendments to the XEVPRM schema and EVWEB Labels

Technical Specifications

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1. Introduction

Amendments to the electronic format published by the Agency on 5th March 2012 are necessary to support new legal obligations placed on the Agency. The amended electronic format requires marketing authorisation holders to provide additional information on the medicines as of 16th June 2014.

This document outlines the changes of the Article 57 format and XSD schema as well as the new business rules.

In addition, in order to further clarify the scope of data elements and the information to be provided, the Agency is re-labelling fields in its data-entry tool (i.e. EVWEB) as described in this document. Please note that the re-label of the fields will only be implemented in EVWEB and not reflected in the data elements of the schema to minimise the technical development on the XEVPRM format. In addition the re-label of the fields does not change the information required to be submitted.

2. Amendments to the XEVPRM Format

The following new information is required to be submitted to the Agency as of 16th June 2014 and by end of December 2014:

Table 1. Amendments to the XEVPRM Format

Field/Data element	Location in the schema	Data type	Business rules
SME Status	Within the "Organisation" entity	Controlled Vocabulary (CV): NA/Micro/Small/ Medium	Mandatory/Not repeatable
SME Number	Within the "Organisation" entity	Free text alphanumeric	Not repeatable Business rules: If SME Status = "NA" this field cannot be populated If SME Status <> "NA" this field is optional
Authorised Pharmaceutical Form	At Product level	Based on the XEVMPD proposed and standard Pharmaceutical Form CV	Mandatory/Repeatable Business rules to prevent repeated submission of the same CV value (within a single product)
Legal Basis	At Product level	Based on Controlled Vocabulary values presented in section 4.1. of this document	Mandatory/Not repeatable
Medicinal Product Type	At Product level	Based on Controlled Vocabulary values presented in section 4.2. of this document	Mandatory/Repeatable Business rules to prevent repeated submission of the same CV value (within a single product)

The following table summarise the new business rules that will be applied as of June 16th 2014 in the XEVPMD as well as the change in the label of the Agency's data entry tool (i.e. EVWEB):

Table 2. Amendments of business rules in processing XEVPRM and labelling of EVWEB data elements

Reference to data element and labels in EVWEB	Change required
Country of Authorisation	**New business rule** to limit only the specific European territories (CV) where EU procedures are selected
Organisation entity within the product	**New business rule** to enforce the following fields mandatory: Address, Postcode
Withdrawn button	In the "Create and Send Product Reports" section, button re-label to be changed to "Invalidate MA"
Operation type "Withdrawn"	Operation type "Withdrawn" to be changed to "Invalidate MA"
All Product Name Fields	Remove leading and trailing spaces, remove non-printing characters
Organisation entity within the product	Remove leading and trailing spaces, remove non-printing characters
Authorisation Status	Change the list value from "Suspended (2)" to "Valid – Suspended (2)"
Intensive Monitoring	Change in the EVWEB field label from "Intensive monitoring" to "Additional monitoring"
MRP/DCP Number	Change in the EVWEB field label from "MRP/DCP Number" to "MRP/DCP/EMEA Number"
Product Generic Name	Change in the EVWEB field label from "Product Generic Name" to "Product INN/Common Name"
Authorisation Date	Change in the EVWEB field label from "Authorisation Date" to "Authorisation/Renewal Date"
Organisation entity within the product	Change in the EVWEB field label from "State" to "Region"
Pharmaceutical Form	Change in the EVWEB field label from "Pharmaceutical Form" to "Administrable Pharmaceutical Form"

NOTE 1: in order to minimise the amendments to the XEVPRM schema, the changes of label of the in the EVWEB field will not be reflected as a change in the name of the data elements of the XSD schema.

NOTE 2: The scope and information required are not amended: the re-label is aimed to further clarify the information that is required to be submitted in the applicable fields.

3. Mock-Up of the XEVPRM Schema

3.1. Changes for the Organisation entity

Summary of schema changes:

- Addition of an **SME status** field based on a schema enumeration with business rules based on Organisation type.
- Addition of optional **SME number** field.

Summary of business rule changes:

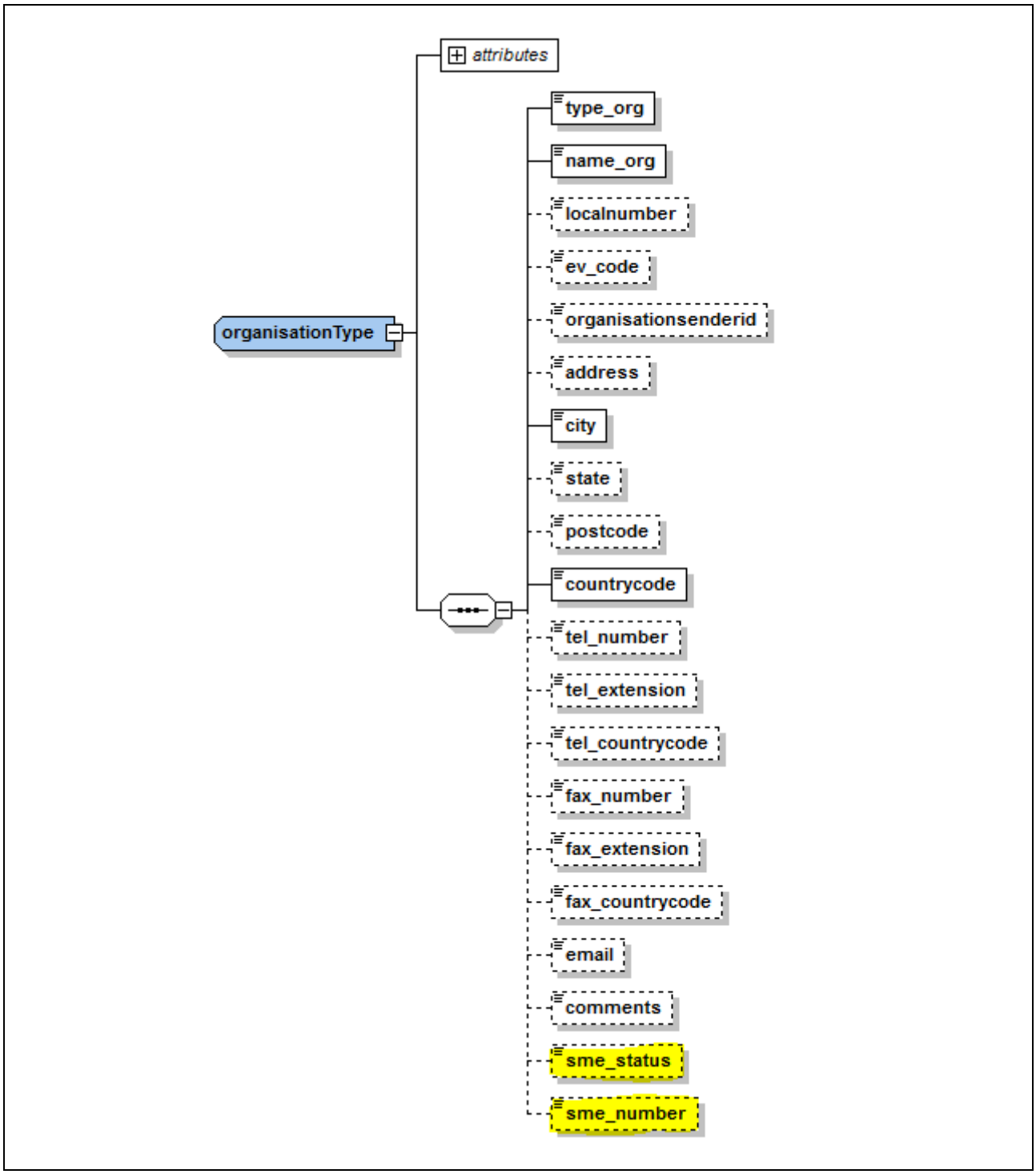
- A new business rule will be added to enforce the presence of the SME status field if the operation type is "insert" or "update" and the organisation type is an MAH.
- A new business rule will be added to prevent the use of the SME status field if the organisation type is Sponsor.
- A new business rule will be added to prevent the use of the SME number field unless the value of the SME status field means "Micro", "Small" or "Medium".
- A new business rule will be added to make the Address field mandatory if the operation type is insert or update (O.6.BR.1).
- A new business rule will be added to make the Postcode field mandatory if the operation type is insert or update (O.9.BR.1).
- A new business rule will be added to prevent insertion or updating of an organisation where the values of all of the following fields match the values in the same fields for an existing organisation of the same type:
  - Organisation Name.
  - Address.
  - City.
  - Post Code.
  - Country Code.

NOTE: The mandatory nature of these changes is controlled through business rules rather than making the elements themselves mandatory; this is to allow for nullifications of organisations without the need to supply this new data.

Violation of any of these new rules will result in the entire message being rejected (i.e. 03 acknowledgement).

The proposed amended Organisation element is shown in the following diagram:

Figure 1. The proposed Organisation Element

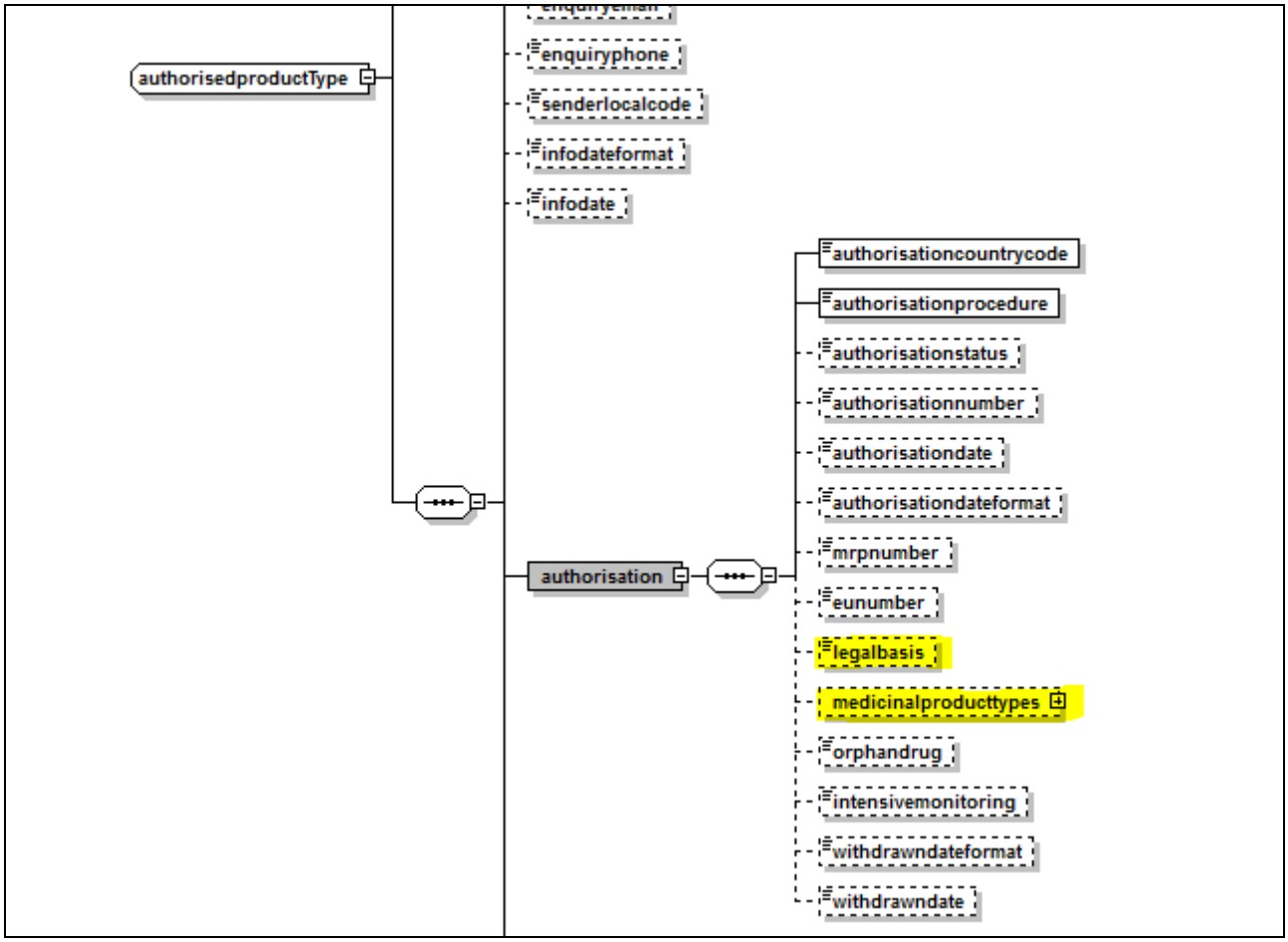


3.2. Changes for the Authorised Product entity

Summary of schema changes:

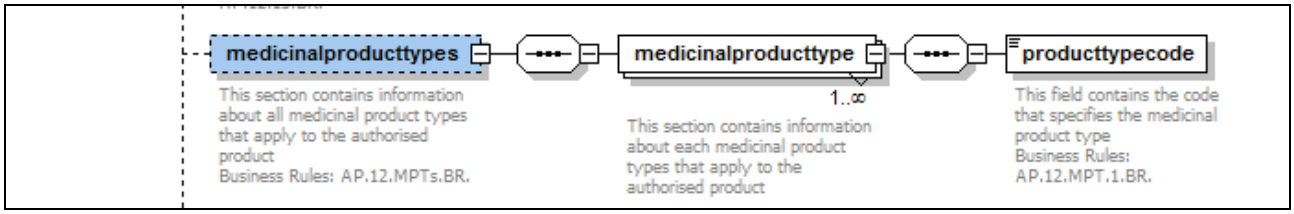
- Addition, within the authorisation element, of a **legal basis** field (AP.12.13) based on a list of controlled values as outlined in section 4.1. of this document; the field will contain an integer value.
- Addition, within the authorisation element, of a **medicinal product types** entity (AP.12.MPTs).

Figure 2. Legal basis



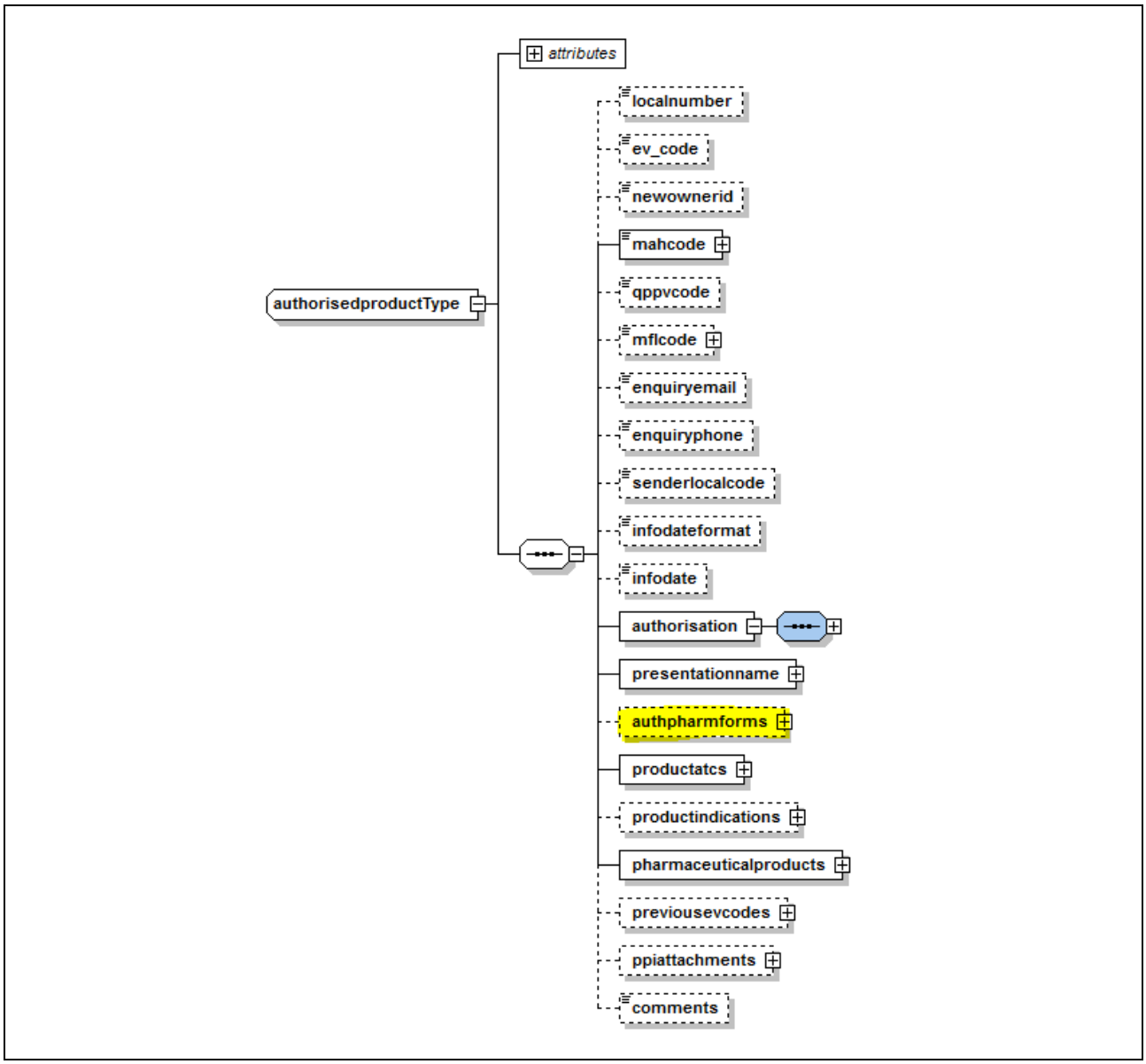
- The medicinal products types element contains repeatable **medicinal product type** elements based on a list of controlled values as outlined in section 4.2. of this document as shown in Figure 3 The product type code will be an integer value.

Figure 3. Medicinal product type entity



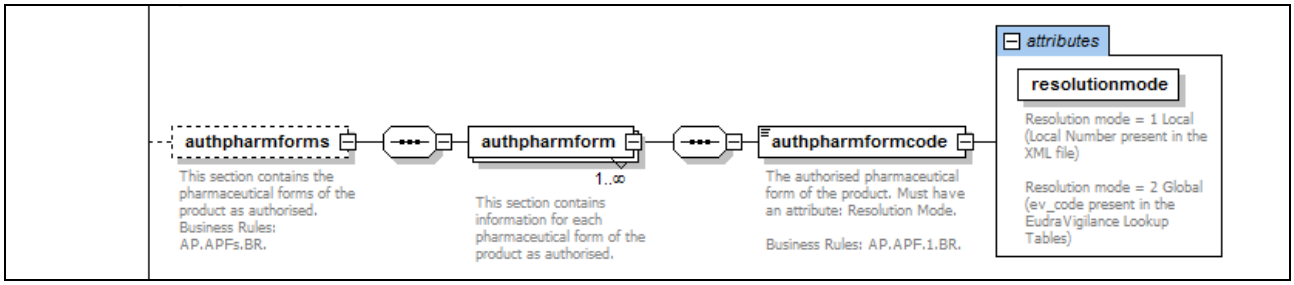
- Addition of an **authorised pharmaceutical forms** element (AP.APFs) at the product level as shown in Figure 4.

Figure 4. Authorised pharmaceutical forms element



This element contains a repeatable authorised pharmaceutical form element which is used to select an existing proposed or standard pharmaceutical form from the xEVMPD or a new proposed pharmaceutical form contained within the same message in exactly the same way as other references to new or existing entity values; the structure of the element is shown in figure 5.

Figure 5. Authorised pharmaceutical form element



Summary of business rule changes for the Authorised Product Entity:

These new elements will be mandatory for all product operations where the resulting product will be an active product in the xEVMPD – in line with the policy adopted by the Agency when new rules are introduced the presence of the new elements will be controlled by business rules rather than the schema to allow users to nullify products without the need to supply the new data elements. The new rules identified to date are summarised in the list below:

- Legal Basis:
  - A new business rule will be added to enforce the presence of the legal basis field if the operation type is "insert", "update" or "variation" and the message sender is not the EMA.
  - A new business rule will be added to ensure that if the legal basis field is present then the value must appear as the code of one of the values in the published legal basis list.
- Medicinal Product Types:
  - A new business rule will be added to enforce the presence of the medicinal product types section if the operation type is "insert", "update" or "variation" and the message sender is not the EMA.
  - A new business rule will be added to ensure that duplicate medicinal product type sections do not appear within the same medicinal product types section (i.e. in the same product).
- Medicinal Product Type:
  - A new business rule will be added to ensure that the medicinal product type field value must appear as the code of one of the values in the published medicinal product type.
- Authorised Pharmaceutical Forms:
  - A new business rule will be added to enforce the presence of the Authorised Pharmaceutical Forms section if the operation type is "insert", "update" or "variation" and the message sender is not the EMA.
  - A new business rule will be added to ensure that no duplicate authpharmformcode values are present within the same Authorised Pharmaceutical Forms section (i.e. in the same product).
- Authorised Pharmaceutical Form:

- A new business rule will be added to ensure that the authorised pharmaceutical form value in the authpharmformcode field is a valid proposed or standard pharmaceutical form in the xEVMPD or a local number of a proposed pharmaceutical form contained within the same message.

- Country of Authorisation (no schema changes):
  - A new rule will be introduced restricting the value of authorisation country to EAA countries if the authorisation procedure represents an EU procedure.

If any of the rules above are violated then the product will be rejected and an 02 acknowledgement generated – message processing will continue with any other products in the message.

4. Values of Controlled Vocabularies

The following list of new XEVPMD controlled Vocabularies and the related codes are available on the EMA's webpage on Documents for electronic submission of information on medicines.

4.1. Legal Basis

The details of the legal basis for the marketing authorisation based on the following EXCLUSIVE selection criteria
Full application (Article 8(3) of Directive No 2001/83/EC)
Generic application (Article 10(1) of Directive No 2001/83/EC)
Hybrid application (Article 10(3) of Directive No 2001/83/EC)
Similar biological application (Article 10(4) of Directive No 2001/83/EC)
Well-established use application (Article 10a of Directive No 2001/83/EC)
Fixed combination application (Article 10b of Directive No 2001/83/EC)
Informed consent application (Article 10c of Directive No 2001/83/EC)
Traditional use registration application for a herbal medicinal product (Article 16a of Directive No 2001/83/EC)
Simplified registration application for a homeopathic medicinal product (Article 14 of Directive No 2001/83/EC)
Medicinal product authorised according to Article 126a of Directive No 2001/83/EC
Application according to Article 58 of Regulation (EC) No 726/2004

4.2. Medicinal Product Type

The description of the type of the medicinal product based on the following non- EXCLUSIVE selection criteria
Authorised homeopathic medicinal product
Authorised herbal medicinal product
Parallel Distributed/Imported medicinal product (Article 76(3) and (4) of Directive No 2001/83/EC)
Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004)
Exceptional Circumstances Marketing Authorisation (Article 14(6) of Regulation (EC) No 726/2004 or Article 22 of Directive 2001/83/EC)
Paediatric Use Marketing Authorisation (PUMA) (Article 31 of Regulation (EC) No 1901/2006)
Other