



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CESSP Phase 1 – status update

Webinar for Industry – 07 May 2019



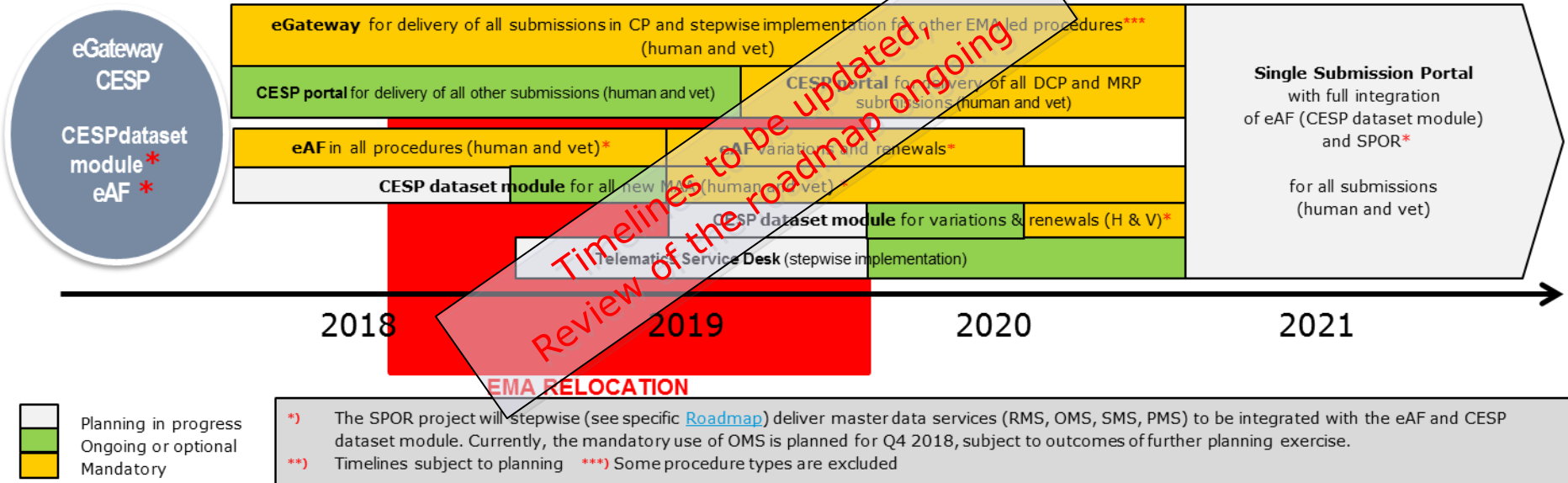
Agenda

- 1) Welcome and objectives – *Georg Neuwirther*
- 2) Essentials, Project status and milestones – *Georg Neuwirther*
 - Scope of the project
 - Process changes (or not changes)
 - Status
 - Rollout Plan and Risks
- 3) Information about UAT#3 – *Anne-Christine Lantin, Jeroen Veen, Gary Wilson, Jose Simarro*
 - The process of publication / invitation
 - Timeframe
 - Scope
- 4) XSD upgrade – *Jose Simarro*
 - Motivation
 - Changes
 - Examples
- 5) Demonstration of new application interface – *Gary Wilson*
- 6) Q&A – *Kristiina Puusaari*

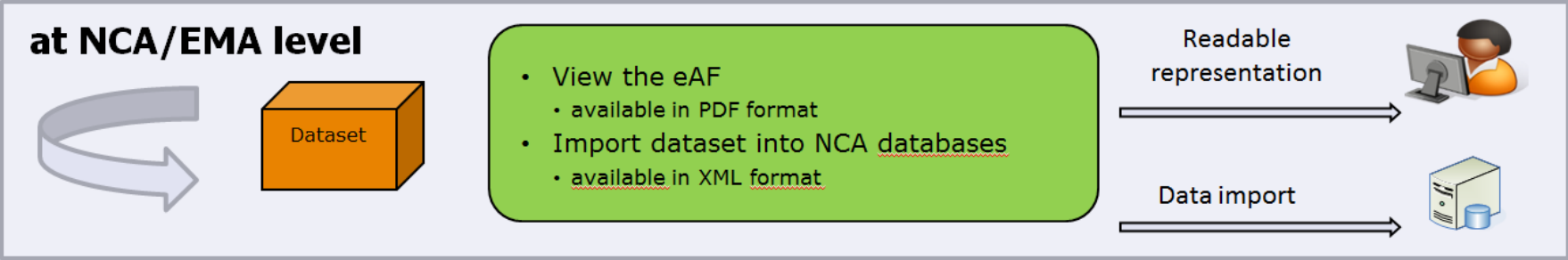
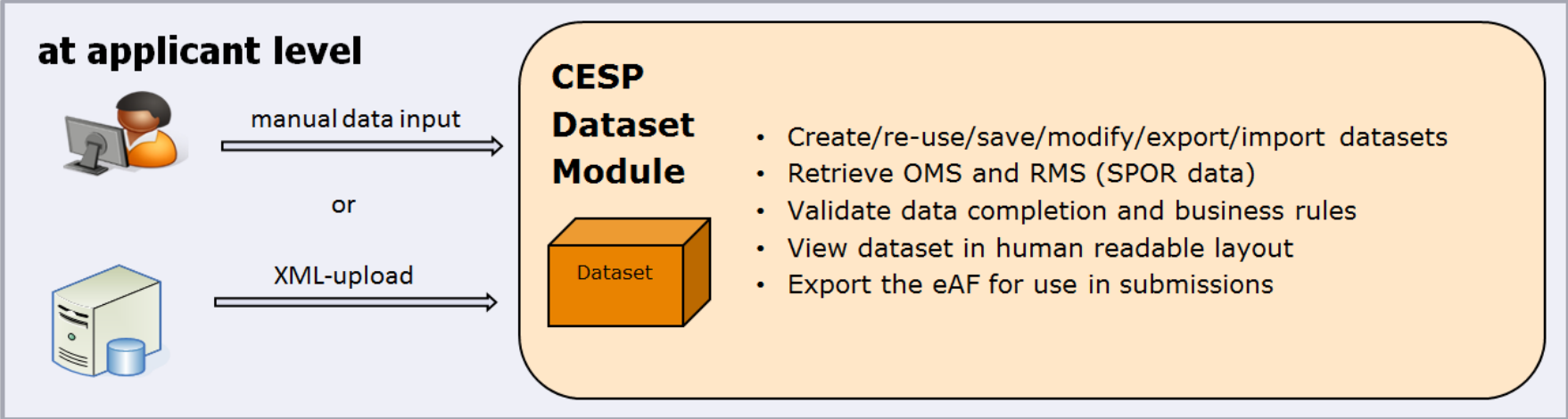
1) Welcome and objectives

- Essentials
- Update on project status, relevant information and next steps
- Time for questions after each part / please use the question pod
 - **Post webinar note:** The CESSP Q&A document will be updated to reflect questions received during the webinar

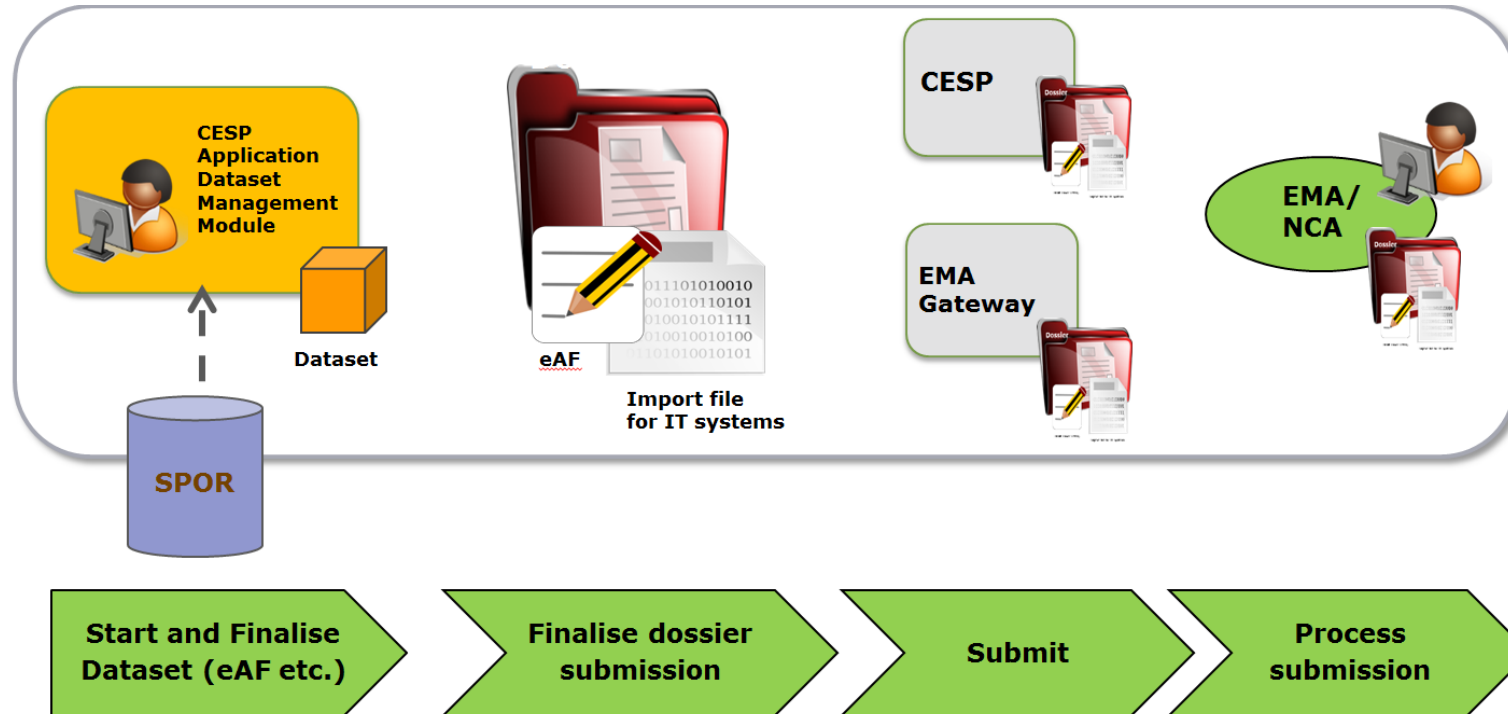
- For information: a similar webinar will be organised for regulators in June 2019



Source: <http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html>



No major process change in CESSP phase 1!



2) Project status and milestones

- **User interface (Demo later in this webinar)**
 - The team is working on the user interface development of the eAF MAA sections
 - Delays (due to several reasons like GDPR, BREXIT) in the past could not be made up yet
 - Risk of not keeping timelines
- **XML – DES (see also <http://esubmission.ema.europa.eu/cessp/cessp.htm>)**
 - Upgraded XML schema draft was published; consultation ended 30th of April
 - A final version will be published 3 months before the Go-Live-Date
- **Communication**
 - Team is trying to keep stakeholders well informed (emails, [website](#), webinar)
 - Please feedback additional needs to us via cesspproject@hma.eu
- **Guidance Material**
 - A first check was done and we will try to keep changes minimal
 - most impacts on <http://esubmission.ema.europa.eu/eaf/index.html>

Technical: [Practical user guide for electronic Application Forms \(eAF\) for human and veterinary products in the EU](#) 17.07.2018

Milestones

Publication of the draft of the updated XML Schema Definition	15/03/2019
Webinar regarding use of the updated XML Schema Definition (Human and Veterinary domains)	27/03/2019
Publication of call for Interest for participation in the User Acceptance Test UAT#3	Q2 2019
Work on updating relevant guidance documents	Q2 2019
Finalisation of complete coding of the CESP application dataset module	Q2 2019
UAT#3 internal release - final testing by people team	Q3 2019
Provision of information about opening of the registration to have access to the CESP application dataset module	Q3 2019
Performing UAT#3	Q3 2019
Go-Live version of the CESP application dataset module implemented	Q3 2019
Publication of the finalised XML Schema Definition	Q4 2019
Start of pre-registration for the CESP application dataset module	Q4 2019
Publication of updated relevant guidance documents	Q3 2020
Organisation of trainings in collaboration with EUNTS Telematics	Q3 2019
Organisation of trainings for Users at industry level	Q3 2019
Go-live of the CESP application dataset module and start of transition phase to replace the eAF MAA (human and vet, optional use)	Q4 2019
Mandatory use of CESP application dataset module (eAF MAA human and vet)	Q2 2020

A next update will be published mid/end of June
Risk of delays

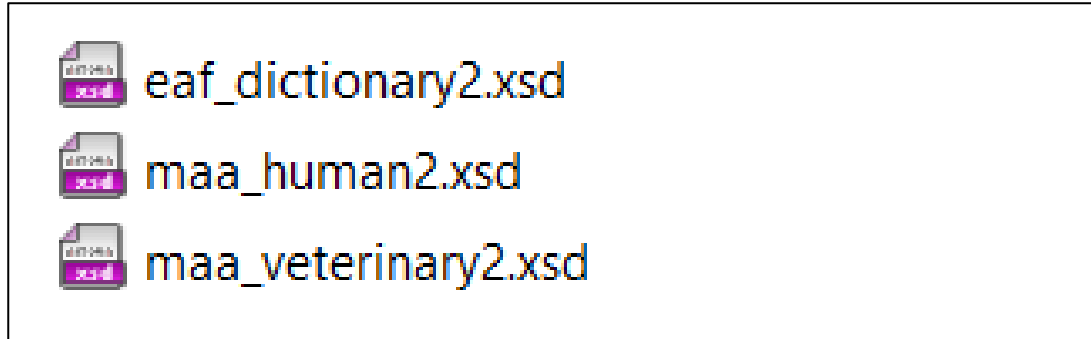
3) Information about UAT#3

- **Objective:** Identify show stoppers which would prevent Go live
- The **process** of publication / invitation
 - Publication of call for Interest for UAT#3 on eSubmission website
 - Completing the registration form online at a dedicated URL - open to all – trade associations to possibly manage feedback – to be confirmed)
 - A preview of the system and the data input concept will be delivered prior to the UAT
 - Results of the UAT will be summarised in a closing meeting
- **Timeframe**
 - Currently Q3 2019 in the published milestones
- **Scope**
 - Login
 - Identify showstoppers (usability and content)
 - Focus on creating valid application forms

4) XSD Upgrade

Contents

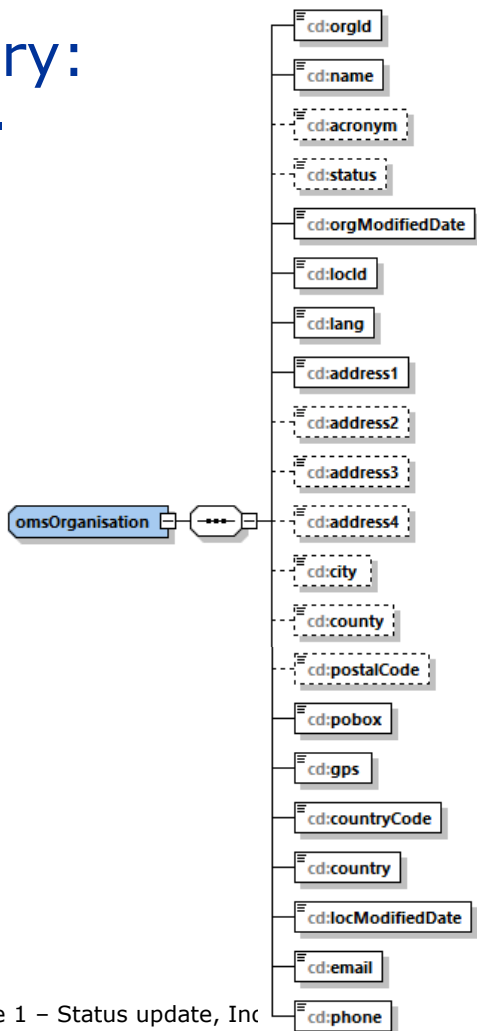
1. New schema structure overview
2. XML Loading



Remarks:

- Three XSD schemas:
 - **maa_human2.xsd** (eAF of **human** domain)
 - **maa_veterinary2.xsd** (eAF of **veterinary** domain)
 - **eaf_dictionary.xsd** (**common** dictionary e.g. Procedure type with type definitions for **both domains**)
- Version should be **2.0** (no backward compatibility with 1.2x.* versions)

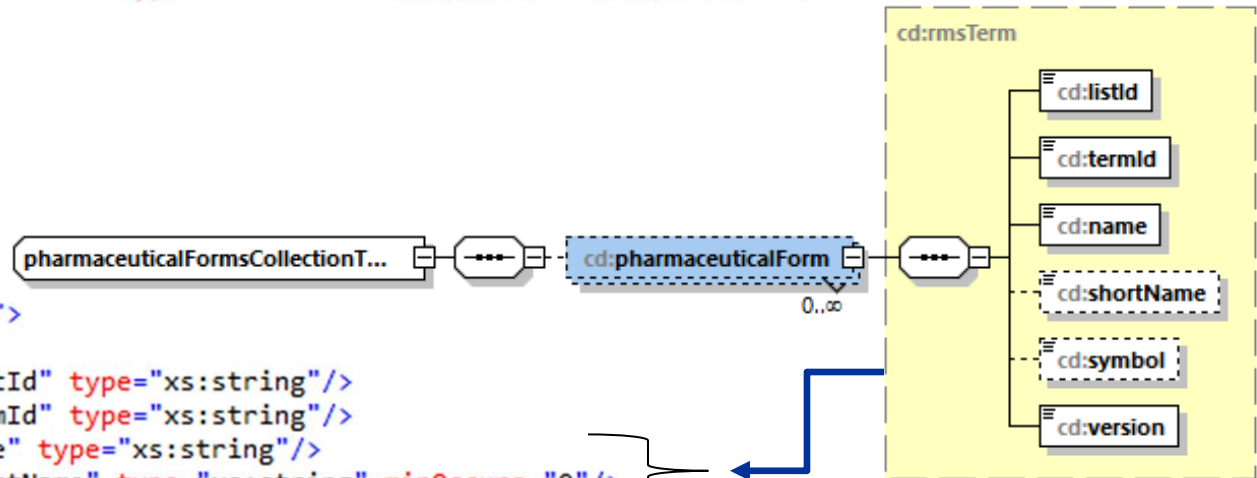
Dictionary: OMS



```
<xs:complexType name="omsOrganisation">
  <xs:sequence>
    <xs:element name="orgId" type="xs:string"/>
    <xs:element name="name" type="xs:string"/>
    <xs:element name="acronym" type="xs:string" minOccurs="0"/>
    <xs:element name="status" type="xs:string" minOccurs="0"/>
    <xs:element name="orgModifiedDate" type="xs:date"/>
    <xs:element name="locId" type="xs:string"/>
    <xs:element name="lang" type="xs:string"/>
    <xs:element name="address1" type="xs:string"/>
    <xs:element name="address2" type="xs:string" minOccurs="0"/>
    <xs:element name="address3" type="xs:string" minOccurs="0"/>
    <xs:element name="address4" type="xs:string" minOccurs="0"/>
    <xs:element name="city" type="xs:string" minOccurs="0"/>
    <xs:element name="county" type="xs:string" minOccurs="0"/>
    <xs:element name="postalCode" type="xs:string" minOccurs="0"/>
    <xs:element name="pobox" type="xs:string"/>
    <xs:element name="gps" type="xs:string"/>
    <xs:element name="countryCode" type="xs:string"/>
    <xs:element name="country" type="xs:string"/>
    <xs:element name="locModifiedDate" type="xs:date"/>
    <xs:element name="email" type="xs:string"/>
    <xs:element name="phone" type="xs:string"/>
  </xs:sequence>
</xs:complexType>
```

```
<xs:complexType name="pharmaceuticalFormsCollectionType">  
  <xs:sequence>  
    <xs:element name="pharmaceuticalForm" type="cd:rmsTerm" minOccurs="0" maxOccurs="unbounded"/>  
  </xs:sequence>  
</xs:complexType>
```

```
<xs:complexType name="rmsTerm">  
  <xs:sequence>  
    <xs:element name="listId" type="xs:string"/>  
    <xs:element name="termId" type="xs:string"/>  
    <xs:element name="name" type="xs:string"/>  
    <xs:element name="shortName" type="xs:string" minOccurs="0"/>  
    <xs:element name="symbol" type="xs:string" minOccurs="0"/>  
    <xs:element name="version" type="xs:integer"/>  
  </xs:sequence>  
</xs:complexType>
```



```
<xs:simpleType name="legalBaseHumanType" final="restriction">  
  <xs:restriction base="xs:string">  
    <xs:enumeration value="article-8-3"/>  
    <xs:enumeration value="article-10-1"/>  
    <xs:enumeration value="article-10-3"/>  
    <xs:enumeration value="article-10-1And10-3"/>  
    <xs:enumeration value="article-10-4"/>  
    <xs:enumeration value="article-10a"/>  
    <xs:enumeration value="article-10b"/>  
    <xs:enumeration value="article-10c"/>  
    <xs:enumeration value="article-16a"/>  
  </xs:restriction>  
</xs:simpleType>
```

- § advancedTherapyMedicinalProductHumanType
- § annexHumanType
- § annexVeterinaryType
- § applicationConsiderationHumanType
- § applicationConsiderationVeterinaryType
- § authorisationGrantedByType
- § changeType
- § functionType
- § legalBaseHumanType
- § legalBaseVeterinaryType
- § multipleApplicationSubmittedType
- § orphanMedicinalProductDesignationStatusType
- § procedureScopeHumanType
- § procedureScopeVeterinaryType
- § proposedAdministrationType
- § qualitativeChangeDetailType
- § standardTimeUnitsType

```
<xs:complexType name="mutualRecognitionProcedureType">
  <xs:sequence>
    <xs:element name="referenceMemberState" type="cd:rmsTerm"/>
    <xs:element name="dateOfAuthorisation" type="xs:date"/>
    <xs:element name="marketAuthorisationNumber" type="cd:stringMax30"/>
    <xs:element name="procedureNumber" type="cd:stringMax50"/>
    <xs:element name="usage" type="cd:usageType"/>
    <xs:choice>
      <xs:element name="memberRenewal" type="cd:memberRenewalType"/>
      <xs:element name="wavesCollection">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="wave" minOccurs="1" maxOccurs="unbounded">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="memberRenewal" type="cd:memberRenewalType"/>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:choice>
    <!-- only veterinary -->
    <xs:element name="waiverOrAmendmentDetails" type="xs:string" minOccurs="0"/>
  </xs:sequence>
  <xs:assert test="(cd:usage = 'repeat' and boolean(cd:wavesCollection)) or (cd:usage = 'first' and boolean(cd:memberRenewal))"/>
</xs:complexType>
```

1.1 THIS APPLICATION CONCERNS

- 1.1.1 A CENTRALISED PROCEDURE
(according to Regulation (EC) No 726/2004)
- 1.1.2 A MUTUAL RECOGNITION PROCEDURE
(according to Article 28(2) of Directive 2001/83/EC)

Reference Member State

Date of authorisation

Marketing authorisation number

(* a copy of the authorisation should be provided - see section 4.2)

Procedure number:

First use Repeat use (Please also complete section 4.2)

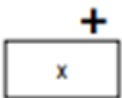
Wave 1

Concerned Member State (specify)

Proposed/Agreed common renewal date

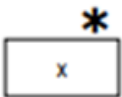
Click arrow button to select concerned Member State. With the drop-down list open, press the first letter of the item you wish to select. To cycle through other items beginning with the same first letter, press repeatedly.

What can be validated through the schema?



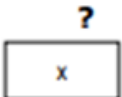
element x is mandatory and repeatable (1..n)

`minOccurs="1" maxOccurs="unbounded"`



element x is optional and repeatable (0..n)

`minOccurs="0" maxOccurs="unbounded"`



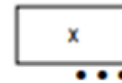
element x is optional

`minOccurs="0"`



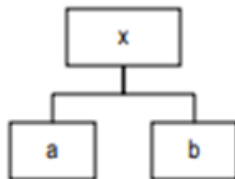
element x has the following content model

```
<xs:sequence>
  <xs:element ....
  <xs:element .....
```



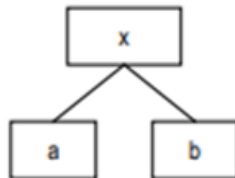
elements are defined elsewhere

`<xs:import namespace`



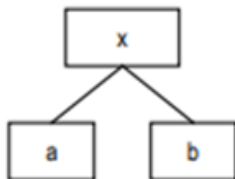
element x contains elements a and b

```
<xs:sequence>
  <xs:element ... minOccurs="1"
  <xs:element ... minOccurs="1"
```



element x contains either element a or b

```
<xs:choice>
  <xs:element ... minOccurs="0"/>
  <xs:element ... minOccurs="0"/>
</xs:choice>
```



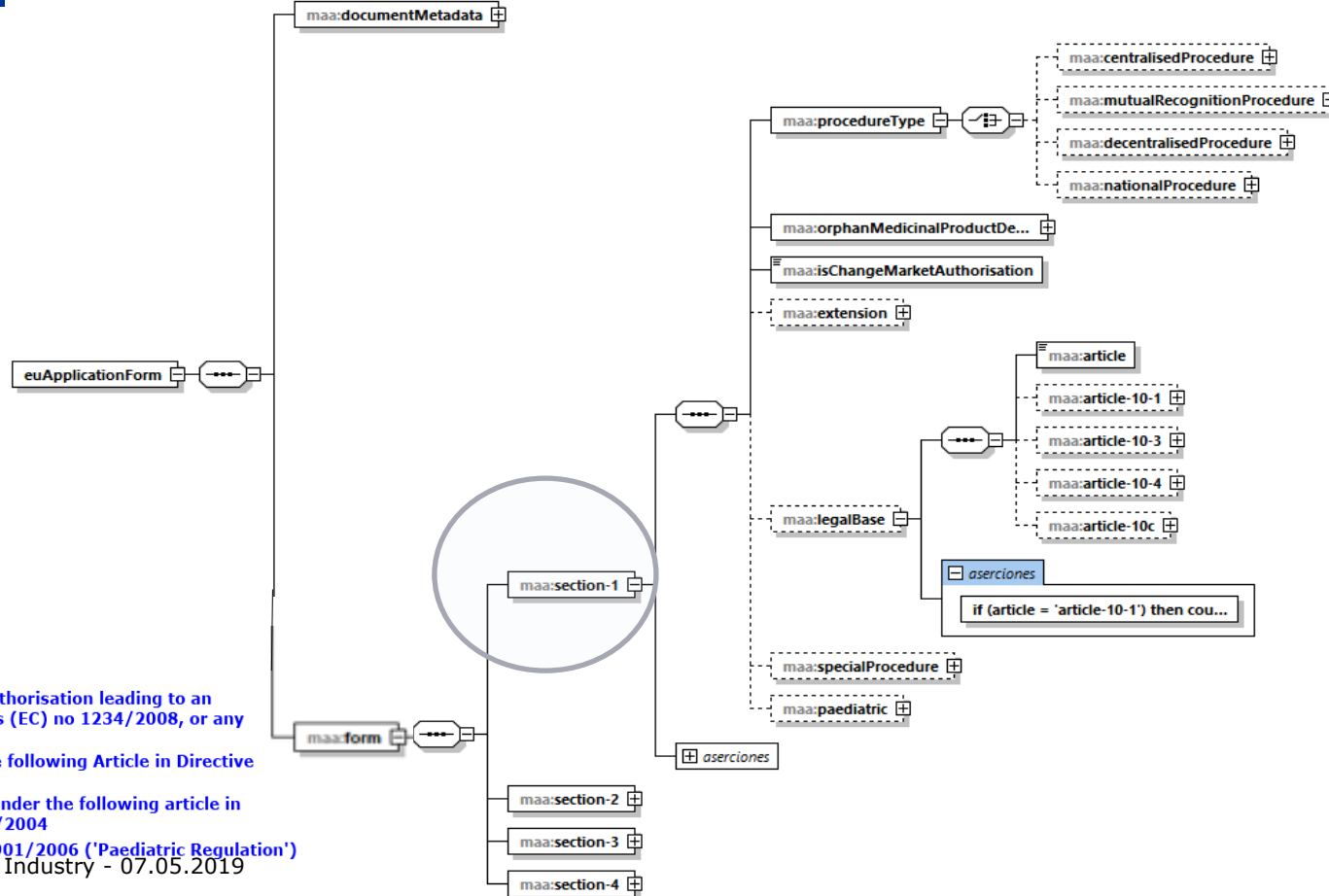
Conditions among elements depending on their values

```
<xs:complexType>
  <xs:sequence>
    <xs:element name="field1" ... minOccurs="0"/>
    <xs:element name="field2" ... minOccurs="0"/>
  </xs:sequence>
  <xs:assert test="field2 or not(field2 = 'value')"/>
```

Max length of a string
`type="cd:stringMax50"`

MAA human

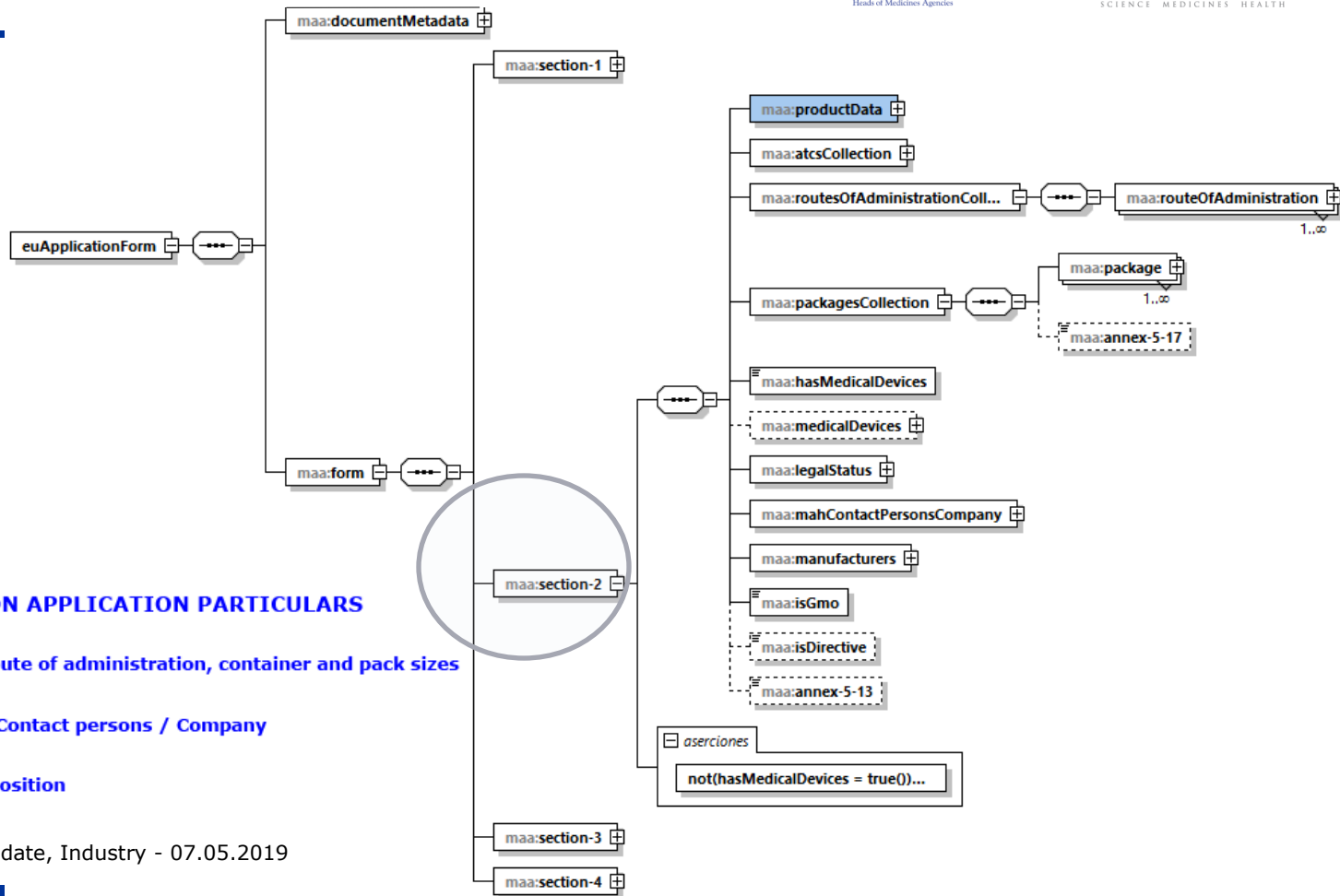
Section 1



1. TYPE OF APPLICATION

- 1.1 This application concerns
- 1.2 Orphan medicinal product information
- 1.3 Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulations (EC) no 1234/2008, or any national legislation, where applicable
- 1.4 This application submitted in accordance with the following Article in Directive 2001/83/EC
- 1.5 Consideration of this application also requested under the following article in Directive 2001/83/EC or Regulation (EC) N° 726/2004
- 1.6 Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')

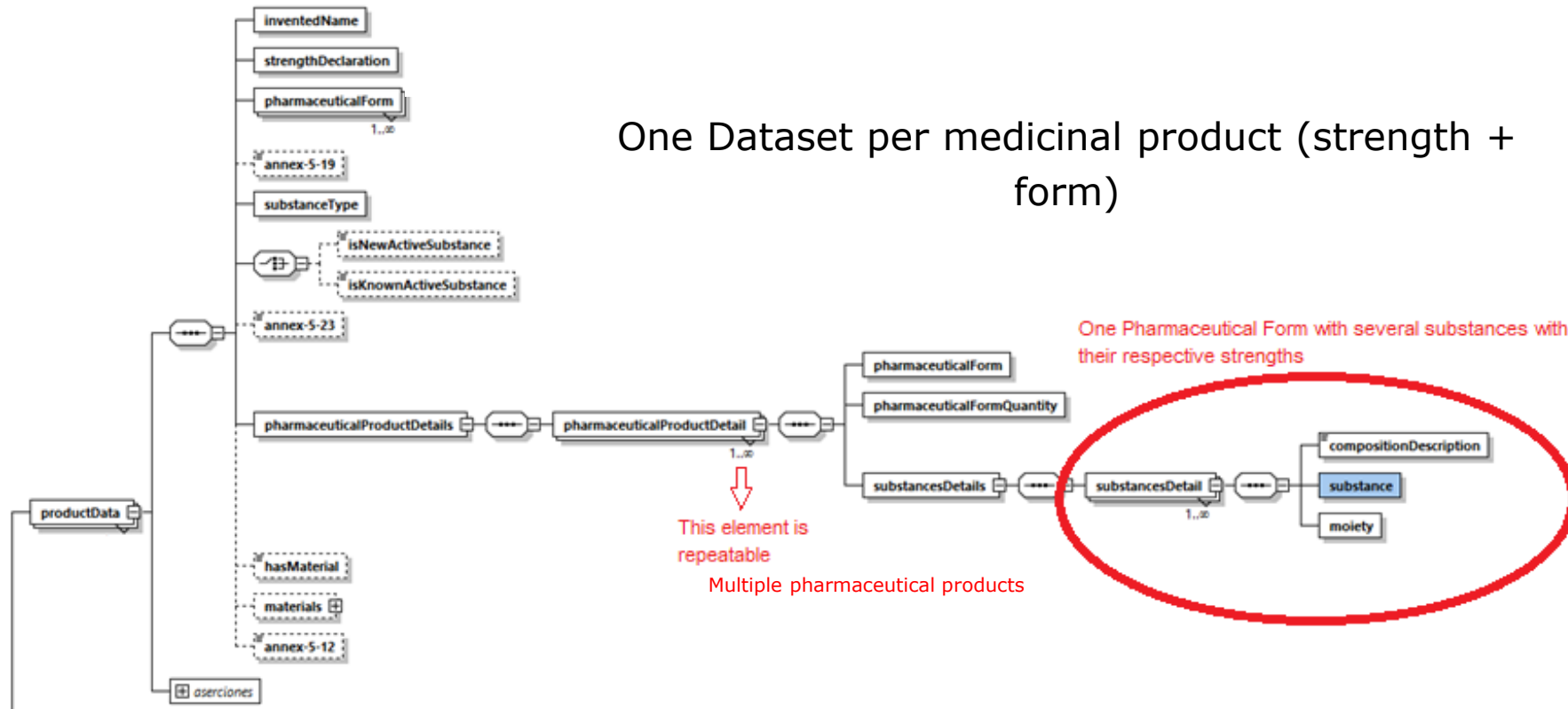
Section 2



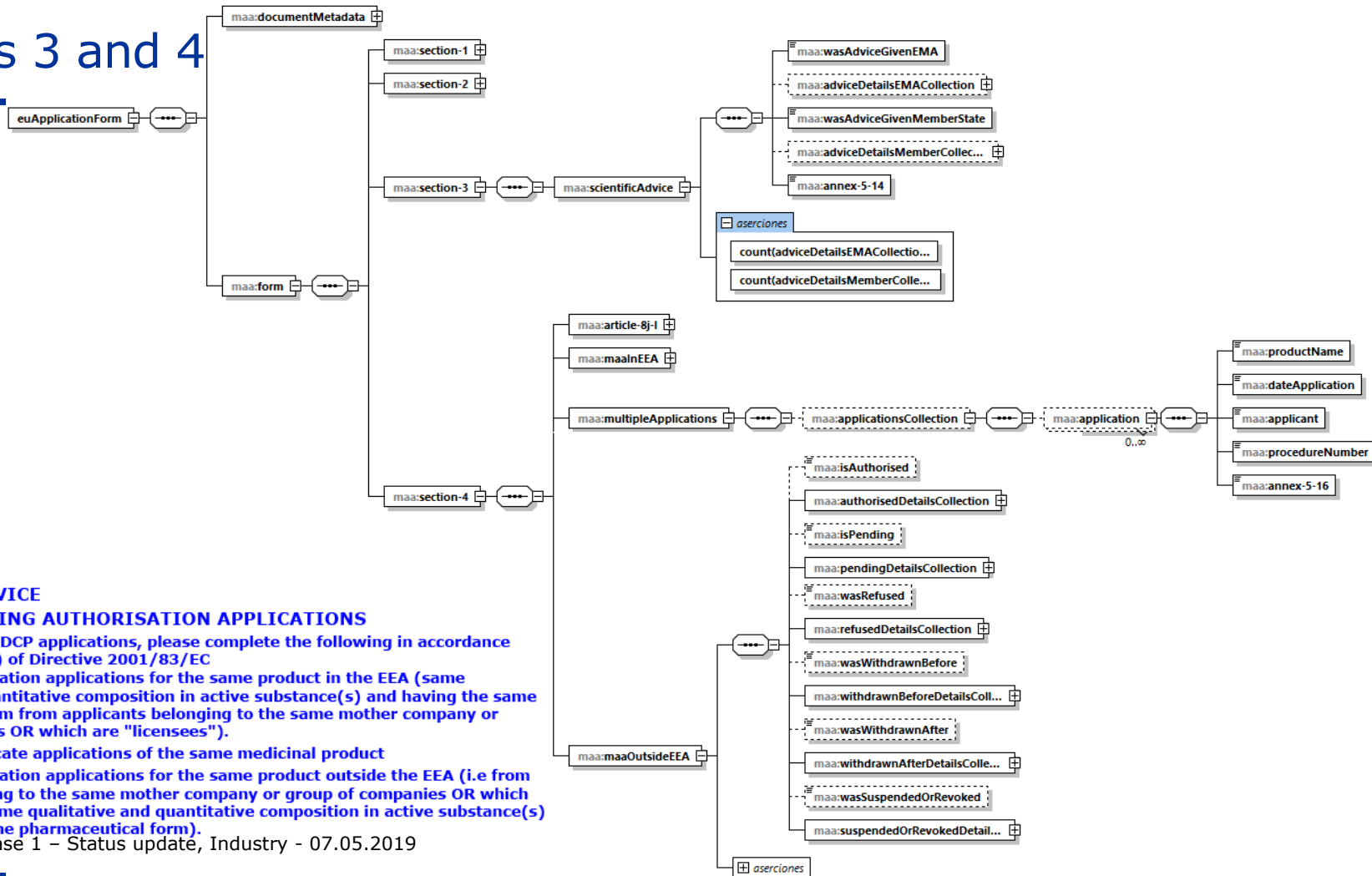
2. MARKETING AUTHORISATION APPLICATION PARTICULARS

- 2.1 Name(s) and ATC code
- 2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
- 2.3 Legal status
- 2.4 Marketing authorisation holder / Contact persons / Company
- 2.5 Manufacturers
- 2.6 Qualitative and quantitative composition

One Dataset per medicinal product (strength + form)



Sections 3 and 4



3. SCIENTIFIC ADVICE

4. OTHER MARKETING AUTHORISATION APPLICATIONS

- 4.1 For National/MRP/DCP applications, please complete the following in accordance with Article 8(j)-(l) of Directive 2001/83/EC
- 4.2 Marketing authorisation applications for the same product in the EEA (same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees").
- 4.3 For multiple/duplicate applications of the same medicinal product
- 4.4 Marketing authorisation applications for the same product outside the EEA (i.e from applicants belonging to the same mother company or group of companies OR which are "licensees". Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form).

New schema structure overview (Cont.)

```
<xs:element name="form">
  <xs:complexType>
    <xs:sequence>
      <!-- section 1 start -->
      <xs:element name="section-1">...</xs:element>
      <!-- section 1 end -->
      <!-- section 2 start -->
      <xs:element name="section-2">...</xs:element>
      <!-- section 2 end -->
      <!-- section 3 start -->
      <xs:element name="section-3">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="scientificAdvice">
              <xs:complexType>
```

Remarks:

- First level children of "form" have names that reflect their position in current PDF structure

New schema structure overview (Cont.)

```
<xs:element name="euApplicationForm">
  <xs:complexType>
    <xs:sequence>
      <!-- meta data start -->
      <xs:element name="documentMetadata" type="cd:documentMetadataType"/>
      <!-- meta data end -->
      <!-- form data start -->
      <xs:element name="form">...</xs:element>
      <!-- form data end -->
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Remarks:

- Document has root node "euApplicationForm" with two children:
 - *documentMetadata*: domain, version, creation date
 - *form*: the eAF data
- Only two namespaces:
 - [maa:http://www.eaf.com/maa/](http://www.eaf.com/maa/) (instances data namespace)
 - [cd:http://www.eaf.com/dictionary/](http://www.eaf.com/dictionary/) (dictionary namespace)
- No external namespaces (~~[xfa=http://www.xfa.org/schema/xfadata/1.0/](http://www.xfa.org/schema/xfadata/1.0/)~~)

New schema structure overview (Cont.)

```
<!-- section 1-1 procedure type end -->
<!-- section 1-2 orphan medicinal product designation start -->
<xs:element name="orphanMedicinalProductDesignation">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="hasBeenApplied" type="xs:boolean"/>
      <!-- section 1-2-1 procedures start -->
      <xs:element name="proceduresCollection" minOccurs="0">
        <xs:complexType>
          <xs:sequence>
```

Remarks:

- Enforced consistent naming conventions (use of *Camel Case* notation)
- Boolean nodes (yes/no) have names that suggest their nature (begin with "has" "is" "was",...)
- Used XSD schema to define/enforce:
 - Data types
 - Be mandatory/optional
 - Cardinality

New schema structure overview (Cont.)

```
<!-- section 1-2-2 market exclusivity start -->
<xs:element name="hasOrphan" type="xs:boolean" minOccurs="0"/>
<xs:element name="procedureNumbersCollection" minOccurs="0">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="procedureNumber" type="cd:stringMax50" maxOccurs="u
    </xs:sequence>
  </xs:complexType>
</xs:element>
<xs:element name="hasGrantedMarketAuthorisation" type="xs:boolean" minOccurs="0"/>
<xs:element name="referenceProductsCollection">
```

Remarks:

- Collections of repeatable nodes always contained in an **exclusive** parent
- Parent name of nodes xxx is named *xxxsCollection* (plural form + "Collection" suffix)
- **exclusive** = no other nodes contained in it

New schema structure overview (Cont.)

```
<!-- section 1-1 procedure type start -->
<xs:element name="procedureType">
  <xs:complexType>
    <xs:choice>
      <xs:element name="centralisedProcedure" type="cd:centralisedProcedureType" minOccurs="0"/>
      <xs:element name="mutualRecognitionProcedure" type="cd:mutualRecognitionProcedureType" minOccurs="0"/>
      <xs:element name="decentralisedProcedure" type="cd:decentralisedProcedureType" minOccurs="0"/>
      <xs:element name="nationalProcedure" type="cd:nationalProcedureType" minOccurs="0"/>
    </xs:choice>
  </xs:complexType>
</xs:element>
<!-- section 1-1 procedure type end -->
```

Remarks:

- Children of 2nd level (or higher) have names that reflect their business meaning (e.g.: *centralisedProcedure*)
- Use of *xs:choice* element to limit document size and avoid inconsistencies (if it is a *centralisedProcedure*, no *nationalProcedure* contents exist)
- Use of types and deferred node definitions (in the dictionary)

New schema structure overview (Cont.)

```
<xs:element name="medicinalProductsWhereBioequivalence">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="medicinalProduct" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="bioStyRefEudractNumber" type="cd:stringMax30" minOccurs="0"/>
            <xs:element name="inventedName" type="cd:stringMax250" minOccurs="0"/>
            <xs:element name="pharmaceuticalForms" type="cd:rmsTerm"/>
            <xs:element name="marketingAuthorisations" type="cd:marketingAuthorisationsTypeWithDate"/>
            <xs:element name="authorisationGrantedBy" type="cd:authorisationGrantedByType" minOccurs="0"/>
            <xs:element name="authorisationMemberState" type="cd:rmsTerm" minOccurs="0"/>
            <xs:element name="memberStateOfSource" type="cd:rmsTerm" minOccurs="0"/>
          </xs:sequence>
          <xs:assert test="authorisationMemberState or not(authorisationGrantedBy = 'memberState')"/>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Remarks:

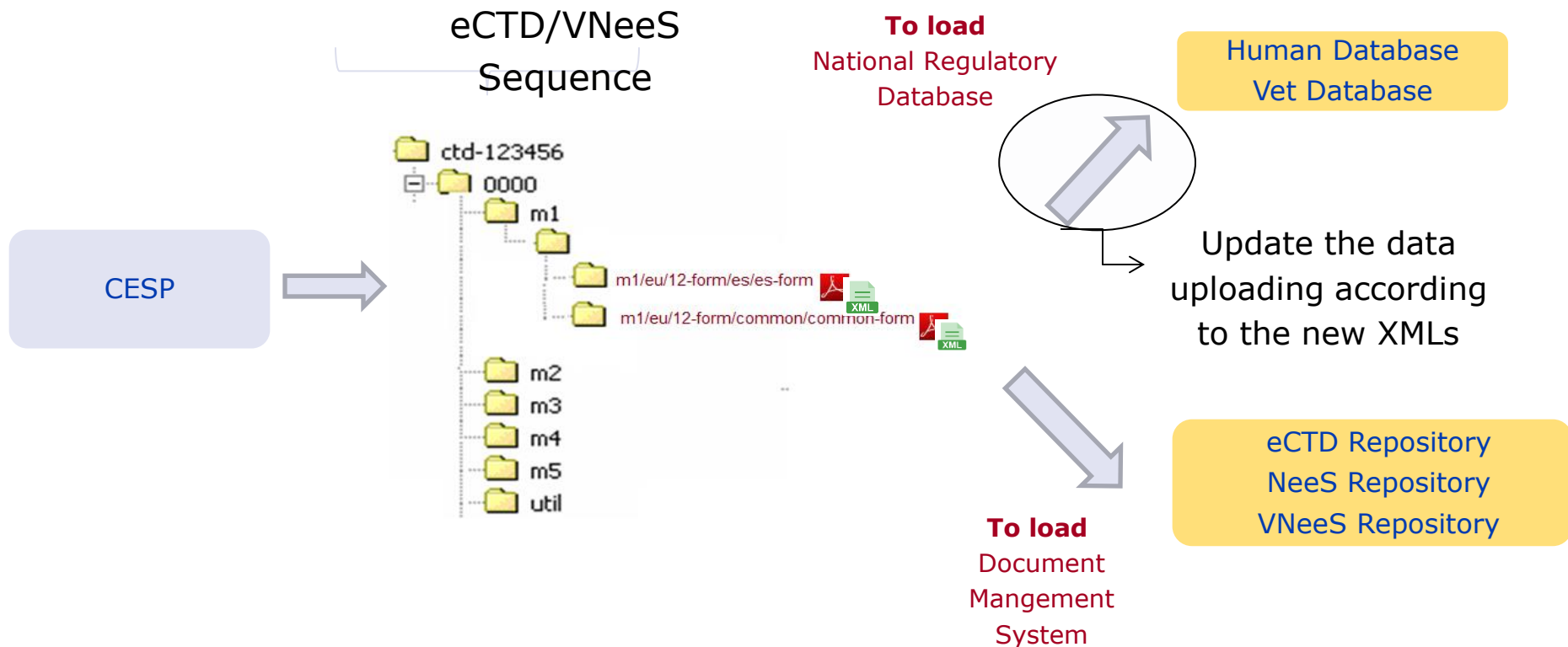
- Use of *xs:assert* elements to enforce complex business rules compliance (**Note:** XSD schema **version 1.1** used)
- Assertions defined after element fields enumeration, so the element definition is always self-contained

Contents

1. New schema structure overview

2. XML Loading

Information Uploading with the new Schemas



5) Demonstration of New Application Interface

An Applicant will be able to:

1. Create the Application Dataset online
2. Search/Input OMS and RMS data from SPOR
3. Reuse/save/modify/export/import Datasets
4. Validate data completion and business rules
5. View dataset in human readable layout
6. Produce PDF to enable offline review/inclusion in submission (PDF will contain XML Dataset as attachment)
7. The application is not a long term data repository
8. Applicants can Import and Export datasets created with this web application.



Log in

demo

••••••••

Remember me

[Forgot password?](#)

Log in

[New tenant | Email activation](#)

CESSP

Welcome to CESPP online application forms



DEMO



Datasets

Datasets

Datasets header info

+ Create new dataset

Search...



▼ Show advanced filters

Id	Friendly name	Version	Last Updated	Actions
13	Test	1	Fri Apr 05 2019 15:48:54 GMT+0100 by 4	Actions

Total: 1

Navigation: < < 1 > > 10

The screenshot displays the HMA Datasets application interface. A modal dialog titled "Create new dataset" is centered on the screen, overlaying the main content. The dialog contains the following fields and controls:

- Title:** "Create new dataset" with a close button (X) in the top right corner.
- Friendly name:** A text input field.
- Area:** A dropdown menu with the placeholder text "Select Area".
- Application Type:** A dropdown menu with the placeholder text "Select Application Type".
- Procedure Type:** A dropdown menu with the placeholder text "Select Procedure Type".
- Buttons:** "Cancel" and "Save" buttons at the bottom right.

The background application interface is dimmed and includes the following elements:

- Header:** HMA logo and navigation icons.
- Left Sidebar:** "Datasets" menu item.
- Main Content:** "Datasets" header, search bar, "Show advanced filters" toggle, and a table with columns "Id" and "Friendly name". A table entry shows "13" and "Test". A "Total: 1" indicator is present below the table.
- Right Panel:** "Actions" section with a "Create new dataset" button and a pagination control showing "1" of "10" items.
- Footer:** "Test v5.5.0.0 [20190403]"

The screenshot displays the HMA Datasets application interface. A modal window titled "Create new dataset" is open, allowing for the creation of a new dataset. The modal contains the following fields and options:

- Friendly name:** A text input field containing "Test 2".
- Area:** A dropdown menu with "Human Medicines" selected.
- Application Type:** A dropdown menu with "New Initial MAA" selected.
- Procedure Type:** A dropdown menu with "Select Procedure Type" selected, and a search input field below it. The search results list the following options:
 - Centralised Procedure
 - Mutual Recognition Procedure
 - Decentralised Procedure
 - National Procedure

The background interface shows a "Datasets" table with one entry: "Test" with ID "13". A "Create new dataset" button is visible in the top right of the main interface. The bottom left corner of the application shows the text "Test v5.5.0.0 [20190403]".



Output Save Cancel Changes

1.1 Centralised Procedure

Select...

Date of Acceptance/Confirmation by CHMP

Click to enter date

EMA Product Number

Enter Product Number

- 1 Type of Application
 - 1.1 Centralised Procedure
 - 1.2 Orphan Medicinal Product
 - 1.2.1 Has Orphan Designation Been Applied For This Medicinal Product?
 - 1.2.2 Information Relating To Orphan Market Exclusivity
 - 1.3 Extension
 - 1.4 Legal Base
 - 1.5 Special Procedure
 - 1.6 Paediatric Regulation

1.2 Orphan Medicinal Product

1.2.1 Has Orphan Designation Been Applied For This Medicinal Product?

Yes No

1.2.2 Information Relating To Orphan Market Exclusivity

Has any medicinal product been designated as an Orphan medicinal Product for a condition relating to the indication proposed in this application?

Yes No

Has any of the designated medicinal product(s) been granted a marketing authorisation in the EU?

Yes No

1.3 Extension



Select...

- Mandatory Scope (Article 3(1) of Regulation (EC) No 726/2004)
- Optional Scope (Article 3(2) of Regulation (EC) No 726/2004)
- Generic of a Centrally Authorised Medicinal Product
- Marketing Authorisation including paediatric indication (Article 28 of Regulation (EC) No 1901/2006)**
- Paediatric Use Marketing Authorisation (PUMA) (Article 31 of Regulation (EC) No 1901/2006)

Marketing Authorisation including paediatric indication picked

Date of Acceptance/Confirmation by CHMP

Click to enter date

EMA Product Number

Enter Product Number

Output Save Cancel Changes

1 Type of Application

- 11 Centralised Procedure
- 12 Orphan Medicinal Product
 - 12.1 Has Orphan Designation Been Applied For This Medicinal Product?
 - 12.2 Information Relating To Orphan Market Exclusivity
- 13 Extension
- 14 Legal Base
- 15 Special Procedure
- 16 Paediatric Regulation

1.2 Orphan Medicinal Product

1.2.1 Has Orphan Designation Been Applied For This Medicinal Product?

Yes No

1.2.2 Information Relating To Orphan Market Exclusivity

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Yes No

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Select...

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Marketing Authorisation including paediatric indication picked

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Select...

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Marketing Authorisation including paediatric indication picked

Date of Acceptance/Confirmation by CHMP

Click to enter date



EMA Product Number

Enter Product Number

Output Save Cancel Changes

- 1 Type of Application
 - 11 Centralised Procedure
 - 12 Orphan Medicinal Product
 - 121 Has Orphan Designation Been Applied For This Medicinal Product?
 - 122 Information Relating To Orphan Market Exclusivity
 - 13 Extension
 - 14 Legal Base
 - 15 Special Procedure
 - 16 Paediatric Regulation

1.2 Orphan Medicinal Product

1.2.1 Has Orphan Designation Been Applied For This Medicinal Product?

Yes

No

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No

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Yes

No



Select...

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- Optional Scope (Article 3(2) of Regulation (EC) No 726/2004)
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Has any of the designated medicinal product(s) been granted a marketing authorisation in the EU?

Yes No

DECLARATION AND SIGNATURE

Product (invented) name Acme catching-road-runner pills

Pharmaceutical Form: Film-coated tablet

Strength:

200

Units:

mg

Active Substance

KRYPTONITE

IronPdf Trial
<http://ironpdf.com/license>



Questions?

CESSP – Common European Single Submission Portal

CESP – Common European submission Portal

DES – Data Exchange Standard

GDPR - The EU General Data Protection Regulation

eAF – electronic Application Form

NCA – National Competent Authority

SPOR – Master data management services for Substances, Products, Organisations, Referentials

- SMS – Substance Management System
- PMS – Product Management System
- OMS – Organisations Management System
- RMS – Referentials Management System

UAT – User Acceptance Test

XSD - XML Schema Definition

For any question about the project please contact:

cesspproject@hma.eu

or visit

<http://esubmission.ema.europa.eu/cessp/cessp.htm>