EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RMS & OMS change requests

SPOR webinar with Industry stakeholders
12 February 2018, 14.00 – 15.00 UK time

Agenda

EUROPEAN MEDICINES AGENCY

Webinar today is in listen only mode.

1. Referentials Management Services (RMS)

- Summary of RMS milestones & impacts
- RMS operating model
- RMS business process particulars
- RMS process to request new Term / update Term - in the context of eAF
- RMS support / guidance
- RMS Q&A
- Demo of RMS

2. Organisations Management Services (OMS)

- Summary of OMS milestones & impacts
- Expanding the OMS dictionary & submission of OMS CRs
- Where did we source data for the OMS dictionary
- OMS Change Request (CR) stages: submission, validation, approval – focusing on guidance for OMS users
- Using OMS data in eAF – process
- OMS support / guidance
- OMS Q&A

Referentials Management Services (RMS)

Summary of RMS milestones & impacts

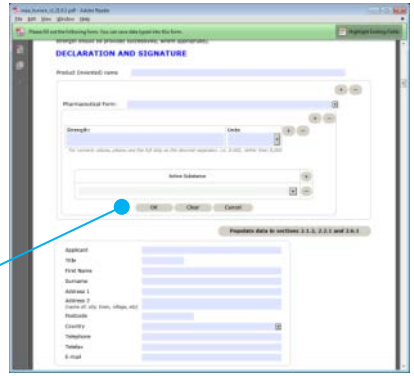
EUROPEAN MEDICINES AGENCY

ISO IDMP compliant **RMS services live** in June 2017.
RMS replaces EUTCT for all lists except for the substance lists which remain in the EUTCT.
No impact on regulatory submissions at go live.

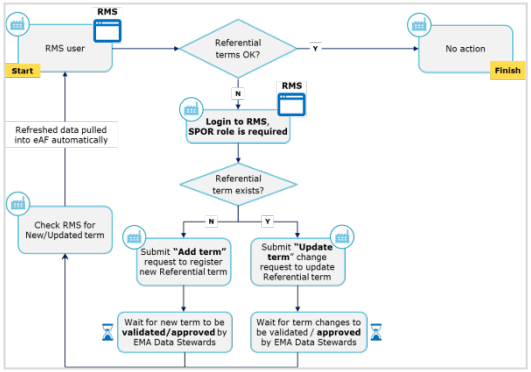
December 2017 industry stakeholders can start registering for SPOR & start using RMS services

Use of mdms@ema.europa.eu to request new terms/updated until end of June 2018

2017 **2018**



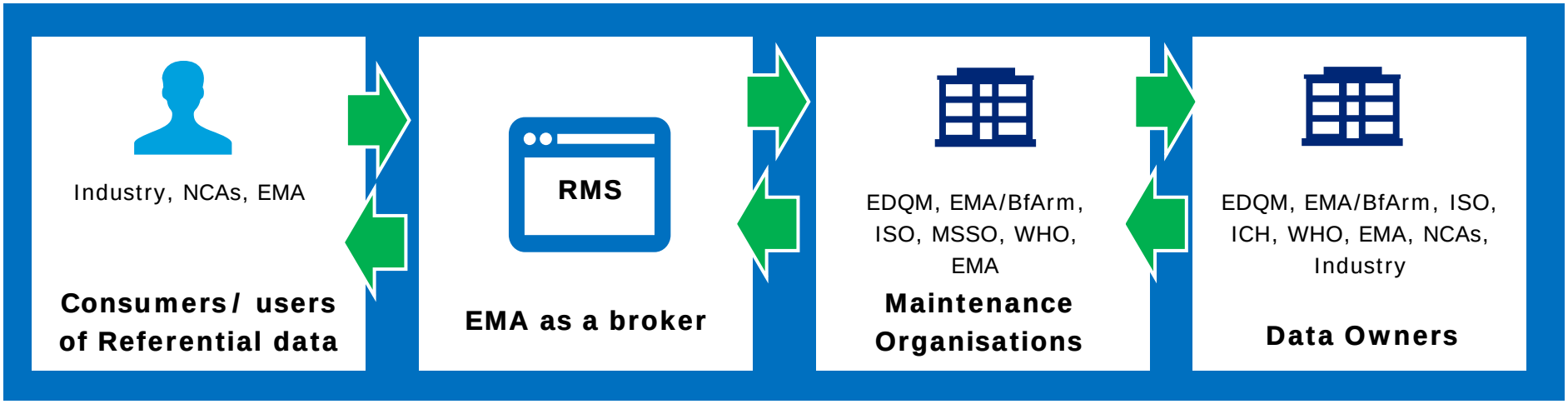
RMS & eAF integration - RMS supplying master data to eAF



New process for industry stakeholders to request new / updated terms via RMS

Use of RMS for requesting new / updated terms mandated as of July 2018

RMS Operating Model



- Use Referentials data for regulatory applications
- Requests new Referential Terms & updates to existing Terms
- Registers legacy Terms in RMS

EMA act as data broker providing Referentials data services to the EU network

- Maintains data centrally in a structured format
- Hosts Referential Lists from different Maintenance Organisations *
- Acts as Maintenance Organisation (MO) for Lists where no MO exists
- Processes request for new Referential Terms & updates to existing Terms

- Undertake data management activities for Referential Terms/Lists that it maintain e.g. regular lists updates, improvements of publication formats
- Register legacy terms in RMS

- Decide how each Term within the List should look and how it will be approved/ published
- Map & register legacy terms specific extensions in RMS
- Undertake translations of Referential Terms/Lists (only NCAs)

(*) EMA will be the maintenance organisation for UofM until BfArM can fully maintain it

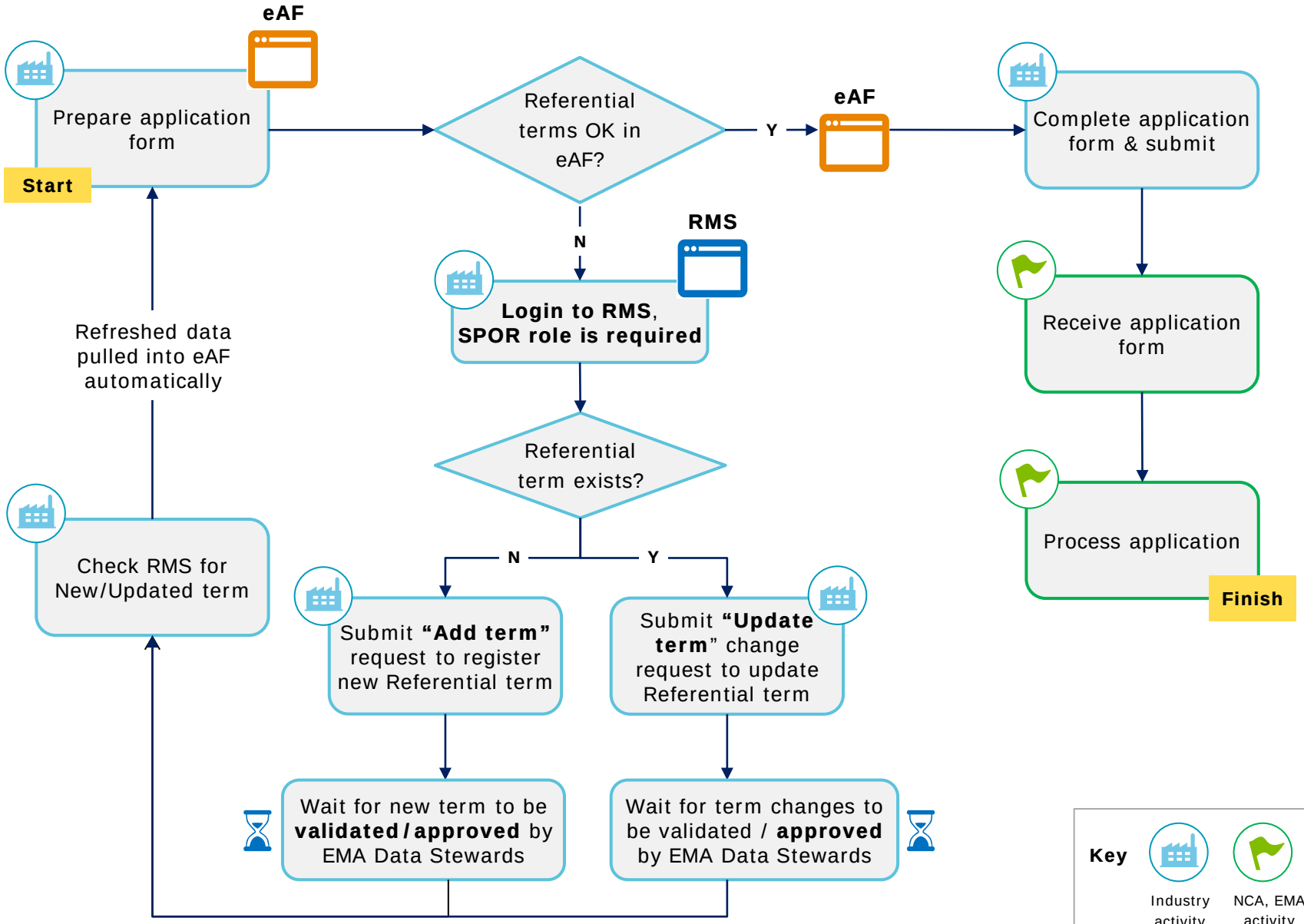
RMS business process particulars

EUROPEAN MEDICINES AGENCY

		All these lists will be held in RMS				
		RMS / EUTCT	**EDQM**	**Bfarm / UCUM***	**WHO**	**MSSO**
		- Country/Language - Target species, Vet lists - EudraCT lists, TIGes lists, etc	- Dosage Forms - Routes of Administration - Containers/packaging - Units of Presentation	- Units of measurement * Done by EMA in the first phase	- ATC Human - ATC Vet - INN	- MedDRA
	RMS business process	**Lists in RMS to which stakeholders have access to**				
NCAs	**Download / access lists via RMS**	Yes	Yes	Yes	Yes	Yes
	Requests changes to lists / terms via RMS	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Unlikely, Industry should have done it in advance	No, request to MSSO Only available in EMA via updates from MSO
	Add / amend translations via RMS	Yes	No	Yes	No	No
Industry	**Download / access lists via RMS**	Yes	Yes	Yes	No Browse only Access through WHO	No Browse only Access through MSSO
	Requests changes to lists / terms via RMS	Yes	Yes	Yes	Request to WHO first and then to EMA	No, request to MSSO Only available in EMA via updates from MSO
	Add / amend translations via RMS	No	No	No	No	No

RMS process to request new Term / update Term - in the context of eAF (1/3)

EUROPEAN MEDICINES AGENCY



RMS process to request new Term / update Term - in the context of eAF (2/3)

EUROPEAN MEDICINES AGENCY

- After submitting "**Add term"** request it will usually take 2-3 working days to be **validated** and get a **provisional** term available for selection in eAF.
  - Data stewards can reject the request at validation level in case is clearly not a valid term. The requestor would have to submit a new term request
  - Data stewards can return the request at validation level in case the request is no complete or if additional information is required. The requestor would have to submit additional information
- Additionally, there is an **approval process** to determine the final term naming conventions. Depending on the List owner it can take from **1 month** to **1 year.**
  - When terms are approved their status becomes **CURRENT** (approved)
  - When terms are rejected their status becomes **NULLIFIED** or **NON-CURRENT** (used but no longer recommended)
    => *use a* ***CURRENT*** *term instead*

RMS process to request new Term / update Term - in the context of eAF (3/3)

- After submitting an "**Update term"** request it will usually take 3-5 working days to be validated. After validation no changes will be reflected in the term.
  - EMA Data stewards can reject the request at validation level in case the changes are not acceptable. The requestor would have to submit a new update term request, if needed.
- Additionally, there is an **approval process** that will take up to 2 months.
  - If the "Update term" request is **approved** the requested changes become visible in RMS/eAF;
  - If the "Update term" request is **rejected** the term information remains the same in RMS/eAF.

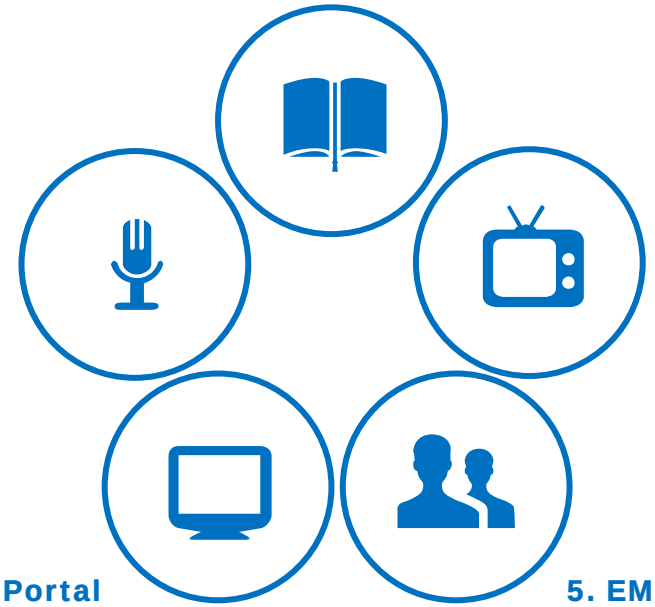
RMS support / guidance

EUROPEAN MEDICINES AGENCY

1. User manuals & reference documents

Provide detailed guidance for the RMS. Accessible via the SPOR portal.

- RMS web user manual
- SPOR user registration manual
- SPOR SLAs



2. Training videos

RMS training videos available to view on-demand by SPOR users on the @emainfo channel

3. Material from SPOR webinars

Topic related content available on the SPOR portal (under documents section) and EMA public website. For example “Industry on-boarding to SPOR”, “Using RMS data in eAF”.

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

Account Management Portal.

5. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the Service Desk Portal.

Demo of RMS

- Short description of RMS
- View lists
- View list information document (including description of what are the changes accepted and the CR process)
- View terms
- Search lists/terms
- Submission of CRs (terms only)
- SLAs

http://spor.ema.europa.eu/sporwi/

Organisations Management Services (OMS)

Summary of OMS milestones & impacts

EUROPEAN MEDICINES AGENCY

No standardisation of organisation data. The consequence is that data is not consistent and it cannot easily be reused.

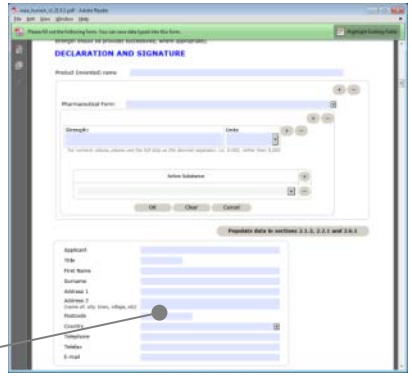
June 2017 new OMS data services live.
No impact on regulatory submissions at go live.
Organisation data is standardised and can be re-used.

December 2017 industry stakeholders can start registering for SPOR & start using OMS services

No standardisation

OMS dictionary expanded with additional data sets

2017 | **2018**



Q3/Q4 plan to mandate the use of OMS in eAF (aligned with CESSP MA go-live) (*)

Dec 2017
OMS & eAF integration - OMS starts supplying organisation master data to the eAF. Use of OMS in eAF initially optional.

(*) – subject to planning

Expanding the OMS dictionary & submission of OMS CRs

EUROPEAN MEDICINES AGENCY

Jan 2018 data set 1 includes:
- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs

Q1/Q2 2018
Manufacturers: (H+V) CAPs
Do not submit OMS change requests for Manufacturers CAPs until EMA communicates.

Q1/Q2 2018
Sponsors (H) CAPs and NAPs

End of Q3 2018
Manufacturers: (H+V) NAPs
Do not submit OMS change requests for Manufacturers NAPs until EMA communicates.

OMS dictionary expanded with additional data sets

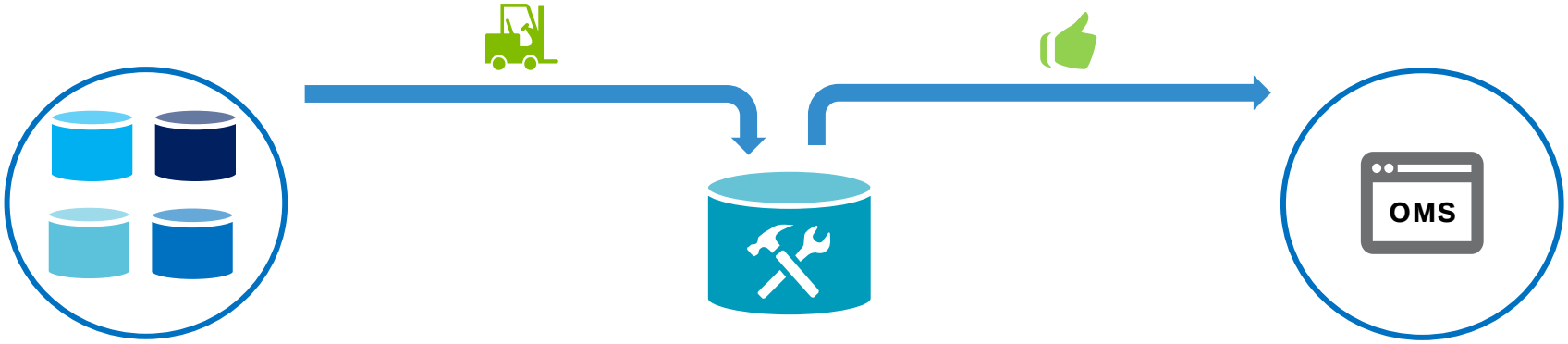
2018 ...

Registered SPOR users can start submitting OMS change requests (**CRs**) for the above data set 1 to request changes or additions to the organisation data:
- **Add Organisation**
- **Update Organisation**
- **Add Location**
- **Update Location**
- **Update Organisation & Location**

Additional Organisation data to be added in future. Its prioritisation will be defined.

Note: in February 2018 EMA plans to communicate the process for inclusion of Veterinary non CAP MAHs in the OMS.

Where did we source data for the OMS dictionary?



The initial content of the OMS dictionary originates from the Telematics systems, *i.e.* xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems. MAHs for Veterinary CAPs were mainly sourced from an EMA corporate repository that is used for the management of centralised procedure. The data was not loaded from EudraPharm Veterinary.
The data was taken from these systems in Q4 2016.

Data mastering process has been applied by EMA Data Stewards to cleanse, consolidate, and standardise data before its publication in the OMS dictionary.

Mastered organisation data has been published in the OMS dictionary and can be reused.

In January 2018 EMA started updating OMS data, based on the latest changes in xEVMPD – Article 57. This means that the relevant changes to the data in Art.57 will be reflected in the OMS.

OMS Change Request (CR) stages

EUROPEAN MEDICINES AGENCY

1

Submit OMS Change Request (CR):
- Add Organisation
- Update Organisation
- Add Location
- Update Location
- Update Organisation & Location

Any registered SPOR user can submit a CR for his organisation or any other organisation.
CR should include relevant documentation/ information.
See slide 17.

2 **Validation:** EMA data stewards validate the request (SLA 5 w/d - indicative).
Except for very minor (administrative e.g. spelling mistakes) changes, documentation must be provided in the change request.

If validation criteria are not met:

a) CR On hold – SPOR Data Stewards requested clarification / information.

b) CR rejected – E.g. Organisation/Location already exists, not enough information to validate the request, provided data is not acceptable, etc. See 'OMS Controlled Vocabularies (CVs)' document in OMS portal.

3 **Approved**: Validation criteria were met (relevant info and/or document(s) were provided).
Following the approval OMS dictionary will be updated automatically and data will be published.

OMS Change Request statistics

EUROPEAN MEDICINES AGENCY

As of 9 February 2018

Change Request Status	Total
APPROVED	187
APPROVED_WC	4
ON_HOLD	19
REJECTED	36
SUBMITTED	9
Grand Total	**255**

Change Request Status	Total
ADD-LOCATION	**19**
APPROVED	16
APPROVED_WC	1
REJECTED	2
ADD-ORGANISATION	**79**
APPROVED	63
APPROVED_WC	2
ON_HOLD	4
REJECTED	8
SUBMITTED	2
UPD-LOCATION	**102**
APPROVED	73
APPROVED_WC	1
ON_HOLD	5
REJECTED	18
SUBMITTED	5
UPD-ORG-AND-LOCATION	**47**
APPROVED	30
ON_HOLD	8
REJECTED	7
SUBMITTED	2
UPD-ORGANISATION	**8**
APPROVED	5
ON_HOLD	2
REJECTED	1
Grand Total	**255**

OMS Change Request (CR) stages - Submission

EUROPEAN MEDICINES AGENCY

Note: Table below is bases on the guidance document "Change Requests validation in OMS" EMA/370721/2016. **Users please refer to the document for comprehensive information.**

Creation of a new organisation/ location		**Update of organisation name**		**Update of location address**		**Creation of an org. following a split of existing org. or merging 2 orgs. & their locations**		**Update loc. comms details & DUNS/ GS1/etc**	**Deactivation of loc. & /or org.**
Org. is within EEA	**Org. is outside EEA**	**Org. is within EEA**	**Org. is outside EEA**	**Org. is within EEA**	**Org. is outside EEA**	**Org. is within EEA**	**Org. is outside EEA**	No doc. required. However, it can be useful for the EMA data steward.	No specific doc. is required. However, documentation supporting the requested change can be required by the EMA data steward.
1. Trade register doc., **or**	**1**. DUNS or GS1 or similar facility identifier, **or**	**1**. New trade register doc + previous trade register doc, **or**	**1**. DUNS or GS1 or similar facility identifier, **or**	**1**. Trade register doc., **or**	**1**.DUNS or GS1 or similar facility identifier, **or**	**1**. Trade register doc. **or**	**1**. DUNS or GS1 or similar facility identifier, **or**		
2. EudraGMDP ref. no, **or** a document, **or**	**2**. Trade register, **or**	**2**. EudraGMDP ref. no, **or** a document, **or**	**2**. Updated trade register doc + previous trade register doc, **or**	**2**. EudraGMDP ref. no, **or** a document, **or**	**2**. Trade register doc., **or**	**2**. EudraGMDP ref. no, **or** a document, **or**	**2**.Trade register doc., **or**		
3. DUNS or GS1 or similar facility identifier, **or**	**3.** EudraGMDP ref number, **or** a document, **or**	**3**. DUNS or GS1 or similar facility identifier, **or**	**3**. EudraGMDP ref. no, **or** a document, **or**	**3**.DUNS or GS1 or similar facility identifier, **or**	**3**. EudraGMDP ref. no, **or** a document, **or**	**3**.DUNS or GS1 or similar facility identifier, **or**	**3**. EudraGMDP ref. no **or** a document		
4. If none of above exists, a headed letter doc	**4.** If none of above exists, a headed letter doc	**4**. If none of above exists, a headed letter doc	**4**. If none of above exists, a headed letter doc	**4**. If none of above exists, a headed letter doc	**4**. If none of above exists, a headed letter doc	**4**. In addition headed letter doc.	**4**. In addition headed letter doc		

OMS Change Request (CR) stages - Validation

OMS users can find “Organisation data quality standards in OMS” guidance useful when requesting additions and/or updates of organisations/locations in the OMS. Document is available on the OMS Portal.

- OMS supports the data management and quality management mainly for information in Latin characters although BG & GR will be stored too
- Organisation names are maintained manually
- Location addresses are validated with additional representation of the address in local languages with the support of the Address Doctor Informatica service
- Communication details (Email and Telephone) are only maintained for Locations

OMS Change Request (CR) stages - Validation

1. Organisation names:

- Organisation name should be in “Title Case”. However, acronyms in the name should be all in capitals e.g. AstraZeneca Limited UK
- Symbols should be avoided unless they are part of the registered name
- Legal entity may or may not need to be part of the organisation name. It can be different in each country.
- Organisation names can be stored in multiple languages:
  - When available, English name will be the preferred name
  - Alternative names are recorded as Translations (these are not true translations)
  - Unlike addresses OMS tool does not validate or suggest changes
- Acronyms can be provided but will not be validated by EMA
- For non-trading companies, the name also included the trading-as name for regulatory purposes. In OMS , the non-trading name will be stored as the preferred name and the org name with the trading name will be stored as a Translation in the same language as the preferred name e.g.

Martindale Pharmaceutical Limited - preferred name
Martindale Pharmaceutical Limited Trading as Martindale Pharma - EN translation name

OMS Change Request (CR) stages - Validation

EUROPEAN MEDICINES AGENCY

2. Legal entity types in organisation names

- There should be no comma before the legal entity type acronym in the name
- Unless specified otherwise, entity types should be at the end of the organisation names
- Acronyms don't necessarily have to follow a generic text casing. This can vary between countries
- The should be no spaces between the letters and/or dots within the legal entity

Note: some types of organisations do not need to be registered with the Trade register

Country	Reference	Legal Entity naming in organisation names (in EN and National languages)
EU	European Justice Business Registers	Provides links to EEA national business register websites (when available).
AT	Austrian Business Register	Ges.m.b.H., mbH but only if word before this abbreviation includes the string "gesellschaft" like in "Entwicklungsgesellschaft mbH", GmbH, AG, EWIV, e.U. Austrian commercial register "Firmenbuchdatenbank" does not provide free access, however some basic information is published at the website of the following private data provider: https://www.kompany.at.
BE	Belgian Business register	B.V., N.V., S.A., GEIE, B.V.B.A., Organisation name in the register has no legal entity type as the preferred name. Translation names can contain the legal entity type. To include both N.V. & S.A., create a translation as 'English' with organisation name starting with N.V. and end the name with S.A. Leave the preferred name without the entity type.
BG	Ministry of Justice Registry Agency	Ltd.,
CH	Swiss Business Register	d.o.o., AG,
CY	Cypriot Registrar of Companies	Limited,
CZ	Czech Business Register EN / CZ	a.s., k.s., s.r.o. = spol. s r.o., v.o.s., EHZS, Basic search – landing page: enter company name and click "hledat". Advanced search – click on the magnifying glass with title "rozšířené vyhledávání": enter the company name in 'Název subjektu' and select 'Vyhledat'.
DE	German company register	AG, GmbH, mbH but only if word before this abbreviation includes the string "gesellschaft" like in "Entwicklungsgesellschaft mbH", KG, AöR, GmbH & Co. KG, EWIV, SE, KGaA,
DK	Danish Company Register	A/S, I/S, K/S, ApS, EØFG,
EE	Estonian Business Register	OÜ, EMHG, AS, AS is usually placed before the actual company name, i.e.: AS Kevelt
EL	Greek Business Registry	S.A., M.E.P.E., A.E., L.P. L.P. = Limited Partnership Enter the name of the company at the field: 'Επωνυμία' (the middle one at the first line)
ES	Spanish chamber of Commerce	S.L., S.A., AEIE,

Legal entity naming in organisation names (in EN and national languages)

OMS Change Request (CR) stages - Validation

EUROPEAN MEDICINES AGENCY

3. Standards on location address

Location will be Title Case except post code and PO Box

Location address represents the physical location.

Address line 1 and country are mandatory data attributes for a location to be created. Where the is no address line info PO Box should be provided in the Address line 1.

Address Doctor (AD) can enrich the provided address with additional address data and Geo coordinates (Longitude and latitude). If required, data steward may choose to ignore the data transformation/enrichment by AD.

Organisation Details

Organisation ID:	ORG-100000823
Organisation Name:	Bristol-Myers Squibb / Pfizer EEIG
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

Location ID:	LOC-100000481
Address:	Bristol-Myers Squibb House Uxbridge Business Park Sanderson Road Uxbridge Middlesex UB8 1DH United Kingdom
GPS Location:	51.55535, -0.47864
xEVMPD Code:	ORG5340
Last Modified Date:	2017-10-17T15:45:28
Status:	ACTIVE

4. Address localised

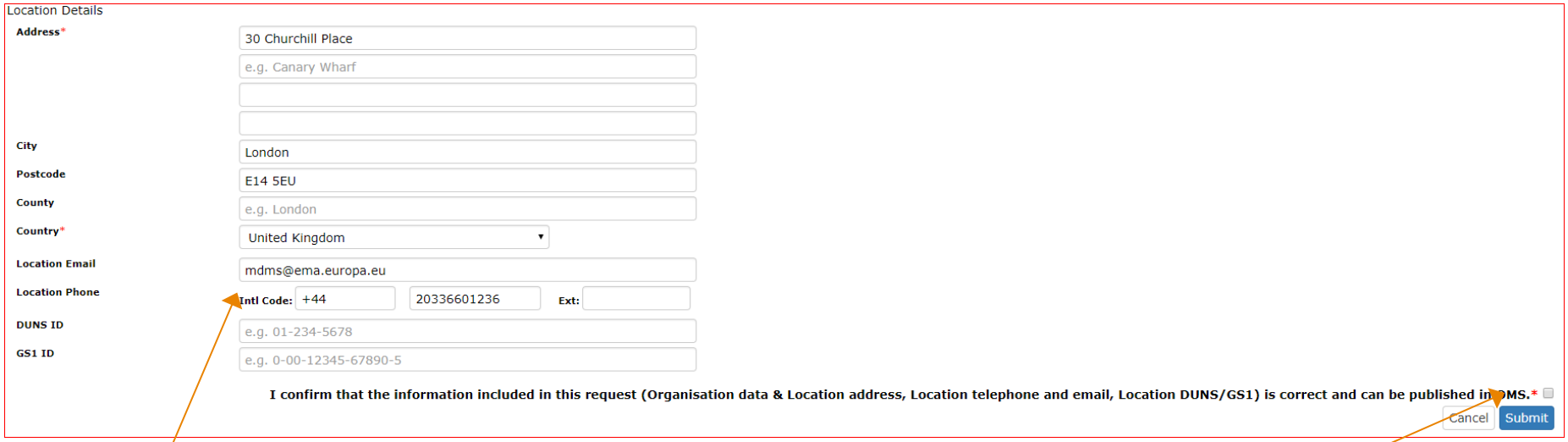
- Address localised is automatically generated by the Address Doctor if the address is verified as with 'Good' quality
- The data generated is derived against the reference address files as provided by the main postal service of that country or jurisdiction
- Although OMS supports the Latin Extended Character set, some postal services may provide the address with letters without the diacritical marks e.g. without accents etc. Example: France
- Each address localised will need to have the language associated to it. There can be multiple address localised addresses created

Users can update address localised through Update Change Request

OMS Change Request (CR) stages - Validation

EUROPEAN MEDICINES AGENCY

5. Communication Details



Telephone and Email only apply to the Location.
These are optional data.
If provided, this information will be published in OMS dictionary.
Provide 'mailbox' email address as much as possible.

GDPR requirements:
The Change request can only be submitted if this box is ticked.
This text will be changed to ensure full compliance with these requirements. Update is expected for end of Q1-2018.

Using OMS data in eAF – process

Applicants are advised to **perform a search** from within the form to **familiarise** themselves **with the use of OMS** and to ensure that they are familiar with the process **before its use becomes mandatory.**

Two outcomes are possible after searching for an organisation:

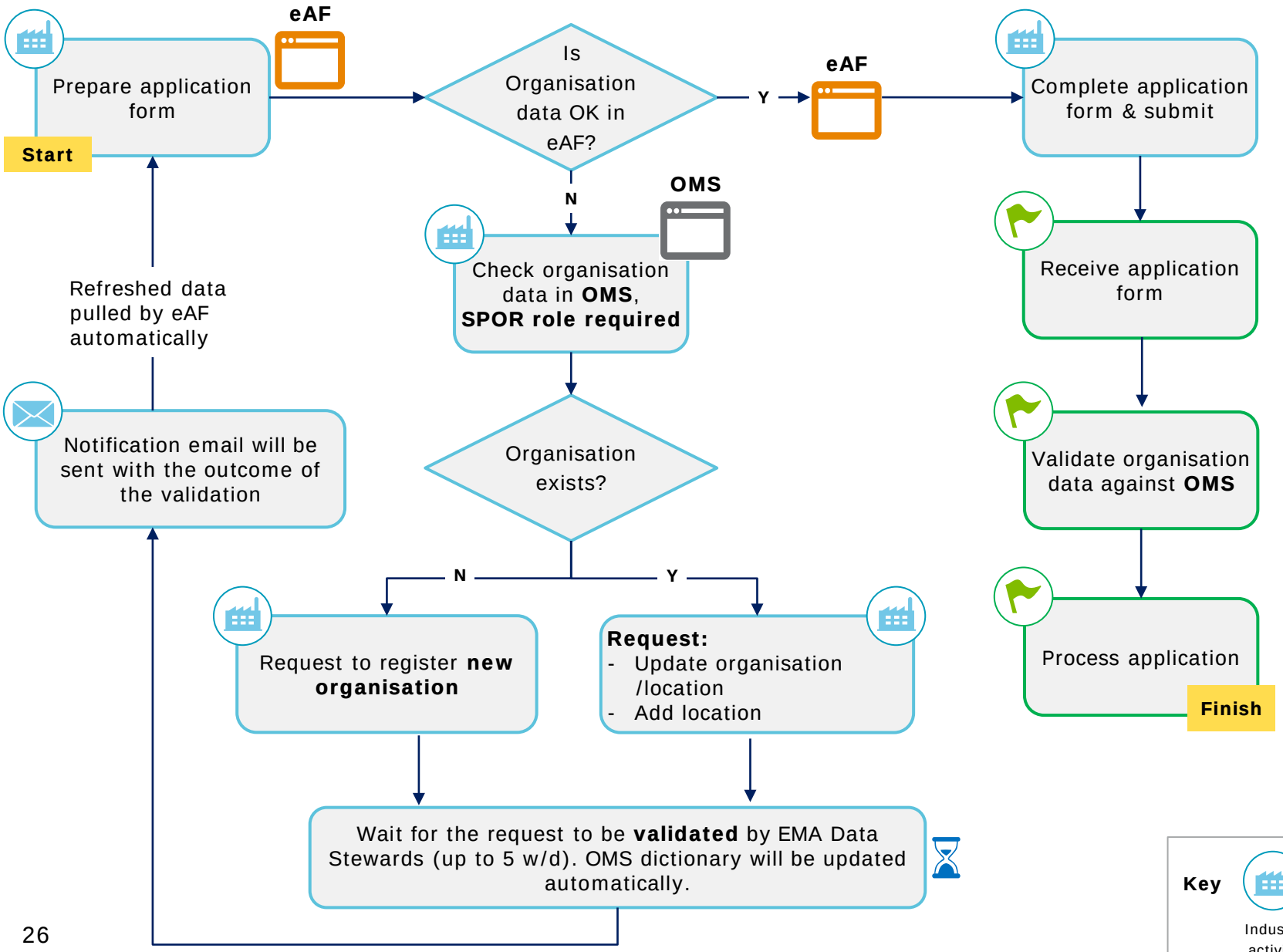
1. If the **address/location is not found or is incorrect**, users are advised to follow the OMS process to submit requests for adding or amending organisation data before the eAF submission.
2. If the **address/location is correct**, users may proceed using the OMS-provided data.

Using OMS data in eAF – submitting OMS CRs

EUROPEAN MEDICINES AGENCY

Domain	Data set	Procedure type	SPOR change request status
Human	MAA	CAP	✓ Stakeholders can start submitting the relevant OMS change requests.
Human	MAH	CAP	✓ Stakeholders can start submitting the relevant OMS change requests.
Human	MAH	NAP (MRP, DCP)	✓ Stakeholders can start submitting the relevant OMS change requests.
Veterinary	MAA	CAP	✓ Stakeholders can start submitting the relevant OMS change requests.
Veterinary	MAH	CAP	✓ Stakeholders can start submitting the relevant OMS change requests.
Veterinary	MAA	NAP (MRP, DCP)	• Do not submit OMS change requests until EMA has communicated.
Veterinary	MAH	NAP (MRP, DCP)	• Do not submit OMS change requests until EMA has communicated.
Human and Veterinary	Manufacturers	CAPs and NAPs (MRP, DCP)	• Do not submit OMS change requests until EMA has communicated (planned Q3/Q4 2018).

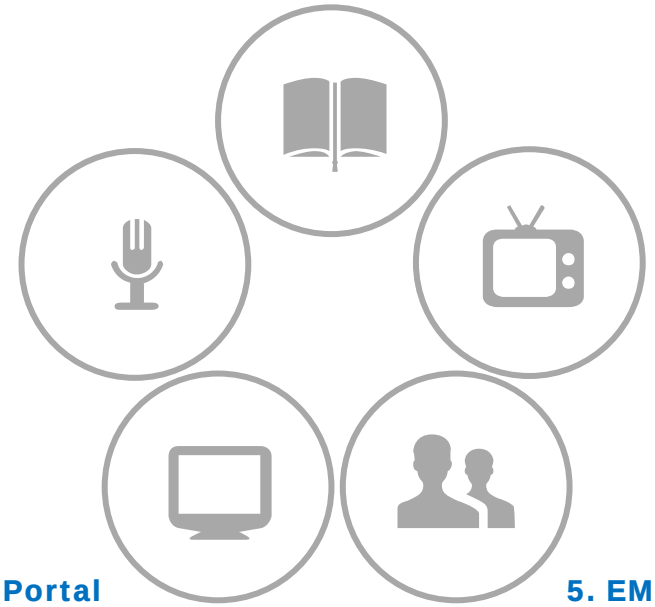
OMS in eAF - process



OMS support / guidance

1. Reference documents provide detailed guidance for the RMS. Accessible via the SPOR portal.

- OMS web user manual
- SPOR user registration manual
- SPOR affiliation template (to register the first industry super user)
- Change Request Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs



3. Material from SPOR webinars

Topic related content available on the SPOR portal (under documents section) and EMA public website. For example “Industry on-boarding to SPOR”, “Using RMS data in eAF”

2. Training videos

OMS training videos available to view on-demand by SPOR users on the @emainfo channel

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

Account Management Portal.

5. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the Service Desk Portal.

Disclaimer

Thank you!
Do you have questions?

Further information

http://spor.ema.europa.eu/sporwi/
SPOR pages on EMA public web.

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a SPOR question via our website SPOR-Change-Liaisons@ema.europa.eu

Follow us on **@EMA_News**