RMS & OMS status

Update to EUNDB

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Agenda

Status of O & R user on-boarding

Change Requests submitted in RMS and OMS

2018 activities in RMS and OMS

RMS & OMS version 2.4 release

New Initiatives

Status of Web Portal user registration:

- SPOR Industry Super users approved - 310
- SPOR Industry users approved - 150
- SPOR NCA Super user – 83% of NCAs registered Super User

NCA user	Industry user	User maintenance

06/2017   12/2017   03/2018
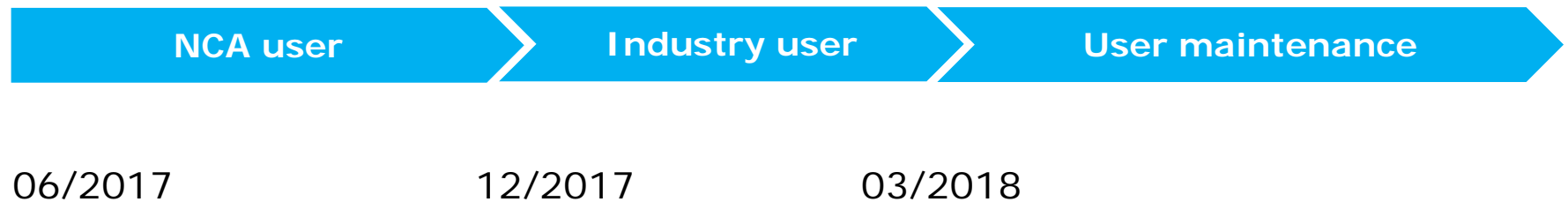
Status of SPOR API user registration:

- 7 NCAs
- 4 Industry users

Most frequent process issues – Web Portal:

- Letter not supplied via EMA Service desk portal (by the 1st super user)

- User unsure about who can sign the letter

- First user is not requesting 'Super user' role

- Only 1 super user registered with no back up

Most frequent process issues – SPOR API:

- Complex process, multiple systems to use

- Using the UAT environment whilst EMA still needs this environment for development work

RMS Change Requests Statistics – 16.03

TYPE OF REQUESTS	REQUEST OUTCOMES
New list: 4	Approved: 72
Update list: 3	Approved with changes: 22
New term: 121	Invalid (validation): 11
Update term: 18	Rejected (approval): 4
Delete term: 6	Returned: 16
Total: 152	Valid (pending approval): 27
	Total: 152

*Statistics as of June 2017 (RMS go live) and cut-off date 16 March 2018

SLAs for Change Requests - RMS

	75% of requests	90% of requests
Add term	• Validated within 2 working days. • Approved within 1 month when owned by RMS.	• Validated within 3 working days. • Approved within 2 month when owned by RMS.
Update Term	• Validated within 3 working days. • Approved within 1 month when owned by RMS.	• Validated within 5 working days. • Approved within 2 month when owned by RMS.
Delete Term	• Validated within 3 working days. • Approved within 1 month when owned by RMS.	• Validated within 5 working days. • Approved within 2 months when owned by RMS.
Add List	• Validated within 5 working days. • Approved within 2 months when owned by RMS.	• Validated within 10 working days. • Approved within 6 months when owned by RMS.
Update List	• Validated within 15 working days. • Approved within 2 months.	• Validated within 20 working days. • Approved within 6 months.
Returned requests	N/A	N/A

SLA compliance difficult to quantify due to the nature of RMS requests. Some requests include clock-stops for issue resolution with requestor and/or the maintenance organisation which are not excluded from the total time. Also, export of RMS CRs doesn´t distinguish the time taken for validation and for approval.

In future the SLAs will be reviewed as these are new services where the workload still needs to be identified. Also, ways to properly quantify SLA compliance will need to be identified.

OMS Change Request statistics – 21.03

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Request Status		Total	%
APPROVED		373	65.6%
APPROVED_WC		39	6.9%
ON_HOLD		19	3.3%
REJECTED		74	13.0%
SUBMITTED		64	11.2%
Grand Total		569	

Request Type		Total	%
ADD-LOCATION		32	5.6%
ADD-ORGANISATION		124	21.8%
UPD-LOCATION		242	42.5%
UPD-ORG-AND-LOCATION		144	25.3%
UPD-ORGANISATION		27	4.7%
Grand Total		569	

Submitted = Pending validation
Statistics period = 15/12/17-21/03/18

Request Status per Type	Total
ADD-LOCATION	32
APPROVED	23
APPROVED_WC	2
ON_HOLD	1
REJECTED	2
SUBMITTED	4
ADD-ORGANISATION	124
APPROVED	95
APPROVED_WC	11
ON_HOLD	3
REJECTED	10
SUBMITTED	5
UPD-LOCATION	242
APPROVED	143
APPROVED_WC	18
ON_HOLD	5
REJECTED	40
SUBMITTED	36
UPD-ORG-AND-LOCATION	144
APPROVED	98
APPROVED_WC	6
ON_HOLD	9
REJECTED	15
SUBMITTED	16
UPD-ORGANISATION	27
APPROVED	14
APPROVED_WC	2
ON_HOLD	1
REJECTED	7
SUBMITTED	3
Grand Total	569

SLAs for Change Requests - OMS

	75% of requests	90% of requests
Add Organisation/ Location	Approved within 5 working days.	Approved within 10 working days.
Add Location(s)	Approved within 5 working days.	Approved within 10 working days.
Update Organisation	Approved within 5 working days.	Approved within 5 working days.
Update Location	Approved within 5 working days.	Approved within 5 working days.
Delete Organisation/ Location	Approved within 10 working days.	Approved within 15 working days.
Add Organisation/ Location due to a split	Approved within 5 working days.	Approved within 10 working days.
Returned on hold	Approved 5 working days after reply from the requestor.	Approved within 10 working days after reply from the requestor.

>10 working days*	8.5%
6 to 10 working days	6.9%
Up to 5 working days	84.6%

*Not taken into account that 29 out of 43 requests were on hold

In future the SLAs will be reviewed as these are new services where the workload still needs to be identified

- New lists for EMA projects:
    - S-REPS CRM
    - CT portal

- New lists for SMS/PMS Implementation

- Improvements of some RMS lists. E.g.Variation classification.

Expanding the OMS dictionary

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

Data set 2:
- **Sponsors (H) CAPs and NAPs**
- **Regulatory Authorities**

Data set 3:
- **Manufacturers: (H+V) CAPs**

Data set 4:
- **EV organisations** (supporting EV user management)

Data set 5:
- **Orphan Designation organisations**

Data set 6 end of Q4 2018
- **Manufacturers: (H+V) NAPs**

As of September 2018: Start populating OMS with MAHs for NAPs Veterinary via the OMS Change Request process

Additional Organisation data to be added in future. Its prioritisation will be communicated Q1-2019.

2018

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Work streams which OMS data stewards support:

1. Continue expanding OMS dictionary with new data sets (see above)

2. Process OMS CRs for date set 1 (see slide 5)

3. Updates of OMS data based on the latest changes in xEVMPD – Article 57

4. Provide support to other project which integrate with OMS (see slide 8)

5. Support bug fix and data fix deployments in OMS

6. Supporting OMS Service desk (OMS business and technical requests)

New

EV User Registration integration with OMS and EMA Account Management. Q2 2018

New

Orphan Designation process integration with OMS data Q2 2018

Q4 2018: Integrate RMS & OMS with Art 57/xEVMPD

Q4 2018: Integrate RMS & OMS with CT Portal

Q4 2018: Integrate RMS & OMS with CESSP (MAA)

2018 ...

Continue consultation with stakeholders on the benefits of using SPOR services in business processes.

New

CTS system plans to integrate with RMS and OMS. They have already started to integrate some of the RMS lists and plan to start consuming OMS data in Q4-2018. The details of what impact that will have on the workload for EMA is yet to be clarified.

CTS supports MRP/DCP human MA procedures

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- **Scope of the OMS fixes/changes applied in this release**:

    - Transliteration of non-EN characters into EN for main address

    - Data management on the address localised (non EN addresses)

    - Language is now created for SE – address localised

    - County removed from FR in main address

    - Improved integration with EMA Account management system (synchronisation every 10 mins)

    - Multiple data fixes to solve some legacy data issues

    - Organisation/Location status change via change requests

    - Various product fixes related to address verification

- **Scope of the RMS fixes/changes applied in this release:**

    - Internal Bulk upload functionality for new lists

    - EDQM automatic delta data loads

- SPOR programme proposes setting up a Key User Group for RMS/OMS – by Q4-2018?

- The Terms of Reference for this group needs to be drafted – by Q2-2018?

- Aspects which may be considered:

  - Future changes (Improvements) to the RMS and OMS solutions

  - Bug fixing for existing functionality

  - Monitoring of SLAs

  - Practical aspects of data management

    - Business rules and data quality standards – Discuss possible improvements

- In the meantime SPOR team will work to increase awareness of existing guidance such as the data quality standards applied in OMS

Thank you!

Do you have questions?