EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 June 2017
EMA/541082/2016
Information Management Division

SPOR Data Services

1. Disclaimer

While the EMA makes every effort to ensure the quality and efficiency of the SPOR data services it acknowledges that these are new services where the process efficiency and workload are still to be verified.

The EMA will aim to provide SPOR data services in the conditions set out below but in the first 12 months of running these services these are merely indicative Service Level Agreements for Support.

2. Service Level Agreement for support

SPOR Data Services aim to answer to the majority of requests within the timeframes set out below:

Solution supported	Type of request	75% of requests	90% of requests	Expected outcome
Data requests				
RMS Portal	Add term	• **Validated within 2 working days** • Approved within 1 month when owned by RMS • *No approval SLA when owned by external providers*	• **Validated within 3 working days** • Approved within 2 month when owned by RMS • *No approval SLA when owned by external providers*	• A provisional Term is available for use if the request if validated • The Term becomes current (final) if the request is approved
	Update Term	• Validated within 3 working days • **Approved within 1 month when owned by RMS** • *No approval SLA when owned by external providers*	• Validated within 5 working days • **Approved within 2 month when owned by RMS** • *No approval SLA when owned by external providers*	• The Term is only updated if the request is validated and approved
	Delete Term	• Validated within 3 working days • **Approved within 1 month when owned**	• Validated within 5 working days • **Approved within 2 months when owned**	• The Term is not physically deleted rather its status is updated to "Non-current" if the request validated and

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 fjbhedfj
Send a question via our website www.ema.europa.eu/contact

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Solution supported	Type of request	75% of requests	90% of requests	Expected outcome
		by RMS • *No approval SLA when owned by external providers*	**by RMS** • *No approval SLA when owned by external providers*	approved
	Add List	• Validated within 5 working days • **Approved within 2 months when owned by RMS** • *No approval SLA when owned by external providers*	• Validated within 10 working days • **Approved within 6 months when owned by RMS** • *No approval SLA when owned by external providers*	• The List is available for use if the request is validated and approved
	Update List	• Validated within 15 working days • **Approved within 2 months**	• Validated within 20 working days • **Approved within 6 months**	• The List is updated if the request is validated and approved
	Returned requests	• NA	• NA	• The requestor has 2 weeks to reply back with additional information required, after which point the request is rejected
OMS Portal	Add Organisation/ Location	• Approved within 5 working days	• Approved within 10 working days	• The Organisation/Location is available for use if the request is approved
	Add Location(s)	• Approved within 5 working days	• Approved within 10 working days	• The Location is available for use if the request is approved
	Update Organisation	• Approved within 5 working days	• Approved within 5 working days	• The Organisation is updated if the request is approved
	Update Location	• Approved within 5 working days	• Approved within 5 working days	• The Organisation is updated if the request is approved
	Delete Organisation/ Location	• Approved within 10 working days	• Approved within 15 working days	• The Organisation is not physically deleted rather its status is updated to "Inactive" if the request is approved
	Add Organisation/ Location due to a Split	• Approved within 5 working days	• Approved within 10 working days	• The Organisation/Location is available for use if the request is approved
	Returned on hold	• Approved 5 working days after reply from the requestor	• Approved within 10 working days after reply from the requestor	• The requestor has 2 weeks to reply back with additional information required, after which point the request is rejected

Solution supported	Type of request	75% of requests	90% of requests	Expected outcome
Customer support				
Substance requests*	Up to and for each group of 20 Substance requests (new/update/translations)	• Approved within 4 working days	• Approved within 8 working days	• The Substance/alias/translation is available for use if the request is approved
JIRA – incident*	Critical	• Response within ¼ hour • Resolution within 4 hours		• The incident is resolved
	Urgent	• Response within 1/2 hour • Resolution within 1 working day		• The incident is resolved
	medium	• Response within 1 hour • Resolution within 2 working days		• The incident is resolved
	Low	• Response within 1 working day • Resolution within 5 working days		• The incident is resolved
JIRA – service request**	Technical or Business query; change request/enhancements to SPOR solutions	• Response within 1 working day • Resolution within 5 working days		• The request is resolved
User management				
IAM	Access request	• Approval within 2 working days	• Approval within 5 working day	• The access is granted if the request is approved

* see how to request new substances here

**see Article "How-to understand the priority assigned to an incident/request" in JIRA here

EMA will use reasonable efforts to provide support in accordance with this Service Level Agreement, and will not be responsible for any delays caused by the customer for reasons beyond EMA's control.

We are constantly monitoring our support channels for critical issues.

3. Business Hours and Response Time

Our business hours are from 9 am to 5 pm GMT+1, Monday to Friday.

Our office is closed on holidays listed on the EMA's website.

4. Support Channels

You can request support through one of the following channels:

- Submitting a data request through the SPOR Portal
- Submitting a service request/issue through EMA's issue tracking system - JIRA - (all users needing access to JIRA need to be registered in the Agency's Identity and Access Management solution first)
- Sending an email to: mdms@ema.europa.eu

5. Support from EMA Includes:

- Referential data requests
- Organisation/Location data requests
- Substance (non-ISO compliant) data requests
- Access management
- Guidelines and best practices regarding SPOR
- Helping with troubleshooting problems with SPOR
- Helping with issues arising after EMA upgrades

6. Support from EMA Does Not Include:

- Phone support
- Support in any language other than English
- Product training