Housekeeping notes – Personal data protection notice

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*Throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

For Questions: www.slido.com code: #SWOCT824

Housekeeping notes – Q&A

Join at
slido.com
#SWOCT824

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Webinar materials sharing

Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page

*1st version of presentation already published, to be updated with final version (if necessary)

Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page

For Questions: www.slido.com code: #SWOCT824

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Substance Management Service (SMS)

8 October 2024, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Pedro Batista

SPOR Webinar Series – 4-14 October 2024

SPOR Webinars

EUROPEAN MEDICINES AGENCY

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

For Questions: www.slido.com code: #SWOCT924

Goals of the session

Increase Awareness of SMS activities

Share status update of SMS service

For Questions: www.slido.com code: #SWOCT824

Agenda

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1. **Welcome**
   10:00 – 10:05
2. **Introduction to SMS**
3. **SMS Processes**
4. **SMS Data Services**
5. **SMS Change request process**
6. **SMS Statistics**
7. **SMS Documentation & Help**
8. **Small Break**
   11:00 – 11:15
9. **SMS Status update**
10. **Key takeaways & Conclusions**
11. **Q&A Session**
    11:45 – 12:00

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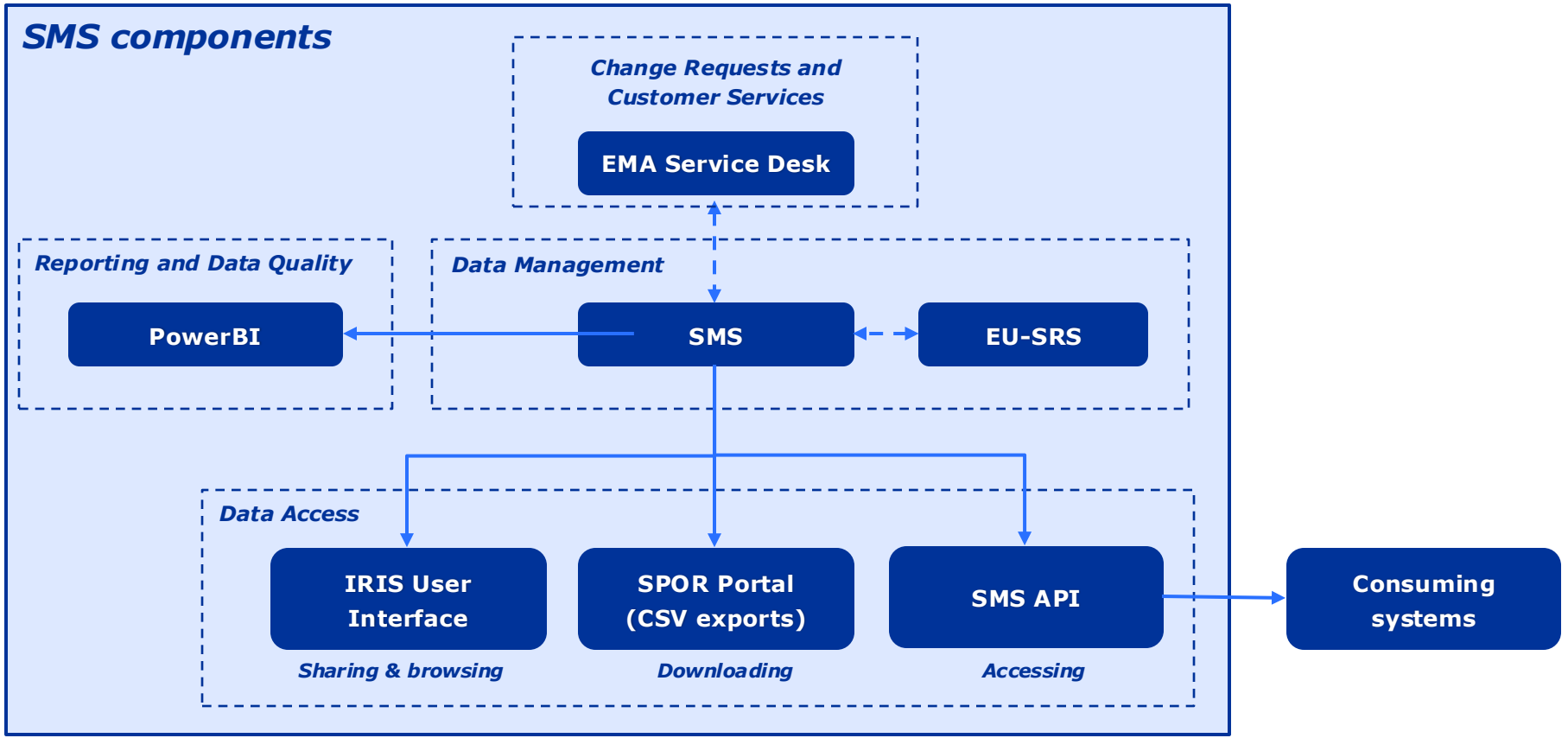
Introduction to SMS

Introduction to SMS – Key components



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Introduction to SMS – SMS and EU-SRS

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	SMS	EU-SRS
Purpose	**SMS provides a** central source of substance data **that supports selection in regulatory processes and therefore enables to distinguish between two or more substances**	**EU-SRS provides a** source of substance data **that supports scientific identification and characterisation of substances**
People	EMA Data stewards are specialised in data management. Substance Validation Group are Substance experts. Using both sets of skills enables for a better substance management	
Technology	EU-SRS is an open-source solution which implements **ISO IDMP logic** therefore enabling to register good quality substance data. SMS benefits from years of **integration of substance data into regulatory processes/systems**. Using both solutions is a cost-effective way to manage and share/re-use substance data.	
Data	**There is only one EU substance list: data between SMS and EU-SRS share the same ID and are being aligned** via data fixes/batches of data. A future real-time sync is desired and has to be prioritised in the Network portfolio. SMS contains **all the substances used in pharmaceutical products available in EU-SRS**, only it contains a **subset of the fields from EU-SRS**.	
Access	SMS public data is accessible via **SMS User Interface** (IRIS), **substance exports** (SPOR Portal), **SMS API** and **consuming systems**. EU-SRS is currently accessible to **NCA users only** (NCAs can request access via EMA Account Management)	

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Introduction to SMS – Data Fields

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Identifiers

- **Primary:** SMS ID, previously known as EUTCT ID
- **Secondary:** EV Code (only for Human substances)

Mandatory data fields

- **Domain:** Human or Veterinary
- **Status:** Current or Non-current – different exports for each status
- **Substance type**
- **Substance Name:** Preferred term, aliases and translations available in export
- **Language**
- **Name source**
- **Data classification:** Public or Restricted – only "Public" names are available in export

Optional data fields

- **Molecular formula/Molecular weight/InChIKey :** Registered for chemicals and available in the export only for "Public" substances
- **Comments:** replacement ID in case of nullification (free text)
- **Substance current:** replacement ID in case of nullification (structured)
- NEW **Parent substance:** registered for chemicals, some proteins and nucleic acids
- **Substance codes:**
  - Unique Ingredient Identifier (UNII, the FDA substance identifier)
  - SVG cleansed flag
  - NEW INN Number (WHO International Non-Proprietary number)
  - NEW EC List/Number (European Commission substance number)

Introduction to SMS – SMS Application Programming Interface (API)

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- SMS API is available for all users but with **different access rights**:
  - NCA users: all substance data
  - Industry users (any non-NCA users): public substance data only
- Besides all data available in the substance exports, it also includes **Custom Attributes**:
  - Active substance used in a human medicinal product approved in EU/EEA
  - Active substance related to Union List of Critical Medicines
- Access managed via EMA Account Management, instructions available in SMS Guidance for External Users (section 4.3)
- Further information to be provided in the **SPOR API Webinar on 14 October**

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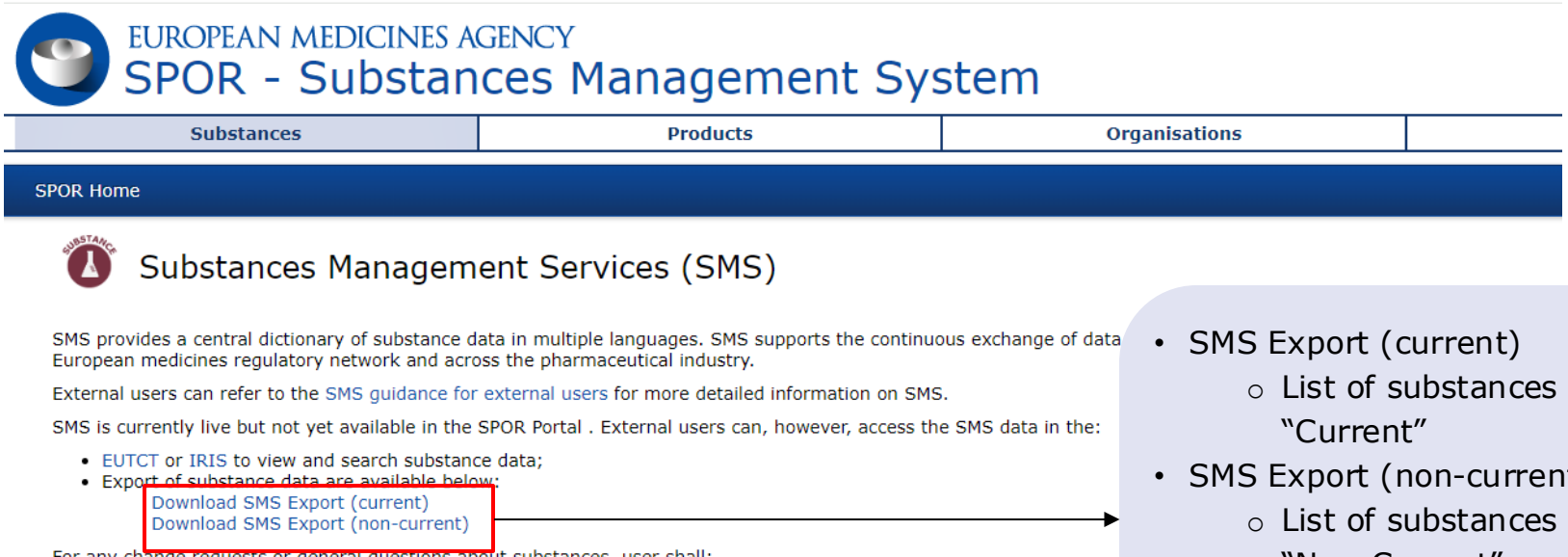
Introduction to SMS – SPOR Portal (CSV exports)



- SMS Export (current)
  - List of substances with status "Current"
- SMS Export (non-current)
  - List of substances with status "Non-Current"
- Both exports:
  - Refreshed daily
  - Only public substance data

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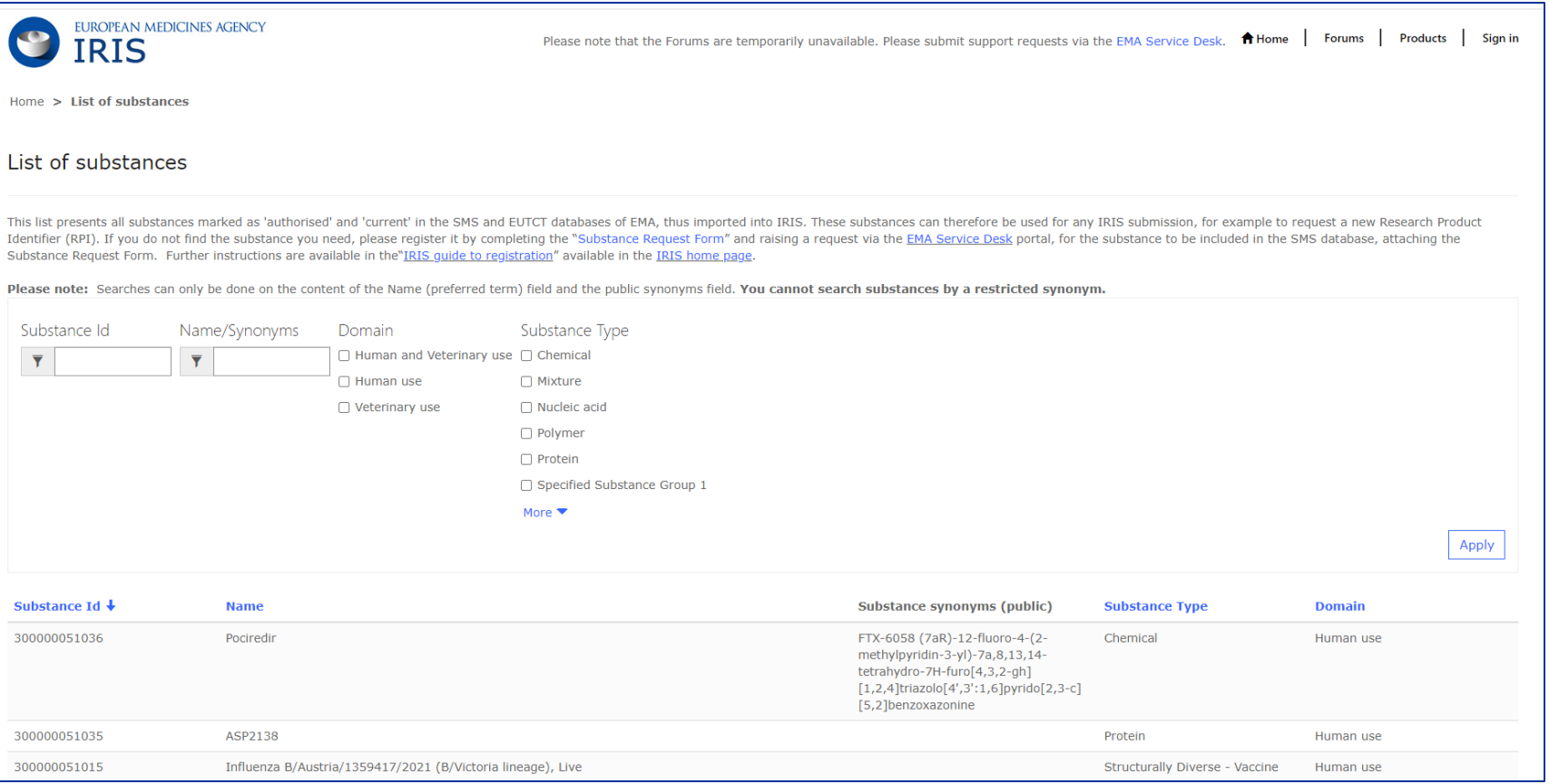
Introduction to SMS – IRIS User Interface (UI)



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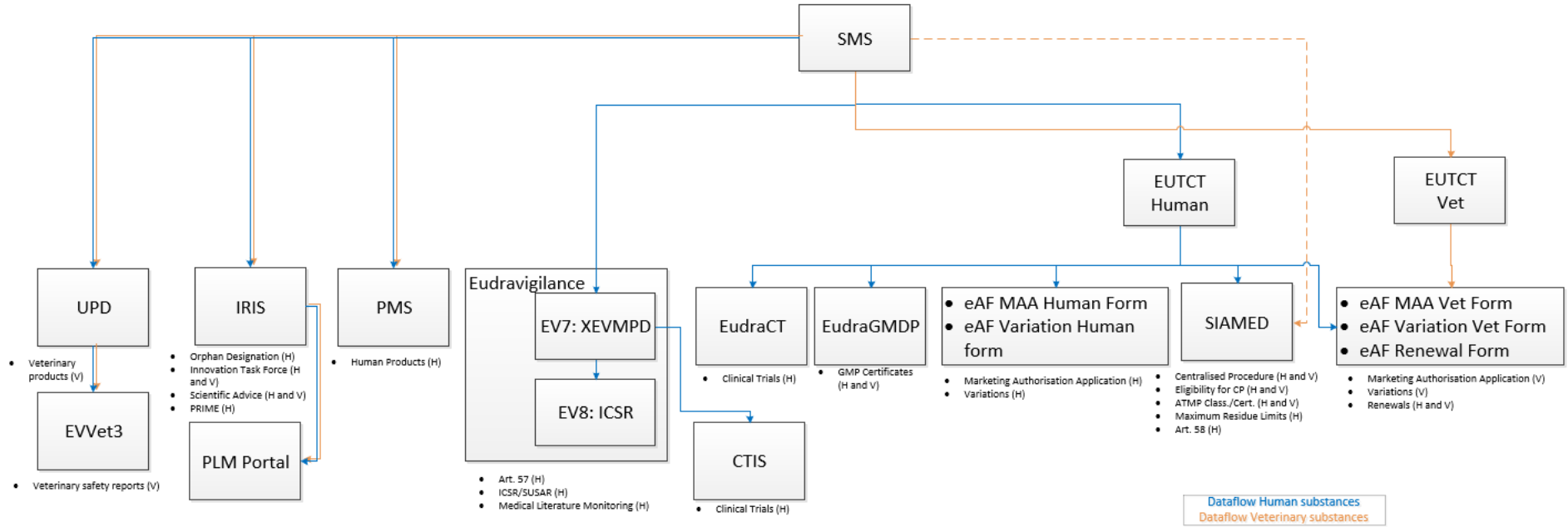
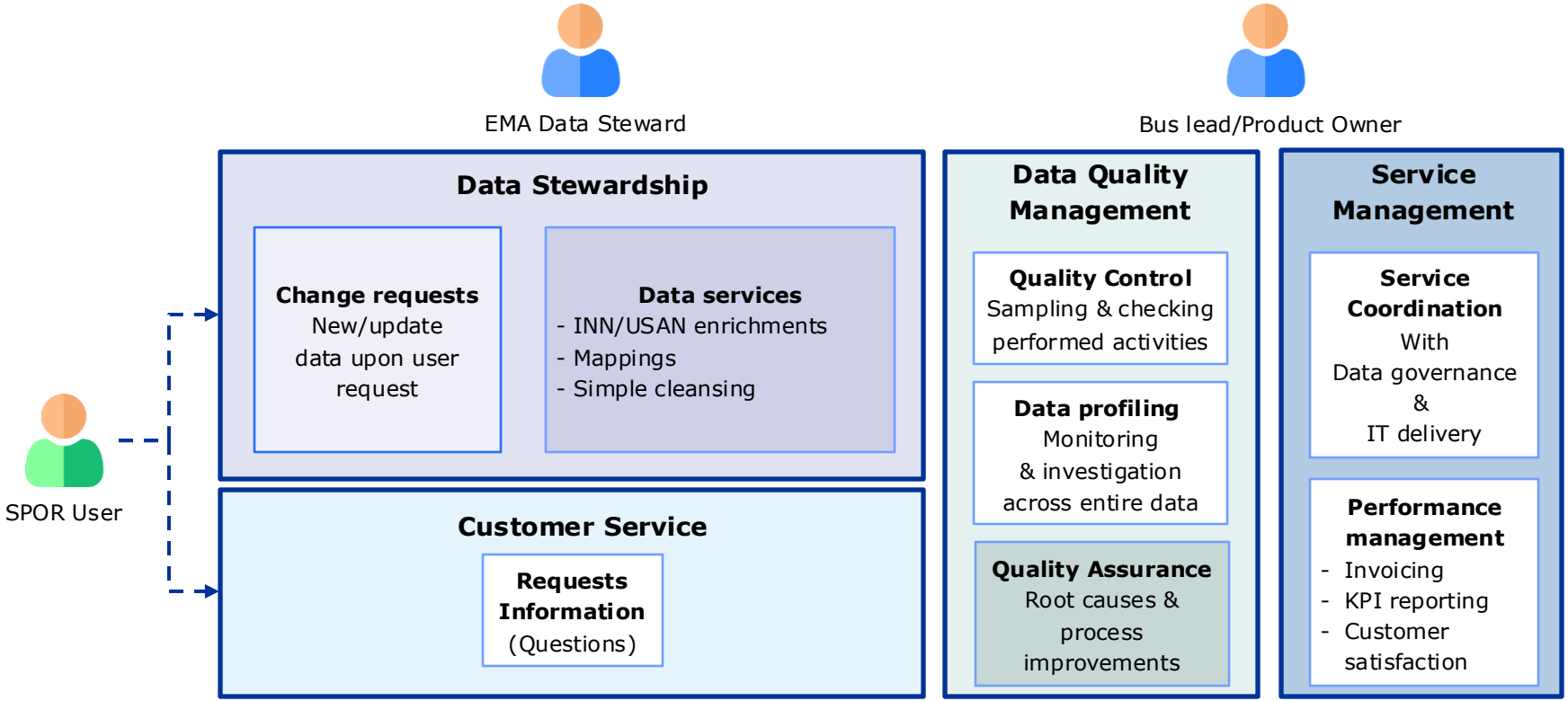
Introduction to SMS – Consuming systems



SMS Process

SPOR Data Management Processes



Data management processes are defined, operational and are monitored/reported on

 For Questions: www.slido.com code: #SWOCT824

SMS Data Services

Data Services at a glance

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Mappings

- consist in **matching substance data existing in legacy systems to SMS**, and the resulting creation/update of relevant data in SMS
- supports **data migrations** and **implementation of SMS in Telematics systems**
- Examples: Vet NCA data for UPD, Orphan Designation substances for IRIS, XEVMPD development substances

SMS Data Services

Enrichments

- consist in **proactively completing SMS data** with reference information
- **improve the data quality in** and, by preventing the submission of change requests, **minimise the burden on Industry/SMS users**.
- Examples: INN and USAN names

Cleansing/ corrections

- consists in proactively looking at the SMS data to **identify and eliminate duplicates,** as well as **verify and standardise SMS data** against established reference information.
- Data cleansing **improves the data quality** and, by preventing the submission of change requests, **minimise the burden on Industry/SMS users**.
  - **The Substance Validation Group (SVG) is cleansing the legacy substance data**, as prioritised by the Network
  - **45%** of substances in SMS have been reviewed. This represents **100%** of active substances in **Veterinary authorised medicinal products** and **82%** of substances used in **Human authorised medicinal products.**

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Substance cleansing – Status

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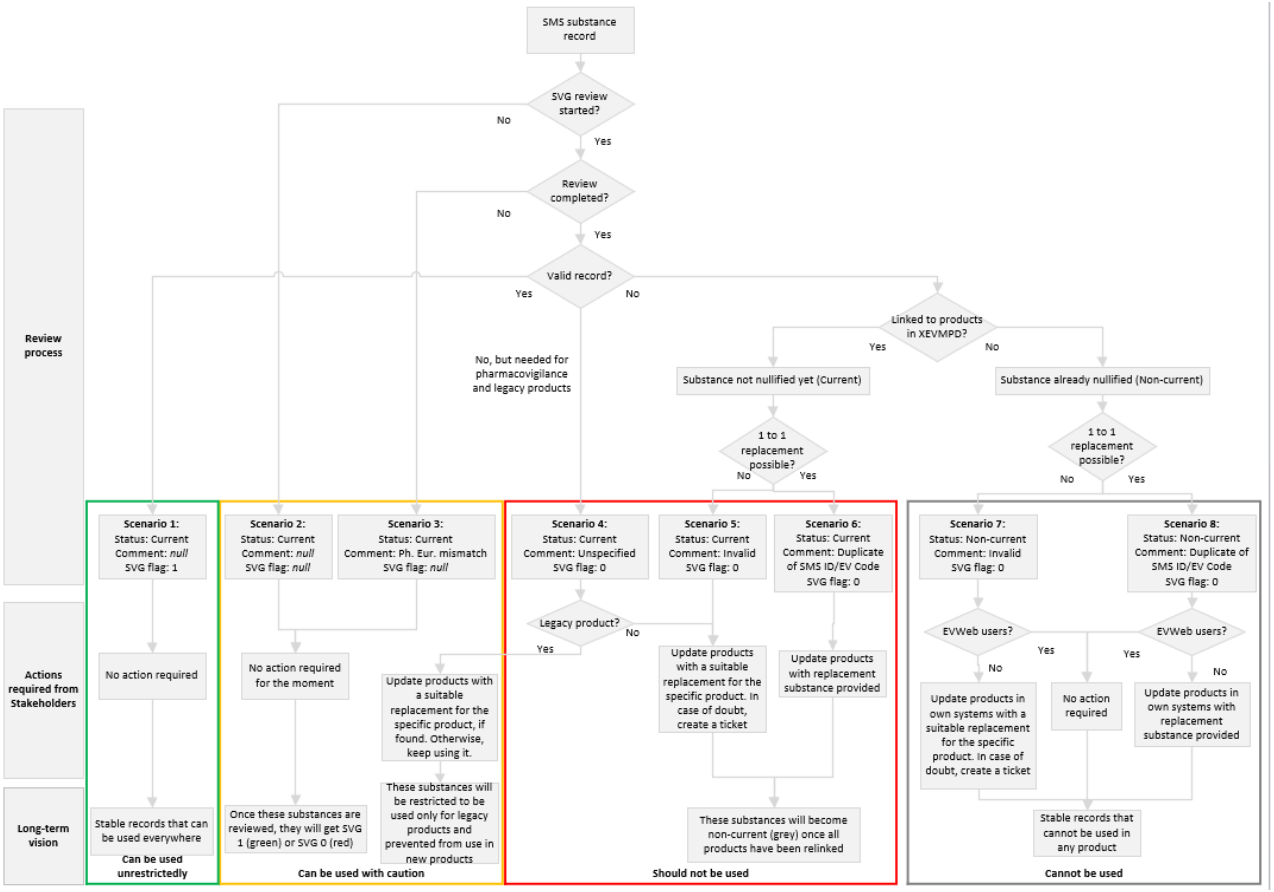
Substance type	Cleansing status	Comments
Chemical	100%	
Specified Substance Group 3	95%	
Structurally Diverse - Vaccine	56%	Veterinary vaccines cleansed, Human vaccines ongoing
Polymer	34%	
Mixture	20%	
Specified Substance Group 1	16%	Includes flavours, coatings, solutions, homoeopathics, herbal extracts
Protein	12%	
Structurally Diverse - Plasma derived	11%	
Structurally Diverse - Herbal	5%	
Nucleic acid	4%	
Structurally Diverse - Other	2%	Includes gene therapy
Structurally Diverse - Allergen	1%	
Structurally Diverse - Cell therapy	0%	
Overall	**45%**	

Substance cleansing – Outcomes



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Substance cleansing – Follow-up actions

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SVG flag 0 and Comment "Duplicate"

Currently

- These substances are no longer available in eAF and UPD (for new products) but still available in XEVMPD
- Not possible to flag them in XEVMPD in the product view
- EMA is preparing a datafix to relink the impacted products in XEVMPD/PMS
- MAH can optionally update them in advance in their XEVMPD products

Q2 2025

- EMA will provide an export of impacted product and substance EV codes
- MAH that are Gateway users should update their systems with the replacement substances provided
- EMA will perform a datafix to relink all impact products
- EMA will nullify the duplicated substances

Pending changes in preferred terms (PT) [flagged by alias with source "Substance Validation Group"]

***NOTE**: changes in PT in SMS do not require MAH to change SmPC/dossier*

Currently	•SVG has identified substances that have an incorrect PT •Changing PTs has an impact on ICSR recoding
Q1 2025	•Technical changes in ICSR recoding algorithm
Q2 2025	•Updating substances preferred terms

SVG flag 0 and Comment "Invalid" or "Unspecified"

- Complex scenarios that require a product-by-product analysis
- To be addressed in Q3/Q4 2025 (after Duplicates are addressed)

SMS Change Request process

SMS Change Request process at a glance

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Submission

Requestor

NEW

Reads the SMS Guidance for External users

Submit SMS CR in EMA Service Desk portal**:**
- Add Substance
- Update Substance

Also include **Substance Request form** and **supporting documentation**

Validation

EMA Data Stewards

Guidance/ references & tools

Data Stewards validate all SMS CRs using guidance/references:
- SVG Data management Manuals
- EMA Substance Naming Rules
- Input from SVG discussions
- External Sources of Information

Approval/ Rejection

EMA Data Stewards *in consultation with SVG*

- New substances (<20): **5-10 working days**
- Translations (<20): **10-15 working days**
- Bulk requests (>20): No guaranteed SLA

Priority to new substances

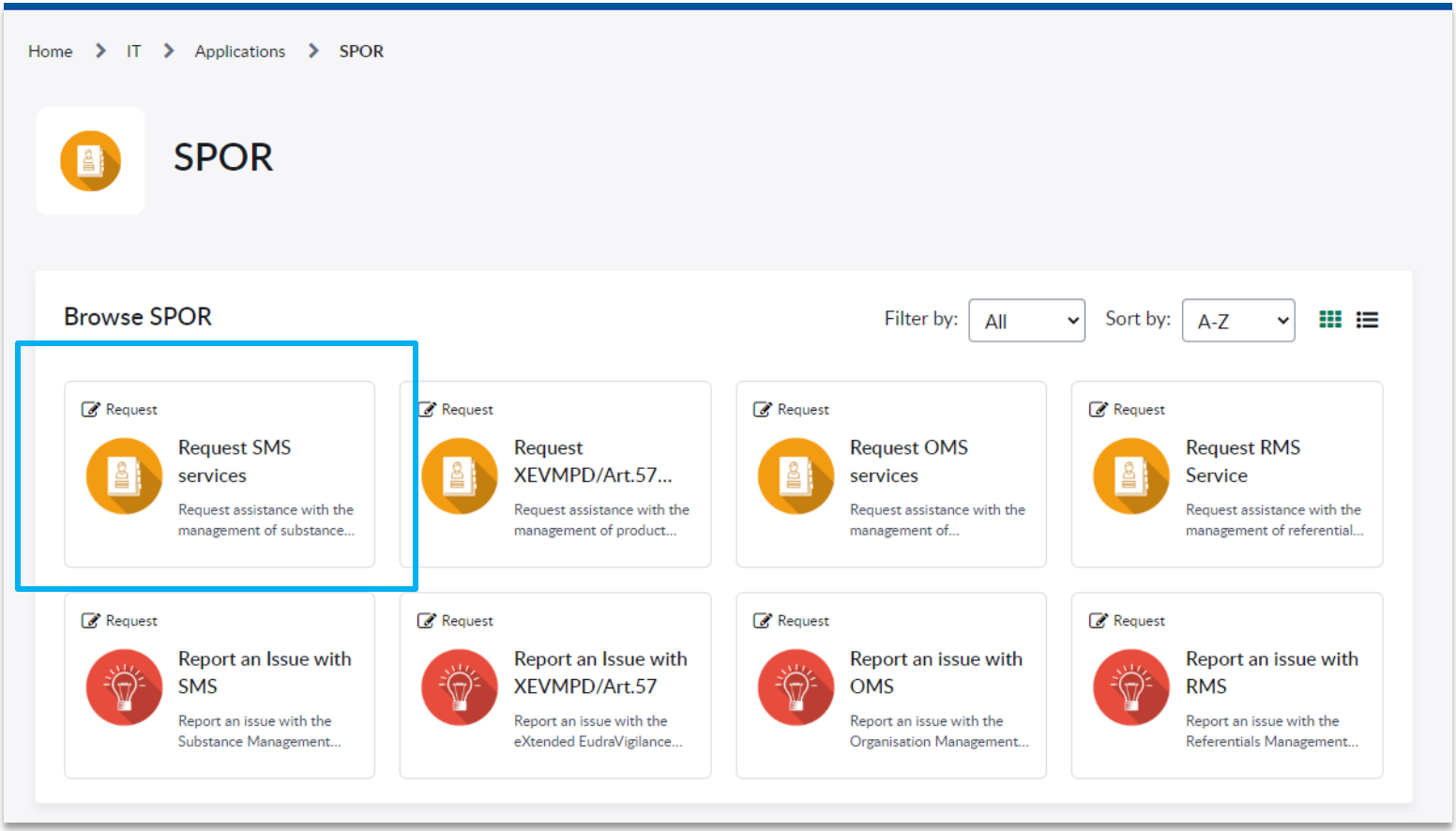
SMS CR approved = data updated in the SMS and published in consuming systems
SMS CR rejected = reasons explained to requestor via EMA Service Desk

Substance data owner

Substance Validation Group (SVG)

- New substances are created with higher data quality **based on SVG defined business rules**
- Newly created substances may eventually be **reviewed by the SVG**
  - End-to-end process discussions are ongoing

SMS change requests – request in EMA Service Desk



 For Questions: www.slido.com code: #SWOCT824

SMS change requests – request in EMA Service Desk

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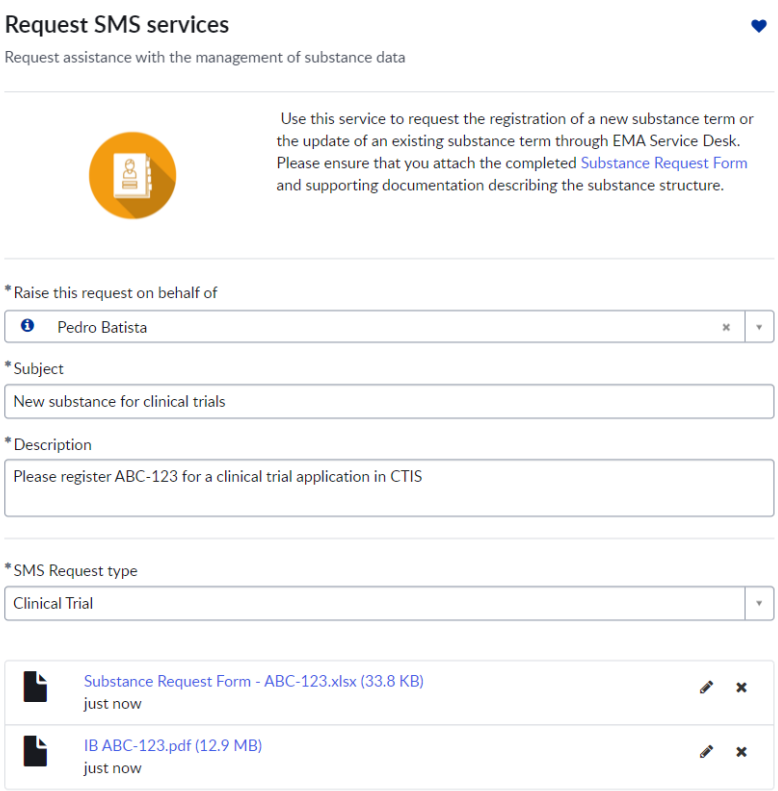

- **Description:**
  - **For creates:** Brief description of the substance
  - **For updates:** provide the SMS ID or EV Code of the substance to be updated and the new name to be added
- **SMS Request type:** select the regulatory procedure
- **Attachments:**
- **Substance request form**
  - **Supporting documentation** describing the substance nomenclature/structure *(e.g. SmPC, Investigator's Medicinal Product Dossier, company specifications, section A.3 Medical Plausibility of Orphan Designation, draft package for Scientific Advice, etc.)*

SMS change requests – request in EMA Service Desk

EUROPEAN MEDICINES AGENCY

- **At least one name** must be made **public**
- **Official names** (INN, USAN, etc.) are **always public**
- **Preferred term** is defined by **SMS data stewards** according to the **business rules**
- pINN and USAN **cannot** be used as substance preferred term
- For OD, PIP and MAA, company codes **cannot** be used as the substance preferred term

Example of a chemical for Clinical Trials

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SCIENCE MEDICINES HEALTH

REQUEST FOR REGISTRATION OF A NEW SUBSTANCE

Please provide at least one preferred term in English and as many aliases as known. Copy the table below if multiple substances are being requested.

Please adjust the privacy settings of each name if your substance is still in development. Public names will be published in EUTCT.

Note: proposed INN and company code are not acceptable for Orphan Designation, Opinions on Paediatric Investigation Plans/waivers, and Marketing Authorisations

Name type	Name	Privacy settings	Comments
Recommended INN		Public	
Proposed INN		Public	
Chemical name	2-ethylbutyl (2S)-2-[[[(2R,3S,4R,5R)-5-(4-aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-5-cyano-3,4-dihydroxyoxolan-2-yl]methoxy-phenoxyphosphoryl]amino]propanoate	Restricted	
Scientific name		Public	
Common name		Public	
Company code	ABC-123	Public	
Other (specify)		Public	
Molecular formula		Public	
CAS number		Public	

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SMS change requests – request in EMA Service Desk

EUROPEAN MEDICINES AGENCY

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Example of a protein for Orphan Designation

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SCIENCE MEDICINES HEALTH

REQUEST FOR REGISTRATION OF A NEW SUBSTANCE

Please provide at least one preferred term in English and as many aliases as known. Copy the table below if multiple substances are being requested.

Please adjust the privacy settings of each name if your substance is still in development. Public names will be published in EUTCT.

Note: proposed INN and company code are not acceptable for Orphan Designation, Opinions on Paediatric Investigation Plans/waivers, and Marketing Authorisations

Name type	Name	Privacy settings	Comments
Recommended INN		Public	
Proposed INN	Examplemab	Public	
Chemical name		Public	
Scientific name		Public	
Common name	Human IgG1 monoclonal antibody against protein X	Public	
Company code	QWERTY-456	Public	
Other (specify)	ASD-456	Public	
Molecular formula		Public	
CAS number		Public	

SMS change requests – request in EMA Service Desk

EUROPEAN MEDICINES AGENCY

- **At least one name** must be made **public**
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Example of a cell therapy for marketing authorisation application

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

REQUEST FOR REGISTRATION OF A NEW SUBSTANCE

Please provide at least one preferred term in English and as many aliases as known. Copy the table below if multiple substances are being requested.

Please adjust the privacy settings of each name if your substance is still in development. Public names will be published in EUTCT.

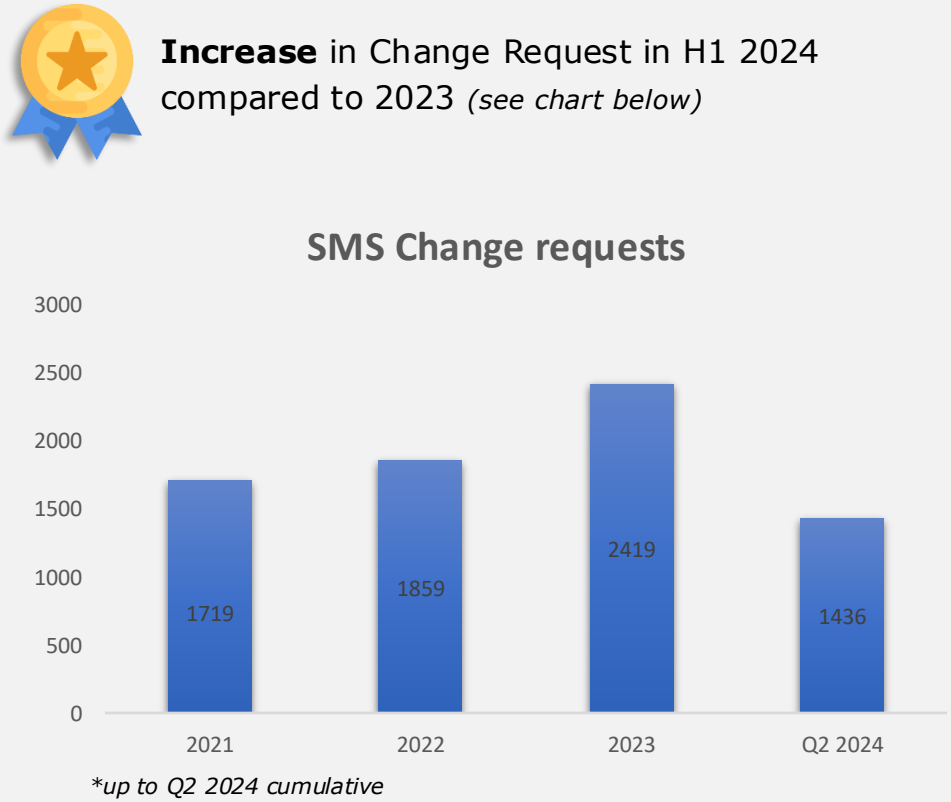
Note: proposed INN and company code are not acceptable for Orphan Designation, Opinions on Paediatric Investigation Plans/waivers, and Marketing Authorisations

Name type	Name	Privacy settings	Comments
Recommended INN	Examplecel	Public	
Proposed INN		Public	
Chemical name		Public	
Scientific name		Public	
Common name	Autologous bone-marrow derived T-cells, ex-vivo expanded	Public	
Company code	XYZ-999	Public	
Other (specify)		Public	
Molecular formula		Public	
CAS number		Public	

SMS Statistics

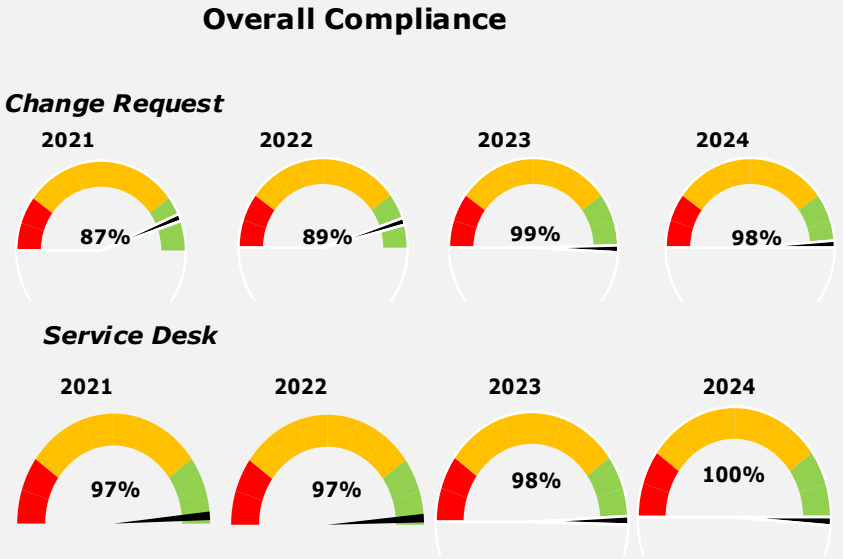
SMS Statistics – SMS Activities

Increase in Change Request in H1 2024 compared to 2023 *(see chart below)*



**up to Q2 2024 cumulative*

Despite the increase in Change requests, the **SLA compliance has remained almost 100%**



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SMS Documentation and Help

SMS Documents & Help

EUROPEAN MEDICINES AGENCY

SPOR portal

Main documentation required to successfully use SMS services:

NEW

- **SMS Guidance for external users**
- Substance data exports
- V2 - RDM Customer Satisfaction Survey 2022
- X - SPOR SLAs

EMA Account Management Portal

- Guidance on to obtain access to EMA systems
- Create a new EMA account

EMA corporate website

- SPOR vision and general introduction to SPOR projects
- SPOR related information and documents

SMS Webinars

- @emainfo channel contains Videos of SPOR & specific SMS webinars
- Industry Webinar – Introduction to SMS services and activities on 6 September 2022
- SMS April Webinar

EMA Service Desk

- For any help needed and not found in docs e.g., Service requests, issues, requests for technical support can be submitted through the ServiceNow Portal
- ServiceNow - Request SMS Services
- Substance request form

Substance Validation Group

NEW

- EU-SRS webinar in EU Network Training Centre Portal
- HMA SVG page
- UNICOM SVG documents

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SMS Documents & Help – Guidance for External Users

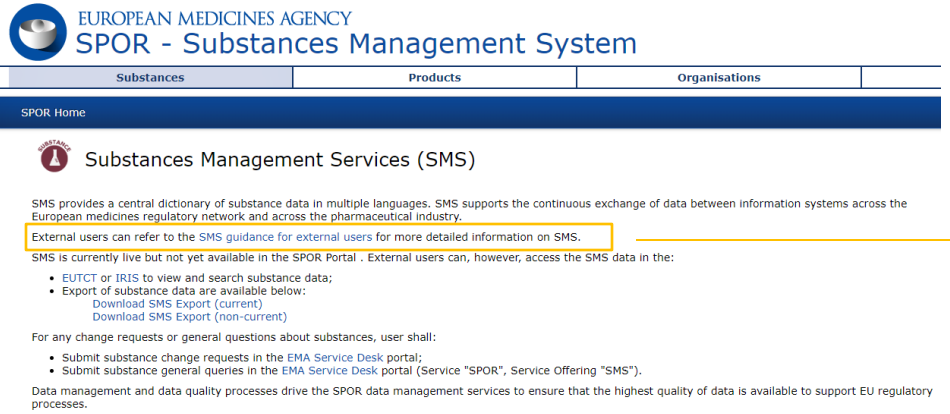

Table of contents

For Questions: www.slido.com code: #SWOCT824

Break (15 minutes)

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Let's have a short break!

Break

 For Questions: www.slido.com code: #SWOCT824

SMS Status update

Planned SMS Activities

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	Q3 2024	Q4 2024	Q1 2025	Q2 2025
Deliver efficient and effective regulatory data services	**Customer Services**			
	Data Management (Change requests & Data services)			
	pINN/rINN/USAN/UNII/Ph. Eur. enrichments			
	Data Quality			
	• Data quality profiles			
	1 SSG1 (solutions)/SSG3 cleansing	Human vaccines cleansing 4		
	2 Critical medicines active substances cleansing			
	5 SVG flag 0 /duplicates cleansing			
Improve customer satisfaction and success	**Documentation**			
	3 SMS Guidance v2	SMS Guidance v3		
	Awareness & visibility			
	SPOR update webinars	SPOR week; SPOR Customer Satisfaction survey	SPOR update webinars	SPOR update webinars
Modernise Data & Information Management	Information Management Modernisation initiatives			

For Questions: www.slido.com code: #STUP02

Work completed – Highlights of what has been done in last quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users

1 SSG1 (solutions) and SSG3 data cleansing	Improve SMS Data Quality	• **Specified substances Group 1** (solutions with defined concentration):
		  • Cleansing in SMS completed
		  • New records only to be registered **if present in Ph. Eur.**
		• **Specified substances Group 3** (with pharmacopoeial references):
		  • Cleansing in SMS completed
		  • **No new records to be registered** in SMS
		• Further details to be included in **SMS Guidance V2**
			• Reducing redundant substance records without comprising quality

2 Critical medicines substance data cleansing	Improve SMS Data Quality	• **Active Substances from Union List of Critical Medicines**
		  • Majority of substances now cleansed (78%)
		  • Cleansing ongoing for the remaining substances
		  • Full SMS implementation expected in Q4
			• Reliable/stable list of active substances used in Union List of Critical Medicines

For Questions: www.slido.com code: #STUP02

What's next? – Highlights of what will be done in next quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users

SMS Guidance V2	3 Reacting to feedback from customer satisfaction survey where customers demanded more/ better documentation	• New version prepared with **SPOR KUG** containing:
		  • **Business rules** for different substance classes
		  • **Data cleansing** guidance
		  • Data quality monitoring
		• Publication expected in **October**
			• Enhanced supporting documentation allowing improved awareness
			• Predictability of how substances will be registered and maintained

Human vaccines cleansing	4 Improve SMS Data Quality	• SVG cleansing ongoing (Priority for vaccines related to Union List of Critical medicines) • SMS implementation expected by Q4 2024	• Improved data quality of human vaccine products

SVG Flag 0/ Duplicates data cleansing	5 Improve SMS Data Quality
	Catch up with backlog of SVG cleansing
		• **SVG flag 0: Duplicated substances** identified during data cleansing
		  ○ July – communication sent to MAHs & NCAs
		  ○ MAH (for Human products) and NCAs (for Vet products) **can update the respective AMPs** in XEVMPD/UPD linked to substances **SVG flag 0 and Comment "Duplicate"** with the provided replacement substances
		  ○ **In 2025*** EMA will perform a datafix to relink any outstanding products linked to Duplicated substances and nullify duplicated substances
		Note: substances with SVG flag 0 and Comment "Invalid" or "Unspecified" will only be addressed at a later stage.
			• Significant data quality improvement by removing 60% of the currently identified duplicates
			• **If/when substances are nullified EV Gateway users will not be able to make further submissions referencing these substances!*

For Questions: www.slido.com code: #SVGF02

Highlights to you

What's changed?

- SMS Guidance published
- SMS API available to Industry
- Molecular weight, INN codes, EC number and Relationships salt-parent in export and API
- Is Active and Is used in Union List of Critical Medicines in SMS API
- Development substances, Critical Medicines, SSG1 (solutions), SSG3 cleansing

Ongoing work

- SMS Guidance version 2 (Business rules and DQ)
- Cleansing Substances from Union List of Critical Medicines

Future changes *(What's next?)*

- Human vaccines cleansing

Future changes *(What's later?)*

- SMS Guidance version 3 (Confidentiality)
- SVG flag 0 cleansing

Acronyms

API: Application Programming Interface

EC: European Commission

INN: International Nonproprietary Names

SVG: Substance Validation Group

Key takeaways and conclusions

 For Questions: www.slido.com code: #SWOCT824

Takeaways & Conclusions

Awareness of SMS activities

- Data stewardship (Change requests) and customer services in place and with excellent performance

Share current and planned activities

- SMS API now available to all users
- Substance export enhanced with additional data fields
- New version of SMS Guidance for external users to be published soon
- Cleansing of Active substances from Critical Medicines ongoing
- Follow-up actions for Stakeholders related to substance data cleansing

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Quiz Time

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Any questions on the webinar?

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SPOR Webinars

EUROPEAN MEDICINES AGENCY

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

 For Questions: www.slido.com code: #SWOCT924

Further information

Contact us through ServiceNow @ https://support.ema.europa.eu/

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Glossary

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

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Glossary (2/4)

Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream

Glossary (4/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

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