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1

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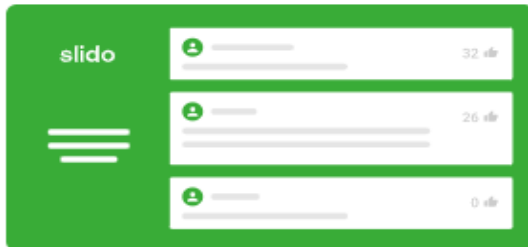
2

**Send or upvote the questions**  
you want to hear answered



3

Questions will be shown on the screen  
and **managed live in the Q&A session**



4

**Questions not addressed**  
**during this session** may be  
addressed in **subsequent**  
**webinars** and/or in **FAQ** document  
in SPOR Portal



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Substance Management Service (SMS)

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19 April 2023

SPOR Week – 17-20 April 2023



SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today

|  Webinar title  |  Date |  Time |
|--|--|--|
| <u><a href="#">SPOR and XEVMPD Data Governance</a></u>   | 17 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Service Desk for SPOR and XEVMPD</a></u>  | 17 April 2023  | 14:00-16:00 CET  |
| <u><a href="#">Referentials Management Service (RMS)</a></u>   | 18 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Organisation Management Service (OMS)</a></u>   | 18 April 2023  | 14:00-16:00 CET  |
|  <u><a href="#">Substance Management Service (SMS)</a></u> | 19 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Product Management Service (XEVMPD)</a></u>   | 19 April 2023  | 14:00-16:00 CET  |
| <u><a href="#">Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</a></u>          | 20 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">EMA Account Management</a></u>  | 20 April 2023  | 14:00-16:00 CET  |



**Increase Awareness of SMS activities**



**Share Planned and future activities**



**Show how SMS is addressing customer feedback**

|   |   |   |    |   |   |
|---|---|---|----|---|---|
| 1 | <b>Welcome</b><br>10:00 – 10:05                     |   | 8  | <b>SMS Documentation &amp; Help</b><br>11:20 – 11:25    |  |
| 2 | <b>Introduction to SMS</b><br>10:05 – 10:20         |   | 9  | <b>SMS in Projects/Systems</b><br>11:25 – 11:30         |  |
| 3 | <b>SMS Processes</b><br>10:20 – 10:45               |  | 10 | <b>What's new in SMS</b><br>11:30 – 11:35               |  |
| 4 | <b>SMS Data Stewardship</b><br>10:45 – 11:00        |  | 11 | <b>Planned SMS Activities</b><br>11:35 – 11:40          |  |
| 5 | <b>SMS Change request process</b><br>11:00 – 11:10  |  | 12 | <b>Key takeaways &amp; Conclusions</b><br>11:40 – 11:45 |  |
| 6 | <b>SMS Data Quality Management</b><br>11:10 – 11:15 |  | 13 | <b>Q&amp;A Session</b><br>11:45 – 12:00                 |   |
| 7 | <b>SMS Statistics</b><br>11:15 – 11:20              |  |    |   |   |





# Introduction to SMS

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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**.





## 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

- **Comments:** replacement substance in case of nullification - available in the export
- **Substance codes:**
  - Unique Ingredient Identifier (UNII, the FDA substance identifier) – available in the export
  - SVG cleansed flag – available in the export



## Before go live

**Two different Human substance "lists"** were maintained in XEVMPD:



- Approved (Authorised): registered by EMA and publicly visible
- Development: registered by Sponsors but only visible to the Sponsor that registered it
  - *This led to 5514 substances with poor data quality (duplicates, undefined substances, etc.)*



## For SMS implementation

- Both Authorised and Development substances have been migrated to SMS and differentiated with the field Authorisation state. This "implies" a different level of Data Quality
- Only Authorised substances i.e. substances validated by EMA are registered/maintained and made available in the SMS API, new consuming systems and substance export
- Development substances are expected to be cleansed/nullified and over time as all substances are Authorised

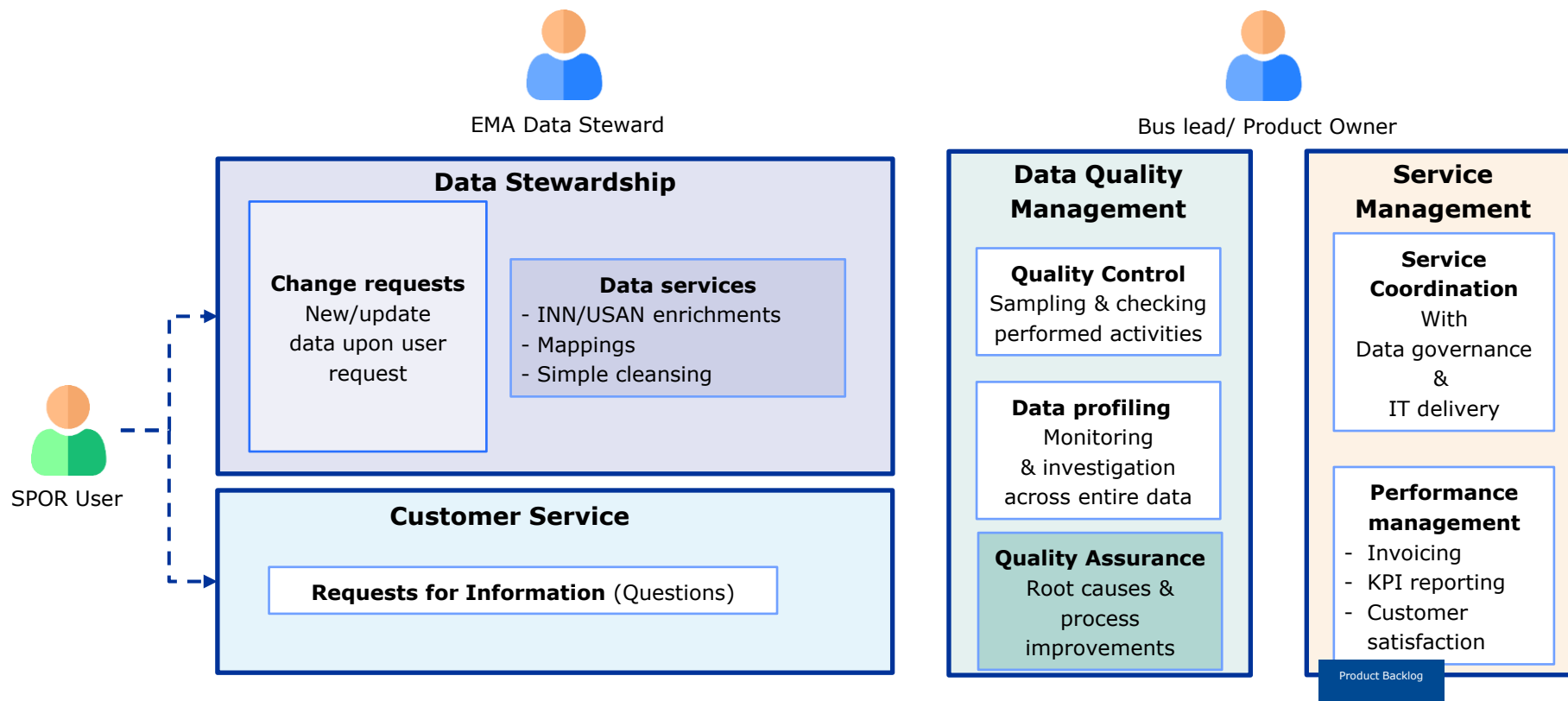
In order to prevent disclosure of confidential substance information, SMS has “**Data Classification**” field for substance names:

|  <b>Public</b>  |  <b>Restricted</b> |
|--|---|
| <p><b>Definition:</b></p> <p>Name publicly visible in all consuming systems, SMS API and in substance export in the SPOR Portal</p> <p><b>Note:</b></p> <ul style="list-style-type: none"><li>• The substance preferred term must always be registered as “Public”</li><li>• Official names (e.g. INN, USAN) are always registered as “Public”</li></ul> | <p><b>Definition:</b></p> <p>Name only visible to EMA Data Steward in SMS and to NCAs via SMS API</p> |



# SMS Process

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# SMS Data Stewardship

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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



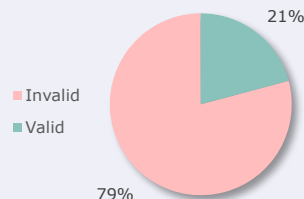
- consists in proactively looking at the SMS data to **identify and eliminate duplicates**, as well as **verify and standardise SMS data** against established reference information.
- Data cleansing **improves the data quality** and, by preventing the submission of change requests, **minimise the burden on Industry/SMS users**.
  - **The Substance Validation Group (SVG) is cleansing the legacy substance data**, as prioritised by the Network
  - **36%** of substances in SMS have been reviewed . This represents **100%** of active substances in **Veterinary authorised medicinal products** and **80%** of substances used in **Human authorised medicinal products**.

# Substance cleansing – SVG cleansing and implementation in SMS

| Domain     | Substance type   | Count of substances | % in approved Human products | SVG Cleansing  | SMS implementation | Comments  |
|------------|--|---------------------|------------------------------|----------------|--------------------|---|
| Veterinary | <b>Active substances:</b> <ul style="list-style-type: none"> <li>Proteins</li> <li>Vaccines</li> <li>Plasma-derived</li> <li>Cell therapy</li> </ul> | ~1.500              | N.A.                         | 100% completed | Completed          | Cleansed and implemented  |
| Human      | <b>Chemical</b>  | ~18.000             | 53%                          | Completed      | Completed          | Mostly cleansed and implemented: <ul style="list-style-type: none"> <li>Some PT changes pending due to impact on ICSRs</li> <li>Not all duplicates/invalids nullified due to links to ICSRs/products</li> </ul> |
| Human      | <b>Insulins</b>  | ~100                | 0.03%                        | Completed      | Completed          |   |
| Human      | <b>Proteins linked to products</b>   | ~1.000              | 0.2%                         | Completed      | Completed          |   |
| Human      | <b>Polymers more used in products</b>  | ~1.500              | 27%                          | Completed      | Completed          |   |
| Human      | <b>Opadry/Opalux</b>   | ~2.500              | 0.6%                         | Completed      | Completed          | Cleansed and implemented  |
| Human      | <b>Vaccines</b>  | ~1.300              | 0.4%                         | Ongoing        | TBC                |   |
| Human      | <b>Homoeopathics</b>   | ~16.000             | 0.3%                         | Ongoing        | TBC                |   |
| Human      | <b>Mixtures</b>  | ~1.000              | 5%                           | Ongoing        | TBC                |   |
| Human      | <b>Herbals/Extracts</b>  | ~7.000              | 2%                           | Not cleansed   | TBC                |   |
| Human      | <b>Flavours</b>  | ~4.000              | 2%                           | Not cleansed   | TBC                |   |
| Human      | <b>Other Specified Substances</b>  | ~4.000              | 10%                          | Not cleansed   | TBC                |   |
| Human      | <b>Remaining</b>   | ~2.500              | 0.6%                         | Not cleansed   | TBC                |   |



## Veterinary active substances

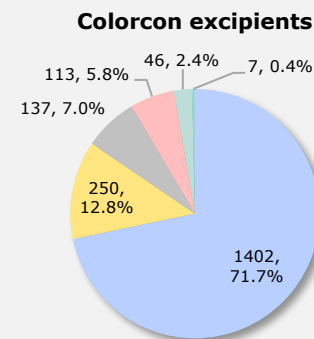
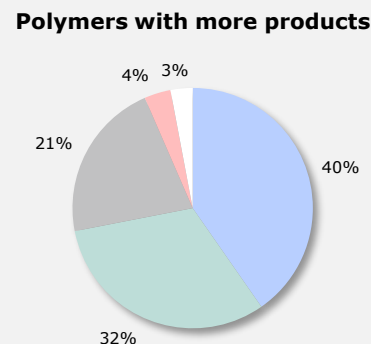
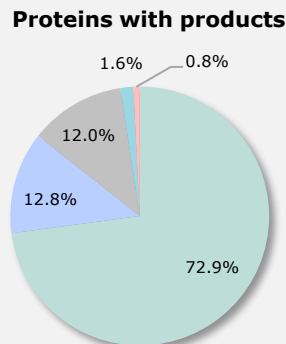
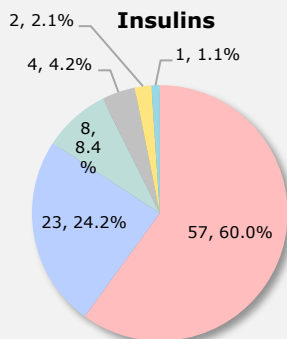
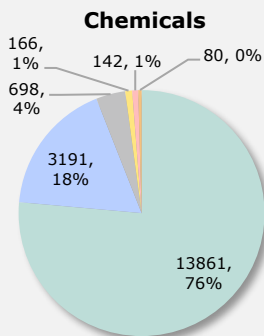


## VET substances:

- Originally, poor level of substance data quality
- Data cleansing has brought a **significant data quality improvement** – 79% duplicates reduced.
- all active substances now cleansed in SMS
- Vet NCA substance data has been mapped to SMS

## HUMAN substances:

- Originally, **mixed level of substance data quality across substance classes**
- Data cleansing has brought **assurance of the level of data quality**
- With the cleansing of Chemicals, Insulins, Proteins, Polymers and Colorcon excipients **80% of substances used in products are of good data quality**
- As cleansing is implemented in SMS, consuming systems/processes benefit from improved Substance data quality



## Impact to users:

- *What has changed?*
- *What users should look out for?*



## Substance Names & codes

- **Substance names changed** (updated preferred term, new names added, names removed, alias converted to translation)
- **UNII codes** were added (when available)
- Some preferred terms to be changed only in the future (impact on ICSR recoding)



## Substance status

- Current
- Non-Current
  - **invalid/duplicated** substances **not used in any medicinals product in XEVMPD or ICSRs** have been made Non-current
  - *Replacement substance available in Comments section*
  - *Users are advised to check if these substances are in use in any other system/context and use the correct substance instead*



## SVG Cleansed Flag

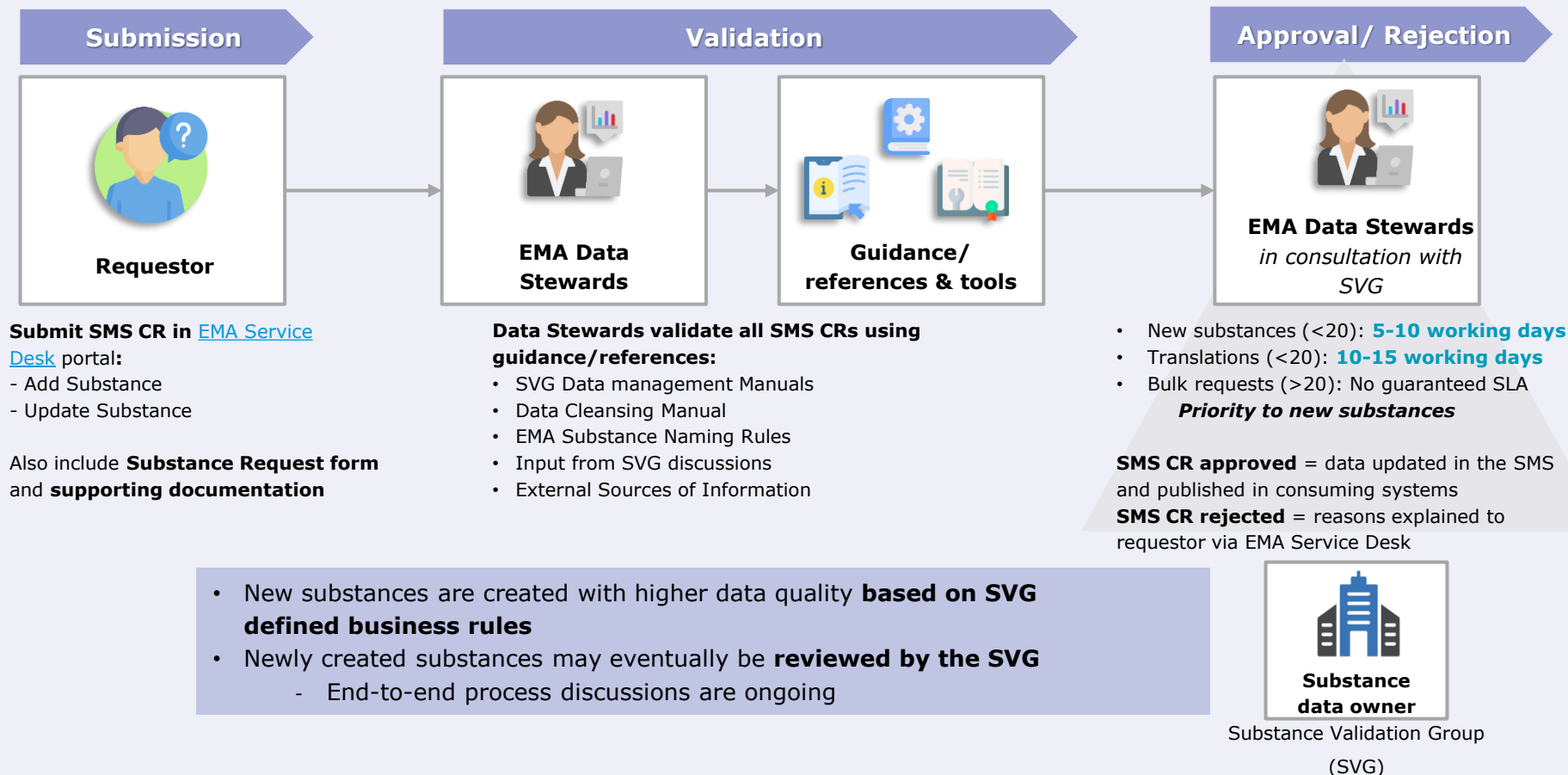
- **Null** – Substance not yet reviewed by SVG
- **1** – Substance reviewed by SVG - **Valid substance**
- **0** – Substance reviewed by SVG - **Invalid substance**
  - This is not a valid substance record and should not be used in regulatory applications
  - **The Substance is in use in one or multiple Authorised medicinal product or ICSR** and will be nullified in due course
  - *Users should correct any medicinal product using these substances, so the substance can be nullified.*
  - *Replacement substance is available in Comments section in the substance export*




# SMS Change Request process

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# SMS Change Request process at a glance




Home > IT > Applications > SPOR




## SPOR

Browse SPOR

Filter by: All Sort by: A-Z




Request




### Request SMS services

Request assistance with the management of substance...




Request




### Request XEVMPD/Art.57...

Request assistance with the management of product...




Request




### Request OMS services

Request assistance with the management of...




Request




### Request RMS Service

Request assistance with the management of referential...




Request




### Report an Issue with SMS

Report an issue with the Substance Management...




Request




### Report an Issue with XEVMPD/Art.57

Report an issue with the eXtended EudraVigilance...




Request




### Report an issue with OMS

Report an issue with the Organisation Management...



Request



### Report an issue with RMS

Report an issue with the Referentials Management...

## Request SMS services

Request assistance with the management of substance data



Use this service to request the registration of a new substance term or the update of an existing substance term through EMA Service Desk. Please ensure that you attach the completed [Substance Request Form](#) and supporting documentation describing the substance structure.

\* Indicate required information

\* Raise this request on behalf of


 Pedro Batista  

\* Subject

\* Description

\* SMS Request type

-- Please Select -- 

 Add attachments

### 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 Brochure, company specifications, section A.3 Medical Plausibility of Orphan Designation, draft package for Scientific Advice, etc.*)





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**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     |      | Public           |          |
| Scientific name   |      | Public           |          |
| Common name       |      | Public           |          |
| Company code      |      | Public           |          |
| Other (specify)   |      | Public           |          |
| Molecular formula |      | Public           |          |
| CAS number        |      | Public           |          |

- **At least one name** must be made **public**
- **Official names** (INN, USAN, etc.) are **always public**
- For Orphan Designation, Paediatric Investigation Plan and Marketing Authorisation Application, company codes **cannot** be used as the substance preferred term

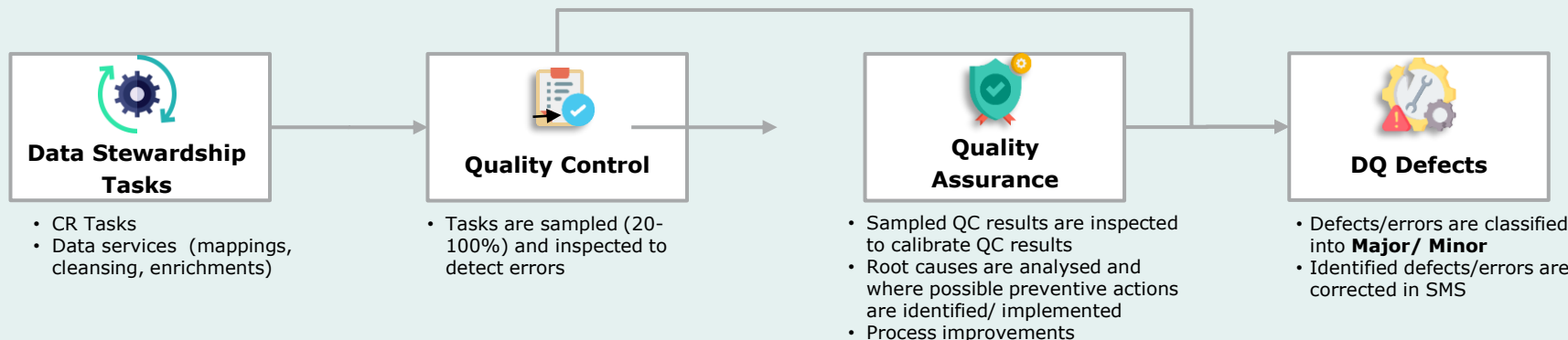


# SMS Data Quality Management

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## Activity based Monitoring - Started



- **Substance data quality** is being improved gradually with the **SVG data cleansing**
- **New substances** will be created with **higher data quality** (i.e. No duplicates, IDMP business rules, SVG input on naming conventions)
- **Data Quality Mgmt** methodologies (Quality Control/Quality assurance) guarantee **we can maintain a very high-level of DQ** for the new/updated data being managed in SMS.

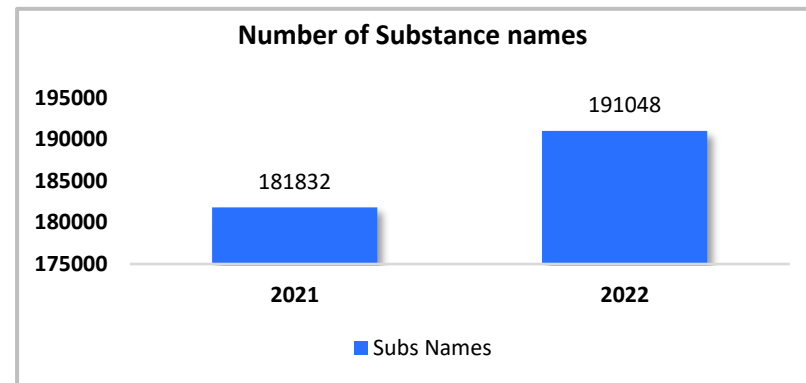
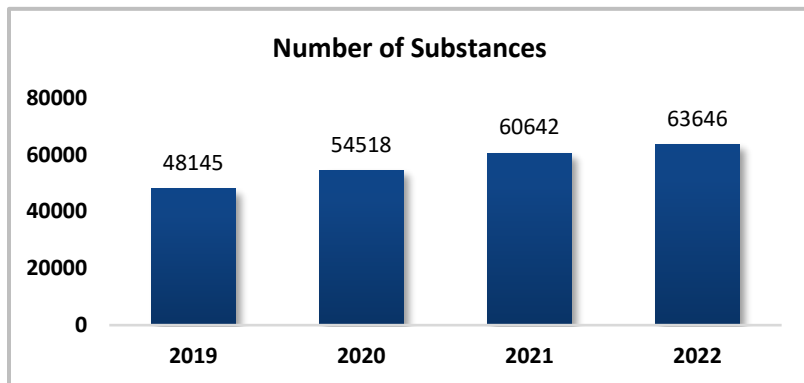
| SMS Acceptable DQ   | Errors percentage in 2022 |
|---|---------------------------|
| <b>&lt;1 % major errors</b><br>(confidentiality, duplicates, wrong PT, incorrect mappings)  | 0.04% major errors        |
| <b>&lt;10 % minor errors</b><br>(inconsistent subst details – incorrect translation/source) | 0.09% minor errors        |

|  Error Type |  Error category |  Justification                              |
|---|--|--|
| Major   | Incorrect preferred term selected  | <ul style="list-style-type: none"> <li>Major impact on regulatory applications</li> <li>Confidentiality disclosures</li> </ul> |
|   | Incorrect alias added  |  |
|   | Incorrect data classification selected   |  |
|   | Duplicated substance created   |  |
|   | Restricted substance registered as public  |  |
|   | Public substance registered as Restricted for Orphan Designation                                 |  |
| Minor   | Incorrect translation added  | Minor or no impact on regulatory applications  |
|   | Use of abbreviations instead of spelled-out word   |  |
|   | Parent substance not created   |  |
|   | Incorrect casing   |  |



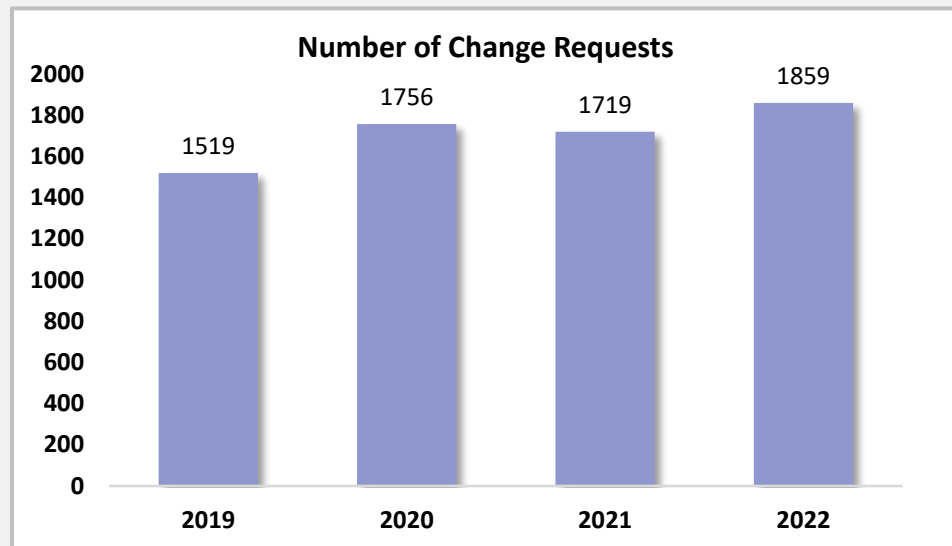
# SMS Statistics

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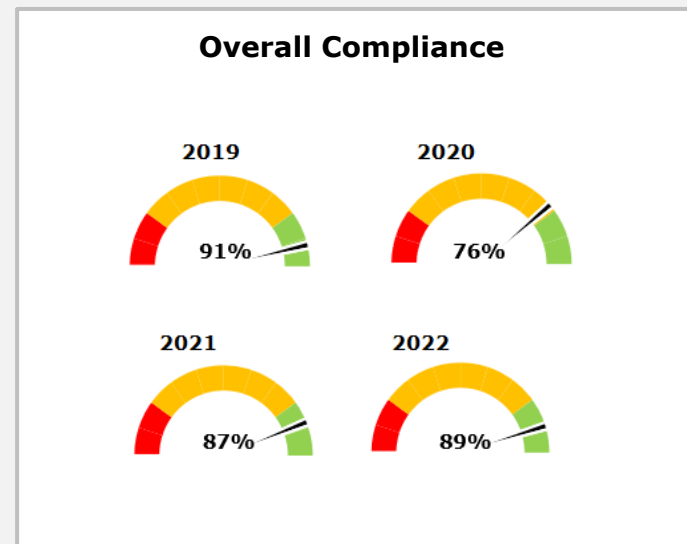


- The **increase in substances** (~+6000) and **substance names** (~+6000) in 2021 due to change requests, data enrichments (INN/USAN) and data mappings (NCA veterinary substances for UPD).
- More modest increase in substances in 2022 (~+3000)



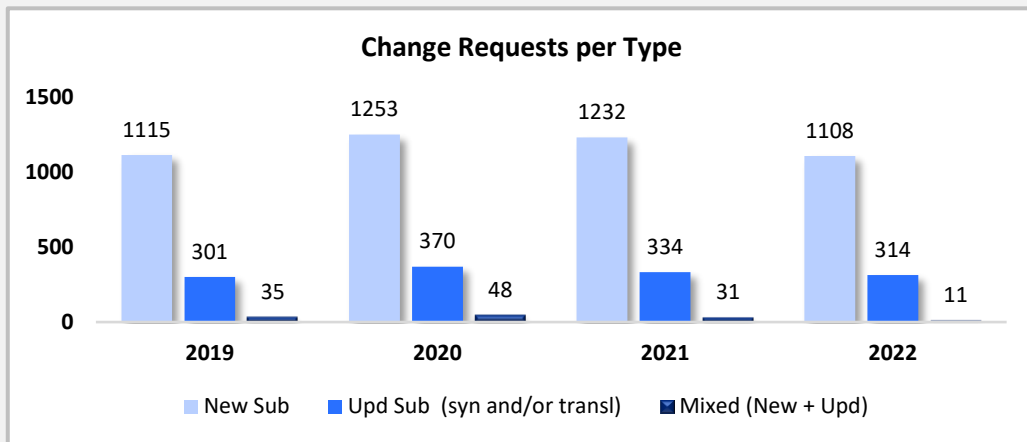


Change requests **increased 8% in 2022**

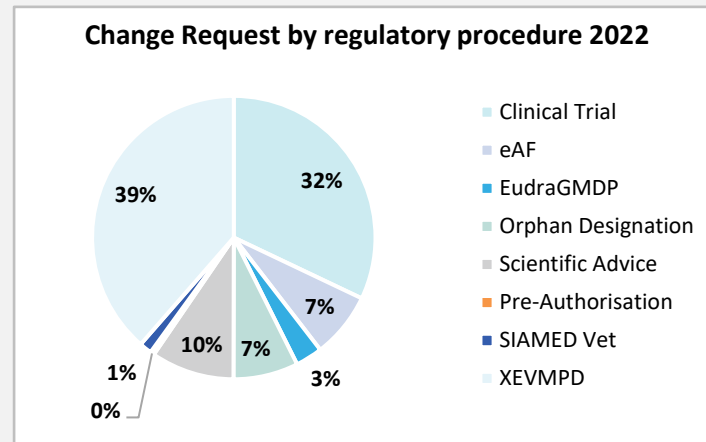
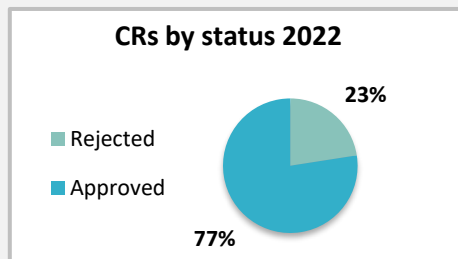


Despite the increase in change request volume, the **SLA compliance has also increased**



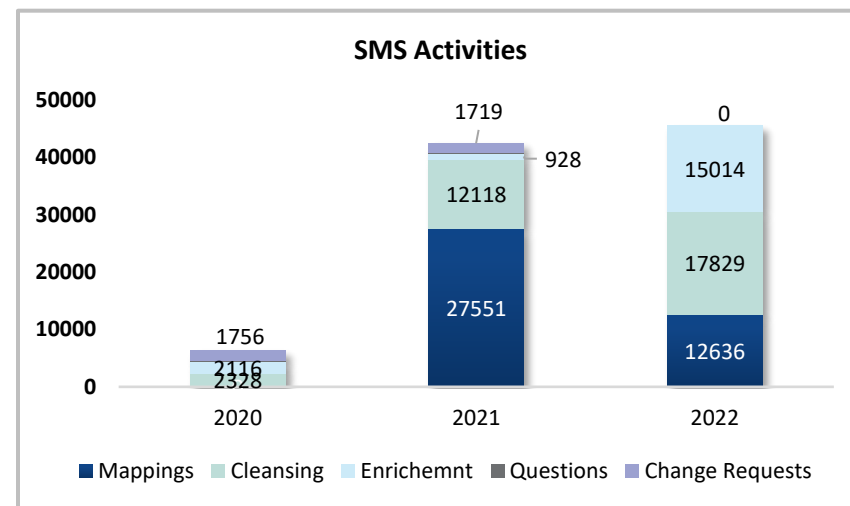
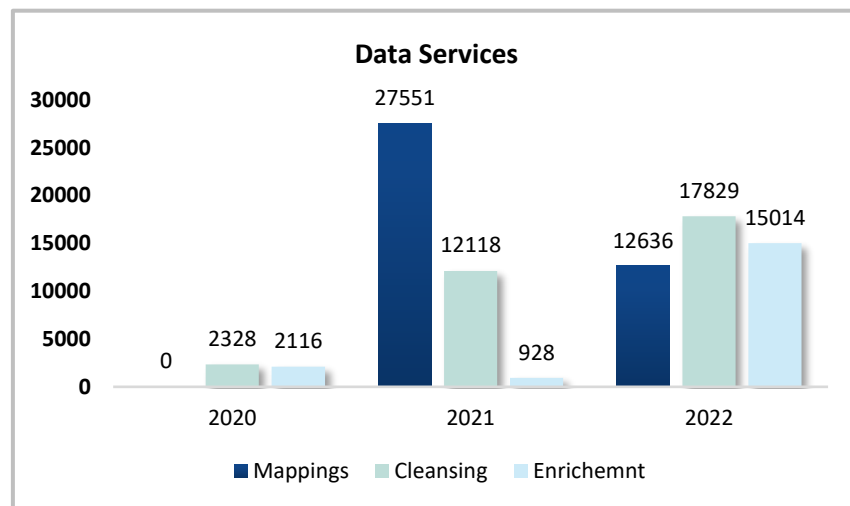


- As usual, **most of the requests (77%)** were **for new substances**.



The **majority of the requests** were **for XEVMPD** (Art.57 and Pharmacovigilance) and **Clinical Trial Applications** (EudraCT and CTIS)

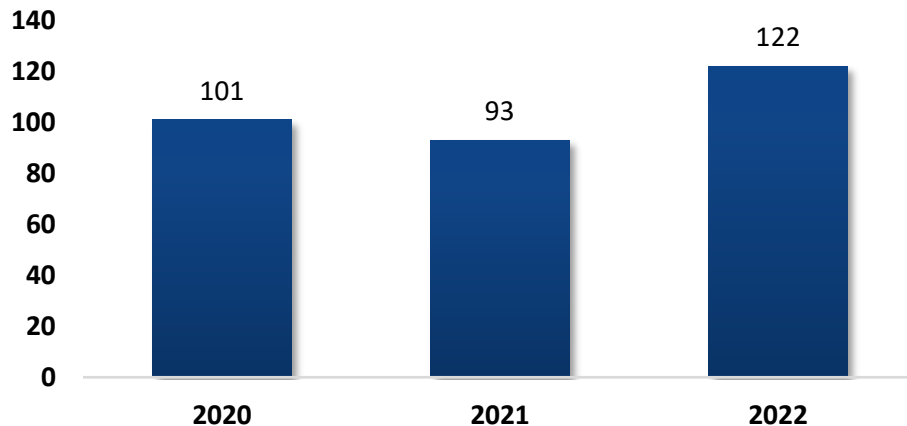
Overall, the **majority of requests** were **approved** (77%)



- Data cleansing was the **most significant task** in 2022: implementation of **SVG** cleansing of chemicals, proteins and polymers
- **High volumes** also on data enrichments (review and registration of all legacy INN) and mappings (development substances)
- Despite the volume of data mappings and change requests, the **number of customer services (questions) was negligible**



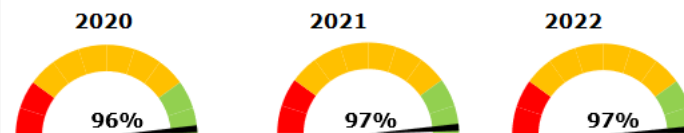
## Number of Questions



**31% increase** in questions, mainly about substance request process and queries related to CTIS



## Overall Compliance



**SLAs met**





## User Perspective

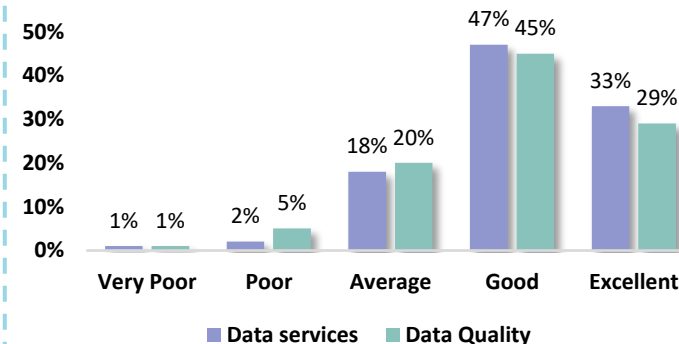
### Customer Satisfaction Survey

63 646 Substances

191 048 Substance Name

14 809 Users

### Customer Satisfaction



Data Services and Data Quality in SMS were **positively rated overall**:

- **80%** of the users graded **Data Services** as "Good" or "Excellent"
- **74%** of the users rated **Data Quality** in SMS Services as either "Good" or "Excellent".



## Useful information on SMS

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## SPOR portal

Main documentation required to successfully use SMS services:

- [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](#)

## 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

- [UNICOM SVG documents](#)
- [HMA SVG page](#)



# SMS in Projects/Systems

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| System          | Domain          | Process   |
|-----------------|-----------------|---|
| EudraCT & CTIS  | H               | Phase 1-4 Trials  |
| IRIS            | H&V – CAPs only | Scientific Advice + Orphan Designation + ITF + Marketing Status + Inspections + Parallel Distribution |
| EU-SRS          | H&V             | Regulatory assessment   |
| eAF & DADI*     | H&V             | Submission MAA, Variations, Renewal   |
| SIAMED          | H&V – CAPs only | Review, Approval  |
| UPD             | V               | Approval  |
| EudraGMDP       | H&V             | Inspections + Manufacturing Import Authorisation  |
| XEVMPD & EV vet | H&V             | Safety reporting  |
| ASU*            | V               | Antimicrobial sales and use data  |

Integration completed  
 Integration planned



## What's new in SMS

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## EUROPEAN MEDICINES AGENCY SPOR - Substances Management System

Substances

Products

Organisations

Referentials

Help

SPOR Home



### Substances Management Services (SMS)

SMS provides a central dictionary of substance data in multiple languages. SMS supports the continuous exchange of data between information systems across the European medicines regulatory network and across the pharmaceutical industry.

SMS is currently live as an EMA internal system. Until it is onboarded in the SPOR portal, external users should use the following systems:

- View and search substance data in [EUTCT](#) or [IRIS](#);
- Submit substance change requests in the [EMA Service Desk](#) portal;
- Export of substance data are available below:

[Download SMS Export \(current\)](#)

[Download SMS Export \(non-current\)](#)

Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

#### Related information

For further information about EMA's implementation of SPOR and the ISO IDMP standards, please see the [EMA corporate website](#). This also includes key business and technical documents.

Both the current and non-current export files contain the following **data fields**:

- SMS ID
- Substance\_Name - preferred term, aliases and translations
- Is\_PREFERRED\_Name- "Yes" refers to preferred term, "No" refers to alias or translation
- Language – Preferred term and aliases in English, Translations are in different EU languages
- Name\_Source- Source of the substance name
- Substance\_Domain- Human or Veterinary
- Status – Current or Non-current (each export only contains one status)
- Substance\_Type - Substance type per RMS list
- Comment - Contains the SMS ID/EV Code of its replacement substance
- Created\_Date
- Last\_Updated\_Date
- External\_Code\_XEVMPD - Substance EV code (only for Human substances)
- External\_Code\_SVG- 1 valid substance, 0 invalid substance, null not yet reviewed
- External\_Code\_UNII- UNII from FDA





## Future SMS Activities

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Q1 2023

Q2 2023

Q3 2023

Q4 2023



Deliver efficient and effective regulatory data services

## SMS – Customer Services

Process improvement – Simplify Incident mgt

## SMS - Data Management (Change requests & Data services)

CR outsourcing

1

Process automation – INN enrichment

Process automation – INN follow-up

Process automation – USAN enrichment

Process improvement – SMS-EU-SRS process

## SMS – Data Quality

2

Development substances mapping

3

InChI and molecular formula

pINN/rINN/USAN enrichments

Herbals, Homeopathics, Human vaccines cleansing (TBC)

4

Process improvement – data profiling/monitoring

## SMS – Documentation

5

Data Steward Manual

Revise SPOR Portal/SMS/Serv Desk text

Documentation – Guidance on Substance registration (CR process, Customer services, confidentiality)

## SMS – Awareness & visibility

SPOR webinars

SPOR webinars

SPOR Customer Satisfaction survey

Information Management Modernisation initiatives

SMS improvements: Enhance substance export (Mol formula, InChIKey, non-current subs replacement)

SMS API (TBC)

Prioritised Epics (eAF, IRIS, ePI, shortages and other)

SMS UI technology selection



Improve customer satisfaction and success



Modernise Data & Information Management

For Questions: [www.slido.com](https://www.slido.com) code: #7799764



## WHY



## HOW & WHEN



## IMPACT to users:

### Automations

Faster data enrichment exercises to increase data quality and prevent change requests

- INNs (new) automation – Q2 2023
- INN (follow-up) automation – Q3 2023
- USAN automation – Q4 2023

Data quality improvement

1

### Development substances mapping

Increasing data quality and ensuring that the same substance ID is used across the product lifecycle

- Requesting supporting documentation – Q2 2023
- Relinking Development products – Q3 2023
- Development substances nullifications – Q4 2023

New substance EV Code to be used in Development products in XEVMPD/CTIS

2

### New data fields

Improve SMS Data Quality

- New data fields to be created and populated in SMS throughout 2023
- InChiKey, Molecular formula and Replacement substance for non-current substances – Q2 2023

New datafields available in substance export

3



## WHY



## HOW & WHEN



## IMPACT to users:

### SMS Data profiling & monitoring

Improve SMS Data Quality

- Build data quality reports – Q3 2023
- Create process to monitor, inspect and correct weekly - Q4 2023

Data quality improvement

4

### Documentation

Reacting to feedback from customer satisfaction survey where customers demanded more/better documentation

- SMS introduction – document describing the key principles, consuming systems, data stewardship activities and confidentiality – Q4 2023
- SMS change request guidance – document describing the change request process and expected supporting documentation – Q4 2023

Enhanced supporting documentation allowing improved awareness

5



## WHY



## HOW & WHEN



## IMPACT to users:

### SMS API for Industry users

Improve access to SMS data

Enable to access to SMS public data  
via API – Q4 2023 TBC

Industry users will be able  
to access public data  
automatically

### SMS User Interface (UI)

Reacting to feedback from  
customer satisfaction  
survey where customers  
demanded more/better  
documentation

Create a portal to allow external  
users to browse, search and  
download SMS public data –  
technology selection Q2 2023

Any user will have a  
centralised location to  
access all public  
substance data



## Key takeaways and conclusions

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## **Awareness of SMS activities**

- Data stewardship (Change requests) and customer services in place and with excellent performance
- Sponsors impacted by the development substance mapping exercise will be made aware of future changes in advance



## **Share Planned and future activities**

- Enhancement of substance export
- Improved data mgmt efficiency through automations, improved Data quality through profiling and monitoring
- SMS UI and API for all users under analysis



## **Show how SMS is addressing customer feedback**

- Plan for guidance documentation in place







# Any questions on the webinar?

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SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today

|  Webinar title  |  Date |  Time |
|--|--|--|
| <u><a href="#">SPOR and XEVMPD Data Governance</a></u>   | 17 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Service Desk for SPOR and XEVMPD</a></u>  | 17 April 2023  | 14:00-16:00 CET  |
| <u><a href="#">Referentials Management Service (RMS)</a></u>   | 18 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Organisation Management Service (OMS)</a></u>   | 18 April 2023  | 14:00-16:00 CET  |
|  <u><a href="#">Substance Management Service (SMS)</a></u> | 19 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">Product Management Service (XEVMPD)</a></u>   | 19 April 2023  | 14:00-16:00 CET  |
| <u><a href="#">Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</a></u>          | 20 April 2023  | 10:00-12:00 CET  |
| <u><a href="#">EMA Account Management</a></u>  | 20 April 2023  | 14:00-16:00 CET  |



## Further information

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

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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