



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.](#)

Join at  
**slido.com**  
**#1131 918**



- 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.



**Presentations** will be\* available at:

- SPOR Portal Documents section
- EMA Events Web Page

\*1<sup>st</sup> 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



*If you would like to **receive recordings and presentations via email**, please register your e-mail address in Slido ([www.slido.com](http://www.slido.com)) using the **event code #5864645**.*



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Substance Management Service (SMS)

---




5 October 2023, 10:00 – 12:00 Central European Summer Time (CEST)

*Presented by Pedro Batista*

SPOR Webinar Series – 2-12 October 2023



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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
<b>Substance Management Service (SMS)</b>	5 October 2023	10:00-12:00 CEST
<b>Product Management Service (XEVMPD)</b>	6 October 2023	10:00-12:00 CEST
<b>Service Desk for SPOR and XEVMPD</b>	10 October 2023	10:00-12:00 CEST
<b>EMA Account Management</b>	11 October 2023	10:00-12:00 CEST
<b>SPOR application programming interface (API) - SPOR API</b>	12 October 2023	10:00-12:00 CEST






**Increase Awareness of SMS activities**



**Share Planned and future activities**



**Show how SMS is addressing customer feedback**

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





# Introduction to SMS

---

## 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



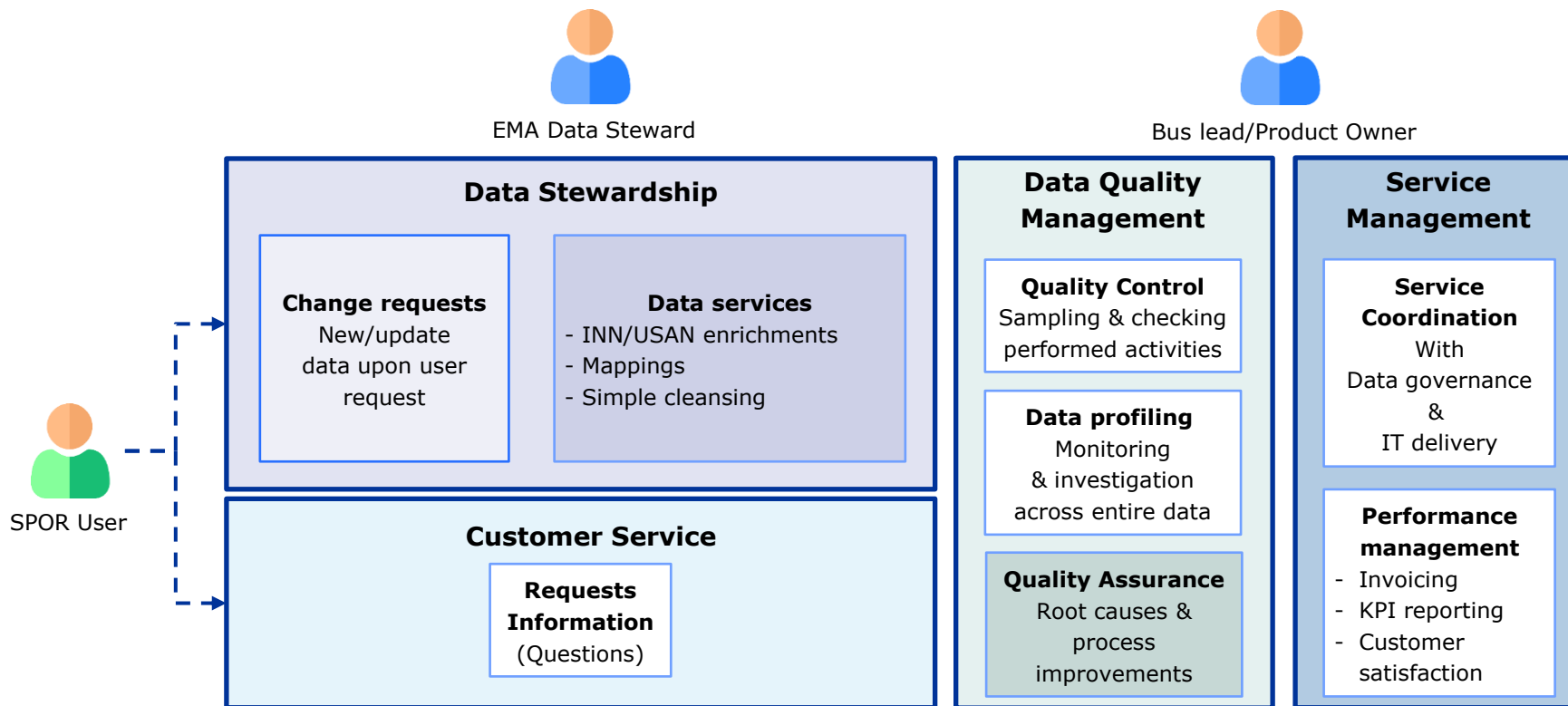
## Optional data fields

- **Molecular formula:** Registered for chemicals - available in the export
- **InChiKey:** Registered for chemicals - available in the export
- **Comments:** replacement substance in case of nullification (free text) - available in the export
- **Substance current:** replacement substance in case of nullification (structured) - 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



# SMS Process

---



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



# SMS Data Stewardship

---

## 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
  - **39%** of substances in SMS have been reviewed. This represents **100%** of active substances in **Veterinary authorised medicinal products** and **79%** of substances used in **Human authorised medicinal products**.

Domain	Substance type	Count of substances	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>	~1.600	Completed	Completed	Cleansed and implemented
Human	<b>Chemical</b>	~20.000	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	Completed	Completed	
Human	<b>Proteins linked to products</b>	~1.000	Completed	Completed	
Human	<b>Polymers more used in products</b>	~1.500	Completed	Completed	Cleansed and implemented
Human	<b>Colorcon excipients</b>	~2.500	Completed	Completed	Cleansed and implemented
Human	<b>Vaccines</b>	~1.300	Ongoing	TBC	
Human	<b>Herbals/Extracts</b>	~5.500	Ongoing	TBC	
Human	<b>Homoeopathics</b>	~16.000	Ongoing	TBC	

## 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
  - **Cannot be used in any medicinal products in XEVMPD or ICSRs** have been made Non-current
  - Replacement substance available in Comments section and in Replacement substance section in substance export
  - *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



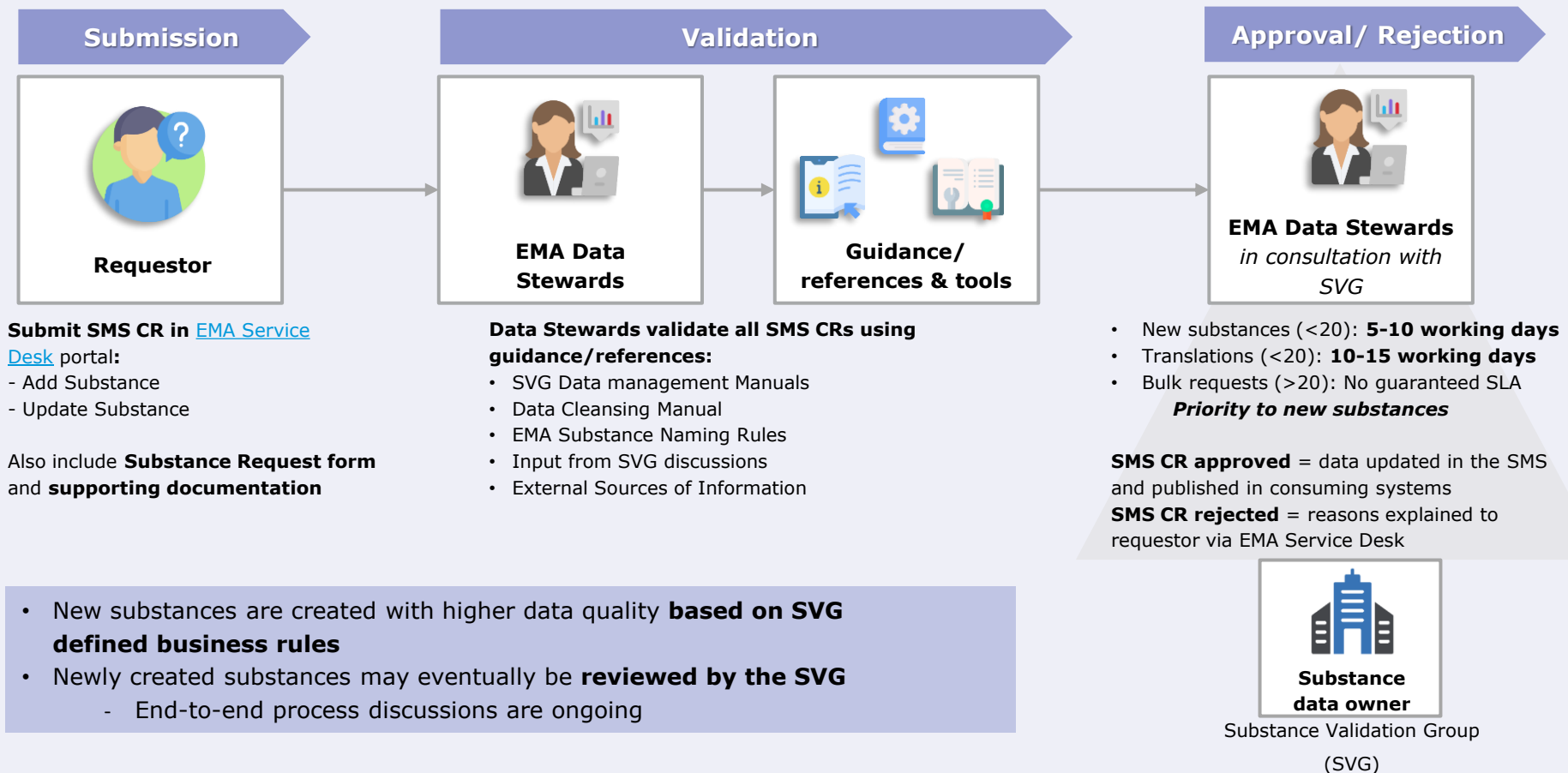
- **Null** – Substance not yet reviewed by SVG
- **1** : Substance reviewed by SVG - **Valid substance**
- **0** : Substance reviewed by SVG - **Invalid substance**
  - This is not a valid substance record and should not be used in regulatory applications
  - **The Substance is in use in one or multiple 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 and Replacement substance section in the substance export*




# SMS Change Request process

---

# SMS Change Request process at a glance











Home > IT > Applications > SPOR



## SPOR

Browse SPOR

Filter by:  Sort by:

 <b>Request SMS services</b> Request assistance with the management of substance...	 <b>Request XEVMPD/Art.57...</b> Request assistance with the management of product...	 <b>Request OMS services</b> Request assistance with the management of...	 <b>Request RMS Service</b> Request assistance with the management of referential...
 <b>Report an Issue with SMS</b> Report an issue with the Substance Management...	 <b>Report an Issue with XEVMPD/Art.57</b> Report an issue with the eXtended EudraVigilance...	 <b>Report an issue with OMS</b> Report an issue with the Organisation Management...	 <b>Report an issue with RMS</b> 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.

\* Raise this request on behalf of

 Pedro Batista  

\* Subject

New substance for clinical trials

\* Description

Please register ABC-123 for a clinical trial application in CTIS

\* SMS Request type

Clinical Trial 

 [Substance Request Form - ABC-123.xlsx \(33.8 KB\)](#)    
just now

 [IB ABC-123.pdf \(12.9 MB\)](#)    
just now

### 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.*)




## Example of a protein for Orphan Designation

- **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

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		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	


## Example of a protein for Orphan Designation

- **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

 EUROPEAN MEDICINES AGENCY SCIENCE. MEDICINES. HEALTH.					
<b>REQUEST FOR REGISTRATION OF A NEW SUBSTANCE</b>					
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	Exemplemab	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			

## Example of a cell therapy for marketing authorisation application

- **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

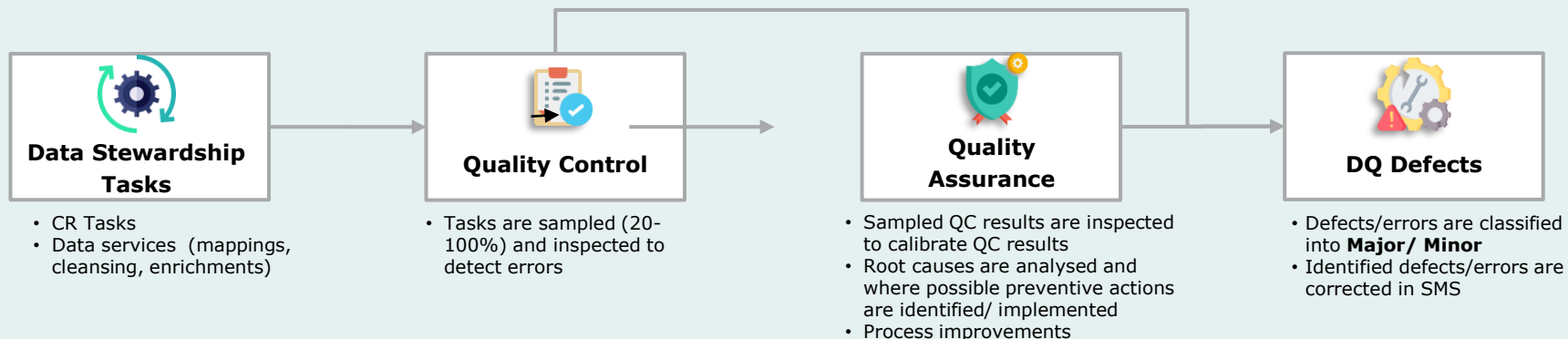
 EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH			
<b>REQUEST FOR REGISTRATION OF A NEW SUBSTANCE</b>			
Please provide at least one preferred term in English and as many aliases as known. Copy the table below if multiple substances are being requested.			
Please adjust the privacy settings of each 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 Data Quality Management

---

## 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 Statistics

---

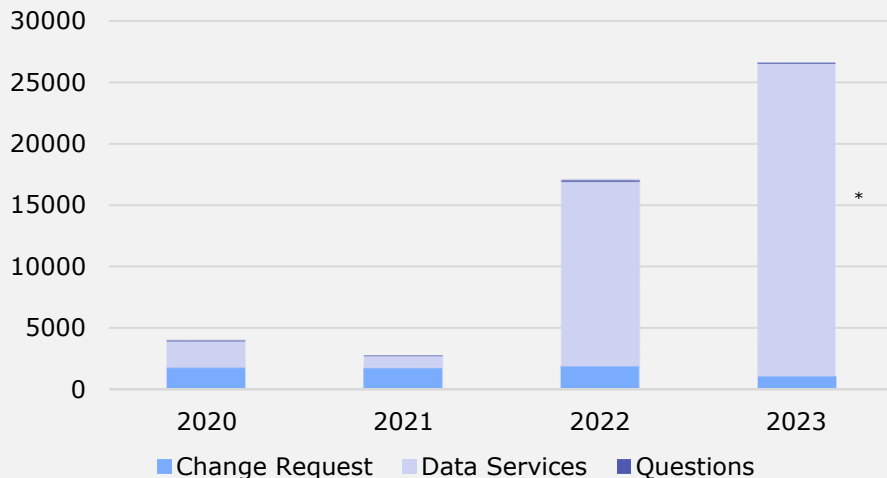


**2x increase** in Data Services in H1 2023 compared to 2022 (see chart below)



Despite the increase in Data Services, the change requests **SLA compliance has also increased**

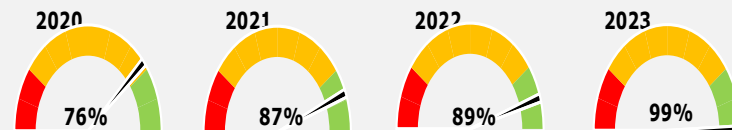
## SMS Activities



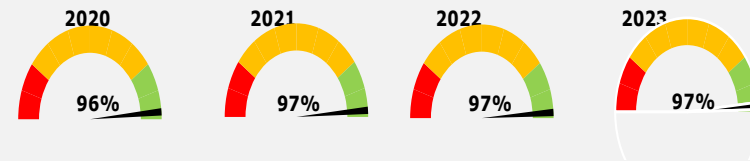
\*2023 up to Q2 cumulative

## Overall Compliance

### Change Request



### Service Desk





## Useful information on SMS

---

## 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](#)
- [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

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




# SMS in Projects/Systems

---



**Legend**

-  Implemented
-  Planned
-  Not planned yet

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

The following **substances** are available in IRIS:

- Status = Current

The following **SMS data fields** are available in IRIS:

Data field name in IRIS	Data field name in SMS
Substance ID	SMS ID
Name	Preferred term
Substance synonyms (public)	Aliases (English names) with data classification "Public"
Substance type	Substance type
Domain	Domain

Home > [List of substances](#)

## List of substances

This list presents all substances marked as 'authorised' and 'current' in the SMS and EUTCT databases of EMA, thus imported into IRIS. These substances can therefore be used for any IRIS submission, for example to request a new Research Product Identifier (RPI). If you do not find the substance you need, please register it by completing the "Substance Request Form" and raising a request via the [EMA Service Desk](#) portal, for the substance to be included in the SMS database, attaching the Substance Request Form. Further instructions are available in the [IRIS guide to registration](#) available in the [IRIS home page](#).

**Please note:** Searches can only be done on the content of the Name (preferred term) field and the public synonyms field. **You cannot search substances by a restricted synonym.**

Substance Id	Name/Synonyms	Domain	Substance Type
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Human and Veterinary use <input type="checkbox"/> Human use <input type="checkbox"/> Veterinary use	<input type="checkbox"/> Chemical <input type="checkbox"/> Mixture <input type="checkbox"/> Nucleic acid <input type="checkbox"/> Polymer <input type="checkbox"/> Protein <input type="checkbox"/> Specified Substance Group 1 <a href="#">More</a>

Substance Id ↓	Name	Substance synonyms (public)	Substance Type	Domain
300000051036	Pociredir	FTX-6058 (7aR)-12-fluoro-4-(2-methylpyridin-3-yl)-7a,8,13,14-tetrahydro-7H-furo[4,3,2-gh][1,2,4]triazolo[4',3':1,6]pyrido[2,3-c][5,2]benzoxazone	Chemical	Human use
300000051035	ASP2138		Protein	Human use
300000051015	Influenza B/Austria/1359417/2021 (B/Victoria lineage), Live		Structurally Diverse - Vaccine	Human use

# SMS in Projects/ Systems – IRIS (registered view)

Domain \*  
Human use

Type of product \*  
Chemical Generic Medicinal Product

Additional information on the product

Product Description

Substances \*

Name ↑

There are no records to display.

Lookup records

Search

<input checked="" type="checkbox"/>	Name ↓	Substance synonyms (public)	Status	Domain	Substance Type	Nature of the active substance	Substance Id
<input type="checkbox"/>	Zirconium phosphate		Active	Human use	Chemical		100000174139
<input type="checkbox"/>	Zirconium dioxide	ZIRCONIUM(IV) OXIDE	Active	Human use	Chemical		100000076777
<input type="checkbox"/>	Zirconium (89Zr) girentuximab	89Zr-TLX250 89Zr-DFO-girentuximab	Active	Human use	Protein	Monoclonal antibody	300000041671
<input type="checkbox"/>	Zirconium (89Zr) dezamizumab	89ZR-GSK2398852	Active	Human use	Protein		300000050575
<input type="checkbox"/>	Zirconium (89Zr)	Zirconium Zr 89	Active	Human use	Protein		300000026117

< 1 .. 8 9 10 11 12 13 14 15 16 .. 500 >

Selected records

Add Cancel



# What's new in SMS

---



## Historically

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

- **Approved:** 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.)*



## With SMS go-live (2019)

- **Only approved substances** are registered/ maintained and made available in the SMS API to new consuming systems and substance export
- **Legacy Development substances** could not be nullified until all the respective Development Medicinal Products (DMP) in XEVMPD were relinked



## WHY

### Cleansing of Development substances

- Ensuring that only approved substances are available in consuming systems
- Ensuring that the same substance ID is used across the whole product lifecycle
- Addressing data quality of legacy development substances before they are heavily used in CTIS



## HOW

- ✓ **Up to Q1 2023** Development substances were analysed and mapped against a replacement approved substance
- ✓ **July 2023** - Sponsors were contacted to confirm the mappings and update their Development Medicinal Products (DMPs) in XEVMPD or provide further information to identify the substance
- ✓ **October 2023** - A data fix will be performed to update any DMP not updated by Sponsors
- **Ongoing** - All mapped development substances will be nullified



## IMPACT to users:

- Depending on the mapping outcome, Sponsors have been asked to:
  - Mapped: confirm the mapping performed and, if desired, to update the respective DMP in XEVMPD
  - Unmapped: provide supporting documentation for a replacement substance to be registered
- Impact in XEVMPD: DMP updated to the replacement approved substance
- Impact in CTIS: CTA might need to be updated with the new updated DMP and approved substance



## WHY



## HOW



## IMPACT to users:

### Automations

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



**Q3 2023** - New INNs enrichment



**Q3 2023** - Bulk update of relationships

Data quality improvement  
Users can see the new records within a few days after publication in reference sources

### Data quality profiles

Improve SMS Data Quality



**Q2 2023** - Correctness (Chemicals and Colorcon excipients)



**Q2 2023** - Completeness (e.g. missing EV Code, missing UNII, missing replacement substance for duplicates)



**Q3 2023** - Standardisation (e.g. trailing spaces, double spaces, special characters)

Data quality improvement



## WHY

### New data fields

Address the demand for extra substance information from consuming systems



## HOW



Molecular formula (chemicals) - **Q2 2023**



InChiKey (chemicals) - **Q2 2023**



Replacement substance (for duplicates) - **Q2 2023**



## IMPACT to users:

New data fields available in substance export



## 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
-  Molecular Formula – mainly for chemicals
-  Molecular Weight – not yet populated
-  InchiKey – only for chemicals
  - 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/duplicated substance, null not yet reviewed
  - External\_Code\_UNII- UNII from FDA
-  Replacement substance – *only for duplicates in the non-current export*



## WHY

### SMS User Interface (UI)

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



## HOW

- Decision taken to use Microsoft Power Apps (IRIS) for the SMS UI
- Prioritisation of this Epic is ongoing and timelines will be communicated once available



## IMPACT to users:

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



# Future SMS Activities

---

# Planned SMS Activities



Activities for 2024 to be adjusted based on Customer Satisfaction Survey's results



Deliver efficient and effective regulatory data services



Improve customer satisfaction and success



Modernise Data & Information Management

Q3 2023

Q4 2023

Q1 2024

Q2 2024

## SMS – Customer Services

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

CR outsourcing

Process automation – INN follow-up

1

Process automation – USAN enrichment

Process improvement – SMS-EU-SRS process

## SMS – Data Quality

pINN/rINN/USAN enrichments

Molecular weight, INN codes

2

Relationships salt->active moiety, EC list/number

Development substances cleansing

Herbals/Homeopathics cleansing

3

## SMS – Documentation

Data Steward Manual

4

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

## SMS – Awareness & visibility

SPOR webinars

SPOR Customer Satisfaction survey

SPOR webinars

## Information Management Modernisation initiatives

SMS API

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

SMS UI prioritisation decision



## WHY



## HOW & WHEN



## IMPACT to users:

### Automations

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

- **Q4 2023** - INN (follow-up) automation
- **Q4 2023** - USAN automation

- Data quality improvement
- Users can see the new records within a few days after publication

1

### New data fields

Improve SMS Data Quality Relationships required in the same API to support Shortages, Vets and Pharmacovigilance

- **Q4 2023** - Molecular weight
- **Q4 2023** - INN codes
- **2024** - Relationships salt->active moiety
- **2024** - EC list/number bulk update

New data fields available in substance export

2



## WHY



## HOW & WHEN



## IMPACT to users:

### Data cleansing

Improve SMS Data Quality

- Development substances – Q4 2023
- Herbals – TBC
- Homeopathics - TBC

Data quality improvement

4

### Documentation

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

- **Q4 2023** - 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

**Q4 2023 (TBC)** - Enable to access to SMS public data via API

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

**Date TBC** - Create a portal to allow external users to browse, search and download SMS public data

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





## Key takeaways and conclusions

---



## **Awareness of SMS activities**

- Data stewardship (Change requests) and customer services in place and with excellent performance
- Sponsors impacted by the development substance mapping have been informed of changes in product/substance data



## **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?

---



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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
<b>Substance Management Service (SMS)</b>	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST



## Further information

---

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

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

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

Follow us on  [@EMA\\_News](https://twitter.com/EMA_News)



# Glossary

---



Acronym	Name
<b>API</b>	Application Programming Interface
<b>Art. 57</b>	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
<b>CAP</b>	Centrally Authorised Product
<b>CR</b>	Change request
<b>CTIS</b>	Clinical Trials Information System
<b>DADI</b>	Digital Application Dataset Integration
<b>DMP</b>	Development Medicinal Product
<b>DCP</b>	De-centralised Procedure
<b>DQ</b>	Data Quality
<b>eAF</b>	Electronic Application Form
<b>ePI</b>	Electronic Product Information
<b>eCTD</b>	Common Technical Document in electronic format
<b>EMA DB</b>	European Medicines Agency Data Board
<b>EMRN</b>	European Medicines Regulatory Network
<b>Epic</b>	<p>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.</p> <p>Business epics are large initiatives that deliver Solutions needed by the business/customers</p> <p>Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream</p>



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



Acronym	Name
<b>MRP</b>	Mutual Recognition Procedure
<b>NAP</b>	Nationally Authorised Product
<b>NCA</b>	National Competent Authority
<b>NDB</b>	Network Data Board
<b>NICTAC</b>	Network ICT Advisory Committee represents the network IT community
<b>NPAG</b>	Network Portfolio Advisory Group represents the Management Board and HMAs
<b>OD</b>	Orphan Designation
<b>OMS</b>	Organisation Management Service
<b>PB</b>	Portfolio Board
<b>PI</b>	Programme Increment, a three month period of work
<b>PI Planning ceremony</b>	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
<b>PIP</b>	Paediatric Investigation Plan
<b>PLM</b>	Product Lifecycle Management Value Stream
<b>PMS</b>	Product (Data) Management Service
<b>PO</b>	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.
<b>RMS</b>	Referential Management Service
<b>R&amp;D</b>	Research and Development Value Stream



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