



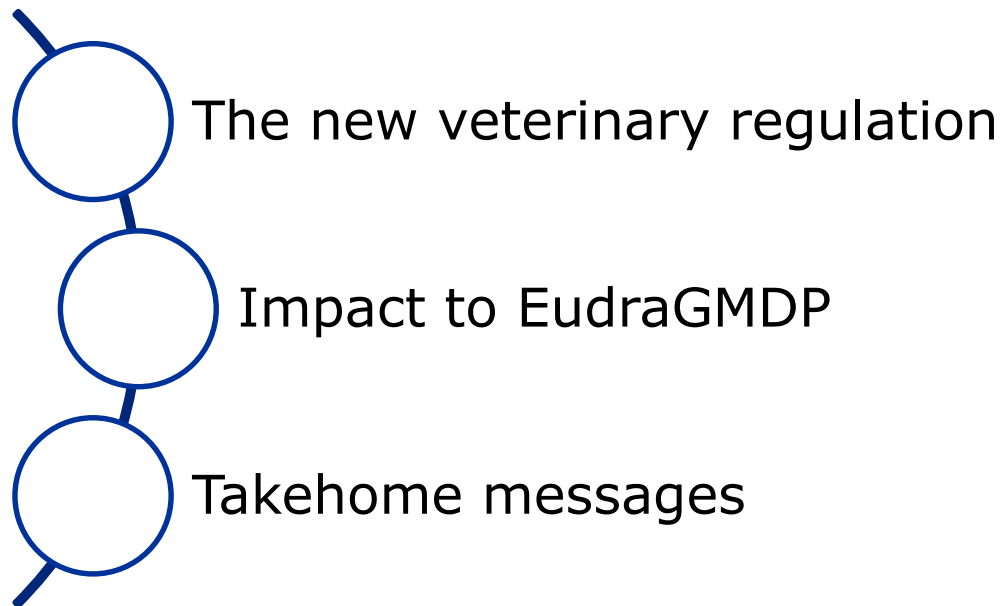
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Integration of EudraGMDP and OMS – implications for industry users

Webinar: OMS integration with EudraGMDP for Industry

Presented by Maria Filancia on 12 October 2021
Scientific administrator Inspections Office,
Quality and Safety of Medicines Department





Regulation (EU) 2019/6 on veterinary medicinal products

As of 28th January 2022 will replace Directive 2001/82/EC within the overall aim of achieving 'Better Regulation' in the EU



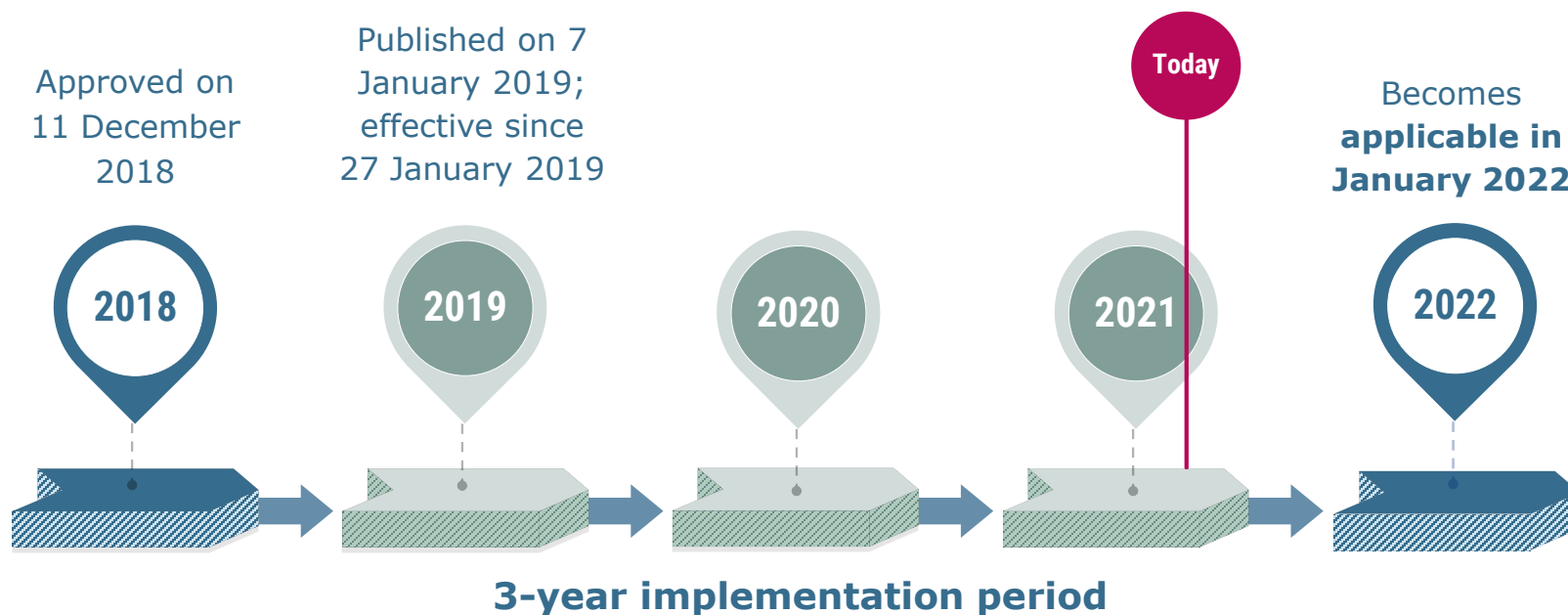
- provides for a modern, innovative and fit for purpose legal framework
- gives incentives to stimulate **innovation**
- gives incentives to increase the **availability** of veterinary medicines
- strengthens EU action to fight **antimicrobial resistance**



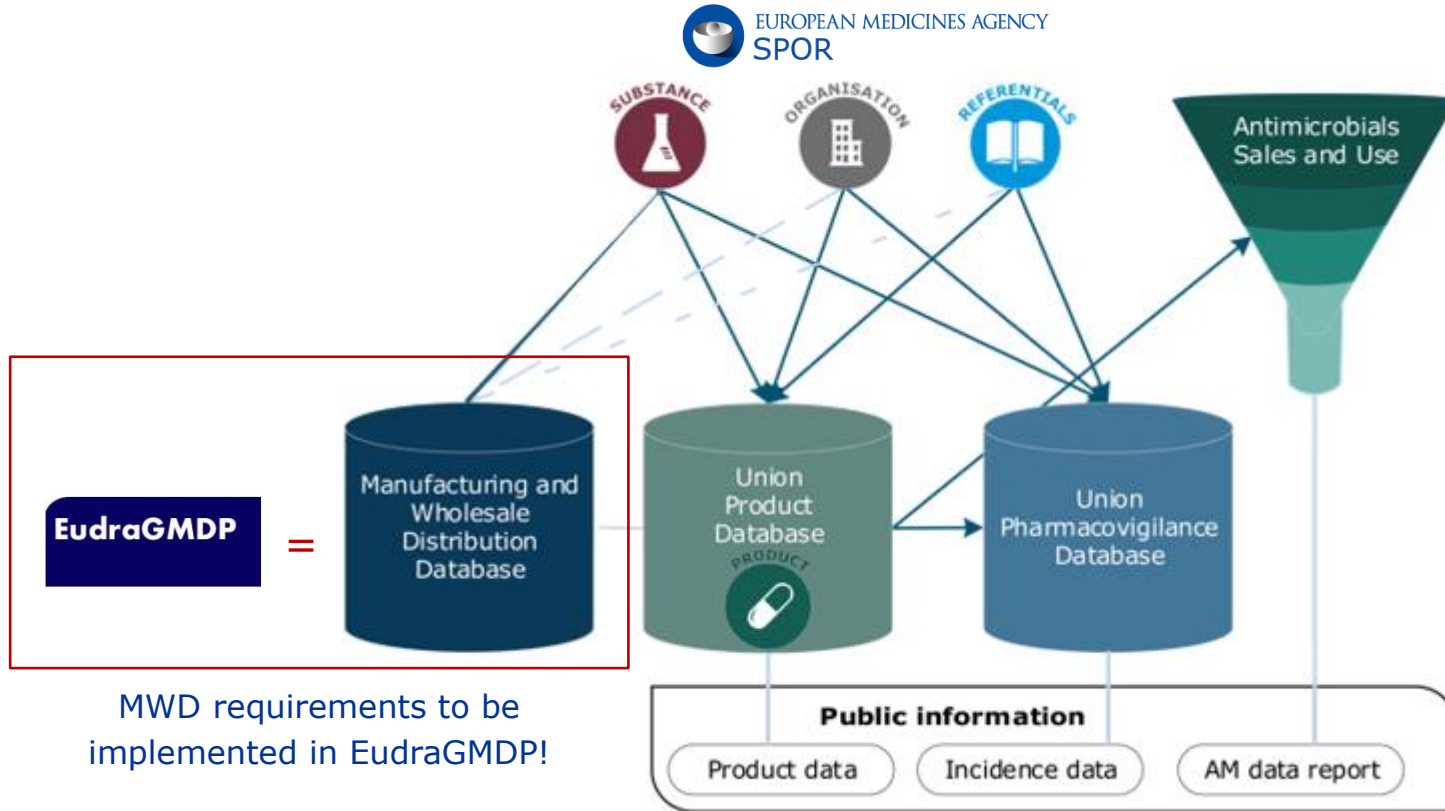
The new veterinary regulation



EUROPEAN MEDICINES AGENCY



The new veterinary regulation



MWD requirements to be implemented in EudraGMDP!




MIA

- Manufacturing and import authorisations



GMP

- Good Manufacturing Practice (GMP) certificates
- Statements of non-compliance with GMP
- GMP inspection planning in third countries



WDA

extended


- Wholesale Distribution Authorisations



GDP

extended

- Good Distribution Practice (GDP) certificates
- Statements of non-compliance with GDP



API REG

extended

- Registration of manufacturers, importers and distributors of active substances for human use located in the EEA

Article 91 Database on manufacturing and wholesale distribution

Article 88 Manufacturing authorisations

Article 94 Certificates of good manufacturing practice

Article 99 Wholesale distribution authorisations



Article 95 - Importers, manufacturers and distributors of active substances

To be implemented after January 2022



- Extend WDA, API reg. and GDP module to include veterinary companies/products.
- Use of SPOR OMS (Organisation Management Services) organisation/location identifiers in EudraGMDP, so that a “referential link” is established with the Union Product Database
 - integration has an impact on all EudraGMDP modules: Manufacturing and Importation Authorisation, GMP certification, Wholesale Distribution Authorisations, GDP certification and API Registration for human and veterinary medicinal products
- Change static text of EudraGMDP portal (e. g. legal base, information provided)



OMS integration: main changes for Industry



- All organisation details (name and address) will be sourced from OMS:
 - As of 28 January 2022, before applying for a new/updated manufacturing or wholesale distribution authorisation with national competent authorities, MAHs have to ensure that the organisation is correctly registered in OMS.
 - OMS change request can be raised by any OMS users.
 - OMS SLA: 5-10 days to approve the change request
 - 1 day to synchronise OMS with EudraGMDP.
 - OMS data standardisation might result in a slightly different address (e.g. presence, absence of commas).



- OMS company organisation and location ID will be displayed in search criteria.



- OMS Dictionary provides a list of standardised organisation/location to be used across all EMA systems - that are currently consuming OMS data.
- The same consistent data for the same organization/location across all EMA systems that are using the respective organization/location.
- Any details related to a specific building or manufacturing line will appear in the 'Restrictions' field.



- New legal basis and veterinary field introduced.



- As of 28 January 2022 ensure that your organisation is correctly registered in OMS.
 - If your organisation and its relevant locations are already correctly registered in OMS, no further action is needed.
 - If your organisation and its relevant locations are not registered in OMS, or if the information in OMS is not up-to-date raise a change request with the OMS team.
 - The same applies to sites located in third countries especially in cases where an inspection is foreseen in the short period and the related potential certificate may be issued after 28th January 2022.



vetchange.programme@ema.europa.eu

[Veterinary Medicines Regulation | European Medicines Agency \(europa.eu\)](#)



Any questions?

Further information

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Industry webinar – Introduction to OMS services and activities (Organisation Management Services)

OMS integration with EudraGMDP

Presented by Débora Martins Braga on October 12th, 2021
Master Data Manager – I-CS-RDM

An agency of the European Union



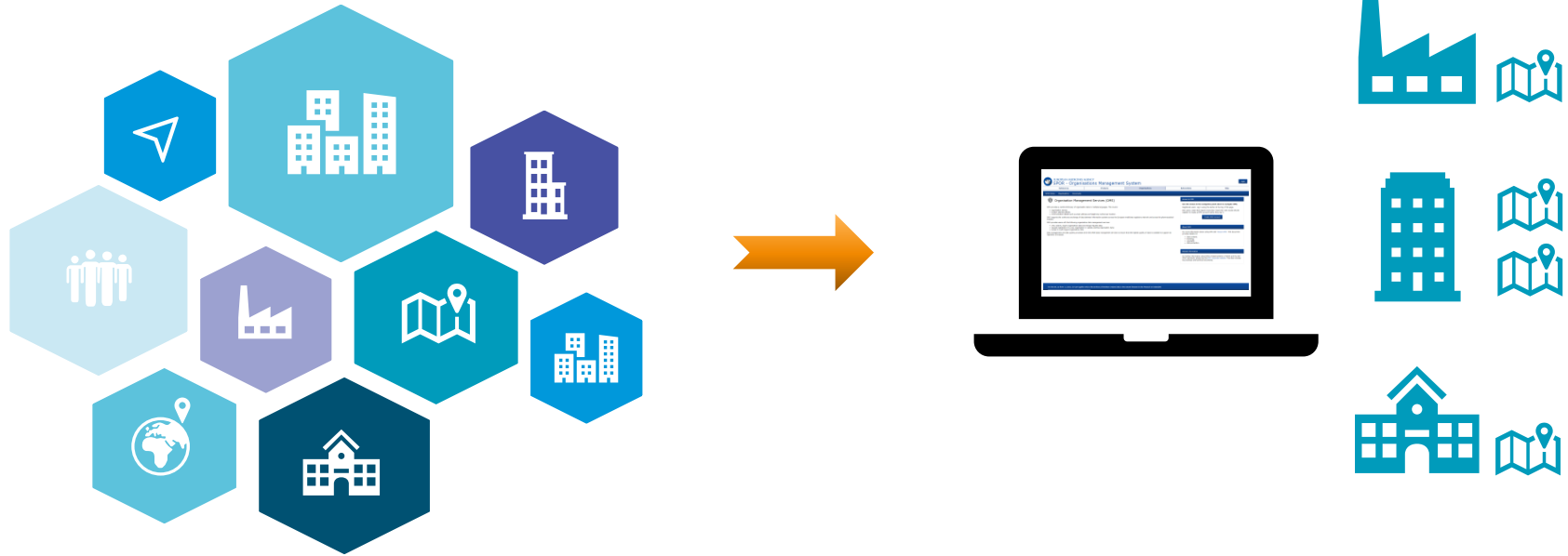
- OMS Introduction
 - Key Principles
 - Web Portal
 - EudraGMDP integration
- OMS processes
 - Change Request process
 - Service Desk
 - Data Quality management





OMS Introduction

There is a need for better organisation data



- OMS data is hosted by EMA, accessible to and used throughout EMA and by external stakeholders
- OMS provides a central source of organisation data (**OMS Dictionary**) which consists on a list of **organisations** with associated **physical locations** to be used as a reference and in support of EU regulatory activities
- An **organisation**, as a legal entity, groups all its physical locations within a **jurisdiction/country**
- Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)
- The **Location_ID** will be unique and will **not change** even after moving the location under another organisation

- In the OMS there is **no differentiation between an organisation** created in the context of a **human** medicinal product *versus* a **veterinary** medicinal product
- OMS **does not define which role(s) the organisation performs** since this depends on the context in which the data will be used, e.g. in theory an organisation can act as a MAH in the context of one medicinal product but as a sponsor or manufacturer for another medicinal product
- OMS does **not have individuals** (for the moment). If individuals act as sponsors, this needs to be dealt directly by each system. If an individual is registered within the business registry, then it's considered a company and hence EMA can register the individual in OMS
- "Big" organisations e.g. Hospitals/Universities are represented by one organisation and one or more locations - details of **Departments are not managed in OMS** and will have to be managed directly by each system

- Versions in OMS are not displayed in the same way as in RMS (e.g. version 1, version 2)
 - **OMS versions** are captured in a date format > **Version Timestamp** (e.g. 2018-06-15T11:00:12+02:00)
- OMS will publish the **latest information available** > do not submit a change request to create an older version of the same organisation/location

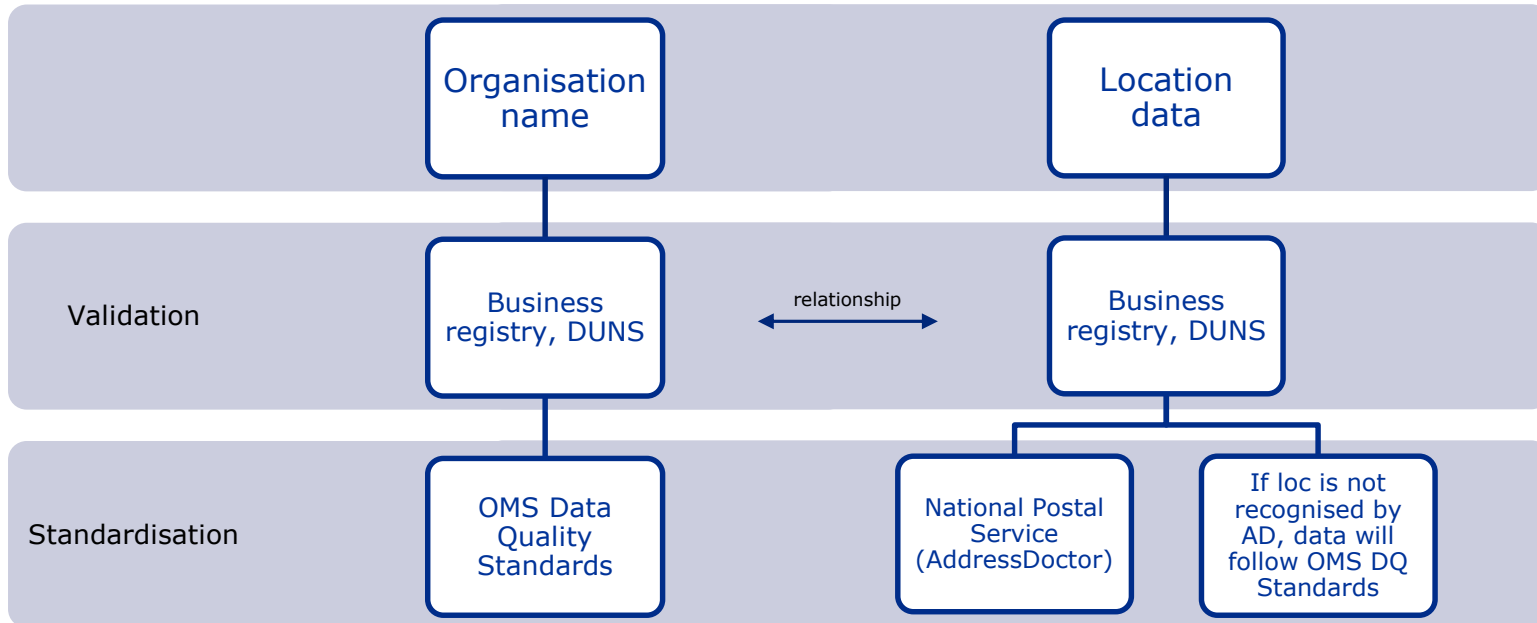
Anyone can submit a Change Request to any organisation/location published in the OMS Dictionary, as long as they submit supporting documentation

Validation of data as per date of the Change Request



OMS is a **standardised** list of Organisations/Locations

- OMS reflects equivalent information as the Trade registry (or other documents/sources) but it is not meant to be the same/"copy" of Trade registry (or other documents/sources)
- OMS should reflect **data that reflects reality***:
 - *correct organisation/legal entity
 - *correct relationship with its address
 - *correct address
- OMS uses **Reference sources of information** (Trade registry, DUNS, other documents/sources) to ensure data correctness/accuracy
- OMS should reflect consistent information i.e. OMS will apply/standardise the Organisation/address information according to the agreed DQ rules



AddressDoctor is an **address library** used for address validation, correction and standardization

World-wide & Certified

- AddressDoctor's validation service is delivered in combination with reference data (reference files) for more than 240 countries and territories around the globe
- AddressDoctor's validation service combines in one engine postal certifications from all five global postal organizations: USPS, Canada Post, La Poste in France, New Zealand Post, Australia Post and Eircode in Ireland
 - This allows to gain mailing discounts when validating addresses in certified mode from specific countries



Standardised

- Addresses are formatted according to local postal standards
 - AddressDoctor's validation service is able to parse, analyse, verify, correct and format addresses according to local postal standards - ensuring that correct elements appear in the appropriate hierarchical alignment

Up-to-date

- The reference database is updated throughout the year

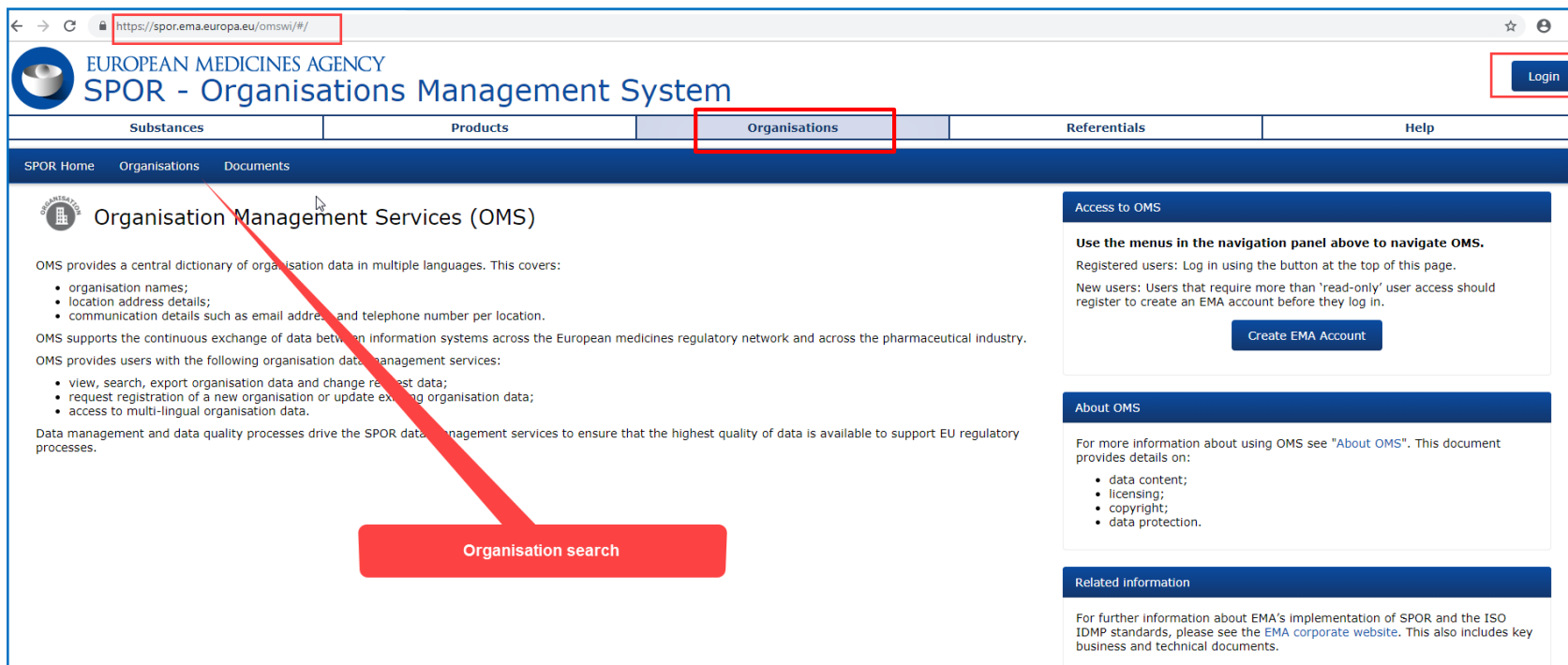
Enriched

- AddressDoctor's validation service allows to enrich address data with geocodes


Character set & transliteration

- Address Verification supports 40 different character sets and transliterates addresses into Latin characters from six different writing systems: Latin, Greek, Cyrillic, Japanese, Chinese Pinyin and Korean
- When available in the reference files (good quality) addresses can be automatically transliterated – address localised will be generated

- <https://spor.ema.europa.eu/omswi/#/>



← → 🔒 <https://spor.ema.europa.eu/omswi/#/> ☆ ⓘ ⋮

 EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Login

Substances Products **Organisations** Referentials Help

SPOR Home Organisations Documents

Organisation Management Services (OMS)

OMS provides a central dictionary of organisation data in multiple languages. This covers:

- organisation names;
- location address details;
- communication details such as email address and telephone number per location.

OMS supports the continuous exchange of data between information systems across the European medicines regulatory network and across the pharmaceutical industry.

OMS provides users with the following organisation data management services:

- view, search, export organisation data and change request data;
- request registration of a new organisation or update existing organisation data;
- access to multi-lingual organisation data.

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.

Access to OMS

Use the menus in the navigation panel above to navigate OMS.

Registered users: Log in using the button at the top of this page.

New users: Users that require more than 'read-only' user access should register to create an EMA account before they log in.

Create EMA Account

About OMS

For more information about using OMS see "About OMS". This document provides details on:

- data content;
- licensing;
- copyright;
- data protection.

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.

Organisation search



- Access & permissions
 - Guest user – read only
 - Logged-in user – access rights as per the user role matrix

Roles and permissions

Guest	Unaffiliated	SPOR Industry User	SPOR Industry Super User
<ul style="list-style-type: none">• Everyone• View content	<ul style="list-style-type: none">• Automatic with creation EMA account• Export information• Create organisations - limited to 1 pending request at a time	<ul style="list-style-type: none">• Per request in EMA Account Management• Export information• Create/Update organisation and location data	<ul style="list-style-type: none">• Per request in EMA Account Management• Export information• Create/Update organisation and location data• Manage users

For the first Super User the requester's e-mail should be a work e-mail from the same organisation on behalf of which the user is requesting the user access

- Access & permissions
 - Guest user – read
 - Logged-in user – a user role matrix
- Document section

EUROPEAN MEDICINES AGENCY SPOR - Organisations Management System			
Substances	Products	Organisations	Referentials
SPOR Home Organisations View Requests Documents			
Home / View Documents			
General Technical			
Document Name ▲	Document Description †		
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.		
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.		
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS		
C1 - OMS DQ - Webinar 25 September 2018	Webinar - Key principles and rules covered in OMS Data Quality standards - 25 September 2018		
C2 - OMS DQ - Webinar 26 February 2019	Webinar - OMS Data Quality Issues - 26 February 2019		
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS		
E - OMS Change Requests	Guidance - Rules and Supporting documentation required for change requests		
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.		
G - Using OMS data in eAF - Webinar 27 June 2018	Webinar - OMS landscape and its use in eAF and in CESP in the future - 27 June 2018		
H - Manufacturer organisations in the OMS dictionary	Process - Manufacturer organisation data lifecycle in the context of regulatory activities and who is responsible for registration/updated organisation data about manufacturers in the OMS.		
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.		
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, Industry on-boarding, and eAF integration.		
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.		
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.		
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 October 2017		
Z2 - SPOR Super User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.		
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers		
Z4 - SPOR API Access - Webinar 27 November 2017	Webinar - SPOR API Access - 27 November 2017		
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use		



- Access & permissions
 - Guest user – read only
 - Logged-in user – access rights as per the user role matrix
- Document section
- Search organisation
 - Concept of “one organisation per country”
 - Once mastered at back end, the organisation appears on the portal almost instantly
 - Organisations with at least one active locations are published on the portal
 - Search results can be sorted by column
 - Filters

- Search results – one organisation per country

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003142	Alliance Healthcare Nederland B.V.	Netherlands	LOC-100000370	Veghel	De Amert 603	5462 GH	ACTIVE	2018-06-12T13:49:30	+ 🔗 🔍
ORG-100009467	Alliance Healthcare S.A.	Portugal	LOC-100017722	Porto	Rua Engenheiro Ferreira Dias 738	4149-014	ACTIVE	2018-12-17T14:10:07	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100009345	Villanueva De Gallego	Calle Sector Dos 4	50830	ACTIVE	2017-12-15T13:37:26	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100005527	Arrigorriaga	Poligono Industrial Martiartu II 1-24	48480	ACTIVE	2017-12-04T11:41:14	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100007571	Jerez De La Frontera	Poligono Industrial El Portal 82	11408	ACTIVE	2017-12-11T14:14:27	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100007670	Soria	Calle D 4	42005	ACTIVE	2017-12-11T15:10:03	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100007722	Salamanca	Calle Doctor Ferran 108	37008	ACTIVE	2017-12-11T15:42:10	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100007392	Valladolid	Calle Vazquez De Menchaca 21	47008	ACTIVE	2017-12-11T10:18:56	+ 🔗 🔍
ORG-100004121	Alliance Healthcare S.A.	Spain	LOC-100009030	Miranda De Ebro	Poligono Bayas, Parcelas R 51	9200	ACTIVE	2017-12-14T15:09:30	+ 🔗 🔍
ORG-100004320	Alliance Medical Molecular Imaging Limited	United Kingdom	LOC-100008489	Guildford	Unit 19	GU3 1LU	ACTIVE	2017-12-13T10:54:34	+ 🔗 🔍
ORG-100004319	Alliance Medical Limited	United Kingdom	LOC-100008486	Guildford	Unit 19	GU3 1LU	ACTIVE	2017-12-13T10:52:53	+ 🔗 🔍
ORG-100001386	Alliance Pharmaceuticals Limited	United Kingdom	LOC-100004909	Chippenham	Avonbridge House	SN15 2BB	ACTIVE	2018-06-30T15:08:37	+ 🔗 🔍

ORG-100000789	Sanofi-Aventis Groupe	France	LOC-100001368	Paris	54 Rue La Boetie	75008	ACTIVE	2019-08-28T17:37:51	+ 🔗 🔍
ORG-100026749	Sanofi	France	LOC-1000014428	Paris	54 Rue La Boetie	75008	ACTIVE	2020-08-21T14:56:22	+ 🔗 🔍
ORG-100010027	Sanofi Pharma Bristol-Myers Squibb SNC	France	LOC-1000014368	Paris	54 Rue La Boetie	75008	INACTIVE	2020-03-03T14:09:38	+ 🔗 🔍
ORG-100001962	Sanofi Clir S.N.C.	France	LOC-1000005474	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-11T11:57:00	+ 🔗 🔍
ORG-100014407	Sanofi Mature Ip	France	LOC-1000020362	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-03T15:28:54	+ 🔗 🔍

Organisation Details

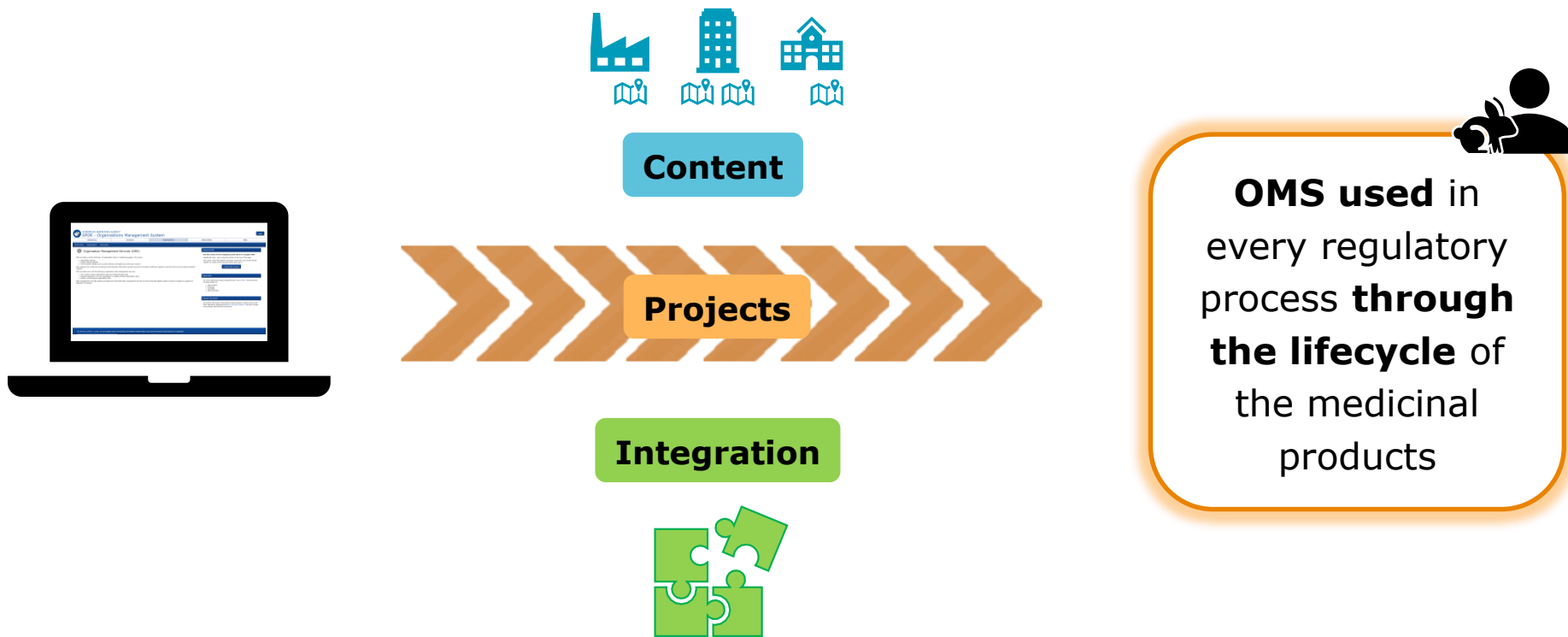
Organisation ID:	ORG-100004121
Organisation Name:	Alliance Healthcare S.A.
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

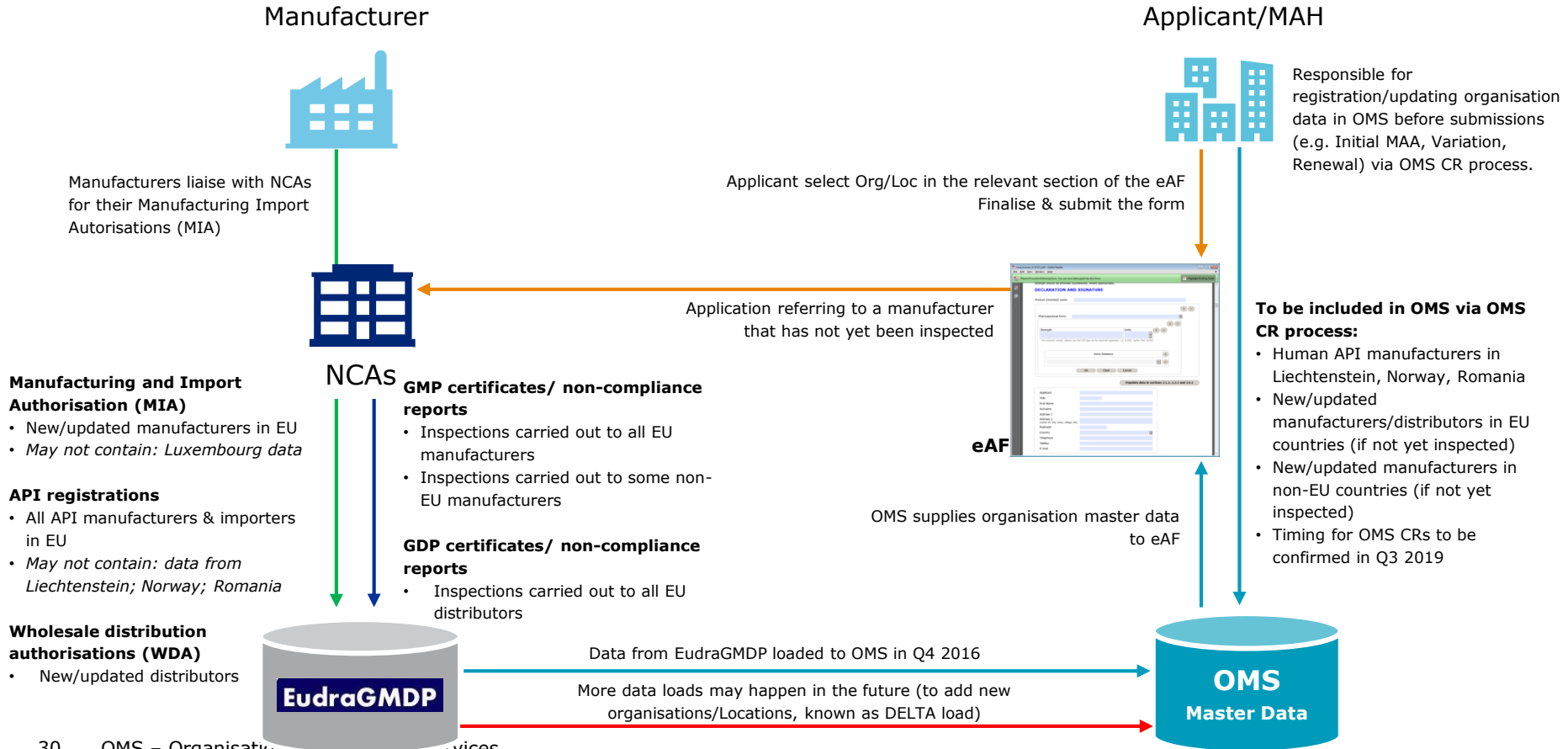
Location Details

Location ID:	LOC-100007392
Address:	<input type="text" value="EN"/> Calle Vazquez De Menchaca 21 Valladolid 47008 Spain
GPS Location:	41.6244275051081, -4.73257049837565
EudraGMDP Number:	37603
Last Modified Date:	2017-12-11T10:18:56
Status:	ACTIVE



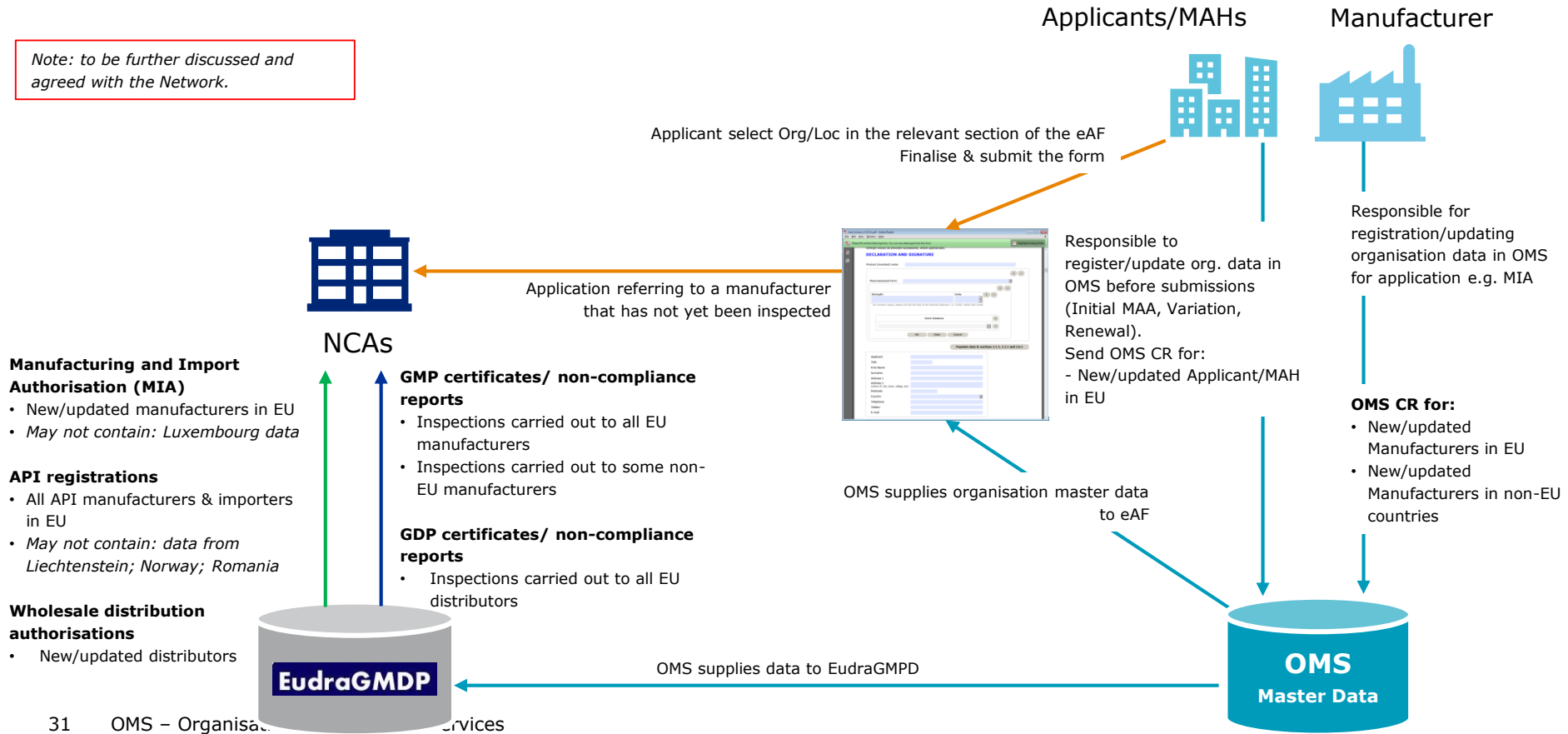
EudraGMDP integration with OMS





EudraGMDP integration with OMS - Manufacturers (proposed to be)

Note: to be further discussed and agreed with the Network.





Organisation Details

Alternative names

- Translations
- Trading as
- Legal forms i.e. translations, Belgium and French organisations



Organisation ID:	ORG-100032140
Organisation Name:	Opella Healthcare Belgium
Alternative Name:	EN - N.V. Opella Healthcare Belgium S.A. EN - Opella Healthcare Belgium Trading As Sanofi Belgium FR - Opella Healthcare Belgium S.A. NL - Opella Healthcare Belgium N.V.



Location Details


Additional information not mastered in OMS:

- Department
- Manufacture facility
- Manufacture line

Multiple door addresses not recognised by postal service – multiple records need to be created

EudraGMDP

Use OMS Organisation name & Location details



OMS Alternative names & other locations details can be captured under the remark section (free text field) of the certificate

New release will allow NCAs to search organisations using remarks

Organisation Details

Location Details

examples

Organisation Details

Organisation ID: ORG-100000546

Organisation Name: Sandoz GmbH

Status: ACTIVE

Organisation Type: Industry
Pharmaceutical company

Location Details

Location ID: LOC-100000450

Address: Biochemiestrasse 10
Kundl
Tirol
6250
Austria

xEVMPD Code: ORG1431

EudraGMDP Number: 6236, 6506, 6513, 6536, 6618, 7357,
5296, 5298, 9027, 9400, 9530, 16284, 18205

Last Modified Date: 2021-05-20T15:58:30

Status: ACTIVE

	A	D	F	G	H	EudraGMDP		
	Name	Status	Straße	Hausnummer	PLZ	Ort	Staat	
1								missing information in OMS and needed for certificates
2	Sandoz GmbH	GA - aktiv	Stella-Klein-Löw-W	17	1020	Wien	Österreich	
3	Sandoz GmbH	GA - aktiv	Jakov-Lind-Straße	5.Top 3.05	1020	Wien	Österreich	
4	Sandoz GmbH	GA - aktiv	Schemmerlstraße	72	1110	Wien	Österreich	
5	Sandoz GmbH	GA - aktiv	Logistikzentrum Wi	10-18	2201	Hagenbrunn	Österreich	
6	Sandoz GmbH	GA - aktiv	Irfflerwee	95	6060	Hall	Österreich	
7	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
8	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
9	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
1	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
1	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
1	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
1	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich	
14	Sandoz GmbH	GA - aktiv	Gewerbepark	9	6300	Wörgl	Österreich	
15	Sandoz GmbH	GA - aktiv	Gewerbepark	2	6300	Wörgl	Österreich	
16	Sandoz GmbH	GA - aktiv	Gewerbepark Süd	8	6330	Kufstein	Österreich	
17	Sandoz GmbH	GA - aktiv	Sportplatzweg	13	6336	Langkampfen	Österreich	
18	Sandoz GmbH	GA - aktiv	Sportplatzweg	23	6336	Langkampfen	Österreich	
1	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6336	Langkampfen	Österreich	
2	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6336	Langkampfen	Österreich	
2	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6336	Langkampfen	Österreich	
2	Sandoz GmbH	GA - aktiv	Biochemiestrasse	10	6336	Langkampfen	Österreich	

Details can be captured under certificate's remark section (free text field)

Organisation Details

Location Details

examples

EudraGMDP



National Agency For The Safety Of Medicine And Health Products


MANUFACTURER'S AUTHORISATION

1. Authorisation Number [REDACTED]
2. Name of authorisation holder
SANOFI WINTHROP INDUSTRIE
3. Address(es) of manufacturing site(s)
SANOFI WINTHROP INDUSTRIE, 30-36 avenue Gustave Eiffel, TOURS, 37100, France

ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100021550	Tours	30 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100022820	Tours	31 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100050505	Tours	32 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100050506	Tours	33 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100050507	Tours	34 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100050508	Tours	35 Avenue Gustave Eiffel	37100
ORG-100011564	Sanofi Winthrop Industrie	France	LOC-100050509	Tours	36 Avenue Gustave Eiffel	37100

MANUFACTURER'S AUTHORISATION

1. Authorisation Number [REDACTED]
2. Name of authorisation holder
SANOFI WINTHROP INDUSTRIE
3. Address(es) of manufacturing site(s)
SANOFI WINTHROP INDUSTRIE, 30 avenue Gustave Eiffel, TOURS, 37100, France



Details can be captured under certificate's remark section (free text field)



Any questions?

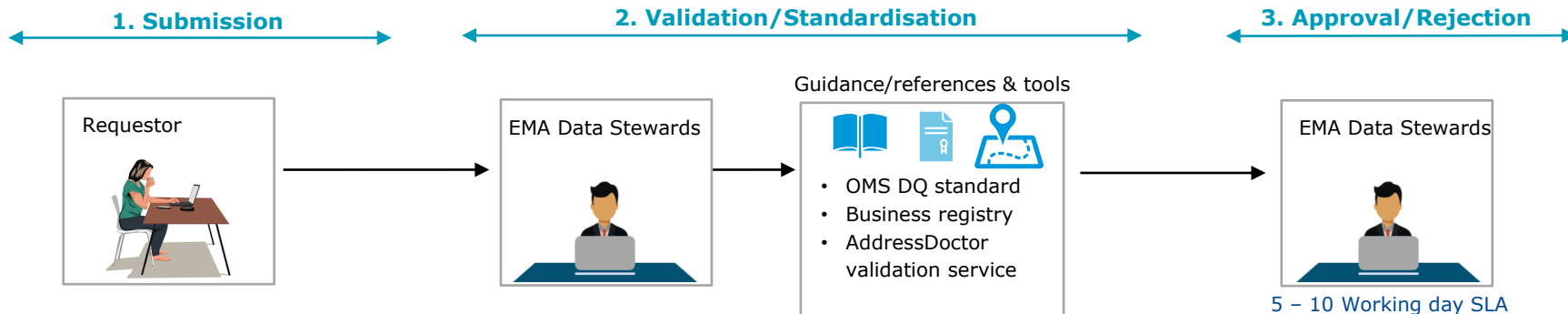
OMS Introduction





OMS Change Request process

OMS Change Request process at a glance



Submit OMS CR:

- Add Organisation
- Update Organisation
- Add Location
- Update Location
- Update Organisation & Location

Include **supporting document**

This can vary from business registry documentation to DUNS registration

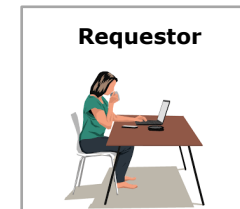
Data Stewards validate all OMS CRs using **guidance/references & tools:**

- OMS DQ standard - it describes the business rules/approach for mastering organisations
- Business registry – used to confirm that the supporting documentation is valid and still current
- AddressDoctor:
 - Used as validation service to check, standardise or enrich address data in English and in local languages
 - Addresses are formatted according to local postal standards

OMS CR approved = data published/updated in the OMS dictionary

OMS CR rejected = reasons explained to requestor via email
If disagreement, raise ticket in Service Desk, identifying the relevant CR number

- Depending on the operation requested:
 - New organisation
 - New location
 - Update organisation and/or location
 - Update organisation
 - Update location
 - Deactivate organisation
 - Deactivate location
- OMS data services team aim to answer to the majority of requests within the defined timeframes



Service-level agreement (SLA)

Type of request	75% of requests	90% of requests	Expected outcome
Add Organisation/ Location	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation/Location is available for use if the request is approved.
Add Location(s)	Resolved within 5 working days.	Resolved within 10 working days.	The Location is available for use if the request is approved.
Update Organisation	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation is updated if the request is approved.
Update Location	Resolved within 5 working days.	Resolved within 10 working days.	The Organisation is updated if the request is approved.
Deactivate Organisation/ Location	Resolved within 10 working days.	Resolved within 15 working days.	The Organisation is not physically deleted rather its status is updated to "Inactive" if the request is approved.
Update Organisation & Location	Resolved within 10 working days.	Resolved within 15 working days.	The Organisation and Location is available for use if the request is approved.
Returned requests	N/A	N/A	The requestor has two weeks to reply back with additional information required, after which point the request is rejected.

Change Requests Submission



New



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances | Products | Organisations | Referentials

SPOR Home | Organisations | View Requests | Documents

Home / Search Organisations / New Organisation Request

CR Information

CR Type: New Organisation
Request Reason*:
Justification:
Requestor:
Contact email*:
Contact Phone:

Organisation Details

Organisation Name*: e.g. European Medicines Agency
Acronym:
Organisation Type*:

Location Details

Address*: e.g. 30 Churchill Place
e.g. Canary Wharf
City: e.g. London
Postcode: e.g. E14 5EU
County: e.g. London
Country*:
Location Email⁽¹⁾: e.g. john.doe@ema.europa.eu
Location Phone⁽¹⁾: Intl Code: e.g. +44 e.g. 02036606000 Ext:
DIUNS ID: e.g. 01-234-5678
GS1 ID: e.g. 0-00-12345-67890-5

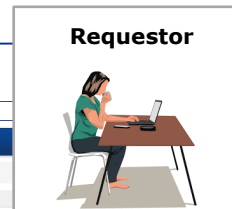
⁽¹⁾ Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields. If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>


Attachments: No documents found, click to add +

Audit trail		
Date ▲	Status to ▾	Comment ▾
No data available in table		

Cancel Submit

Update





EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials

SPOR Home Organisations View Requests Documents

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type: Update Organisation and Location

Request Reason*: [Dropdown]

Justification: [Text Area]

Requestor: [Redacted]

Contact email*: [Redacted]

Contact Phone: [Redacted]

Organisation Details

Organisation ID: ORG-10000011

Organisation Name*: Bayer AG

Acronym: [Text Area]

Organisation Type*: Industry

Location Details

Location ID: LOC-100023192

Only the version of the address currently being displayed will be included in the request

EN Address*: Max-Dohrn-Strasse 8
Charlottenburg

City: Berlin

Postcode: 10589

Country: e.g. London
Germany

Location Email ⁽¹⁾: e.g. john.doe@ema.europa.eu

Location Phone ⁽¹⁾: Intl Code: e.g. +44 e.g. 02036606000 Ext: [Text Area]

DUNS ID: e.g. 01-234-5678

GSI ID: e.g. 0-00-12345-67890-5

⁽¹⁾ Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields.
If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

Attachments: No documents found, click to add +

Date ▲	Status to :	Audit trail	Comment :
No data available in table			

Cancel Submit



- Ask to **change or add data** related to:
 - **Organisation** data - Name, Acronym, Active End Date, Translations
 - **Location** data - main Address, Active End Date, Address Localised, Communication Details, Location mapping IDs
 - **Both**
- Each change request creates a task on the OMS IDD dashboard
 - The record is created in the system with a PROVISIONAL status
 - By Approving new organisation/location CR the status will change from PROVISIONAL to ACTIVE and an OMS identifier is automatically generated by the system
- User can only submit **one change request**, per location, **at a time**

Location Updates:

- Add/edit floor
- Update data, such as postal code or city – even if changes are represented in supporting documentation, always verify the data submitted using the national postal service – in case it's aligned with data provided by AD, CR should be rejected
- Any changes in the address data not aligned with the Data quality standards – should be rejected
 - Abbreviations
 - Non-title case
 - Commas not recognised by the system
 - Deleting area/district/sublocality recognised by AD – common with German addresses
- Moved to another location – update a location from a physical location A (e.g. London) to another physical location B (e.g. Bristol), to be rejected



Create new LOC



Address transformation examples*:

Before address verification	After address verification
Aven. / Av. / Ave	Avenue
St. / St	Street
Indus. / Ind.	Industrial
Blvd / Blvd.	Boulevard
With floor number, department name, ...	Without floor number, department name, ...
Without street number	With street number
6-8 (street number)	6/8 (street number)
Street name contains the word 'street'	Street name does not contain the word 'street'
Renaissance Walk, n. 5	5 Renaissance Walk

- Organisation name should be **validated** and **standardised** against:
 - Supporting documentation
 - Business registry
 - OMS data quality standards
- Organisation Category correctly populated
- Location data verified, enriched and standardised by AddressDoctor
- Address Localised in alignment with EN address, if applicable



Organisation

This entity is in a pending state

Organisation Name: ~~Midatech Ltd~~ PROVISIONAL

Status: PROVISIONAL

Comments:

Organisation Translation: **Midatech Limited**

Organisation Category: **Midatech Limited**

Party Category Code:

Industry

Party Category:

Organisation Mappings:

Organisation Identifiers:

Organisation Location:

Status: PROVISIONAL

Address Line 1: Oddfellows House

Validation



**CERTIFICATE OF INCORPORATION
OF A PRIVATE LIMITED COMPANY**

Company No. [REDACTED]

The Registrar of Companies for England and Wales hereby certifies that **MIDATECH LTD**

is this day incorporated under the Companies Act 1985 as a private company and that the company is limited.


Given at Companies House, Cardiff, the 27th October 2000



COMPANIES HOUSE

HC0078

Standardisation



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 June 2017
EMA/740982/2016
Information Management Division

Organisation data quality standards in OMS
Data quality principles

Country	Reference	Legal Entity naming in organisation names (in EN and National languages)
SE	Swedish Companies Registration Office	AB, AB (publ), EEIG,
SI	Slovenian Business Register	d.o.o., EGIZ, d.d.
SK	Slovakian Business Register	a.s., k.s., s.r.o. = spol. s r.o., v.o.s., EZHZ,
UK	Companies House	Limited, Public, EEIG,

Street	Postcode	City	State	Country	Country	Of Code	Of Long
CF24 0AA	Cardiff	Glamorg...	United Kingdom				

Organisation Location

This entity is in a pending state

Address Line 1	c/o TheVIT AS	Address Line 2	Gunnar Randers' vei 24	Address Line 3	
Address Line 4		Street Number		Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	
GPS Longitude		Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor		To Date	
Comments					

Brønnøysundregistrene **Validation** **Firmaattest**

Organisasjonsnummer:

Organisasjonsform: Under avvikling

Stiftelsesdato:

Registrert i Foretaksregisteret:

Foretaksnavn:

Forretningsadresse:

c/o TheVIT AS
Gunnar Randers' vei 24
2007 KJELLER
3030 LILLESTRØM
Norge

Kommune:

Land:

Organisation Location

This entity is in a pending state

Standardisation

Address Line 1	Gunnar Randers' Vei 24	Address Line 2		Address Line 3	
Address Line 4		Street Number	24	Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	59.974546
GPS Longitude	11.047364	Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor	No	To Date	
Comments	3-Good/ Local Address -> Line1:Gunnar Randers' Vei 24 City:Kjeller Country:Norge Lang:NO				

Record 4 of 4 ◀ ▶

Organisation data quality standards in OMS *National postal service

Country	Mailing address structure
AT	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/autEn.pdf
BE	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/belEn.pdf
BG	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/bgrEn.pdf
CH	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/cheEn.pdf
CY	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/cypEn.pdf
CZ	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/czeEn.pdf
DE	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/deuEn.pdf
DK	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/dnkEn.pdf
EE	http://www.upu.int/fileadmin/documentsFiles/activities/addressingUnit/estEn.pdf



Spain

Postcode Postcode type and position
5 digits to the left of locality name.

Coding method
2 8 0 3 9
 - delivery area, secondary delivery route or link with rural areas
 - large town, main delivery rounds
 - province

Position of the address on the envelope
Bottom right-hand corner

Alignment of address lines
Left-aligned

Address format
The street number follows the street name. Information relating to staircase, floor, door, etc., will be separated from the street number by a comma. The province name is indicated on a separate line.

Font characters

- height of characters between 2 and 8 mm;
- character density between 2 and 5 characters per cm;
- the characters must neither touch nor overlap;
- the space between the words must not be less than the width of the narrowest character;
- fonts types: every commercial type in use;
- font styles: avoid italics, underlining and extreme thicknesses

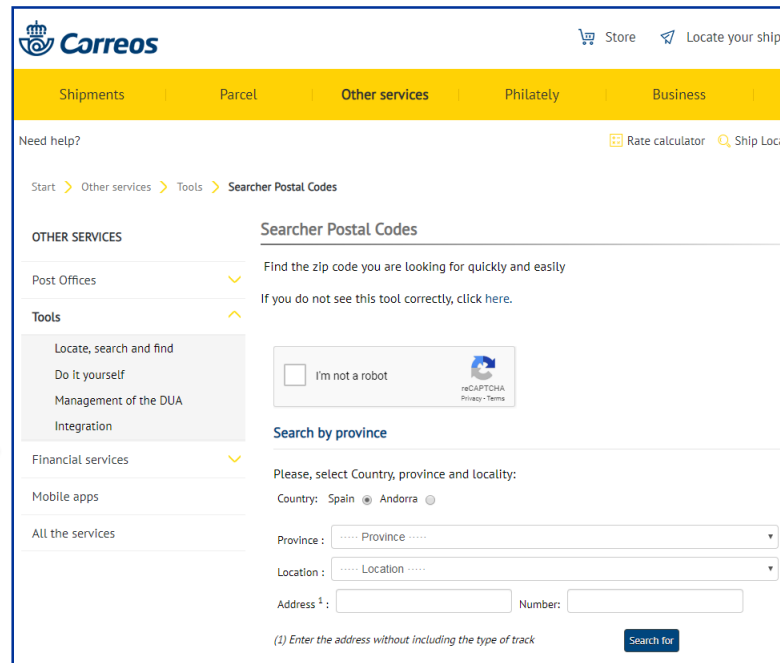
Examples

Urban delivery:
 Sr. D. Jaime Lozano Segui
 Plaza de las Descalzas 27, Esc 2, 3º, C
 45012 TOLEDO
 TOLEDO
 SPAIN

addressee street, premise, stairwell, floor + door.
postcode + locality
province
country

Website www.correos.es

01/2013

Correos

Shipment Parcel Other services Philately Business

Need help? Rate calculator Ship Location

Start > Other services > Tools > Searcher Postal Codes


OTHER SERVICES

- Post Offices
- Tools
 - Locate, search and find
 - Do it yourself
 - Management of the DUA
 - Integration
- Financial services
- Mobile apps
- All the services

Searcher Postal Codes

Find the zip code you are looking for quickly and easily

If you do not see this tool correctly, click here.

I'm not a robot 

Search by province

Please, select Country, province and locality:

Country: Spain Andorra

Province:

Location:

Address ¹: Number:

(1) Enter the address without including the type of track

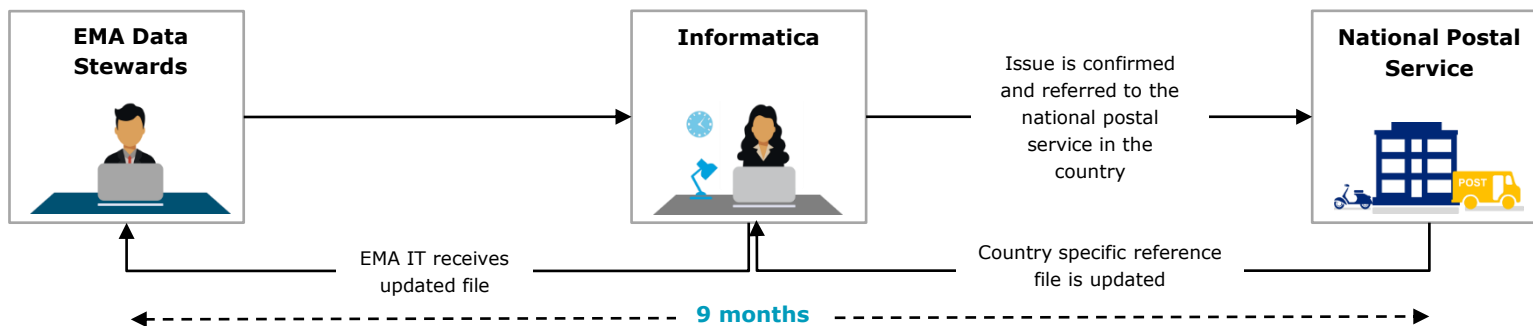
- **1) Investigate:** Check against National Postal Service
 - **2) Confirm AD issue:** confirm the issue relates to AddressDoctor service i.e. country specific reference file, define if AD is incorrect or incomplete
 - **3) Correct:** overwrite OMS data
 - 4) Update DQ issue register
 - **5) Raise Ticket** with EMA IT Service Desk Team > EMA IT refers the issue to Informatica
- **Test if the issue exist** e.g. postal code not up to date
 - These issues have to be raised country by country and planning aspects have to be taken into account
 - Typically AddressDoctor issues are specific to a particular address not region/country

Data Stewardship

- ETL Tasks
- CR Tasks

Service Desk

- DQ Question
- DQ Incident



- **What Data Stewards are doing in the meantime before they receive the updated reference file?**
- Overwrite AddressDoctor only in the case that was correctly reported e.g. postal code not up to date
- **What Data Stewards do when they receive the updated reference file?**
- Once the reference file is updated in the AddressDoctor, Data stewards manually enable AddressDoctor
- Data Stewards revisit Informatica ticket (address by address) > run AD against records that use address > records get updated > ticket is closed > all addresses are corrected/consistent

Rejected change requests:

- *Reject Reason code*
- Comment providing the user with justification and further guidance

OMS does not have change request return option:



- if the user **didn't submit supporting documentation** or forgot to update the relevant data > a **new change request** need to be created in the system
 - For new ORG/LOC – create new change request
 - For updates – 1 change at a time – the first change request needs to be rejected, only after the user will be able to submit the new change request

- After **approving** change request, Data steward ensures that the data is available on SPOR and is showing the correct information, check the organisation and location record on the OMS web portal - <http://spor.ema.europa.eu/omswi/#/>

Organisation Details	
Organisation ID:	ORG-10000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details	
Location ID:	LOC-100005386
Address:	EN Avenue Einstein 12 Wavre Brabant Wallon 1300 Belgium
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE

Organisation Details	
Organisation ID:	ORG-10000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details	
Location ID:	LOC-100005386
Address:	FR Avenue Einstein 12 Wavre Brabant Wallon 1300 Belgique
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE



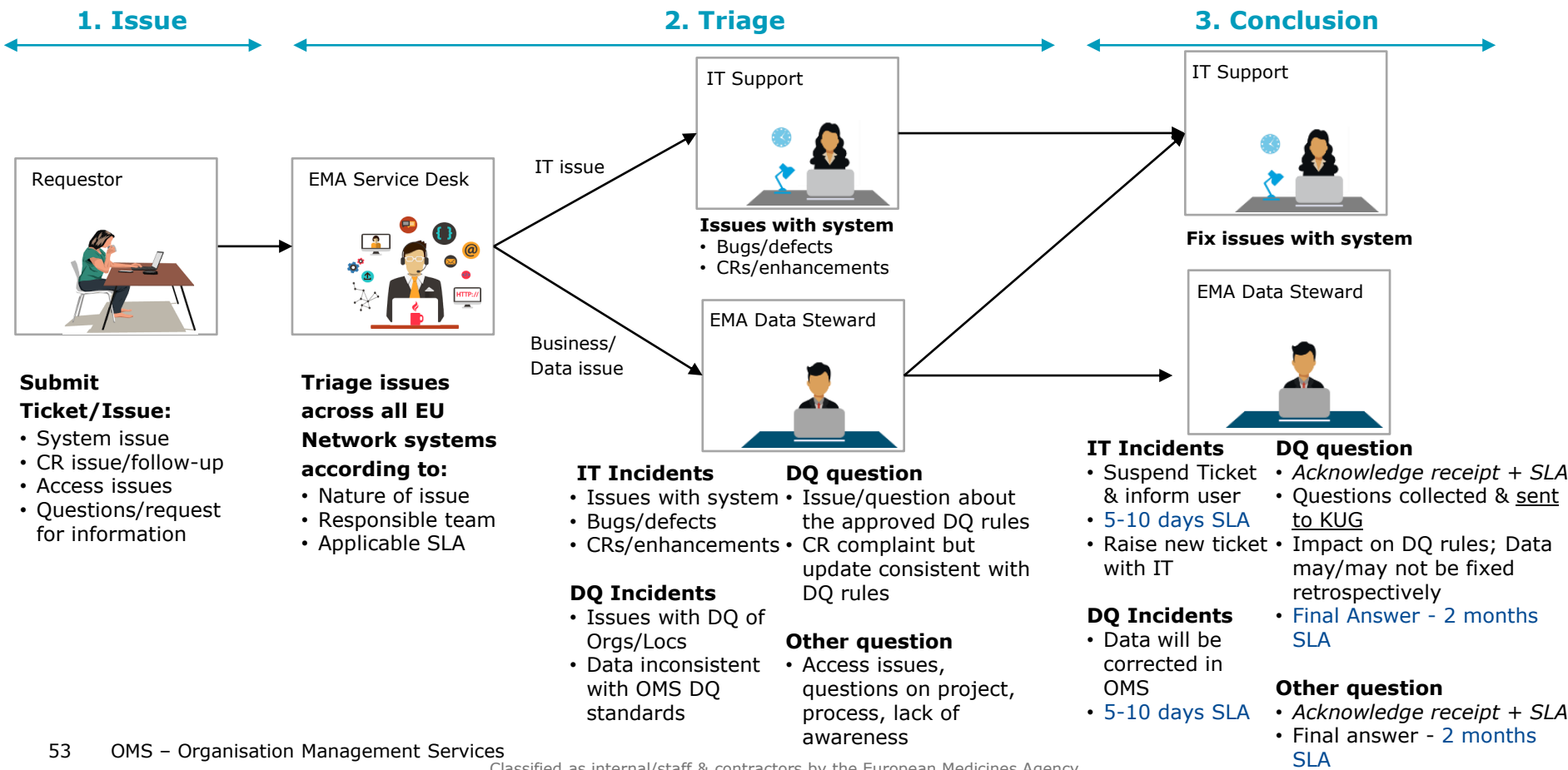
Any questions?

OMS Change Request process





OMS Service Desk





Any questions?

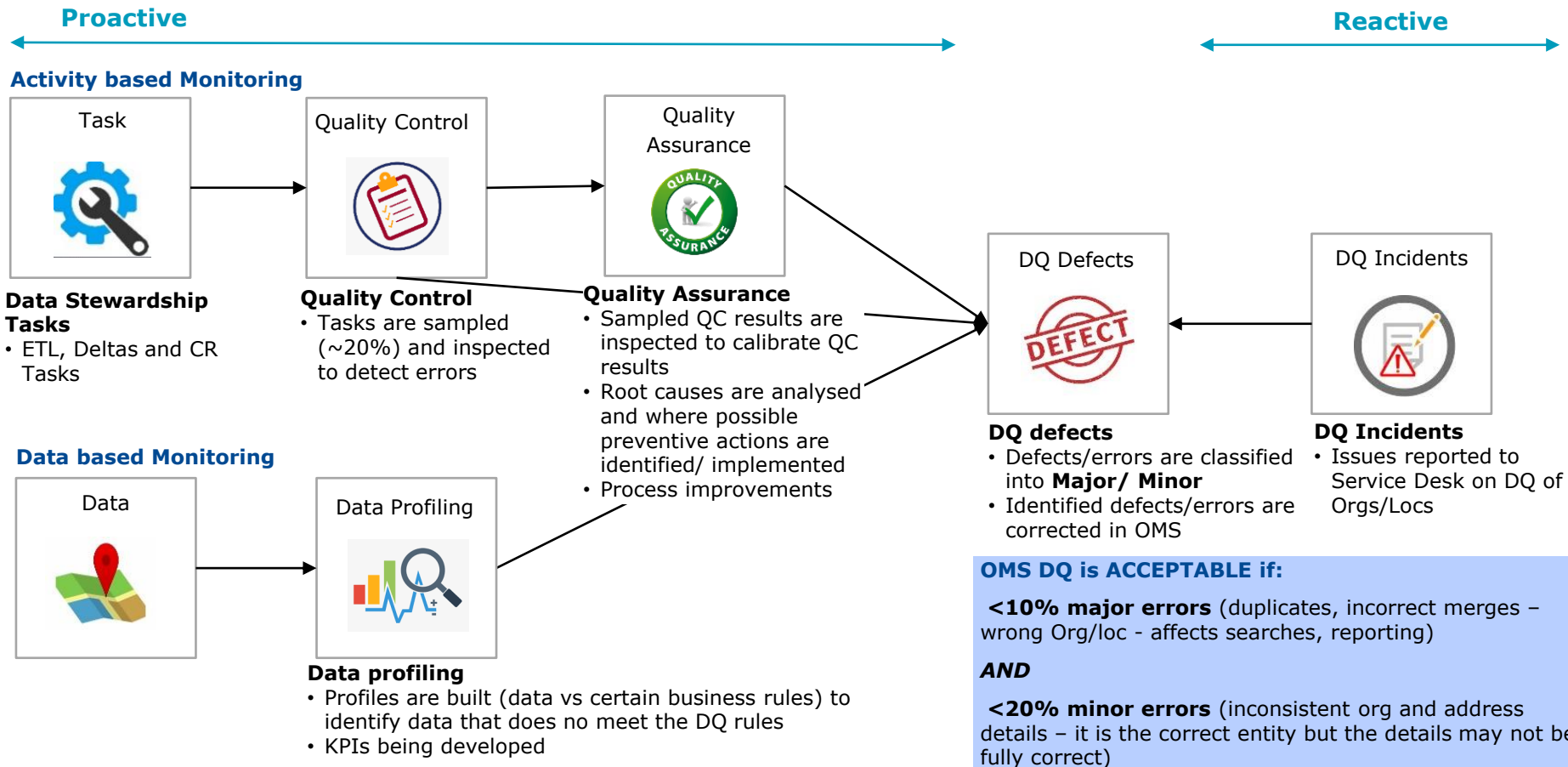
OMS Service Desk





OMS Data Quality Management

OMS Data Quality Management at a glance





Any questions?

OMS Data Quality Management





Supporting material

1. Reference documents accessible from the [SPOR portal](#)

- OMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- Change Request Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)



3. SPOR related information & documents on EMA corporate [website](#)

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

[Account Management Portal.](#)

2. Training videos

RMS & OMS training videos available to view on the [@emainfo](#) channel

5. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the

[Service Desk Portal.](#)



Examples collected by SPOR KUG – Organisation name

Organisation Name as per OMS Data Quality Standards	Equivalent Name Example(s)
Animedica GmbH	aniMedica GmbH AniMedica GmbH ANIMEDICA GMBH aniMedica Gesellschaft mit beschränkter Haftung
Bela-Pharm GmbH & Co. KG	Bela-Pharm GmbH & Co. KG Note: This example is to show that the organisation is listed on 2 separate lines sometimes rather than being typed altogether on one line.
S.P. Veterinaria S.A.	SP VETERINARIA SA SP Veterinaria, S.A.
Industria Italiana Integratori Trei S.p.A.	INDUSTRIA ITALIANA INTEGRATORI TREI S.P.A. Industria Italiana Integratori TREI S.p.A. Industria Italiana Integratori Trei SpA
Industrial Veterinaria S.A.	INDUSTRIAL VETERINARIA, S.A. Industrial Veterinaria, S.A. Industrial Veterinaria SA Industrial Veterinaria, SA



Examples collected by SPOR KUG – Address data

Organization Name as per OMS Data Quality Standards	OMS Address	Equivalent Address Example(s)
Animedica GmbH	Im Suedfeld 9 Boesensell Senden North Rhine-Westphalia 48308 Germany	Im Suedfeld 9 48308 Senden Germany
		Im Südfeld 9 48308 Senden - Bösensell Germany
		Im Suedfeld 9 48308 Senden - Boesensell Germany
Biotherax Biochemisch-Pharmazeutische GmbH	Binger Strasse 173 Ingelheim Am Rhein Rhineland-Palatinate 55216 Germany	Binger Strasse 173 Ingelheim Am Rhein 55216 Germany
		Im Südfeld 9 D-48308 Senden - Bösensell Germany
Boehringer Ingelheim Animal Health Netherlands B.V.	Comeniusstraat 6 Alkmaar Noord-Holland 1817 MS Netherlands	Comeniusstraat 6 Alkmaar 1817 MS Netherlands

Organization Name as per OMS Data Quality Standards	OMS Address	Equivalent Address Example(s)
Boehringer Ingelheim RCV GmbH & Co. KG	Dr.-Boehringer-Gasse 5-11 Meidling Vienna 1120 Austria	Dr.-Boehringer-Gasse 5-11 1121 Vienna Austria
Elanco Animal Health	Heinz-Lohmann-Strasse 5 Grodten Cuxhaven Lower Saxony 27472 Germany	Heinz-Lohmann- Strasse 5 27472 Cuxhaven Deutschland
		Heinz-Lohmann-Strasse 5 27472 Cuxhaven Deutschland
		Heinz-Lohmann- Str. 5 27472 Cuxhaven Deutschland
Industria Italiana Integratori Trei S.p.A.	Via Affarosa 4 Rio Saliceto RE 42010 Italy	Via Affarosa, 4, Rio Saliceto (RE), 42010, Italy
		Via Affarosa, 4 42010 RIO SALICETO (RE) Italy



Examples collected by SPOR KUG – Address data

Organization Name as per OMS Data Quality Standards	OMS Address	Equivalent Address Example(s)
Industrial Veterinaria S.A.	Avinguda Universitat Autònoma 29 Parc Tecnològic Del Valles Cerdanyola Del Valles Barcelona 08290 Spain	Avinguda Universitat Autònoma 29 Cerdanyola Del Valles Barcelona 08290 Spain Av. Universitat Autònoma, 29 08290 Cerdanyole del Vallès Barcelona Spain
Industrial Veterinaria S.A.	Calle Esmeralda 19 Esplugues De Llobregat Barcelona 08950 Spain	Calla Esmeralda 19 Esplugues De Llobregat Barcelona 08950 Spain Calla Esmeralda, 19 08950 Esplugues de Llobregat Barcelona Spain C/Esmeralda , 19 Esplugues de Llobregat 08950 Barcelona Spain

Organization Name as per OMS Data Quality Standards	OMS Address	Equivalent Address Example(s)
Krka d.d. Novo Mesto	Smarjeska Cesta 6 Novo Mesto Jugovzhodna Slovenija 8501 Slovenia	Šmarješka cesta 6 8000 Novo mesto Slovenija Šmarješka cesta 6 8501 Novo mesto Slovenija
Novartis Pharma GmbH	Jakov-Lind-Strasse 5/305 Leopoldstadt Vienna 1020 Austria	Jakov-Lind-Straße 5, Top 3.05 1020 Wien Austria
Novartis Sverige AB	Torshamnsgatan 48 Spanga-Kista Kista Stockholms Lan 164 40 Sweden	Torshamnsgatan 48 Kista 164 40 Sweden
Novartis Gene Therapies EU Limited	Block B The Crescent Building Northwood Crescent Northwood D09 C6X8 Dublin 9 Co. Dublin Ireland	BLOCK B THE CRESCENT BUILDING NORTHWOOD, SANTRY DUBLIN 9



Examples collected by EMA on multiple doors addresses - NL

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS the same as to Trade registry <i>This applies for the odd numbers</i>	Map data
Keizersgracht 62/64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>standardised</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
62-64 Keizersgracht Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>standardised</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam Noord-Holland 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry i.e. same meaning but <u>enriched</u> according to OMS DQ rules (AddressDoctor) <i>This applies for the odd numbers</i>	Map data – if a CR is submitted it will be rejected
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 63 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different meaning, different physical place <i>This applies for opposite scenario</i>	Submit CR to <u>create new location</u> & attach TR copy Note: Requires verification with National postal service but even if equivalent the TR determines if they are legally different
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CT Netherlands	Location/address in OMS equivalent/NOT equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to update location & attach TR copy Note: Requires verification with National Postal Service - If same physical location > we update the postal code - If is a different physical location > we create new location



Examples collected by EMA on multiple doors addresses - NL

Reference Sources	Data in OMS	Case	Impact/Process for mappings & CRs
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 63-65 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different physical place as Addresses contain multiple consecutive odd or even numbers	Submit CR to <u>create new location</u> & attach TR copy
Keizersgracht 61 Amsterdam 1015 CS Netherlands	Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Location/address in OMS NOT equivalent to Trade registry i.e. different physical place As Addresses contain multiple consecutive odd or even numbers	Submit CR to <u>create new location</u> & attach TR copy
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CS Netherlands	Location/address in OMS partially equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD a new loc will be created</i>
Keizersgracht 62-64 Amsterdam 1015 CS Netherlands	Keizersgracht 62-66 Amsterdam 1015 CS Netherlands	Location/address in OMS equivalent to Trade registry + additional location/address not reflected in the Trade Registry but available in other references <i>This applies for the odd numbers</i>	Submit CR to <u>update location</u> & attach TR copy. Note: address data verified according to information provided by AddressDoctor. <i>- If not recognised by AD a new loc will be created</i>
Keizersgracht 62 Amsterdam 1015 CS Netherlands	Keizersgracht 62 Amsterdam 1015 CT Netherlands	Location/address in OMS equivalent/NOT equivalent to Trade registry <i>This applies for the odd numbers</i>	Submit CR to update location & attach TR copy Note: Requires verification with National Postal Service <i>- If same physical location > we update the postal code</i> <i>- If is a different physical location > we create new location</i>

Data Quality Rule in NL:

- Addresses can contain multiple consecutive odd or even doors numbers
- Addresses can not contain multiple non- consecutive doors numbers
- Odd or even doors number is displayed at the end after the street name
- Doors numbers are separated by hyphen with no space
- Postal code has 4 digits and 2 capital letters



Any questions?

Further information

Contact us through Service Desk.

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

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

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