



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

OMS web user manual

Version 1.0

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1. Purpose of this document

OMS (Organisation Management System) is part of the centralised EU master data service covering **S**ubstance, **P**roduct, **O**rganisation and **R**eferential (SPOR) in relation to medicines. Each of these domains is accessible through the common SPOR web portal as described below.

OMS implements Master Data Management services around registration and maintenance of organisation data and the provision of an organisation dictionary via a web user interface (UI) and an Application Programming Interface (API). The content of the organisation dictionary will be expanded incrementally. Examples of organisation data include: Marketing Authorisation Holders (MAHs), Marketing Authorisation Applicants (MAAs), Sponsors and Manufacturers. A new centralised organisation registration process is put in place as part of the OMS solution. The implementation of structured organisation data with unique IDs will also support the implementation of ISO IDMP standards such as the ISO 11615 for medicinal product identification and ISO 11238 for substance identification. Although these standards apply to human medicinal product only the SPOR services will also support veterinary regulatory activities.

This manual gives step-by-step instructions how to use the OMS web interface in order to search the organisation dictionary, view available data, request new records and update current records.

This manual does not describe the EMA internal data and process flows.

2. Web portal user roles

Refer to 'SPOR User Registration' document on the OMS web page, in the "view documents" section:

<http://spor.ema.europa.eu/omswi/#/viewDocuments>

3. Definitions of OMS data entities

Entity	Description
Organisation	Represents an organisation as a legal entity (e.g. organisation name). Organisations are <u>country-specific</u> . All locations under one organisation must be located in the same country. For the purpose of OMS, global companies are split per country even if they have the same name. Assignment of organisation IDs follows these principles.
Location	Represents a physical location (address) within an organisation. A location can only be associated with a single parent organisation at any one time. Each active organisation must have at least one active location associated with it. An address can be present in multiple locations. Each location will have a unique location ID. This location ID is maintained when the location is moved from one organisation to another organisation.

For more information about the data supported by the OMS services, refer to 'Data Quality standards in OMS' document on the OMS view documents page:

(<http://spor.ema.europa.eu/omswi/#/viewDocuments>)

4. Access to SPOR services

4.1. SPOR web landing area and log in to OMS

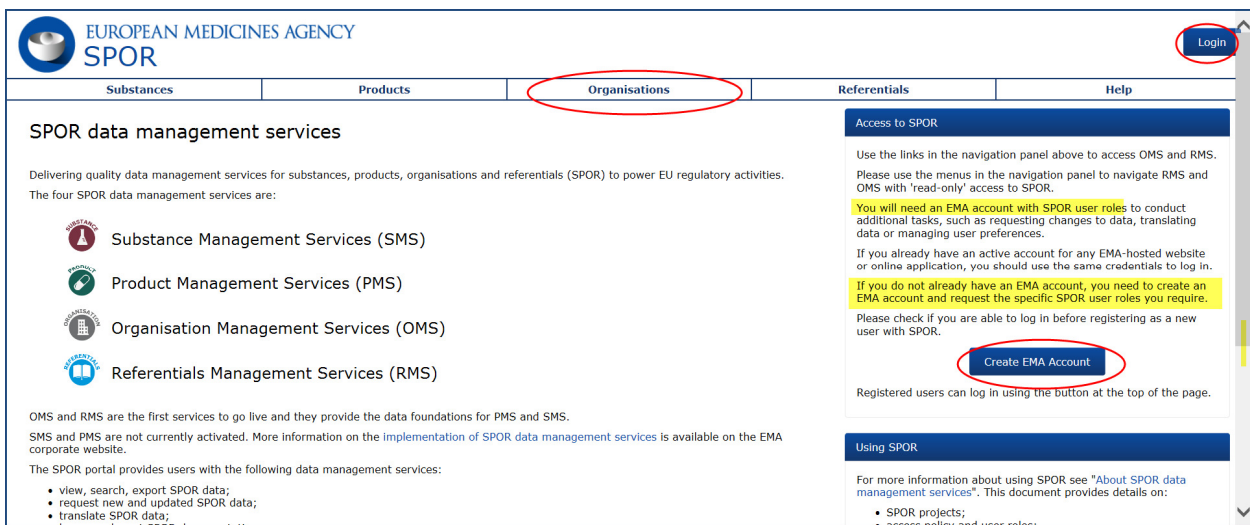
Users can access SPOR services directly through the URL for SPOR,

<http://spor.ema.europa.eu/sporwi/>

Links to referentials (RMS), organisations (OMS), products (PMS; disabled until PMS goes live) and substances (SMS; disabled until SMS goes live) landing pages are available on the SPOR top menu bar.

There is also a help tab which contains general help document "About SPOR".

Figure 1. SPOR web landing page



This OMS SPOR user manual is accessible in the Organisation section, under the tab "documents" (see below).

Guest users can access the publicly available information on the SPOR Portal Website without logging in.

SPOR users will need to be registered to use additional functionality on the SPOR portal.

Registered users who already have an EMA account (for Eudralink, EudraCT Secure, IT Service Desk portal (JIRA), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR as examples), can just click on the log in button on the top right hand corner of the SPOR landing page to log into the SPOR portal. They will be logged in as unaffiliated users.

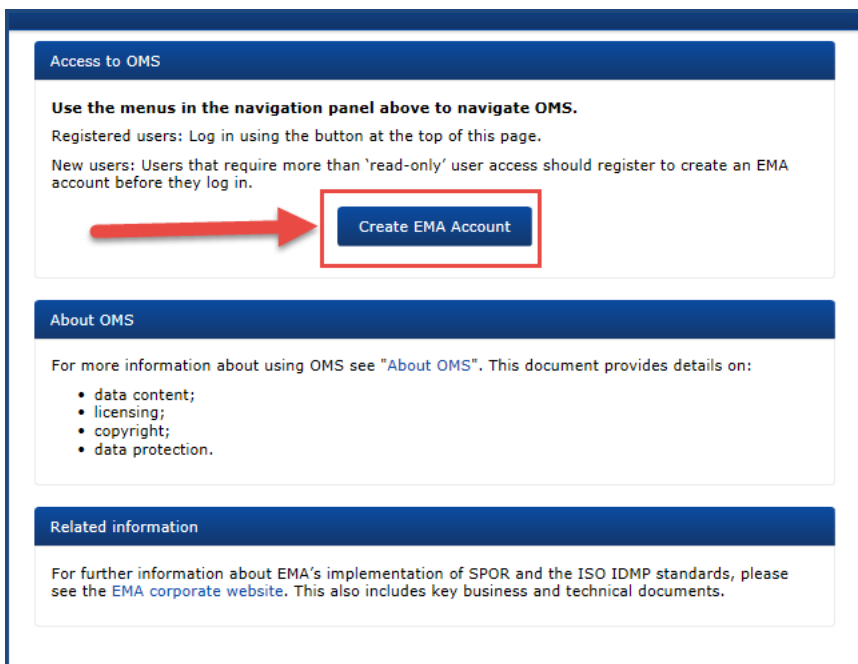
Figure 2. OMS SPOR log in page for registered users



Registered users who wish to request SPOR user roles need to log in through the IAM (IIQ) portal under “create EMA account” as described below and log in with their EMA account username and password. They should not register again.

User registration and access to SPOR user roles is managed through the IAM identity and access management tool IdentityIQ (IIQ). The link to the IAM (IIQ) system is available on the SPOR homepage as highlighted in *fig. 1* – click on “create EMA account”. The same link is also available on the OMS home page as highlighted in *fig. 3* below.

Figure 3. Create EMA account or request SPOR roles



☞ **For the registration process and access rights requests please go to SPOR user registration manual on the OMS home page**

<http://spor.ema.europa.eu/omswi/#/viewDocuments>

Of note, there is one single registration process for all SPOR domains, i.e. by registering for one domain (e.g. OMS), the user will automatically have access to the other domains (e.g. RMS). The RMS specific SPOR user roles need to be requested in the same way as any other SPOR user roles.

5. New user registration for SPOR access

Please refer to 'SPOR User Registration Manual' on the OMS view documents page here:

<http://spor-test.ema.europa.eu/omswi/#/viewDocuments>

6. OMS services

6.1. OMS web landing area – before log in

To access the OMS landing page, the user must select the OMS tab on the SPOR top menu (see *fig. 1*). Before logging in, users can view OMS documentation, search for organisations/locations data and view it on the screen. To export any organisation dictionary content, the user needs to be logged in.

The log/registration screen can be accessed through 'Create EMA Account' box from the SPOR main landing page (see *fig. 1*) and from the OMS home page (see *fig. 4*).

Within the OMS domain, the available menu options are (see *fig. 4*)

- SPOR Home - opens the SPOR homepage. The same page opens by clicking on the EMA logo
- Organisations – opens the organisation dictionary search page
- Documents – view

Figure 4. OMS web landing area with log in, create EMA account and access to organisation dictionary

The screenshot shows the SPOR - Organisations Management System (OMS) web landing area. The top navigation bar includes 'Substances', 'Products', 'Organisations', 'Referentials', and 'Help'. The 'Organisations' tab is selected, and a red box highlights the 'Access to organisation dictionary' link. The main content area is titled 'Organisation Management Services (OMS)' and includes a list of services and a 'Create EMA Account' button. A red box highlights the 'Create EMA Account' button. The right sidebar contains 'Access to OMS' instructions, 'About OMS' details, and 'Related information'.

6.2. View help

The help menu link provides access to the 'About OMS' document. This document is available for guest users, i.e. without logging in.

The guidance documents related to OMS are accessible once the user selects the OMS menu option as in *fig. 4*.

6.3. View documents

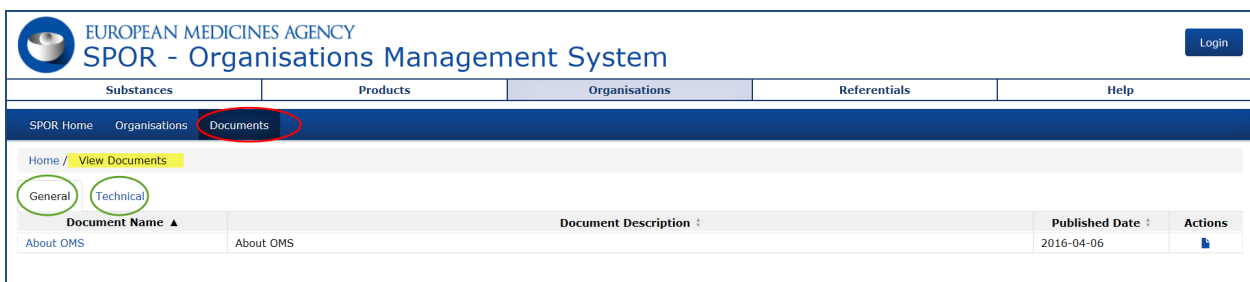
There are two categories of supporting documents published on the OMS web portal, general and technical. When selected, each of them opens in a new tab.

The 'General' tab includes a list of business documents pertaining to the OMS solution. From data quality standards, change request documentation requirements to OMS operating model and process related documentation, including this OMS user manual. It also includes instruction on user registration and requesting SPOR roles.

The 'Technical' tab provides access to more technical documentation such as the SPOR API specification or the OMS data model.

All documents are downloadable for any user (registered or not).

Figure 5. OMS – view documents



7. Search, view and export

To search and view organisations and locations, the user does not have to be logged in the OMS (guest user).

To export organisation and location data, search results or list of change requests sent in the past the user **does** need to be logged in.

7.1. Organisation and location search

This functionality allows the user to search for the organisations and locations published in OMS. Subject to permissions, they may then choose to view organisation details for an organisation returned in the search results, add a location to an organisation returned in the search results, request a change to an organisation and/or location returned in the search results, create a request to add a new organisation or export the details of the organisations in their result list.

The search is based on exact character matching. This applies to all search fields e.g. if searching for Székesfehérvár, special characters "é" and "á" will need to be used.

Once the search criteria are inserted, clicking on "search" will run the query.

Default sort order is organisation ID, organisation name and country.

All columns are sortable.

There can be more than one page of results, up to the limit 200 rows in the result. If more than 200 rows meet the search criteria, the system will throw an error message.

Figure 6. Search start

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations Documents

Home / Search Organisations

Hide search

Organisation ID Contains

Organisation name Contains

Location ID Contains

Address Contains

City Contains

Postcode Contains

Country

Modified Since

Location status

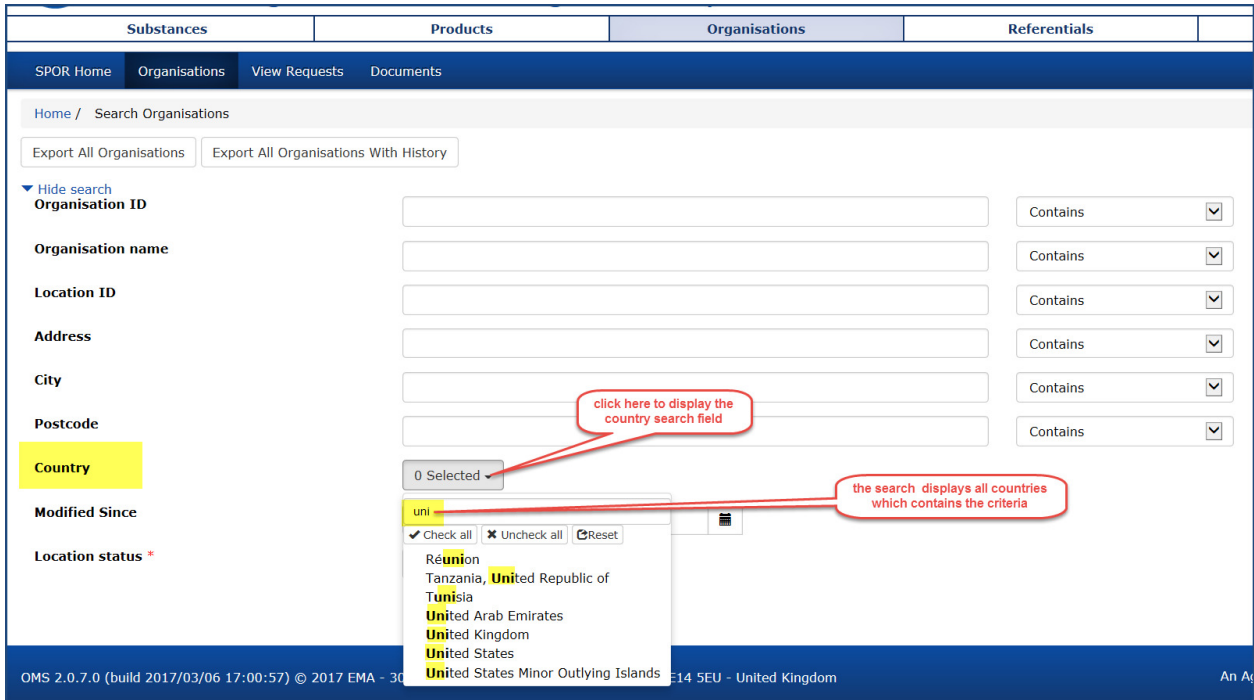
Search organisations:

Organisation-based search:

☞ ***Please note that organisations are country-specific as described in section 3.***

- Criteria entered in "Organisation Name" will be searched against all the different name fields (Organisation Name, Acronym, Translations) and against all historic version of those names
- The user enters the name of the organisation (or part of the name) that they wish to search for
- The search results include all of the locations that are associated to organisations that match the entered organisation name. For each returned location the name and ID of the parent organisation is shown
- In order to get more refined results, the user can also use "country" as a selection criterion – type in a value in the country search field. Please note the country search field covers "modified since" and "status" fields while open and collapses once a selection is made

Figure 7. Country selection



- The "modified since" and "status" fields are related to location entity and not the organisation
- Organisation ID based search will provide the organisation containing that ID. The search result will list all the locations linked to that organisation and with the organisation data repeated in each row
- The default search mode is "contains" for all fields; this can be changed to "begins with"
- The search is case insensitive
- Please note that fuzzy search for special characters is to be implemented in a future release (i.e. if searching for Grünenthal, special character "ü" needs to be used as the system is currently not able to find this name by searching for "Grunenthal")
- Country and Location status fields allow multiple selection. Location status is the only mandatory field in the search.
- One or more criteria (in addition to location status which has a default value that can be changed) must be selected/entered before choosing "Search"
- The user can choose if to display 20, 50 or 100 rows in the search results. The default sort order is the organisation ID, name and country. The result list is sortable by all columns apart from "location ID" and "modified since".
- There can be more than one page of results – see *fig. 8*

Figure 8. Search results – selection of 20, 50 or 100 search results

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000025	Bonn	Friedrich-Ebert-Str. 38-40	53177	ACTIVE	2017-05-25T16:24:19	+ ☒ 🔍
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000024	Bonn	Kurt-Georg-Kiesinger-Allee 3	53175	ACTIVE	2017-05-25T16:20:30	+ ☒ 🔍
ORG-100003963	German Institute for Medical Documentation and Information	Germany	LOC-100000119	Cologne	Walsenhausgasse 36-38a	50676	ACTIVE	2017-06-20T14:46:08	+ ☒ 🔍
ORG-100003958	Institute for Control of Biological Products and Veterinary Medicines	Romania	LOC-100000104	Bucharest	Strada Dudului 39	060603	ACTIVE	2017-06-02T14:55:13	+ ☒ 🔍
ORG-100003960	Institute for State Control of Veterinary Biologicals and Medicaments	Slovakia	LOC-100000107	Nitra	Blhovetska 34	949 05	ACTIVE	2017-06-07T12:10:54	+ ☒ 🔍
ORG-100003949	Institute for State Control of Veterinary Biologicals and Medicaments	Czech Republic	LOC-100000076	Brno 21	Hudcova 232/56a	621 00	ACTIVE	2017-06-01T15:31:04	+ ☒ 🔍
ORG-100003956	National Food and Veterinary Risk Assessment Institute	Lithuania	LOC-100000100	Kauno M. Sav.	Risk Assessment Department	48332	ACTIVE	2017-06-02T13:42:31	+ ☒ 🔍
ORG-100003956	National Food and Veterinary Risk Assessment Institute	Lithuania	LOC-100000101	Vilniaus M. Sav.	Jono Kairiukscio G. 10	08409	ACTIVE	2017-06-02T13:41:42	+ ☒ 🔍
ORG-100003925	National Institute of Pharmacy and Nutrition	Hungary	LOC-100000028	Budapest	Po Box 450	1372	ACTIVE	2017-05-26T11:45:15	+ ☒ 🔍
ORG-100003925	National Institute of Pharmacy and Nutrition	Hungary	LOC-100000027	Budapest V	Zrinyi utca 3.	1051	ACTIVE	2017-05-26T11:41:48	+ ☒ 🔍
ORG-100003925	National Institute of Pharmacy and Nutrition	Hungary	LOC-100000030	Budapest V	Egesszeguyi Tudomanyos Tanacs	1051	ACTIVE	2017-05-26T11:52:39	+ ☒ 🔍
ORG-100003925	National Institute of Pharmacy and Nutrition	Hungary	LOC-100000029	Budapest XII	Dios Arok 3	1125	ACTIVE	2017-05-26T11:49:29	+ ☒ 🔍
ORG-100003922	Paul-Ehrlich-Institute	Germany	LOC-100000022	Langen (Hessen)	Paul-Ehrlich-Str. 51-59	63225	ACTIVE	2017-05-25T16:06:14	+ ☒ 🔍

- Search results are limited to 200 results. If the search was to return more than 200 results, the user will see an error message informing that the search criteria should be further refined.
- Click on “search”
- Search criteria are automatically collapsed to make more space for the search results. It can be expanded by clicking on ‘show search’.

Figure 9. Search results with the collapsed “show search” button

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000025	Bonn	Friedrich-Ebert-Str. 38-40	53177	ACTIVE	2017-05-25T16:24:19	+ ☒ 🔍
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000024	Bonn	Kurt-Georg-Kiesinger-Allee 3	53175	ACTIVE	2017-05-25T16:20:30	+ ☒ 🔍
ORG-100003963	German Institute for Medical Documentation and Information	Germany	LOC-100000119	Cologne	Walsenhausgasse 36-38a	50676	ACTIVE	2017-06-20T14:46:08	+ ☒ 🔍
ORG-100003958	Institute for Control of Biological Products and Veterinary Medicines	Romania	LOC-100000104	Bucharest	Strada Dudului 39	060603	ACTIVE	2017-06-02T14:55:13	+ ☒ 🔍
ORG-100003960	Institute for State Control of Veterinary Biologicals and Medicaments	Slovakia	LOC-100000107	Nitra	Blhovetska 34	949 05	ACTIVE	2017-06-07T12:10:54	+ ☒ 🔍
ORG-100003949	Institute for State Control of Veterinary Biologicals and Medicaments	Czech Republic	LOC-100000076	Brno 21	Hudcova 232/56a	621 00	ACTIVE	2017-06-01T15:31:04	+ ☒ 🔍
ORG-100003956	National Food and Veterinary Risk Assessment Institute	Lithuania	LOC-100000100	Kauno M. Sav.	Risk Assessment Department	48332	ACTIVE	2017-06-02T13:42:31	+ ☒ 🔍

Click on “show search” and the search criteria panel appears above the search results

Figure 10. Search criteria expanded above the search results

Home / Search Organisations

These results may include organisations selected because their historic versions meet the criteria. You can export the data to see historic versions.

Hide search

Organisation ID: Contains

Organisation name: Contains

Location ID: Contains

Address: Contains

City: Contains

Postcode: Contains

Country: 0 Selected

Modified Since:

Location status: ACTIVE, INACTIVE

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000025	Bonn	Friedrich-Ebert-Str. 38-40	53177	ACTIVE	2017-05-25T16:24:19	+ 🔗 🔍
ORG-100003923	Federal Institute for Drugs and Medical Devices	Germany	LOC-100000024	Bonn	Kurt-Georg-Kiesinger-Allee 3	53175	ACTIVE	2017-05-25T16:20:30	+ 🔗 🔍
ORG-100003963	German Institute for Medical Documentation	Germany	LOC-	Cologne	Waisenhausgasse 36-38a	50676	ACTIVE	2017-06-	+ 🔗 🔍

The search form can be cleared by clicking on “reset”

Figure 11. Reset the search criteria

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SPOR - Organisations Management System

kbusrikova

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations

These results may include organisations selected because their historic versions meet the criteria. You can export the data to see historic versions.

Show search

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003917	State Institute for Drug Control	Czech Republic	LOC-100000010	Prague 10	Šrobárova 48	100 41 PRAGUE 1	ACTIVE	2017-05-25T14:24:51	+ 🔗 🔍
ORG-100003941	State Institute for Drug Control	Slovakia	LOC-100000061	Bratislava - Ruzinov	Kvetna 11	821 08	ACTIVE	2017-05-31T14:56:20	+ 🔗 🔍

Location based search:

- The user enters location level search criteria (e.g. address, Location ID). The search results include all locations that match the entered search criteria. For each returned location the name and ID of the parent organisation is shown.
- Criteria entered in “Location ID” will only be searched against Location ID, although other IDs held (e.g. EVcode) will be included in the organisation detailed data display and export

Combination search:

- The user enters both organisation level and location level search criteria. The search results include locations where the location data matches the location level search criteria, and its parent organisation matches the organisation level search criteria. For each returned location the name and ID of the parent organisation is also shown.

Alternative search results:

- no results found
- minimum search criteria not entered, please enter minimum search criteria
- too many results returned, please refine your search

Further actions are possible from the results screen:

- Click on the address link – shows organisation and location details
- + icon – request to add a location for this organisation => triggers a change request
- Pencil icon – request change to this organisation and/or location => triggers a change request
- Magnifying glass icon – view organisation and location details
- Request new organisation
- In case the pencil icon is greyed out, the location record is inactive and cannot be changed. This does not mean that the organisation is inactive too. The organisation status can be seen on the organisation and locations details page.

Figure 12. Search results and further actions

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

bursikova8k Logout

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations

These results may include organisations selected because their historic versions meet the criteria. You can export the data to see historic versions.

Show search

Reset Search

Organisation ID	Organisation Name ▲	Country ↓	Location ID ↓	City ↓	Address	Postcode ↓	Location status ↓	Modified ↓	Actions
ORG-100000147	Glaxo Operations UK Limited	United Kingdom	LOC-100000111	London	7 Westferry Circus	E14 4HB	ACTIVE	2017-03-12T15:16:57	+ ⓧ 🔍
ORG-100000023	GlaxoSmithKline Consumer Healthcare	United Kingdom	LOC-100000110	London	30 Churchill Place	E14 5EU	ACTIVE	2017-03-12T15:16:57	+ ⓧ 🔍
ORG-100000023	GlaxoSmithKline Consumer Healthcare	United Kingdom	LOC-100000109	BRENTFORD	G S K HOUSE	TW8 9GS	ACTIVE	2017-03-12T15:16:57	+ ⓧ 🔍

Request New Organisation Export Results Export Results With History

7.2. View organisation location

The user is able to view the details of a particular organisation that they have selected from the results of an organisation search.

Clicking on the address or on the magnifying glass displays organisation location details.

Figure 13. View organisation and location details and take further actions

Home / Search Organisations / View Organisation Location

Organisation Details

Organisation ID:	ORG-100001482
Organisation Name:	Flynn CL Pharma Ltd
Status:	ACTIVE
Organisation Type:	Industry

Location Details

Location ID:	LOC-100000038
Address:	21 Churchill Place Canary Wharf London E14 5EU United Kingdom
Last Modified Date:	2017-03-12T15:16:57
Last Modified By:	admin
Status:	ACTIVE

[Request New Organisation](#) [Add Location](#) [Request Change](#) [Export](#) [Export With History](#)

Organisation and Location details

- The default language is English
- A drop-down is enabled if the location address details are also stored in a different language

Figure 14. Drop-down list for an address in different language from English

Organisation Details	
Organisation ID:	ORG-100003914
Organisation Name:	Bulgarian Drug Agency
Alternative Name:	BG - Българската агенция по лекарствата ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА
Acronym:	BDA
Status:	ACTIVE
Organisation Type:	Regulatory Authority EEA National Competent authority

Location Details	
Location ID:	LOC-100000007
Address:	<div style="display: flex; align-items: center;"> <div style="border: 1px solid red; border-radius: 50%; padding: 2px; margin-right: 5px;">BG</div> <div style="font-size: 0.8em;"> Ул.дамян Груев 8 София София 1303 Bulgaria </div> </div>
GPS Location:	42.69896, 23.30993
Location Email:	bda@bda.bg
Location Phone:	+359 28903555
Last Modified Date:	2017-05-25T13:33:03
Last Modified By:	[REDACTED]
Status:	ACTIVE

- If location status and Organisation status are both inactive, the “request change” button is disabled as it is not possible to request a change.
- If the location status is inactive but the organisation status is active, the ‘request change’ button should be active in order to request a change to the organisation data only.
- Organisation type refers to the categorisation of organisations in OMS. To see the full list of organisation categories with definitions, refer to the ‘Definitions of OMS Controlled Vocabularies’ document in the OMS general documents page (<http://spor.ema.europa.eu/omswi/#/viewDocuments>)

Further actions are possible from the “view organisation location” screen:

- Request new organisation
- Add a location for this organisation
- Request change to this organisation and/or location
- Export organisation and location details

- Export organisation and location details with history

Figure 15. Further action

Substances	Products	Organisations	Referentials	Help
SPOR Home Organisations View Requests Documents				
Home / Search Organisations / View Organisation Location				
Organisation Details				
Organisation ID:	ORG-100003914			
Organisation Name:	Bulgarian Drug Agency			
Alternative Name:	BG - Българската агенция по лекарствата ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА			
Acronym:	BDA			
Status:	ACTIVE			
Organisation Type:	Regulatory Authority EEA National Competent authority			
Location Details				
Location ID:	LOC-100000007			
Address:	BG <input type="checkbox"/> Ул.Давид Гуген 8 София 1303 Bulgaria			
GPS Location:	42.69896, 23.30993			
Location Email:	bda@bda.bg			
Location Phone:	+359 28903555			
Last Modified Date:	2017-05-25T13:33:03			
Last Modified By:	borkowiczj			
Status:	ACTIVE			
Request New Organisation Add Location Request Change Export Export With History				

7.3. Export all organisations

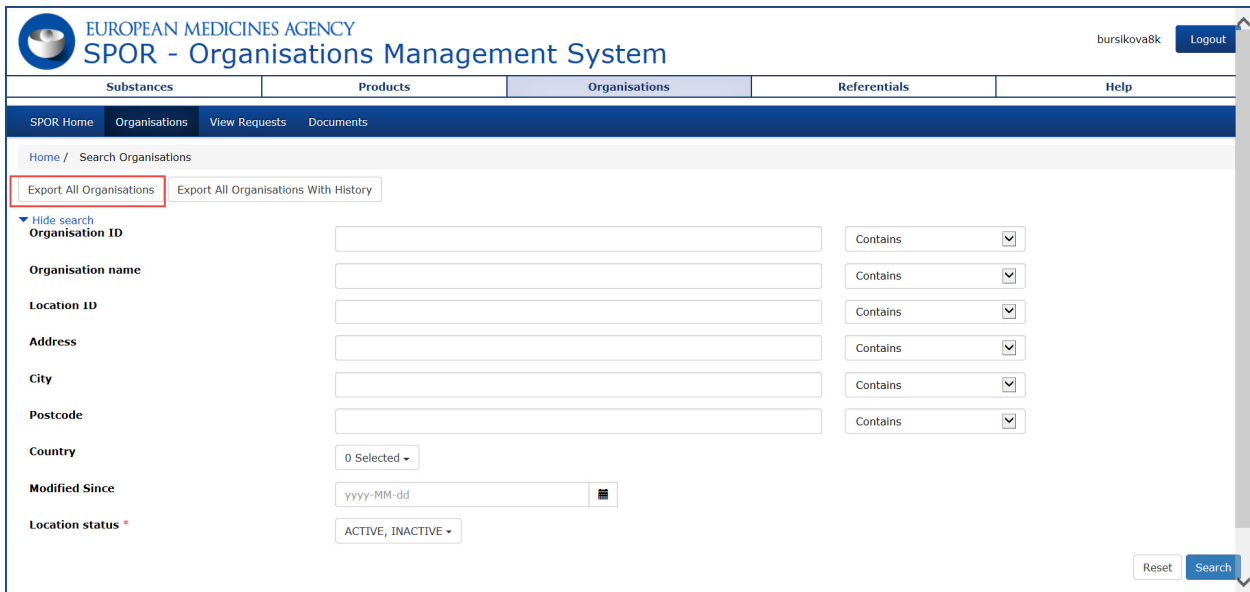
The user can export the complete organisation dictionary from the system in csv format, after logging in. The functionality is available under “search organisation” tab. The export of the complete dictionary can only be performed before starting any search or after clicking “reset”.

The content of the OMS dictionary can be exported as data without history (current version of oms organisations/locations only) or with history (current as well as previous versions of OMS organisations/locations).

7.3.1. Export all organisations – current version

In order to display exported organisation data correctly including all special characters, the file needs to be downloaded and opened as per the instructions below.

Figure 16. Export all organisations



In Google Chrome (version 58.0 minimum), the file is downloaded to the 'downloads' folder from where the user can move the file to another drive. Click on the downloads file in the bottom left corner; the location of the file on your computer appears (see *fig. 7*)

Figure 17. Export all organisations – Google Chrome - downloads folder

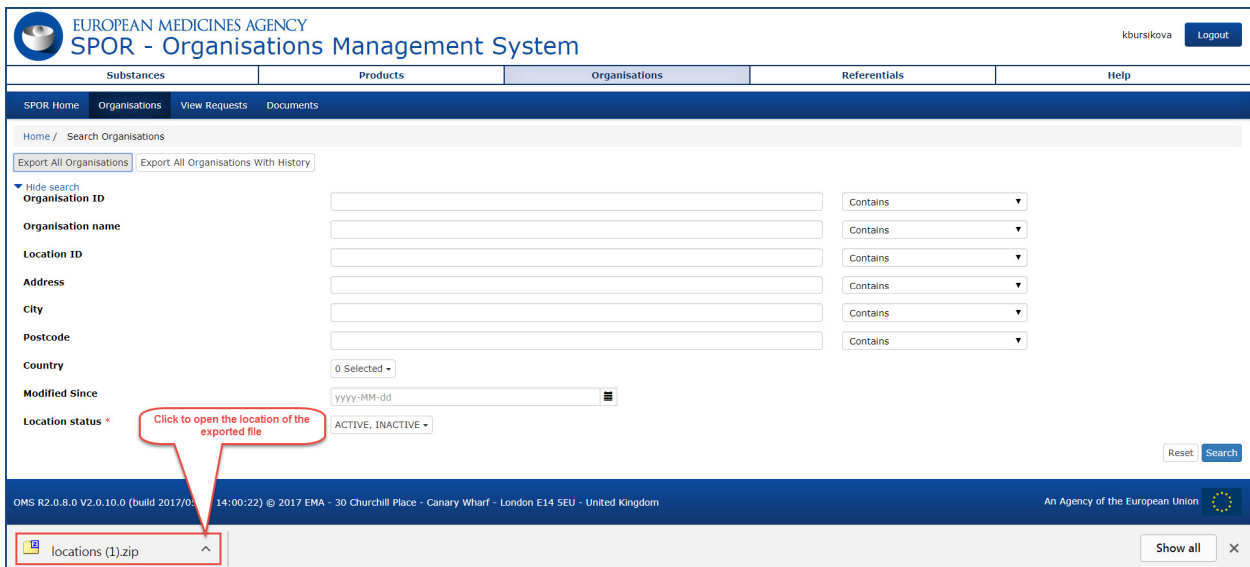
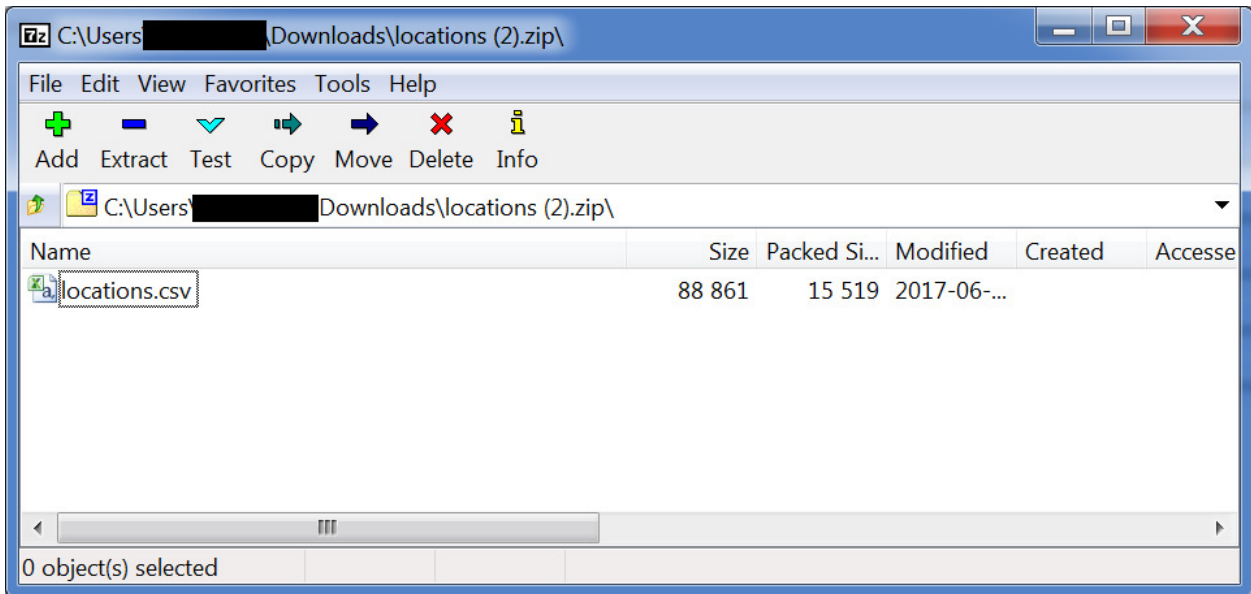
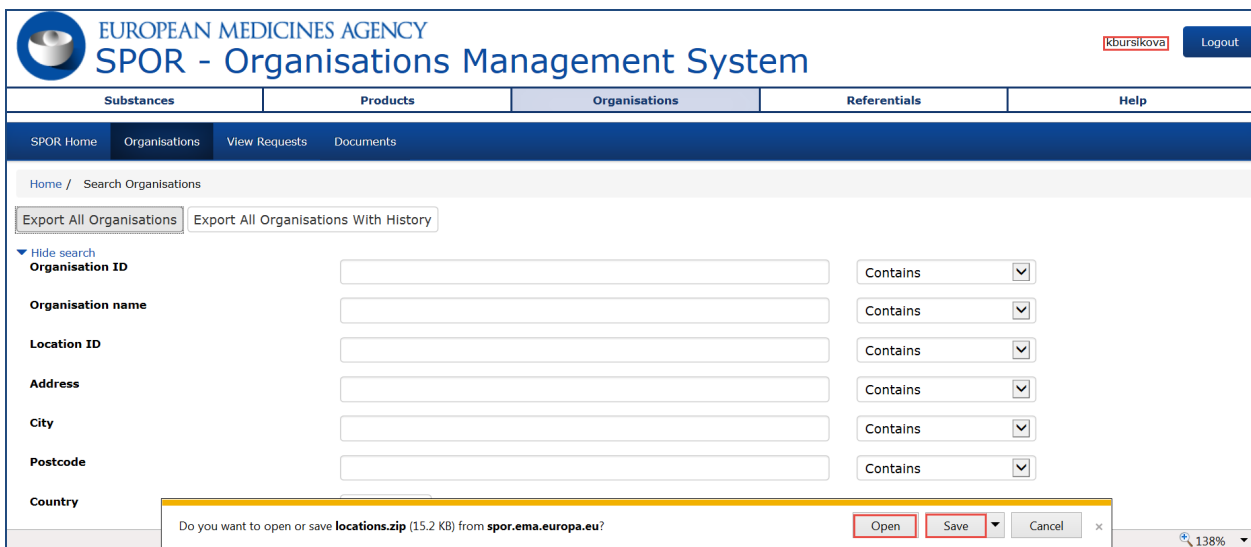


Figure 18. Open the downloads folder – csv. file



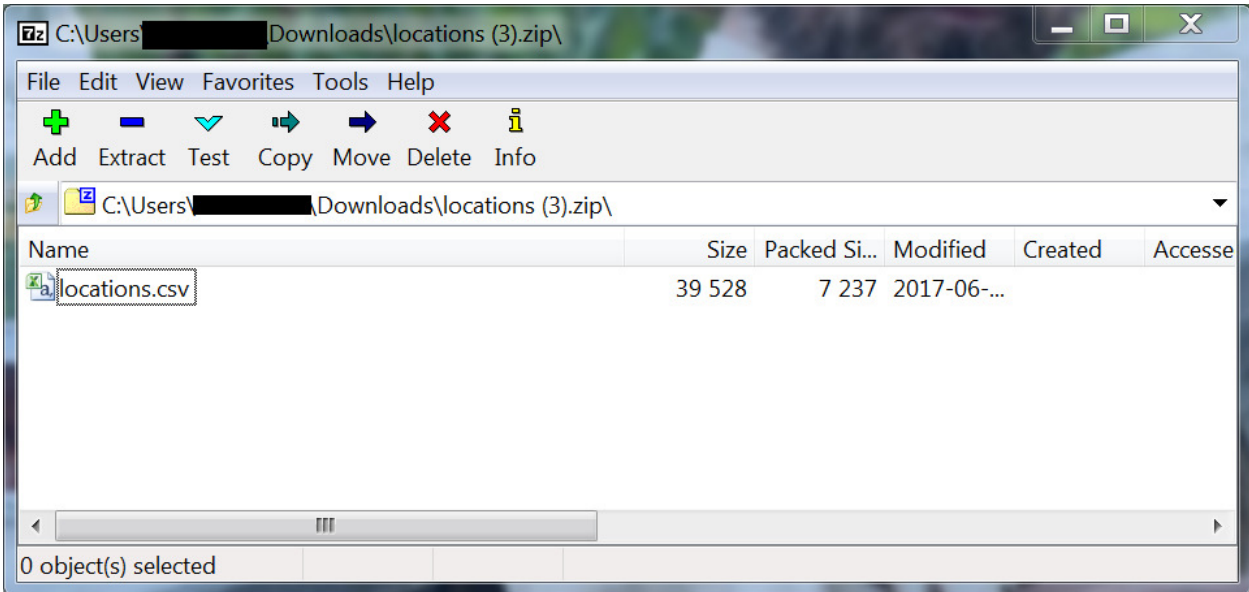
In Internet Explorer (IE version 11 minimum), a pop-up window gives the user the option to either open or save the file as shown in *fig. 7*:

Figure 19. Export all organisations – Internet Explorer – pop-up window to open or save



Open the file. The location downloads folder appears.

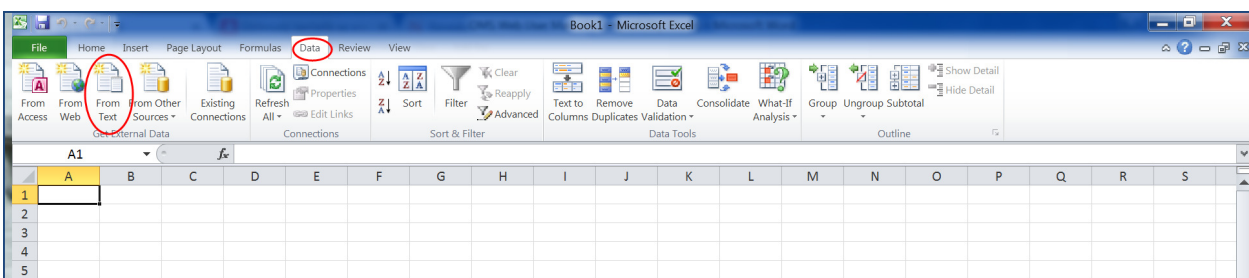
Figure 20. Open the downloads folder – csv. file



The next steps are the same both for Google Chrome and the Internet Explorer.

- Open the document and save it locally (e.g. on your desktop or an additional drive) – you cannot save it from the screen above
- Close the document
- Open a new clean Excel file
- Go to Data tab in Excel and click on "From Text"

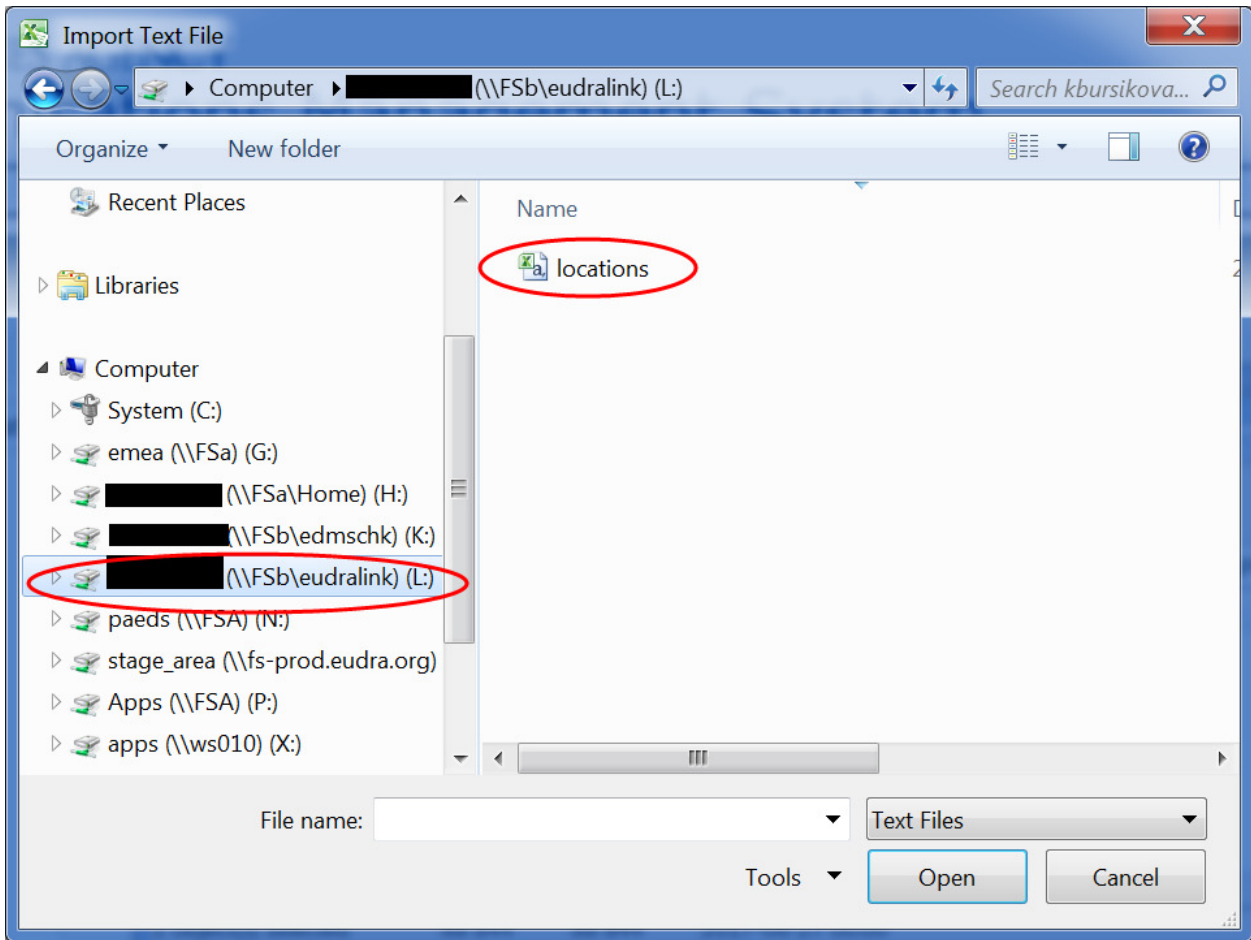
Figure 21. Data tab in Excel



A pop-up window appears

- Select the location of the file you saved previously and open it

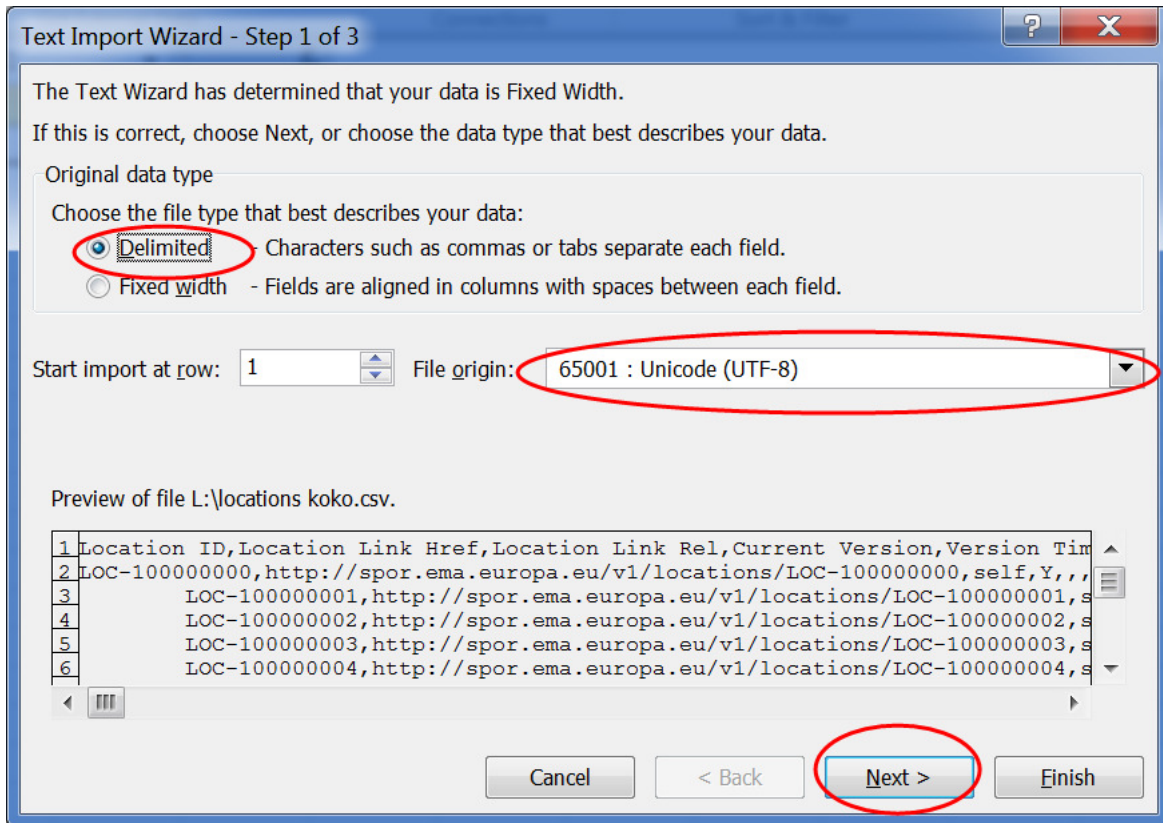
Figure 22. Location of the saved file



The following options are displayed:

- Select "Delimited" as file type
- Select "Unicode (UTF-8)" as file origin.
- Select Next

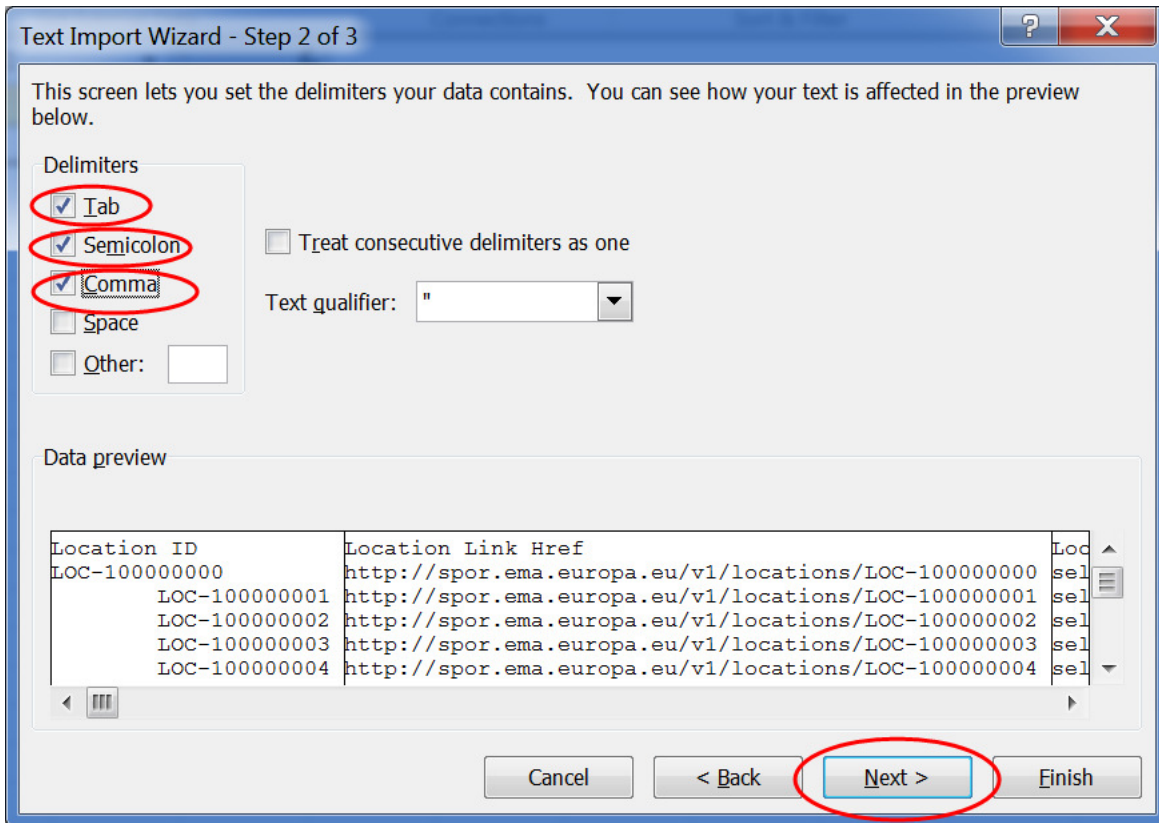
Figure 23. Import wizard to select file parameters



For Delimiters:

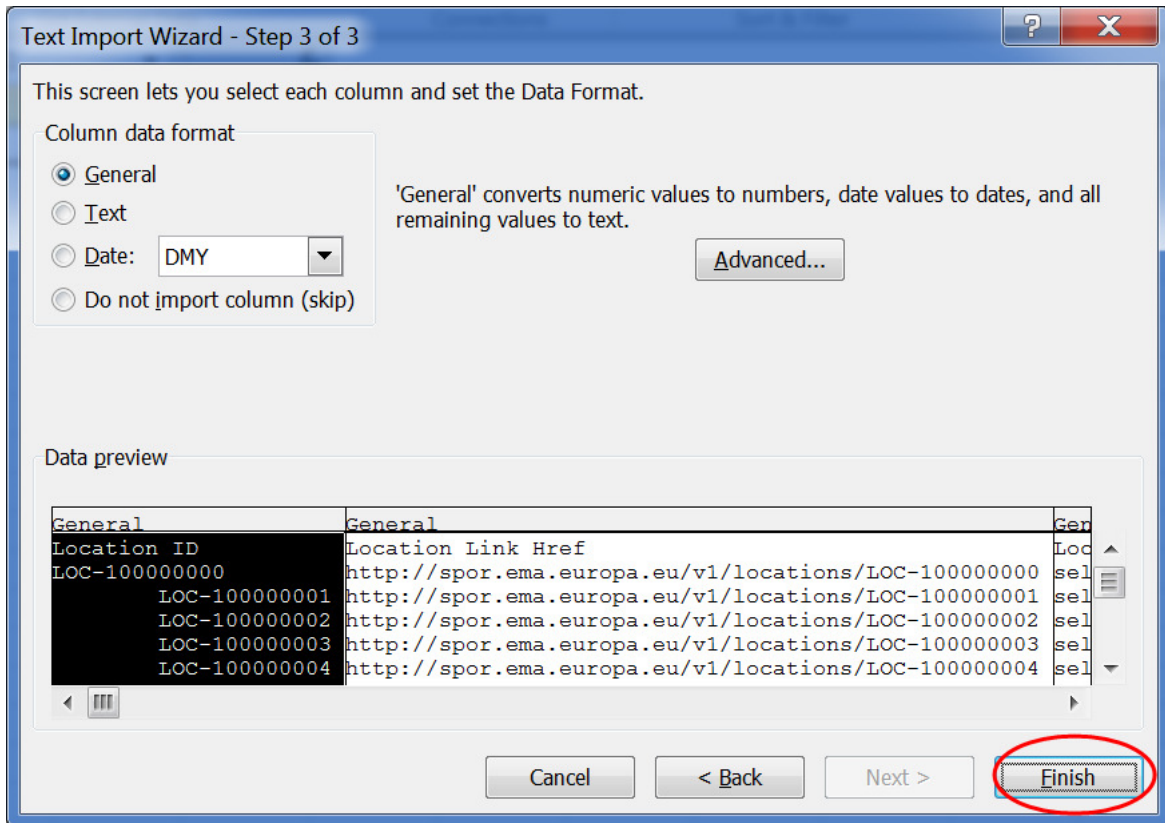
- Select Tab, Semicolon, Comma
- Select Next

Figure 24. Set the delimiters



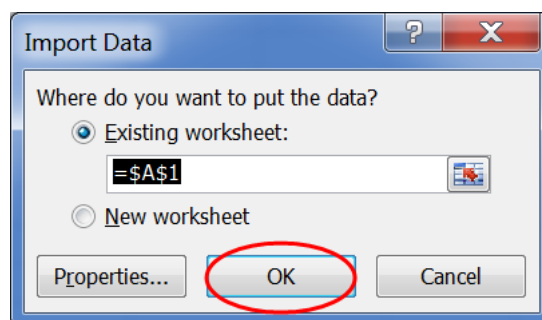
- Select Finish

Figure 25. Finish the file import



- Select OK

Figure 26. Location of the data



The file opens in the correct format, including special characters

Figure 27. Search results exported including special characters (examples highlighted)

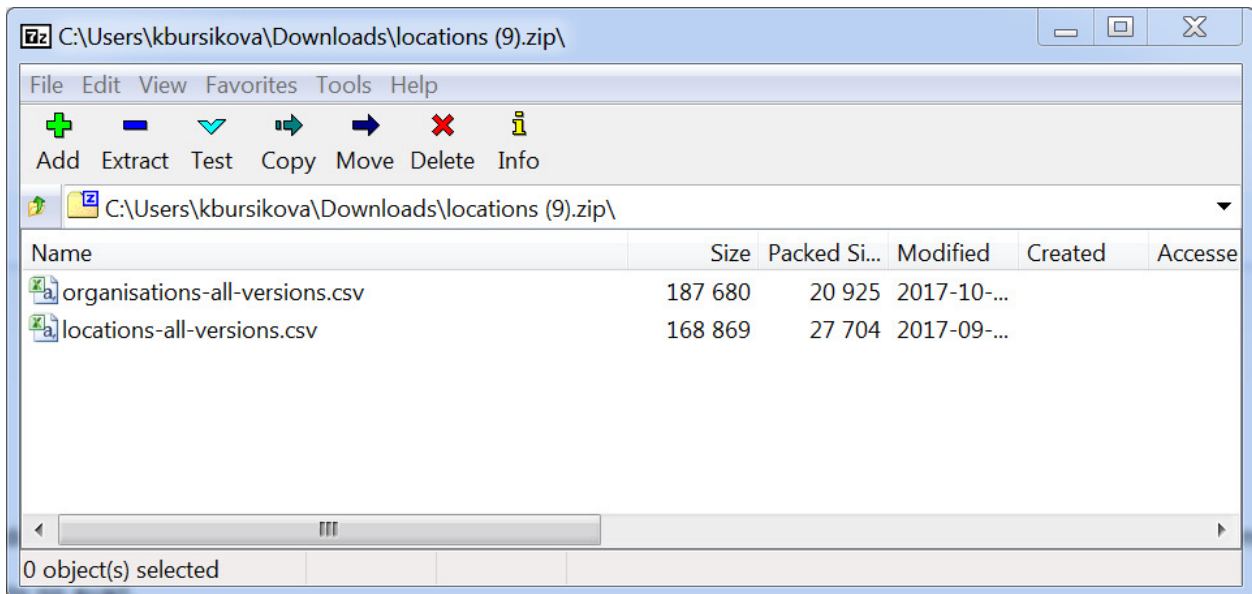
	AE	AF	AG	AH
1	Address GPS Location	Address Language	Address Line 1	Address Line 2
2	48.25147, 16.48305	EN DE DE DE	Spargelfeldstrase 191 Spargelfeldstraße 191 Spargelfeldstraße 191 Spargelfeldstraße 191	Vienna,donaustadt ;
3	47.075627, 15.450706	EN DE DE DE DE	Beethovenstrase 6-8 Beethovenstraße 6 Beethovenstraße 6 Beethovenstraße 6-8 Beethovenstr	Graz,03.Bez.:Geidorf ;
4	48.076881, 16.303951	EN DE DE	Robert Koch-Gasse 17 Robert Koch-Gasse 17 Robert Koch-Gasse 17	Modling ;
5	48.209504, 16.318259	EN DE	Possingergasse 38 Possingergasse 38	Vienna,ottaking ;
6	48.234094, 16.384692	EN DE DE	Traisengasse 5 Traisengasse 5 Traisengasse 9	Vienna,Brigittenau ;
7	47.075964, 15.449859	EN DE DE	Zinzendorfasse 27/1 Betriebsstatte Graz Zinzendorfasse 27/1	Graz,03.bez.:geidorf Zinzendorfasse 27/1 ;
8	50.83632, 4.33411	EN FR FR FR FR	Place Victor Horta 40 Place Victor Horta 2 Eurostation Gebouw Eurostation Blok 2 Place Victor	Eurostation 2 ;Place Victor Horta/40/place V
9	42.69896, 23.30993	EN BG BG	Ul. Damyan Gruев 8 Ул.дамян Груев 8 Ул.дамян Груев 8	;
10	45.83537, 15.97786	EN HR HR HR	Ksaverska Cesta 4 Ksaverska Cesta 4 Ksaverska Cesta 4 Ksaverska Cesta 4	;
11	55.661380, 12.569610	EN	Axel Heides Gade 1	;
12	58.36593, 26.69561	EN	Nooruse 1	;
13	60.20324, 24.89936	EN FI FI	Mannerheimintie 103b Mannerheimintie 103b Mannerheimintie 103b	;
14	62.88997, 27.62966	EN FI FI	Microkatu 1 Microkatu 1 Microkatu 1	;
15		EN	P.O. Box 55	;
16	60.44507, 22.26149	EN FI FI	Itsenäisyydenaukio 2 Itsenäisyydenaukio 2 Itsenäisyydenaukio 2	;
17	45.72664, 4.83084	EN FR FR	321 Avenue Jean Jaures 321 Avenue Jean Jaures Site De Lyon	;;321 Avenue Jean Jaures
18	43.65251, 3.94899	EN FR FR	635 Rue De La Garenne 635 Rue De La Garenne 635 Rue De La Garenne	Cs 60007 ;Cs 60007
19	48.93993, 2.35547	EN FR FR	143 - 147 Boulevard Anatole France 143 Boulevard Anatole France 143 Boulevard Anatole France	;
20	48.804278, 2.489059	EN FR FR	7 Avenue Des Arts 7 Avenue Des Arts 7 Avenue Des Arts	;
21		EN FR	105 Route Des Chappes 105 Route Des Chappes	Cs 20111 Biot Cs 20111 Biot
22	64.130729, -21.765277	EN	Vinlandsleid 14	;

7.3.2. Export all organisations with history

The process of exporting all organisations with history follows the same path as for all organisations in current version

- The export comes out in two files – organisations and locations
- Opening and saving of the files is the same as above for current versions of organisation data

Figure 28. Export all organisations with history



7.4. Export search results

Search results can be also exported.

The user can export the details for all organisation locations in their search results. The export is triggered by clicking on “export results” button at the end of the search result page (see *fig. 18*).

Please note that the maximum number of results is 200. The details are exported as a csv file. See section 7.3 to learn about viewing the content of the csv file from an Excel file, in order to display the results correctly with special characters.

Export results with history - details exported include all historic versions of the same organisations and locations in the search result. The details are exported as a csv file.

The csv file includes the OMS data (including the extended Latin characters) in UTF-8 format; however, to view it correctly when using the MS Excel application the same steps as for exporting all organisations should be followed (see section 7.3)

- Perform search
- Export the file from OMS and proceed as per section 7.3

Figure 29. Export search results

ORG-100003912	Austrian Agency for Health and Food Safety	Austria	LOC-100000003	Vienna	Possingergasse 38	1160	ACTIVE	2017-05-25T12:11:39	+ ⌂ 🔍
ORG-100003912	Austrian Agency for Health and Food Safety	Austria	LOC-100000000	Vienna	Spargelfeldstrase 191	1220	ACTIVE	2017-05-25T12:00:37	+ ⌂ 🔍
ORG-100003912	Austrian Agency for Health and Food Safety	Austria	LOC-100000117	Vienna	Zimmermannngasse 3	1090	ACTIVE	2017-06-09T17:06:48	+ ⌂ 🔍
ORG-100003912	Austrian Agency for Health and Food Safety	Austria	LOC-100000002	Modling	Robert Koch-Gasse 17	2340	ACTIVE	2017-05-25T12:06:59	+ ⌂ 🔍
ORG-100003914	Bulgarian Drug Agency	Bulgaria	LOC-100000007	Sofia	Ul. Damyan Gruiev 8	1303	ACTIVE	2017-05-25T13:33:03	+ ⌂ 🔍
ORG-100003946	Bulgarian Food Safety Agency	Bulgaria	LOC-100000069	Sofia	Pencho Slaveikov Blvd. 15a	1606	ACTIVE	2017-06-08T14:17:10	+ ⌂ 🔍
ORG-100003946	Bulgarian Food Safety Agency	Bulgaria	LOC-100000070	Sofia	Shose Bankya 7	1331	ACTIVE	2017-06-08T14:48:47	+ ⌂ 🔍
ORG-100003946	Bulgarian Food Safety Agency	Bulgaria	LOC-100000108	Sofia	Iskarsko Shose 5	1528	ACTIVE	2017-06-08T14:50:07	+ ⌂ 🔍
ORG-100003918	Danish Medicines Agency	Denmark	LOC-100000011	Copenhagen S	Axel Heides Gade 1	2300	ACTIVE	2017-05-25T14:35:04	+ ⌂ 🔍
ORG-100003913	Federal Agency for Medicines and Health Products	Belgium	LOC-100000006	Brussels	Place Victor Horta 40	1060	ACTIVE	2017-06-22T09:24:30	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000013	Helsinki	Mannerheimintie 103b	00280	ACTIVE	2017-05-25T15:16:02	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000015	FIMEA	P.O. Box 55	00034	ACTIVE	2017-05-25T15:19:45	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000014	Kuopio	Microkatu 1	70210	ACTIVE	2017-05-25T15:06:33	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000016	Turku	Itsenaisydenaukio 2	20800	ACTIVE	2017-05-25T15:15:10	+ ⌂ 🔍
ORG-100003950	French Agency for Food, Environmental and Occupational Health and Safety	France	LOC-100000083	Niort Cedex	B.p. 3081	79012	ACTIVE	2017-06-01T16:50:14	+ ⌂ 🔍

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Showing 20 of 52 results

Request New Organisation **Export Results** Export Results With History

OMS R2.0.8.0 V2.0.10.0 (build 2017/05/17 14:00:22) © 2017 EMA - 30 Churchill Place - Canary Wharf - London E14 5EU - United Kingdom An Agency of the European Union

As for export all organisations, the way to export the data differs between Google Chrome and Internet Explorer:

Figure 30. Export search results – Google Chrome - dowloads folder

100003913	Finnish Medicines Agency	Finland	LOC-100000006	Helsinki	Mannerheimintie 103b	00280	ACTIVE	22T09:24:30	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000013	FIMEA	P.O. Box 55	00034	ACTIVE	2017-05-25T15:16:02	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000015	Kuopio	Microkatu 1	70210	ACTIVE	2017-05-25T15:19:45	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000014	Turku	Itsenaisydenaukio 2	20800	ACTIVE	2017-05-25T15:06:33	+ ⌂ 🔍
ORG-100003920	Finnish Medicines Agency	Finland	LOC-100000016	Turku	Itsenaisydenaukio 2	20800	ACTIVE	2017-05-25T15:15:10	+ ⌂ 🔍
ORG-100003950	French Agency for Food, Environmental and Occupational Health and Safety	France	LOC-100000083	Niort Cedex	B.p. 3081	79012	ACTIVE	2017-06-01T16:50:14	+ ⌂ 🔍

Page 1 of 3

Showing 20 of 52 results

Request New Organisation **Export Results** Export Results With History

locations (4).zip

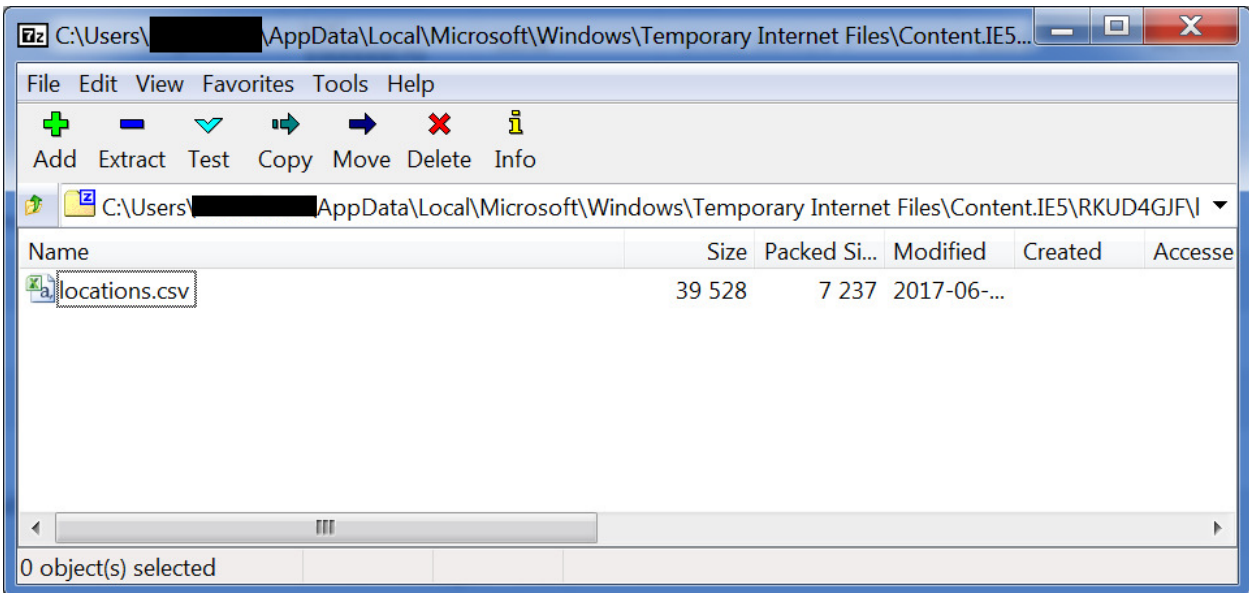
Show all

Figure 31. Export search results – Internet Explorer – pop-up window to open or save



Again, the downloads file appears with the exported file

Figure 32. Open the downloads folder – csv. file



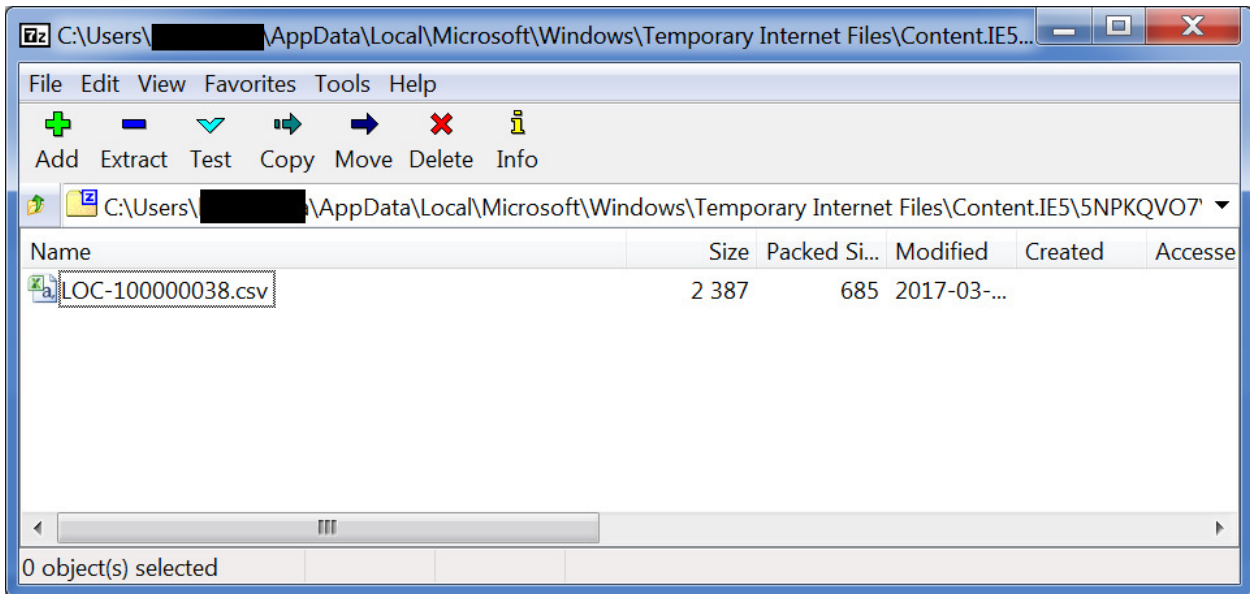
From here on, please proceed as per section 7.1.

7.5. Export organisation details

The web user can export organisation and location details. The details are exported as a csv file. The user has the option of exporting the organisation and location details shown on the screen only or also with all historic versions of the selected organisation and location.

A pop-up window shows for the user to open or save the file, then the following screen appears:

Figure 33. Export organisation and location details - csv file



See section 7.3 to learn about how to view the content of the csv file from an Excel file.

8. Request new organisation, new location or request a change in organisation or location

8.1. Request options based on search result

Before submitting any request to the OMS, the user must search the available records. The option to request new organisation is only made available after a search is performed.

Based on the search results, the following options are available:

- If the user is not able to find the requested organisation – defined by name and country – they can **request creation of a new organisation**
- The request can be accessed directly from the search results page (once “No results found” message is displayed) or from View Organisation/Location Details page

Figure 34. No results found and option to request new organisation

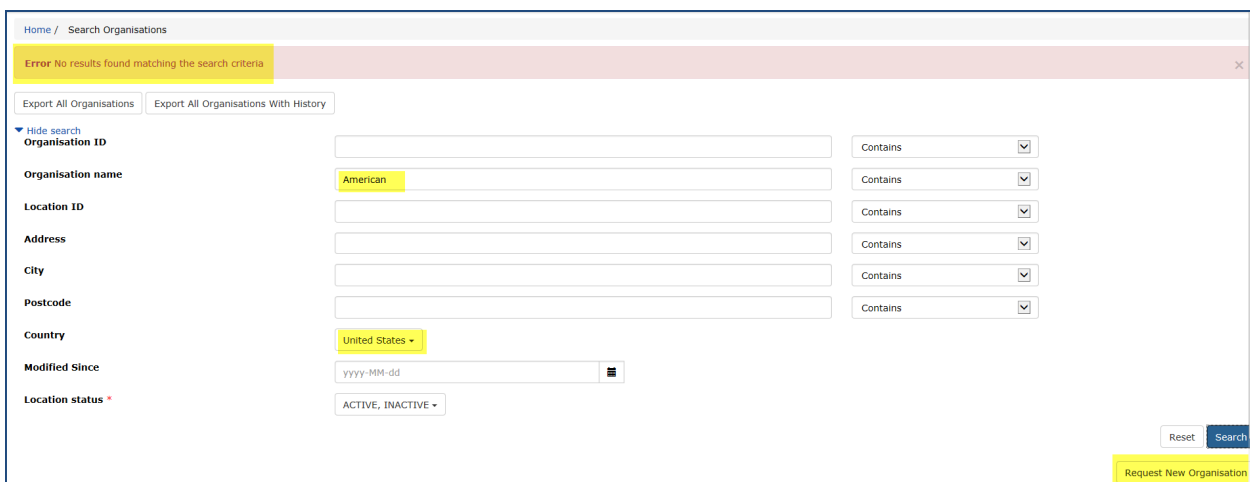
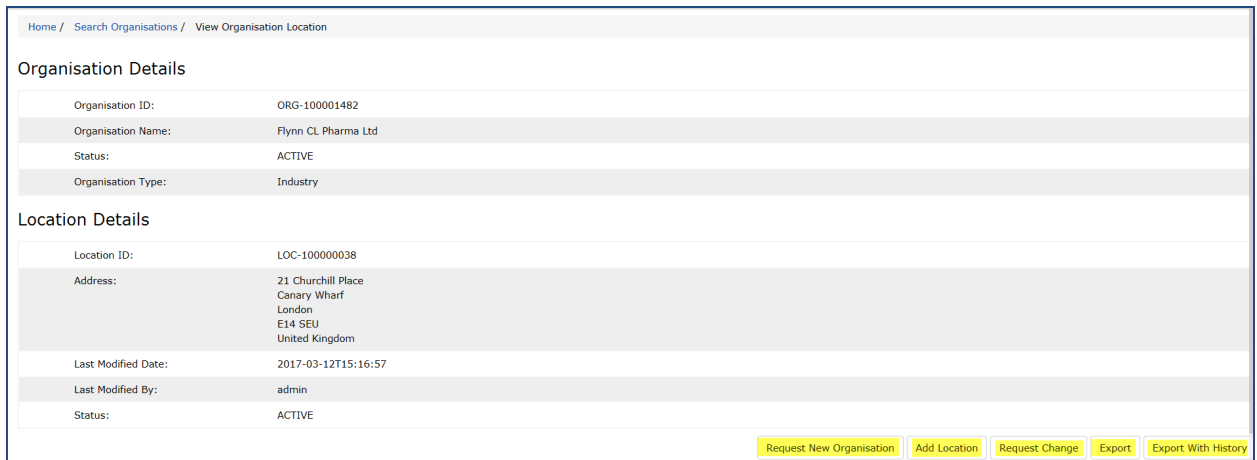


Figure 35. Request new organisation from View Organisation Details

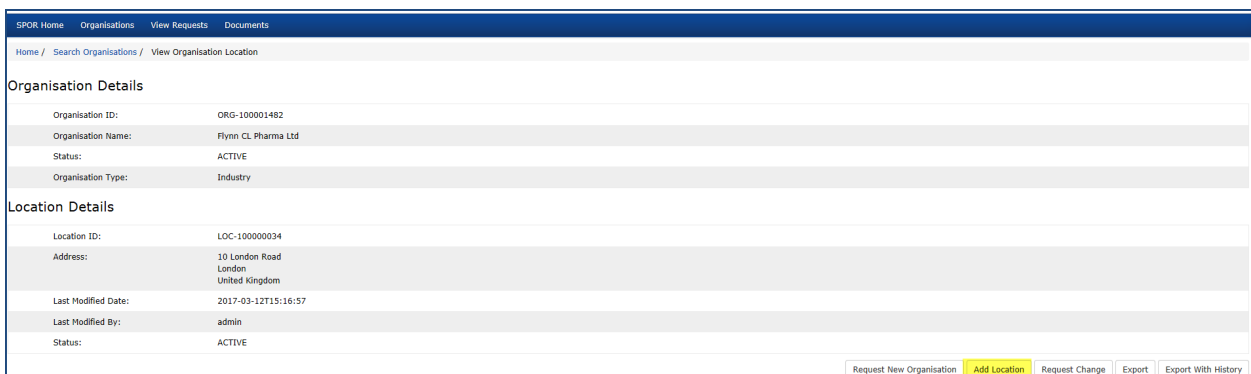


- If the organisation is found, but the required location is not, the requestor needs to submit a request to add a **new location to the existing organisation**
- This can be done from the search results screen or from the organisation/location details screen

Figure 36. Request new location for an existing organisation from the search results screen



Figure 37. Request new location for an existing organisation from the organisation/location details screen



- Alternatively, a user locates an existing organisation and location, but determines that the organisation and/or location need to be changed.

- In this situation the **“request a change”** process would be used to perform the change.
- The request for a change can include changes to
 - Organisation name and acronym
 - Location address (in EN)
 - Location address (in non EN)
 - Telephone and/or email
 - DUNS and/or GS1 numbers
 - Status of Organisation and/or Location i.e. this is for the inactivation of organisation and/or location.
- The change can be requested from the search results screen or from the organisation/location details screen

Figure 38. Request an organisation/location change from the search results screen

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100001482	Flynn CL Pharma Ltd	United Kingdom	LOC-100000034	London	10 London Road		ACTIVE	2017-03-12T15:16:57	+ Q
ORG-100001482	Flynn CL Pharma Ltd	United Kingdom	LOC-100000038	London	21 Churchill Place	E14 SEU	ACTIVE	2017-03-12T15:16:57	+ Q

Figure 39. Request organisation/location change from the organisation/location details screen

Substances		Products		Organisations		Referentials		Help	
SPOR Home - Organisations - View Requests - Documents									
Home / Search Organisations / View Organisation Location									
Organisation Details									
Organisation ID:	ORG-100001482								
Organisation Name:	Flynn CL Pharma Ltd								
Status:	ACTIVE								
Organisation Type:	Industry								
Location Details									
Location ID:	LOC-100000034								
Address:	10 London Road London United Kingdom								
Last Modified Date:	2017-03-12T15:16:57								
Last Modified By:	admin								
Status:	ACTIVE								
Request New Organisation Add Location Request Change Export Export With History									

After selecting an option to request a new organisation or request a change to an existing organisation, a change request form appears (see fig. 43, 48 and 52).

8.2. Change request process – general rules

8.2.1. Contact details

Contact details of the requestor (e.g. name, email address, telephone number) must be provided with all requests. The contact details allow OMS data stewards to contact the requestor in the event of there

being queries relating to the new organisation/location. Only the requestor will be able to see these details after the request is submitted.

Contact details of the requestor will be pre-populated/defaulted as the form is opened. If required, the requestor can overwrite the default contact details, for example if they want a colleague to act as the contact for a particular request.

A user can request creation or update of any organisation or location; not only the one he or she is affiliated to.

8.2.2. Request generation

The requestor needs to fill in all mandatory fields on the request screen. For each of the request options mentioned above, the OMS Web Portal validates that all mandatory data (marked by a red asterisk) has been provided by the user, and issues appropriate error messages if any data is missing. If all mandatory data is present the request is submitted by the OMS Web Portal to the OMS.

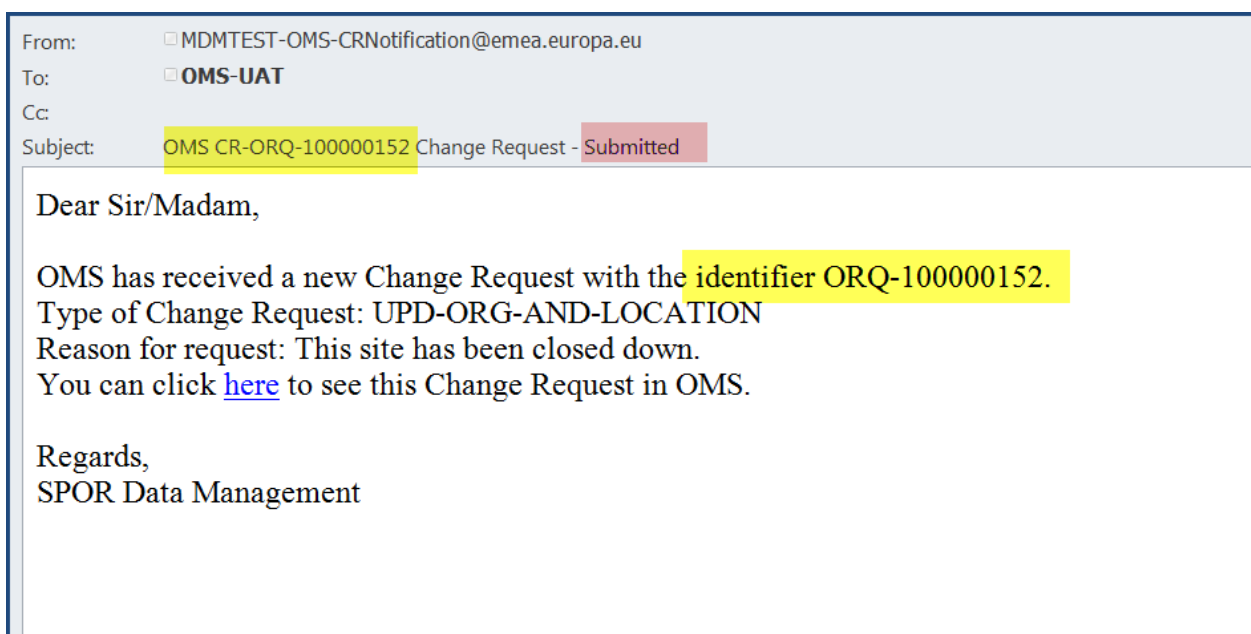
Sufficient evidence needs to be provided to have the request approved. When creating a request, the user is able to upload documents (e.g. Word documents, PDFs) to support it. Requirements for the submission of documentation are explained in 'Change request validation in OMS' in the 'view documents' page.

8.2.3. Request processing

Once the request has been submitted, the system sends an email acknowledgement to the requestor – using the contact details provided with the request – informing them that the request has been successfully received by OMS. The email acknowledgement contains the Request ID (ORQ-xxxxxxx) that has been assigned to the request.

The request receipt contains a link to the OMS page where the requestor can view the progress of the request. The user will need to be logged in to view their own requests.

Figure 40. Sample e-mail confirmation of request receipt with highlighted status and request ID



In case more information is needed to process the request, an e-mail is sent to the requestor, specifying the requirements and a deadline for reply.

When the request is processed by an EMA data steward, an e-mail is automatically sent to the request contact – using the contact information provided with the request - informing them that the request has been approved or rejected. The email includes the Request ID and the approval/rejection comment.

Figure 41. Sample e-mail confirmation of request approval with highlighted status and request ID

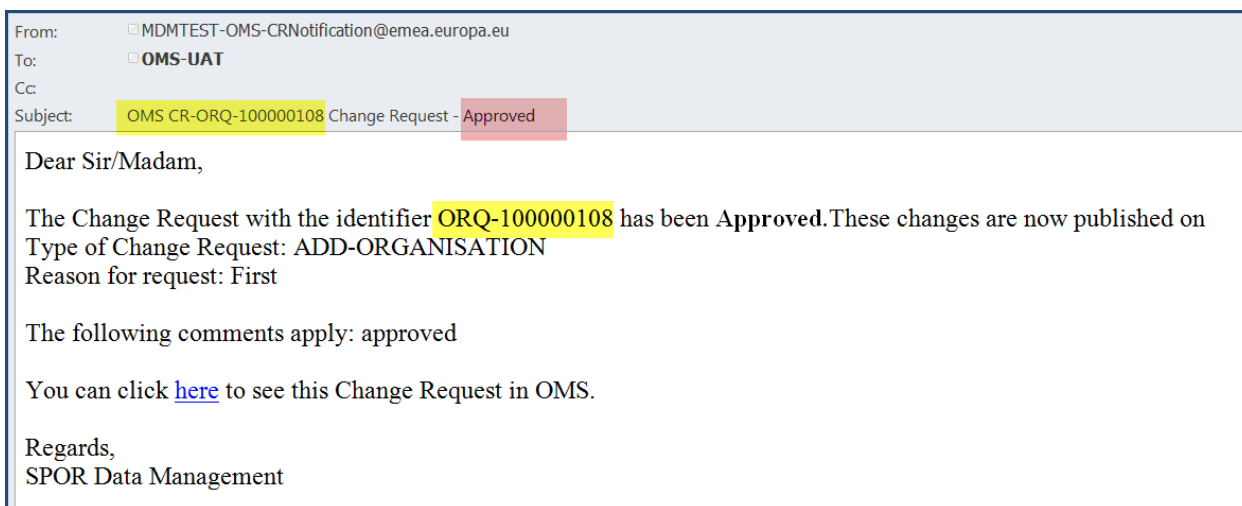
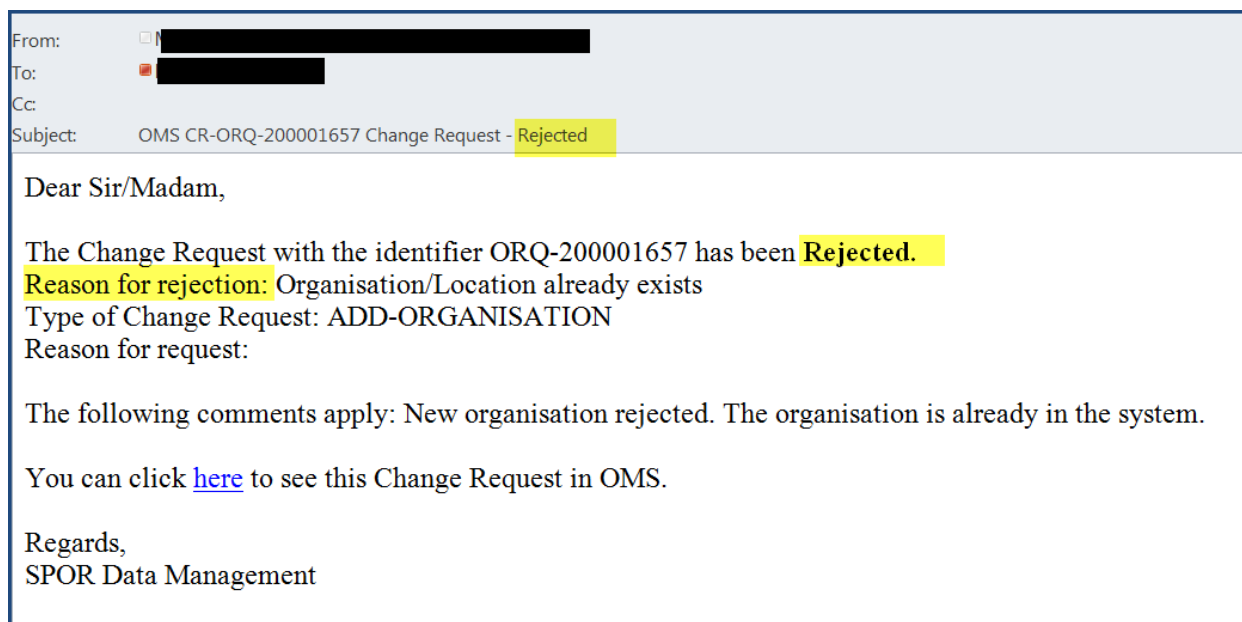


Figure 42. Sample e-mail confirmation of request rejection with highlighted status



The confirmation contains a link where the requestor can view the request process.

8.3. Request new organisation

When raising a request to create a new organisation the requestor is required to provide data for the organisation (e.g. organisation name and organisation type), and the physical location (e.g. address). In addition, other Location related information can be provided such as telephone number, email address, DUNS and/or GS1 numbers.

Only data for a single location can be provided with each request; therefore, if a new organisation requires multiple locations a request must initially be raised to create the organisation and its initial location. Once the new organisation has been approved, additional requests need to be raised to add the additional locations (one request per location).

Figure 43. Request new organisation – screen overview with highlighted areas for change request information, organisation details, location details and attachments

The screenshot shows the 'Request new organisation' form in the SPOR system. The form is divided into sections: CR Information, Organisation Details, and Location Details. The CR Information section includes fields for CR Type (set to 'New Organisation'), Request Reason, Comments, Requestor, Contact email, and Contact Phone. The Organisation Details section includes Organisation Name, Acronym, and Organisation Type. The Location Details section includes Address, City, Postcode, Country, Location Email, Location Phone, DUNS ID, and GS1 ID. A red callout box points to the Requestor, Contact email, and Contact Phone fields, stating: 'Contact details of the requestor will be pre-populated/defaulted from log in but can be overwritten'. The form also features an Attachments section and an Audit trail table.

Figure 44. Request new organisation – form

Home / Search Organisations / New Organisation Request

▼ CR Information
 CR Type: New Organisation
 Request Reason*:
 Comments:
 Requestor:
 Contact email*:
 Contact Phone*:

▼ Organisation Details **for the new proposed organisation**
 Organisation Name*: e.g. European Medicines Agency
 Acronym:
 Organisation Type*: **drop-down list**

▼ Location Details **first location for the new organisation**
 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: e.g. john.doe@ema.europa.eu
 Location Phone: Intl Code: e.g. +44 e.g. 0203660600C Ext:
 DUNS ID: e.g. 01-234-5678
 GS1 ID: e.g. 0-00-12345-67890-5

Business rules:

- Mandatory fields are marked by red asterisk
- The CR type is "New Organisation" and cannot be changed
- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 45. Request reason – new organisation

▼ CR Information
 CR Type: New Organisation
 Request Reason*:
 Create a new organisation - as new legal entity
 Create a new organisation - split from existing organisation
 Comments:
 Requestor:
 Contact email*:
 Contact Phone*:

- Organisation is country specific – i.e. the country of the first location determines the country for all associated locations
- Preferred language is English. Organisation and location details can also be entered in other EEA official¹ languages but the system will supplement the record with English transcription where possible
- The Agency is not responsible for the correctness of information in Greek and Bulgarian which is submitted in Greek and Cyrillic characters. OMS dictionary will store and validate information on Greek and Bulgarian addresses as long as it is in Latin characters (transliterated). Once the addresses in Latin characters are validated, the OMS mastering tool will automatically generate Greek and Cyrillic versions of the address. There is no need to request the creation of these addresses using Greek and Cyrillic characters unless corrections are necessary.
- E-mail addresses must contain "@" and "."
- Organisation type is a drop-down list – the requestor needs to choose what is most appropriate from the options available. Please note that it covers the address when expanded; it collapses after a choice is made

Figure 46. Organisation type drop-down list

The screenshot shows a web form with two main sections: 'Organisation Details' and 'Location Details'. Under 'Organisation Details', there are three fields: 'Organisation Name*' (with a placeholder 'e.g. European Medicines Agency'), 'Acronym', and 'Organisation Type*'. The 'Organisation Type*' field is expanded, showing a list of options: 'Educational Institution', 'Health care', 'Industry', 'Not-for-profit', and 'Regulatory Authority'. The 'Location Details' section below it has an 'Address*' field.

- Contact phone numbers needs to contain the country code
- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance
- Once submitted, the request cannot be edited or resubmitted

Attachments:

- To support a change request, documents must be submitted to allow the EMA data stewards to validate the request
- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *fig. 45*) by clicking on "+" symbol

Figure 47. Attachments

¹ European Economic Area

Attachments		
No documents found, click to add +		
Audit trail		
Date ▲	Status to ▲▼	Comment ▲▼
No data available in table		

8.4. Request new location to an existing organisation

New location can be added to an existing organisation by this process. The requestor is required to provide data for the new physical location (i.e. address, phone/e-mail, DUNS/GS1 numbers).

Only data for a single location can be provided with each request; therefore, if a new organisation requires multiple locations a request must initially be raised to create the organisation and its initial location. Once the new organisation has been approved additional requests need to be raised to add the additional locations (one request per location).

Figure 48. Add new location to an existing organisation – screen overview with highlighted areas for change request information, organisation details, location details and attachments

Figure 49. Request new location for an existing organisation – form

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

CR Information
CR Type Add Location
Request Reason*
Comments
Requestor
Contact email*
Contact Phone*

Organisation Details not editable
Organisation ID ORG-100001482
Organisation Name Flynn CL Pharma Ltd
Acronym
Organisation Type Industry

Location Details
Address*

City
Postcode
County
Country* United Kingdom not editable
Location Email
Location Phone **Intl Code:** **Ext:**
DUNS ID
GSI ID

If the addition of the location is as a consequence of that (physical) location being taken over by the selected organisation, select the request reason “create a new organisation – split from existing organisation’. In the comments/supporting documentation, identify from which organisation (with OMS Organisation ID) the mentioned location needs to be moved under the selected organisation in the change request.

Business rules:

- Mandatory fields are marked by red asterisk
- The CR type is “add location” and cannot be changed
- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 50. Request reason – add new location

The screenshot shows a web form titled 'CR Information'. The 'Request Reason*' field is highlighted in yellow. A dropdown menu is open, showing three options: 'Add a physical location - as new legal entity', 'Add a physical location - move from one physical location to another', and 'Add a physical location - following a merger/take over'. The first option is highlighted in blue. Other fields in the form include 'CR Type' (set to 'Add Location'), 'Comments', 'Requestor', 'Contact email*', and 'Contact Phone*'.

- Organisation type is entered on the organisation level and is the same for all locations – therefore, the field is not editable
- Organisation is country specific – i.e. the country of the organisation determines the country for all associated locations. Therefore, the country is not editable
- If the requested location is not in the same country as the first location, please request creation of a new organisation
- Preferred language is English. Organisation and location details can also be submitted in other EEA official languages but the system will supplement the record with English translation/transcription where possible
- The Agency is not responsible for the correctness of information in Greek and Bulgarian which is submitted in Greek and Cyrillic characters. OMS dictionary will store and validate information on Greek and Bulgarian addresses as long as it is in Latin characters (transliterated). Once the addresses in Latin characters are validated, the OMS mastering tool will automatically generate Greek and Cyrillic versions of the address. There is no need to request the creation of these addresses using Greek and Cyrillic characters unless corrections are necessary.
- E-mail addresses must contain "@" and "."
- Contact phone numbers need to contain the country code
- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance
- Once submitted, the request cannot be edited

Attachments:

- To support a new organisation request, documents can be submitted to confirm the organisation existence and the details
- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *fig. 49*) by clicking on "+" symbol

Figure 51. Attachments

Attachments		
No documents found, click to add +		
Audit trail		
Date ▲	Status to ▲▼	Comment ▲▼
No data available in table		

8.5. Update organisation or location

The user can request an update to organisation or location details.

If there is a pending change for the organisation but not the location in the system, then the details of the organisation are read only and an explanatory message is displayed; e.g. "you can only request a change to the location details as there is already a change pending for the organisation".

If there is a pending change for the location in the system, then all the location details are read only and an explanatory message is displayed; e.g. "you cannot request a change currently as there is already a change pending".

Figure 52. Update organisation or location - screen overview with highlighted areas for change request information, organisation details, location details and attachments

Figure 53. Update organisation and/or location – form

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

▼ CR Information

CR Type Update Organisation and Location

Request Reason*

Comments

Requestor

Contact email*

Contact Phone*

▼ Organisation Details

Organisation ID ORG-100001482

Organisation Name* Flynn CL Pharma Ltd

Acronym

Organisation Type* Industry **not editable**

▼ Location Details

Location ID LOC-100000034

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

Address* 10 London Road
e.g. Canary Wharf

City London

Postcode e.g. E14 5EU

County e.g. London **not editable**

Country* United Kingdom

Location Email e.g. john.doe@ema.europa.eu

Location Phone **Intl Code:** e.g. +44 e.g. 02036606000 **Ext:**

DUNS ID e.g. 01-234-5678

GS1 ID e.g. 0-00-12345-67890-5

Business rules:

- Mandatory fields are marked by red asterisk
- The default CR type is “update organisation and location”. If the user edits only the organisation data, the system will automatically change the CR type to ‘update organisation’. If the user changes only location data, then the CR type will change to ‘update location’. If the user updates both, then the CR type will remain as the default value.
- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 54. Request reason – update organisation and location

The screenshot shows a web form with a sidebar on the left containing fields: CR Type, Request Reason*, Comments, Requestor, Contact email*, and Contact Phone*. The 'Request Reason*' field is highlighted in yellow and has a dropdown menu open. The dropdown menu is currently set to 'Update Organisation and Location' and lists the following options:

- Update of organisation name - only name change
- Update of organisation name - following a merger/take over
- Update to physical location data - Administrative data change
- Deactivate organisation
- Deactivate location

- Preferred language is English. Organisation and location details can also be entered in other EEA official languages but the system will supplement the record with English transcription where possible
- Organisation type is recorded upon the first organisation data entry and is the same for all locations – therefore, the field is not editable
- Organisation is country specific – i.e. the country of the organisation determines the country for all associated locations. Therefore, the country is not editable
- E-mail addresses must contain "@" and "."
- Contact phone numbers need to contain the country code
- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance
- Once submitted, the request cannot be changed

Attachments:

- To support a new organisation request, documents can be submitted to confirm the organisation existence and the details
- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *Fig. 53*) by clicking on "+" symbol

Figure 55. Attachments

The screenshot shows the 'Attachments' section of a form. At the top, it says 'Attachments' and 'No documents found, click to add +' with a plus sign icon. Below this is an 'Audit trail' table with columns for 'Date', 'Status to', and 'Comment'. The table is currently empty, displaying 'No data available in table'.

9. View requests

- Once submitted, the requests cannot be edited, only viewed.

- Requests can be viewed either from the OMS landing page or from any other screen as the top bar always remains the same
 - Only the user who sends the request can view that request
- ☞ **Please note that the requested data is displayed in this view, not the data which is published in the OMS as a result of the request.**

Figure 56. View requests – from the OMS landing page

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations

SPOR Home Organisations **View Requests** 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.

The user can see a list of their active and historic requests and optionally also the details of each request, after clicking on the magnifying glass or on the address link

- The request status is displayed – submitted, approved, approved with change, rejected, on hold (i.e. information requested from the user)
- CR type – ADD-ORGANISATION, ADD-LOCATION, UPD-ORGANISATION, UPD-LOCATION, UPD-ORGANISATION-LOCATION
- The columns can be sorted
- Default sort order is the change request date
- The user can choose 20, 50 or 100 results
- The maximum number the user can see is the first 500 requests

Figure 57. View requests (no edit mode) and sorting by CR date

CR ID	CR Type	Requestor	CR Date	Organisation Name	Address	Status	Status Date	Actions
ORQ-200001656	UPD-ORG-AND-LOCATION	ema_a	2017-06-28T13:09:00	SPIRIG EASTERN	Bratislava, Bratislava	SUBMITTED	2017-06-28T13:09:00	Q
ORQ-200001655	UPD-LOCATION	ema_a	2017-06-28T13:06:54	ALIUD Pharma GmbH	Stadastrase 2-18, Bad Vilbel	SUBMITTED	2017-06-28T13:06:54	Q
ORQ-200001654	ADD-ORGANISATION	ema_a	2017-06-28T12:51:38	BIOVETA, a. s.	Komenského 212, Ivanovice na Hané	APPROVED	2017-06-28T12:58:31	Q
ORQ-200001653	ADD-ORGANISATION	ema_a	2017-06-28T12:49:26	ALIUD Pharma GmbH	Stadastrasse 2-18, Bad Vilbel	APPROVED	2017-06-28T12:56:17	Q
ORQ-200001381	ADD-ORGANISATION	ema_a	2017-05-09T11:36:18	EMA	30 churchill road, London	SUBMITTED	2017-05-09T11:36:18	Q
ORQ-200001346	ADD-LOCATION	ema_a	2017-05-04T12:44:49	PS Pharma A04	1 reyanards coppice, london	APPROVED_WC	2017-05-16T10:18:40	Q

There can be more than 1 page of results.

Figure 58. Number of results and pagination of results

Substances	Products	Organisations	Referentials	Help
SPOR Home	Organisations	View Requests	Documents	

Examples of requests expanded for viewing:

Figure 59. Overview of the request page – includes request status

Substances	Products	Organisations	Referentials	Help
SPOR Home	Organisations	View Requests	Documents	

CR Information		Attachments	
CR Type	Update Location	Audit trail	
Request Reason	Update to physical location data - Administrative data change	Date ▲	Status to ▾
Comments		2017-06-28T13:06:54Z	SUBMITTED
Requestor	ema_a	2017-06-28T13:16:10Z	APPROVED
Contact email	[REDACTED]		e-mail added as requested
Contact Phone	[REDACTED]		
Organisation Details			
Organisation ID	ORG-100034194		
Organisation Name	ALIUD Pharma GmbH		
Acronym			
Organisation Type			
Location Details			
Location ID	LOC-200000861		
Address	Stadastrase 2-18 Dortelweil		
City	Bad Vilbel		
Postcode	61118		

Figure 60. View request details – new organisation

SPOR Home	Organisations	View Requests	Documents
Home / View Requests / View Request			
▼ CR Information			
CR Type	New Organisation		
Request Reason	Create a new organisation - as new legal entity		
Comments			
Requestor	ema_a		
Contact email	[REDACTED]		
Contact Phone	[REDACTED]		
▼ Organisation Details			
Organisation Name	BIOVETA, a. s.		
Acronym			
Organisation Type			
▼ Location Details			
Address	Komenského 212		
City	Ivanovice na Hané		
Postcode	683 23		
County			
Country	Czech Republic		
Location Email			
Location Phone	Intl Code:		

Figure 61. View request details – update location

SPOR Home Organisations **View Requests** Documents

Home / View Requests / View Request

▼ CR Information

CR Type	Update Location
Request Reason	Update to physical location data - Administrative data change
Comments	
Requestor	[REDACTED]
Contact email	[REDACTED]
Contact Phone	[REDACTED]

▼ Organisation Details

Organisation ID	ORG-100034194
Organisation Name	ALIUD Pharma GmbH
Acronym	[REDACTED]
Organisation Type	[REDACTED]

▼ Location Details

Location ID	LOC-200000861
Address	Stadastrase 2-18 Dortelweil
City	Bad Vilbel
Postcode	61118
County	[REDACTED]
Country	Germany

Figure 62. View request details – request rejected

SPOR Home	Organisations	View Requests	Documents
Home / View Requests / View Request			
▼ CR Information			
CR Type	New Organisation		
Request Reason	Create a new organisation - as new legal entity		
Rejection Reason	New organisation rejected. The organisation is already in the system.		
Comments			
Requestor	[REDACTED]		
Contact email	[REDACTED]		
Contact Phone	[REDACTED]		
▼ Organisation Details			
Organisation Name	ALIUD Pharma GmbH		
Acronym			
Organisation Type			
▼ Location Details			
Address	Stadastrase 2-18		
City	Bad Vilbel		
Postcode	61118		
County			
Country	Germany		
Location Email			

In addition, the user will be able to export the request data in csv format. This is for individual requests as well as the request list.

Figure 63. Exporting requests

SPOR Home Organisations View Requests Documents

Home / View Requests

Showing 20 of 8 results

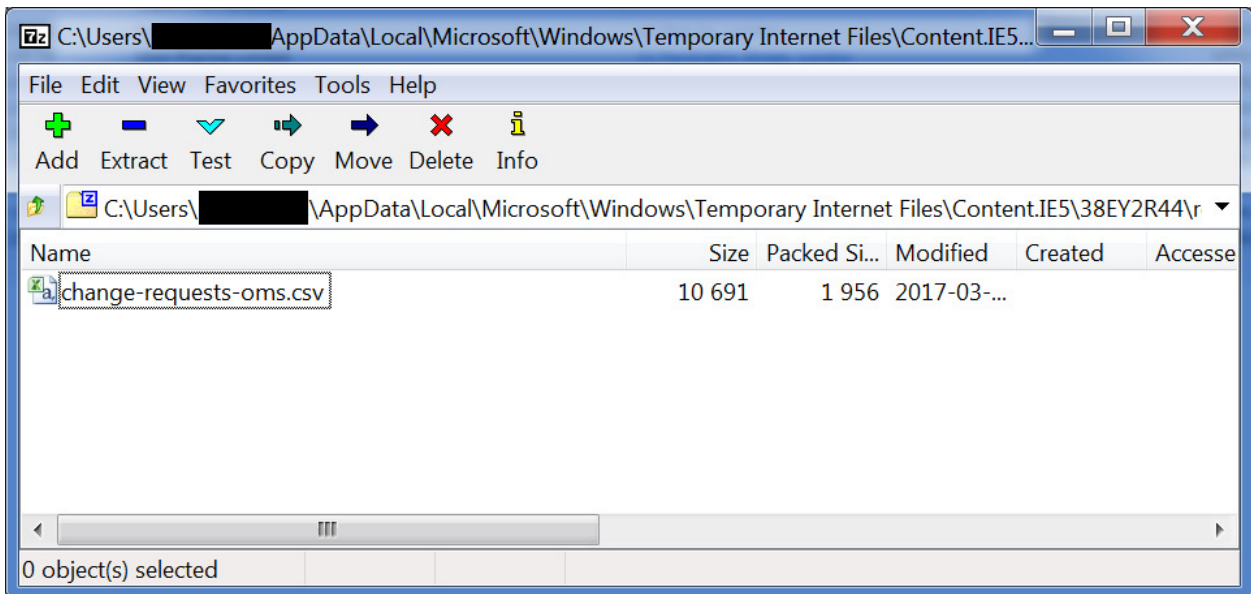
CR ID	CR Type	Requestor	CR Date	Organisation Name	Address	Status	Status Date	Actions
ORQ-200001657	ADD-ORGANISATION	ema_a	2017-06-28T13:25:38	ALIUD Pharma GmbH	Stadastrase 2-18, Bad Vilbel	REJECTED	2017-06-28T13:41:39	Q
ORQ-200001656	UPD-ORG-AND-LOCATION	ema_a	2017-06-28T13:09:00	SPIRIG EASTERN	Bratislava, Bratislava	APPROVED_WC	2017-06-28T13:11:12	Q
ORQ-200001655	UPD-LOCATION	ema_a	2017-06-28T13:06:54	ALIUD Pharma GmbH	Stadastrase 2-18, Bad Vilbel	APPROVED	2017-06-28T13:16:10	Q
ORQ-200001654	ADD-ORGANISATION	ema_a	2017-06-28T12:51:38	BIOVETA, a. s.	Komenského 212, Ivanovice na Hané	APPROVED	2017-06-28T12:58:31	Q
ORQ-200001653	ADD-ORGANISATION	ema_a	2017-06-28T12:49:26	ALIUD Pharma GmbH	Stadastrase 2-18, Bad Vilbel	APPROVED	2017-06-28T12:56:17	Q
ORQ-200001381	ADD-ORGANISATION	ema_a	2017-05-09T11:36:18	EMA	30 churchill road, London	SUBMITTED	2017-05-09T11:36:18	Q
ORQ-200001346	ADD-LOCATION	ema_a	2017-05-04T12:44:49	PS Pharma A04	1 reyanards coppice, london	APPROVED_WC	2017-05-16T10:18:40	Q
ORQ-200001338	ADD-LOCATION	ema_a	2017-05-04T09:44:15	PS Pharma A02 ΚΑΛΩΝΗ ΘΟΩΩ Update Org BL7	1 reynards coppice, telford	SUBMITTED	2017-05-04T09:44:15	Q

Showing 20 of 8 results

Export List

A pop-up window shows for the user to open or save the file, then the following screen appears:

Figure 64. Exporting change requests



See section 7.3 to learn how to view the content of the csv file from an Excel file.

10. Technical support for OMS

Technical support for the OMS is provided by the EMA Service Desk that also authorises OMS super user access.

IT Service Desk link:

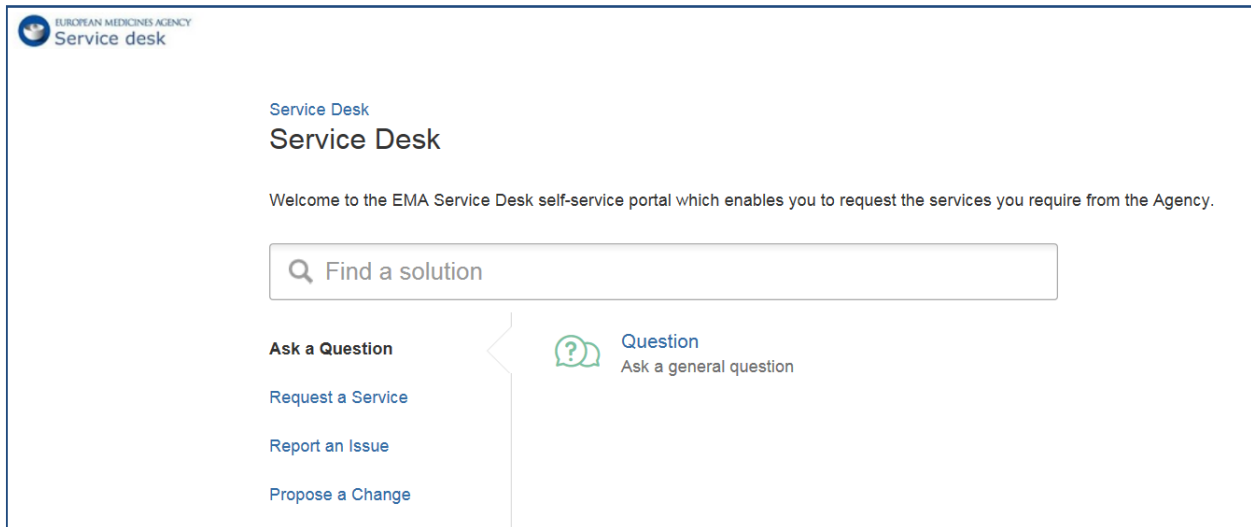
<https://servicedesk.ema.europa.eu>

In order to request support, the user should log in with their EMA log in and password.

The technical support can be requested in the following categories

- For general or business-related questions on SPOR, click on “Ask a Question” link in the screen below
- For any technical/software-related issues, click on “Report an Issue” (as shown in the screen below) and on “Report an issue with business applications/software” in the next screen
- To request SPOR Super User access, click on “Request a Service” and follow the instructions provided in the document “SPOR user registration manual.”

Figure 65. IT Service Desk interface



11. Reference documents - tbc

SPOR

OMS

IAM (IIQ)

Tbc