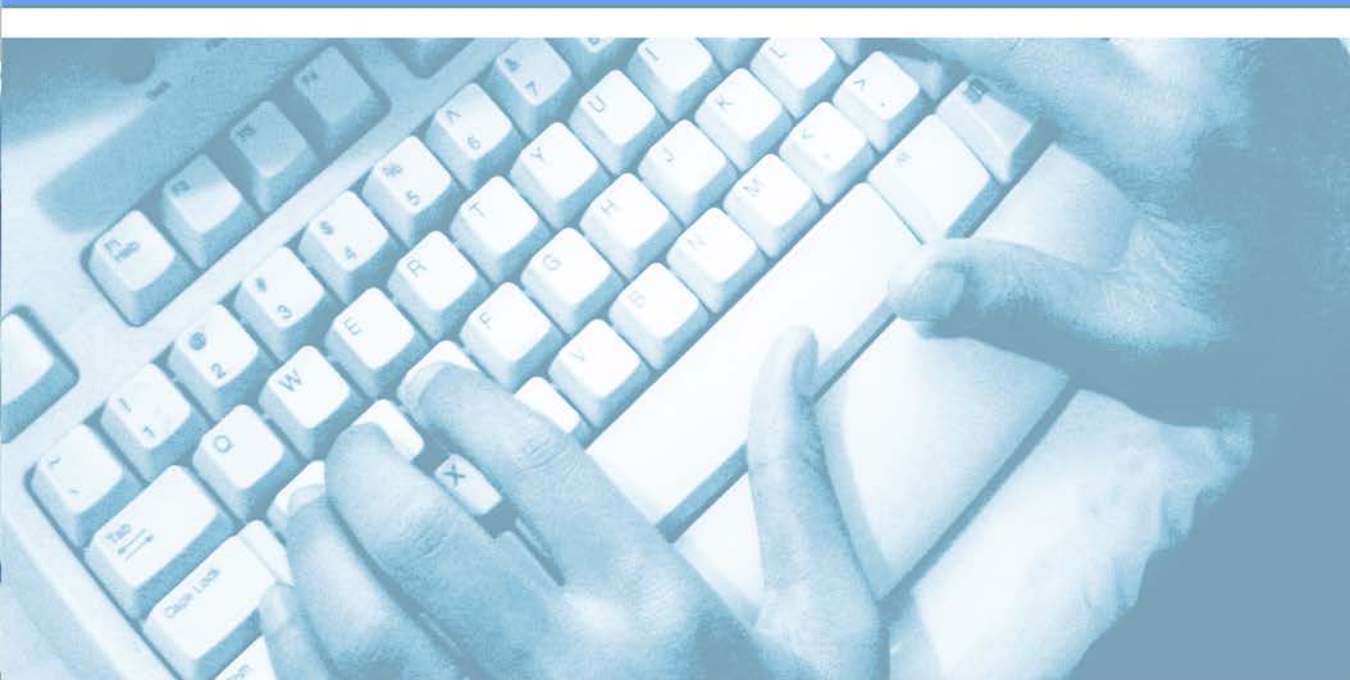




GUÍA DE AYUDA AL SOLICITANTE PARA LA CREACIÓN / GESTIÓN DE USUARIOS Y SUPERUSUARIOS (PROGRAMA SPOR)

Versión 1.0

**Agencia Española de Medicamentos
y Productos Sanitarios**



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1. INTRODUCCIÓN

Organizations Management Services (OMS) es un nuevo servicio que EMA está implementando para la red regulatoria de medicamentos de la UE. OMS proporcionará una fuente central de datos de organización (diccionario OMS) que consiste en listas de organizaciones, con ubicaciones físicas asociadas, que se utilizarán en apoyo de las actividades regulatorias en la UE.

eAF es el primer proceso que incluye la integración con el diccionario OMS.

- En OMS no se diferencia entre organización creada en el ámbito de medicamentos de uso humano o veterinarios.
- Una empresa/organización puede tener diferentes organizaciones subsidiarias, cada una con su propio ID de organización.
- Las estructuras y jerarquías de la compañía no están definidas en OMS (Titular de la autorización de comercialización -TAC, Representante Local, Fabricante...). En teoría una organización puede actuar como TAC en el contexto de un medicamento, y como fabricante o representante en otro distinto.
- La población de Usuarios y Superusuarios de la industria en SPOR para una organización se ve impulsada por varios factores:
 - Necesidades del negocio
 - Procesos y políticas con respecto a la concesión de acceso
 - Overall número de productos
 - Algunas empresas pueden subcontratar asuntos regulatorios a proveedores de servicios externos
- Cada organización debe decidir sobre el número de roles SPOR que tienen acceso a SPOR en su nombre
- Se puede acceder a los datos de OMS directamente a través del portal web OMS

Cualquiera puede acceder al portal SPOR y ver / buscar datos de OMS

Los usuarios podrán buscar organizaciones, ubicaciones, y ver detalles de organizaciones y ubicaciones.

La búsqueda es un punto de partida para que el usuario solicite cambios en los datos de la organización.

- Las siguientes opciones están disponibles:

Si el usuario no puede encontrar la organización solicitada, definida por nombre en un país determinado, puede solicitar la creación de una nueva organización;

Si se encuentra la organización, pero no se encuentra la ubicación requerida, el solicitante debe enviar una solicitud para agregar una nueva ubicación a la organización existente;

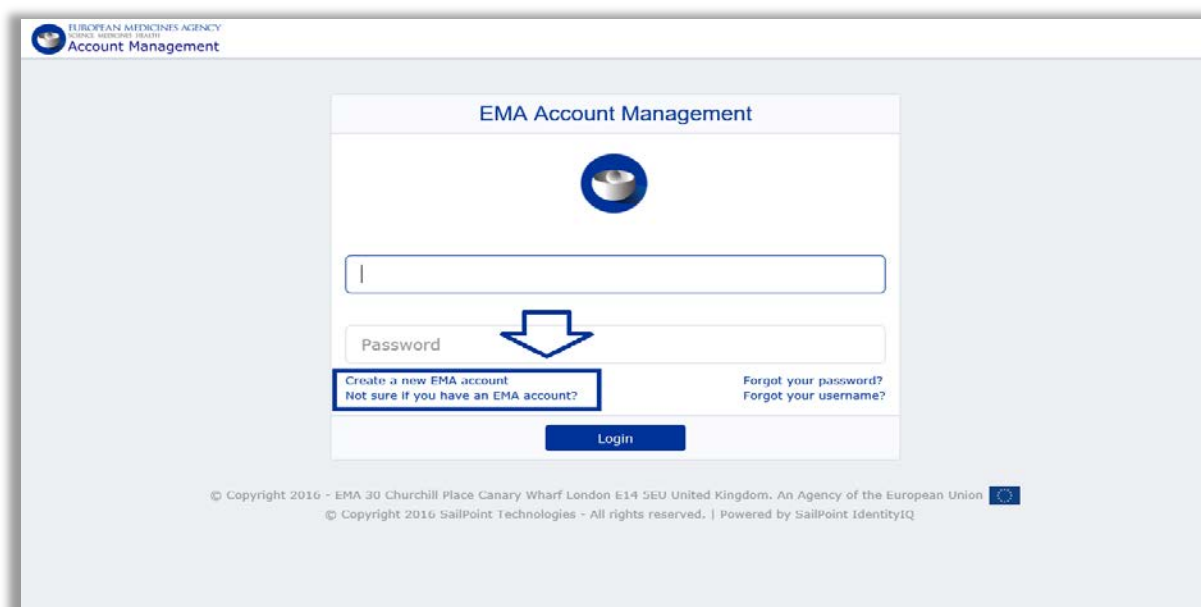
Si se encuentra algún error, o hubiera cambiado la denominación o dirección de organización y/o localización, el solicitante debe enviar una solicitud para corregir la información errónea.

2. SOLICITAR ROL SUPERUSUARIO

2.1 Alta en EMA Account Portal

Los nuevos usuarios deberán registrarse como Nuevo Usuario “Create a New EMA Account” en el portal de la EMA “[EMA Account Manager Portal](#)”, a no ser que dispusieran anteriormente de acceso a cualquiera de los servicios web gestionados por la EMA:

Eudralink, EudraCT Secure, Service Desk Portal, European Union Telematics Controlled Terms (EUTCT), Meeting Management System (MMSe), Managing Meeting Document System (MMD), EudraVigilance Data Analysis System (EVDAS), EudraPORTAL, European Union Good Manufacturing and Distribution Practices Database (EUDRAGMDP), Paediatrics Records Application (PedRA), SIAMED Business Intelligence Dashboard (BI DASHBOARD), Corporate GxP Database (CORPGXP), European Pharmacovigilance Issues Tracking Tool (EPITT) or Periodic Safety Update Repository (PSUR Repository).



The screenshot displays the 'EMA Account Management' portal. At the top left is the 'EUROPEAN MEDICINES AGENCY' logo with the tagline 'WORKING FOR YOUR HEALTH'. The main heading is 'EMA Account Management'. Below this is a large blue circular icon containing a white medical mortar and pestle. There are two input fields: a top one for a username and a bottom one labeled 'Password'. A blue arrow points from the password field to a box containing the text 'Create a new EMA account' and 'Not sure if you have an EMA account?'. To the right of this box are links for 'Forgot your password?' and 'Forgot your username?'. A blue 'Login' button is positioned below the account creation box. At the bottom of the page, there is copyright information: '© Copyright 2016 - EMA 30 Churchill Place Canary Wharf London E14 5EU United Kingdom. An Agency of the European Union' and '© Copyright 2016 SailPoint Technologies - All rights reserved. | Powered by SailPoint IdentityIQ', accompanied by the European Union flag.

EMA - Self-service Registration Form

Submit the following form to register.

First Name *

This is used to create your username and to address you in email correspondence.

Last Name *

This is used to create your username and to address you in email correspondence.

Email *

We require a valid/active email address to create an EMA Account.

Password *

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

Confirm Password *

Mobile (optional)

This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.

Data Protection Statement

Policy

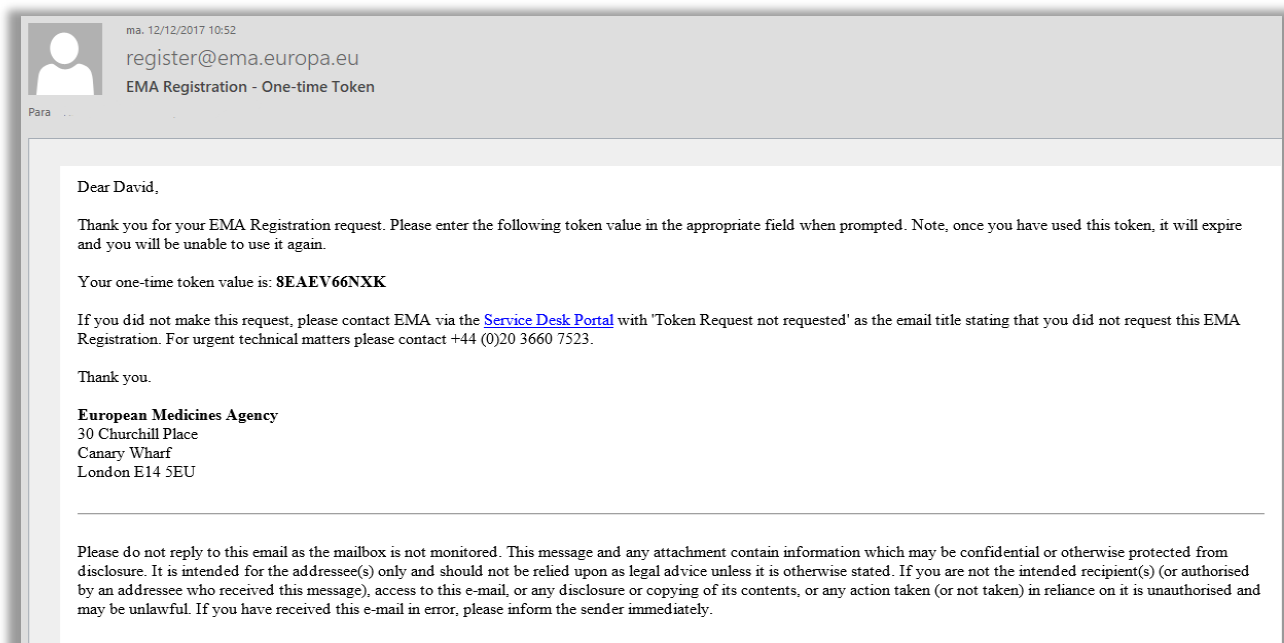
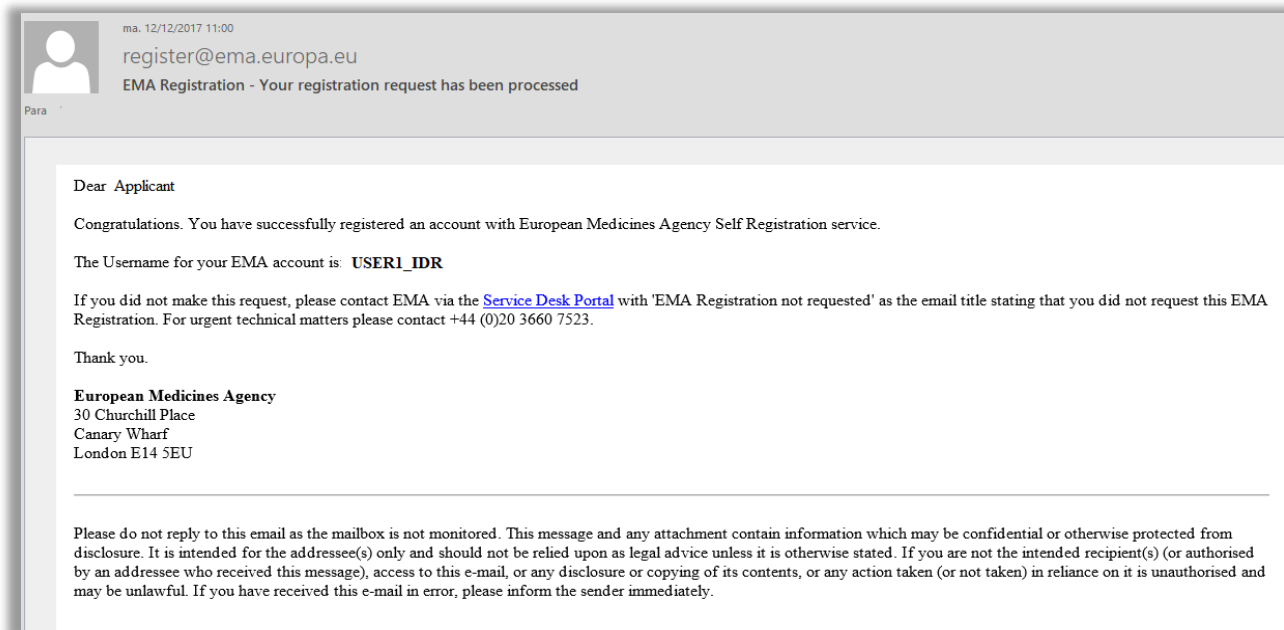
DATA PROTECTION STATEMENT

Your personal data are processed in accordance with Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. To find out more about your rights and about how the EMA processes personal data, please check the Privacy Statement on EMA's website.

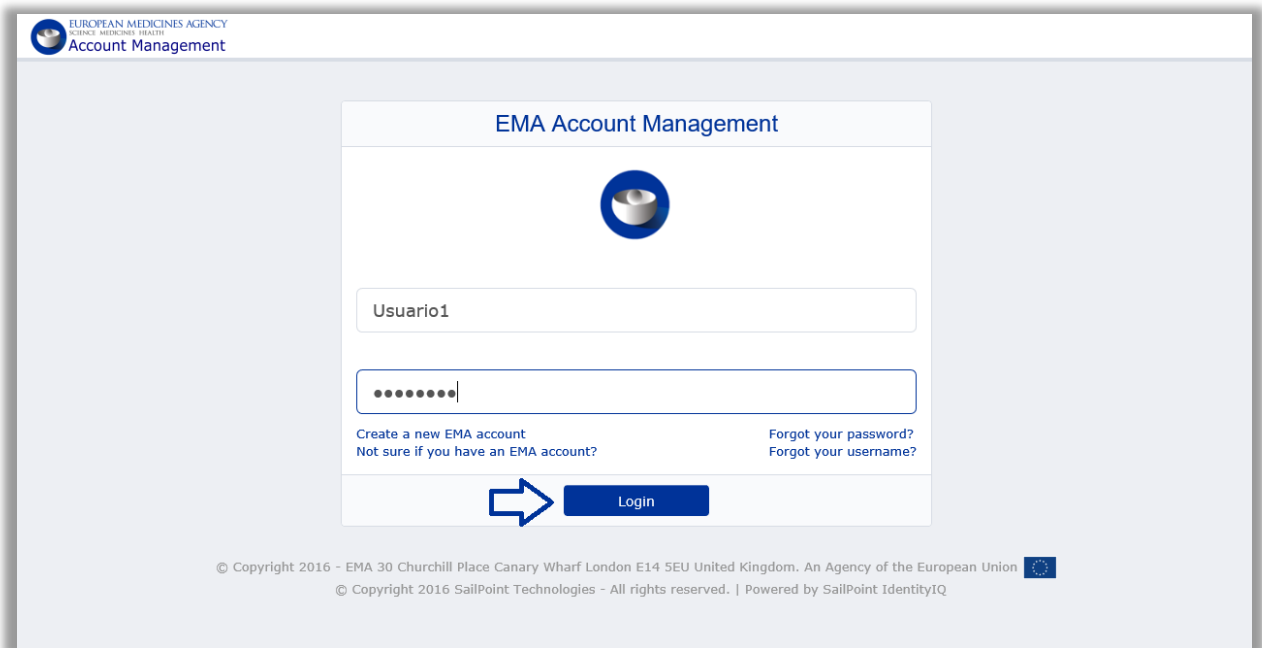
The information we collect is used to manage direct access to EMA's systems and to verify users' accounts. We will collect and use personal data such as your e-mail address and phone number (if provided), to communicate any next steps or key changes to the system. Your data will be deleted after 180 days of inactivity on our systems.

Should you wish to learn more about the way your personal data are being processed please contact AskEMA at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0

- Tras completar y enviar el correspondiente formulario electrónico de la solicitud, recibiremos un correo con las credenciales de acceso.



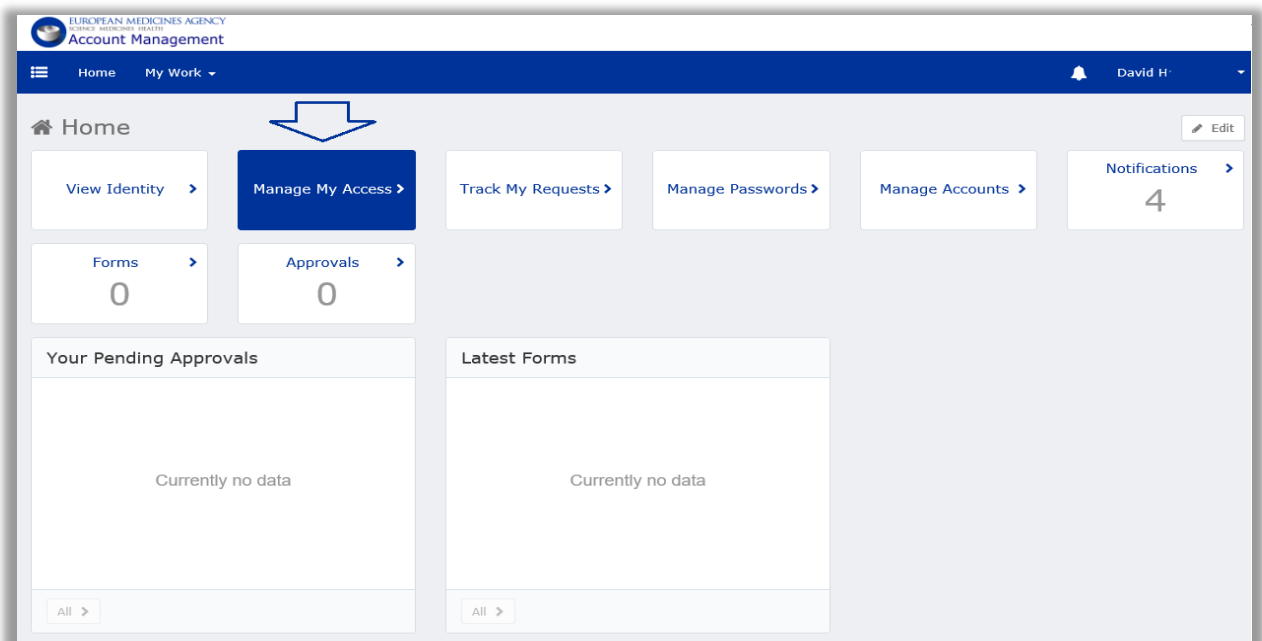
o Nos acreditamos con las credenciales facilitadas:



The image shows the EMA Account Management login interface. At the top, it says 'EUROPEAN MEDICINES AGENCY' and 'Account Management'. The main heading is 'EMA Account Management'. Below this is a circular profile icon. There are two input fields: the first is labeled 'Usuario1' and the second contains masked characters '.....'. Below the password field, there are links for 'Create a new EMA account', 'Not sure if you have an EMA account?', 'Forgot your password?', and 'Forgot your username?'. A large blue arrow points to a 'Login' button. At the bottom, there is copyright information: '© Copyright 2016 - EMA 30 Churchill Place Canary Wharf London E14 5EU United Kingdom. An Agency of the European Union' and '© Copyright 2016 SailPoint Technologies - All rights reserved. | Powered by SailPoint IdentityIQ'.

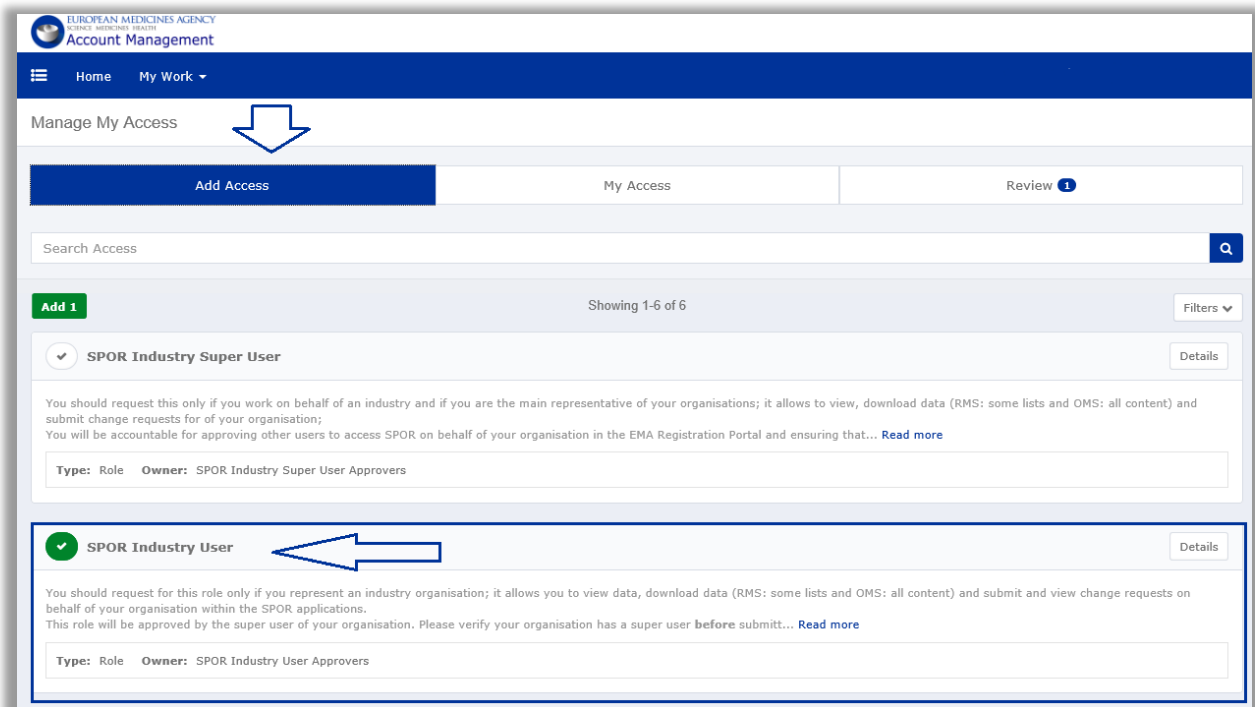
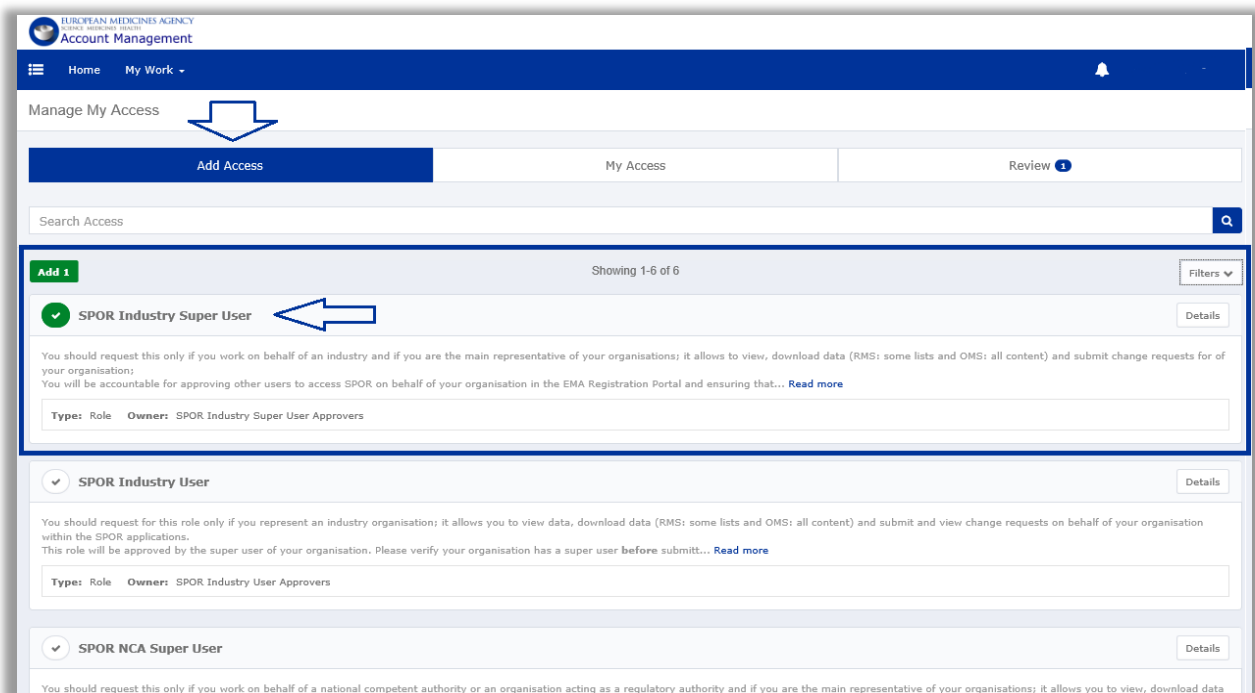
2.2 Solicitar rol de Usuario/ Superusuario

o Desde “Manage My Access” accederemos a la gestión de nuestros roles:



The image shows the EMA Account Management dashboard. At the top, it says 'EUROPEAN MEDICINES AGENCY' and 'Account Management'. The dashboard has a navigation bar with 'Home' and 'My Work'. A blue arrow points to the 'Manage My Access' button in the top navigation bar. Below this, there are several tiles: 'View Identity', 'Manage My Access', 'Track My Requests', 'Manage Passwords', 'Manage Accounts', 'Forms' (with a count of 0), and 'Approvals' (with a count of 0). There is also a 'Notifications' tile with a count of 4. Below these tiles, there are two sections: 'Your Pending Approvals' and 'Latest Forms', both showing 'Currently no data'. At the bottom of each section, there is an 'All' link.

o Seleccionaremos el rol a solicitar (Superusuario o Usuario) y pinchamos en “Add Access”:

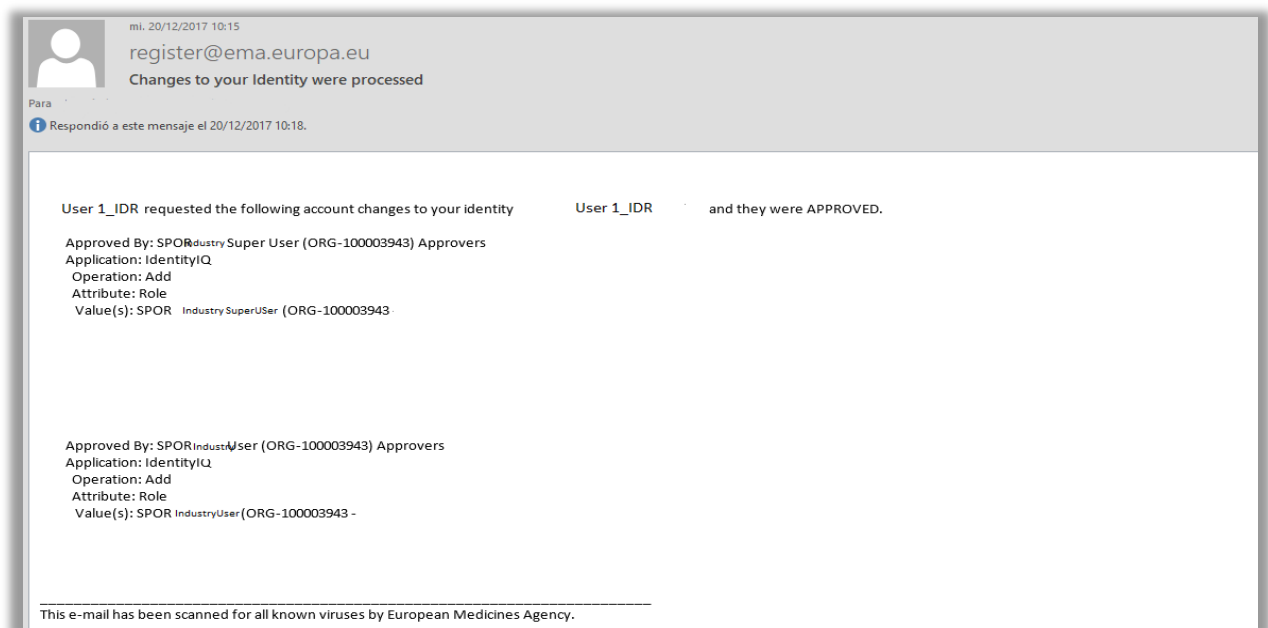


o Desde la pestaña “Review”, veremos las solicitudes de roles seleccionadas, y podremos enviarlas:

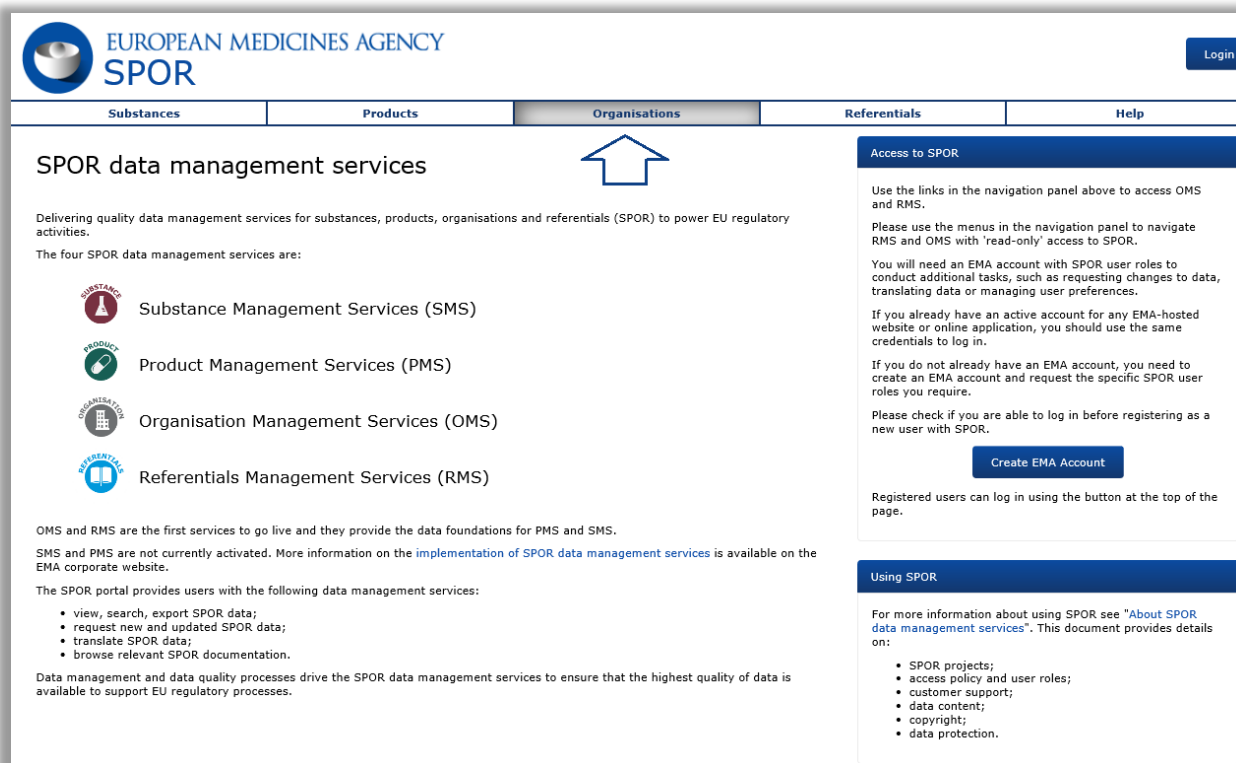
The screenshot shows the 'Manage My Access' page with three tabs: 'Add Access', 'My Access', and 'Review'. The 'Add Access' tab is active, showing a form for 'SPOR Industry Super User'. The form includes a description of the role and a 'Type: Role' field with 'Owner: SPOR Industry Super User Approvers'. A blue arrow points to the 'Submit' button at the bottom right.

The screenshot shows the 'Manage My Access' page with three tabs: 'Add Access', 'My Access', and 'Review'. The 'Add Access' tab is active, showing a form for 'SPOR Industry User'. The form includes a description of the role and a 'Type: Role' field with 'Owner: SPOR Industry User Approvers'. A blue arrow points to the 'Submit' button at the bottom right.

- o En caso de haber un Superusuario ya registrado, a este le llegara un e-mail solicitando la aceptación de la solicitud; en caso contrario, será la EMA la que acepte el primer Superusuario, depositando la responsabilidad en este sobre el resto de accesos una vez tramitado:



3. ACCESO A SPOR



EUROPEAN MEDICINES AGENCY
SPOR

Substances Products **Organisations** Referentials Help

SPOR data management services

Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.

The four SPOR data management services are:

-  **Substance Management Services (SMS)**
-  **Product Management Services (PMS)**
-  **Organisation Management Services (OMS)**
-  **Referentials Management Services (RMS)**

OMS and RMS are the first services to go live and they provide the data foundations for PMS and SMS.

SMS and PMS are not currently activated. More information on the [implementation of SPOR data management services](#) is available on the EMA corporate website.

The SPOR portal provides users with the following data management services:

- view, search, export SPOR data;
- request new and updated SPOR data;
- translate SPOR data;
- browse relevant SPOR documentation.

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 SPOR

Use the links in the navigation panel above to access OMS and RMS.

Please use the menus in the navigation panel to navigate RMS and OMS with 'read-only' access to SPOR.

You will need an EMA account with SPOR user roles to conduct additional tasks, such as requesting changes to data, translating data or managing user preferences.

If you already have an active account for any EMA-hosted website or online application, you should use the same credentials to log in.

If you do not already have an EMA account, you need to create an EMA account and request the specific SPOR user roles you require.

Please check if you are able to log in before registering as a new user with SPOR.

[Create EMA Account](#)

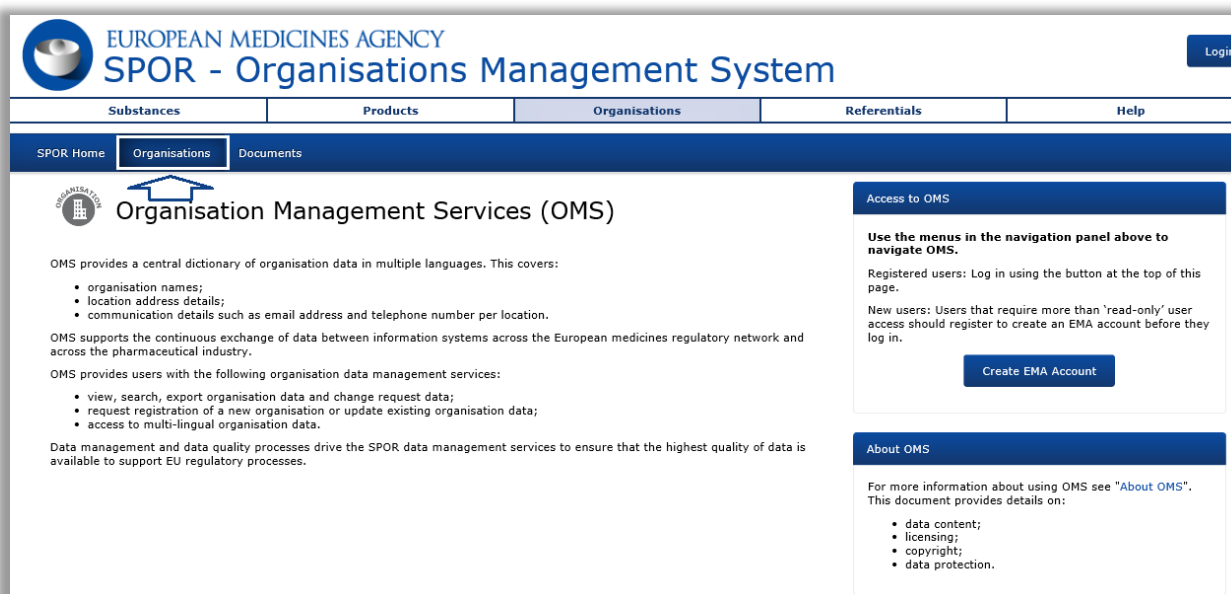
Registered users can log in using the button at the top of the page.

Using SPOR

For more information about using SPOR see "[About SPOR data management services](#)". This document provides details on:

- SPOR projects;
- access policy and user roles;
- customer support;
- data content;
- copyright;
- data protection.

o Acceso OMS:



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

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.

o Búsqueda “Organization”:



EUROPEAN MEDICINES AGENCY

SPOR - Organisations Management System

Log in

Substances	Products	Organisations	Referentials	Help
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SPOR Home

Organisations

Documents

Home / Search Organisations

▼ Hide search

Organisation ID

Organisation name

Location ID

Address

City

Postcode

Country

Modified Since

Location status *

0 Selected ▼

yyyy-MM-dd

ACTIVE, INACTIVE ▼

Contains ▼

Contains ▼

Contains ▼

Contains ▼

Contains ▼

Contains ▼

Reset

Search

0 Ver detalle:



EUROPEAN MEDICINES AGENCY

SPOR - Organisations Management System

Login

SubstancesProductsOrganisationsReferentialsHelp

SPOR Home

Organisations

Documents

Home / Search Organisations

These results may include organisations selected because their historic versions meet the criteria.

Show search

Reset

Search

Organisation ID

Organisation Name ▲

Country ▼

Location ID ▼

City ▼

Address

Postcode

Location status ▼

Modified ▼

Actions

ORG-100002846

Astrom Biosciences DK ApS

Denmark

LOC-100001470

Kastrup

Oliefabriksvej 45

2770

ACTIVE

2017-09-28T14:14:34

Q

ORG-100002948

Astellas d.o.o.

Croatia

LOC-100010331

Zagreb

Ilica 1

10000

ACTIVE

2017-12-20T16:01:58

Q

ORG-100003709

Astellas Farma Lda.

Portugal

LOC-100007220

Sintra

Estrada Nacional 9 Km 17

2711-901

ACTIVE

2017-12-11T11:49:11

Q

ORG-100003709

Astellas Farma Lda.

Portugal

LOC-100007212

Porto Salvo

Lagoas Park 5 A 6

2740-245

ACTIVE

2017-12-08T14:22:16

Q

ORG-100000088

Astellas Pharma

France

LOC-100008419

Levallois Perret

26 Quai Charles Pasqua

92300

ACTIVE

2018-01-09T15:49:17

Q

ORG-100000088

Astellas Pharma

France

LOC-100010408

Levallois Perret

114 Rue Victor Hugo

92300

ACTIVE

2018-01-09T15:51:03

Q

ORG-100002638

Astellas Pharma A/S

Denmark

LOC-100008064

Glostrup

Naverland 4

2600

ACTIVE

2017-12-12T11:08:57

Q

ORG-100002638

Astellas Pharma A/S

Denmark

LOC-100006028

Kastrup

Kajakvej 2

2770

ACTIVE

2017-12-05T13:41:49

Q

ORG-100003241

Astellas Pharma AG

Switzerland

LOC-100010091

Wallisellen

Grindelstrasse 6

8304

ACTIVE

2017-12-19T10:23:32

Q

ORG-100001183

Astellas Pharma B.V.

Netherlands

LOC-100005408

Leiden

Sylviusweg 62

2333 BE

ACTIVE

2017-12-01T17:49:39

Q

ORG-100005729

Astellas Pharma B.V.

Belgium

LOC-100010020

Anderlecht

Square Marie Curie 50/1

1070

ACTIVE

2017-12-18T16:24:16

Q

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Showing 20 of 164 results



EUROPEAN MEDICINES AGENCY

SPOR - Organisations Management System

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Organisation Details

Organisation ID:	ORG-100002846
Organisation Name:	Aastrom Biosciences DK ApS
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

Location ID:	LOC-100001470
Address:	Oliefabriksvej 45 Kastrup 2770 Denmark
GPS Location:	55.625486, 12.592371
Location Email:	
Location Phone:	
xEVMPD Code:	ORG21957
Last Modified Date:	2017-09-28T14:14:34
Status:	ACTIVE

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o Nos acreditamos en SPOR:



EUROPEAN MEDICINES AGENCY

SPOR



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Referentials

Help

SPOR data management services

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-  Organisation Management Services (OMS)
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Access to SPOR

Use the links in the navigation panel above to access OMS and RMS.

Please use the menus in the navigation panel to navigate RMS and OMS with 'read-only' access to SPOR.

You will need an EMA account with SPOR user roles to conduct additional tasks, such as requesting changes to data, translating data or managing user preferences.

If you already have an active account for any EMA-hosted website or online application, you should use the same credentials to log in.

If you do not already have an EMA account, you need to create an EMA account and request the specific SPOR user roles you require.

Please check if you are able to log in before registering as a new user with SPOR.

Create EMA Account

Registered users can log in using the button at the top of the page.

o Volveremos a logarnos en EMA "Account portal":

- o Y accederemos a SPOR/OMS. Veremos que dispondremos de más opciones al acceder con credenciales, entre ellas "Solicitar nueva localización" o "Modificar datos" del registro seleccionado:

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modifi
ORG-100002846	Aastrom Biosciences DK ApS	Denmark	LOC-100001470	Kastrup	Oliefabriksvej 45	2770	ACTIVE	2017-09-28T14:14:34
ORG-100002948	Astellas d.o.o.	Croatia	LOC-100010331	Zagreb	Ilica 1	10000	ACTIVE	2017-12-20T16:01:58
ORG-100003709	Astellas Farma Lda.	Portugal	LOC-100007220	Sintra	Estrada Nacional 9 Km 17	2711-901	ACTIVE	2017-12-11T11:49:11
ORG-100003709	Astellas Farma Lda.	Portugal	LOC-100007212	Porto Salvo	Lagoas Park 5 A 6	2740-245	ACTIVE	2017-12-08T14:22:16
ORG-100000088	Astellas Pharma	France	LOC-100008419	Levallois Perret	26 Quai Charles Pasqua	92300	ACTIVE	2018-01-09T15:49:17
ORG-100000088	Astellas Pharma	France	LOC-100010408	Levallois Perret	114 Rue Victor Hugo	92300	ACTIVE	2018-01-09T15:51:03
ORG-100002638	Astellas Pharma A/S	Denmark	LOC-100008064	Glostrup	Naverland 4	2600	ACTIVE	2017-12-12T11:08:57
ORG-100002638	Astellas Pharma A/S	Denmark	LOC-100006028	Kastrup	Kajakvej 2	2770	ACTIVE	2017-12-05T13:41:49
ORG-100003241	Astellas Pharma AG	Switzerland	LOC-100010091	Wallisellen	Grindelstrasse 6	8304	ACTIVE	2017-12-19T10:23:32
ORG-100001183	Astellas Pharma B.V.	Netherlands	LOC-100005408	Leiden	Sylviusweg 62	2333 BE	ACTIVE	2017-12-01T17:49:39
ORG-100005729	Astellas Pharma B.V.	Belgium	LOC-100010020	Anderlecht	Square Marie Curie 50/1	1070	ACTIVE	2017-12-18T16:24:16
ORG-100003292	Astellas Pharma Co. Limited	Ireland	LOC-100004915	Dublin 24	5 Waterside		ACTIVE	2017-11-28T15:01:02
ORG-100003292	Astellas Pharma Co. Limited	Ireland	LOC-100008959	Dublin 15	Damastown Road		ACTIVE	2017-12-14T14:31:32
ORG-100005275	Astellas Pharma d.o.o.	Slovenia	LOC-100001895	Ljubljana	Smartinska Cesta 53	1000	ACTIVE	2017-10-18T17:11:58
ORG-100000003	Astellas Pharma Europe B.V.	Netherlands	LOC-100007137	Meppel	Hogemaat 2	7942 JG	ACTIVE	2017-12-08T11:49:08
ORG-100000003	Astellas Pharma Europe B.V.	Netherlands	LOC-100003138	Leiderdorp	Elisabethhof 19	2353 EW	ACTIVE	2017-11-15T21:11:36
ORG-100000003	Astellas Pharma Europe B.V.	Netherlands	LOC-100005321	Leiden	Sylviusweg 62	2333 BE	ACTIVE	2017-11-29T22:55:50
ORG-100001189	Astellas Pharma Europe Limited	Netherlands	LOC-100007063	Leiden	Sylviusweg 62	2333 BE	ACTIVE	2017-12-08T10:35:46
ORG-100002615	Astellas Pharma Ges.m.b.h.	Austria	LOC-100007915	Vienna	Donau-City-Strasse 7	1220	ACTIVE	2017-12-11T18:18:55
ORG-100003505	Astellas Pharma GmbH	Germany	LOC-100006961	Munich	Weihenstephaner Strasse 28	81673	ACTIVE	2017-12-07T15:25:14

3.1. Solicitudes de alta, cambio, o nueva localización.

- o Al ir al detalle dispondremos de más opciones ("Dar de alta Nueva Organización", "Dar de alta nueva localización", "Modificar datos" o "Exportar resultados"):

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SPOR - Organisations Management System
Spanish Agency of Medicines and Medical Devices [Logout](#)

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[SPOR Home](#) [Organisations](#) [View Requests](#) [Documents](#)

[Home](#) / [Search Organisations](#) / [View Organisation Location](#)

Organisation Details

Organisation ID:	ORG-100002846
Organisation Name:	Aastron Biosciences DK ApS
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

Location ID:	LOC-100001470
Address:	Oliefabrikvej 45 Kastrup 2770 Denmark
GPS Location:	55.625486, 12.592371
Location Email:	
Location Phone:	
xEVMPD Code:	ORG21957
Last Modified Date:	2017-09-28T14:14:34
Status:	ACTIVE

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

Request New Organisation

- Solicitar Nueva Organización

Add Location

- Añadir Localización a una organización ya existente

Request Change

- Solicitar algún cambio o modificación sobre una Localización o Organización

Export

Export With History

- Exportar
- Exportar con Histórico

o “View Request” Ver estado de las solicitudes realizadas:

EUROPEAN MEDICINES AGENCY
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Spanish Agency of Medicines and Medical Devices [Logout](#)

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[Home](#) / [View Requests](#)

CR ID	CR Type	Requestor	CR Date	Organisation Name	Address	Status	Status Date	Actions
No data available in table								

Showing 20 of 0 results

Showing 20 of 0 results

[Export List](#)

3.2 Roles SPOR



Usuario Invitado “Guest” (Cualquiera que pueda acceder a SPOR)



Supersuario Agencia



Usuario Agencia



Superusuario Industria



Usuario Industria



Usuario Traductor Industria

- Usuario invitado: un usuario que no requiere credenciales de inicio de sesión (nombre de usuario y contraseña) podrá acceder al portal SPOR. Pueden ver y buscar datos disponibles públicamente (listas públicas de RMS; todo el contenido de OMS).
- Los Superusuarios y los usuarios son roles específicos de la organización, es decir, a estos usuarios se les otorgan sus derechos de acceso en nombre de una organización específica. El usuario de la industria está afiliado a una organización industrial específica.

	Usuario Invitado	Súper usuario Industria	Usuario Industria
Login	No requerido	Requerido	Requerido
Ver Datos Públicos	Si	Si	Si
Realizar búsquedas	Si	Si	Si
Descargar datos	No	Si	Si
Solicitar cambios y actualizaciones de datos	No	Si	Si
Permiso para autorizar usuarios	No	Si	No

Permiso para autorizar usuarios SPOR, es la única diferencia entre Superusuario y Usuario

- Para cada organización industrial, EMA aprobará el primer Superusuario
- Cualquier solicitud de acceso de Superusuario o Usuario posterior será aprobada por el Superusuario de la organización del solicitante
- Los Superusuarios son responsables en nombre de sus organizaciones de la aprobación de roles. EMA no controlará esta actividad.
- Las responsabilidades del Superusuario son:

Aprobar y verificar el acceso de los usuarios en su organización

Confirmar que los usuarios pertenecen a la organización antes de otorgarles el acceso

Asegurarse de que haya una cantidad suficiente de Usuarios Superusuarios y Usuarios de SPOR por organización

[Inactivar saltos, etc.] Una vez que el Súper Usuario o Usuario deja la organización, el Superusuario debe desactivar su acceso en el Portal de Gestión de Cuentas de EMA.

Referencias:

1. Portal SPOR

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

2. EMA Presentation - Introduction to SPOR data services

http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2016/08/WC500212059.pdf

3. AEMPS – Implementación nueva versión del “Electronic Application Form” (eAF v.1.22) integrado con programa SPOR

https://www.aemps.gob.es/informa/notasInformativas/industria/2017/NI-SG_12-2017-implementacion-electronic-application-form.htm

4. RMS & OMS – Industry on-boarding to SPOR

http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2017/12/WC500240747.pdf