



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DADI eAF Training session

2 September 2022, 11:00 – 12:25 Central European Time (CET)
Webinar: WebEx





1

Introduction

11:00 – 11:15

Kristiina Puusaari

DADI Product Owner, EMA

2

Access Management demonstration

11:15 – 11:35

Noel Diamant

*DADI Product Owner, AGES/UNICOM**

João Costa,

DADI Product Manager, EMA

3

Demonstration of the User Interface

11:35 – 11:55

Kristiina Puusaari

DADI Product Owner, EMA

Noel Diamant

*DADI Product Owner, AGES/UNICOM**

4

Q&A Session

11:55 – 12:20

Moderator:

Cristina Pepato

DADI & PMS Change Manager

5

Closing

12:20 – 12:25

Joris Wiemer

EMA Change Management Lead



*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.



Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website**.



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the [EMA Data Privacy Statement for Slido](#).



1. Join via the QR code or link



2. Send or upvote the questions you want to hear answered



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



Introduction

Kristiina Puusaari, *DADI Product Owner, EMA*

Context

- > The **Digital Application Dataset Integration (DADI) Network Project** will replace current interactive PDF format electronic application forms with **new web-based application forms** hosted on a **dedicated portal**
- > The new web-forms will facilitate compliance with **ISO Identification of Medicinal Products (IDMP)** standard for human medicinal products in accordance with Commission Implementing Regulation (EU) No 520/2012 (art. 25 and 26)
- > DADI will provide a human readable PDF output in line with the Notice to Applicants requirements
- > The PDF output will contain a machine-readable component with a larger dataset in a **FHIR** xml format, that facilitates exchange of the applications information across different systems



DADI will change:



- > **PDF-format electronic application forms to web forms for:** Variations; Initial marketing authorisations; Renewals (human only); Forms for other procedures under consideration
- > **Human** and **veterinary** forms
- > **Centrally authorised product (CAPs)** applications at initial release of the form, and **Nationally authorised product (NAPs)** applications at second release.



DADI will NOT change:

- > The **current PDF output format**
- > The process to apply for or submit **Variations** and **Marketing authorisation applications**
- > The content of the **application form in the submission package**



October 2022 Go-live

- > **First release** of the web-based variation form for human medicinal products



Scope

- > Limited to **Centrally Authorised Products (CAPs)** only
- > **Applications containing NAPs**, including National Procedures, Mutual Recognition Procedure and Decentralised Procedure **not yet supported**
- > **Available data for CAPs** coming from **EMA's internal database**



The scope change is due to the **complexity in synchronisation of the data between xEVMPD and PMS**



March 2023 Release

- > **Second release** of the web-based variation form for human medicinal products



Scope

- > Support **all** types of EU variations procedures (**both CAPs and NAPs**)
- > Includes **bug fixes**

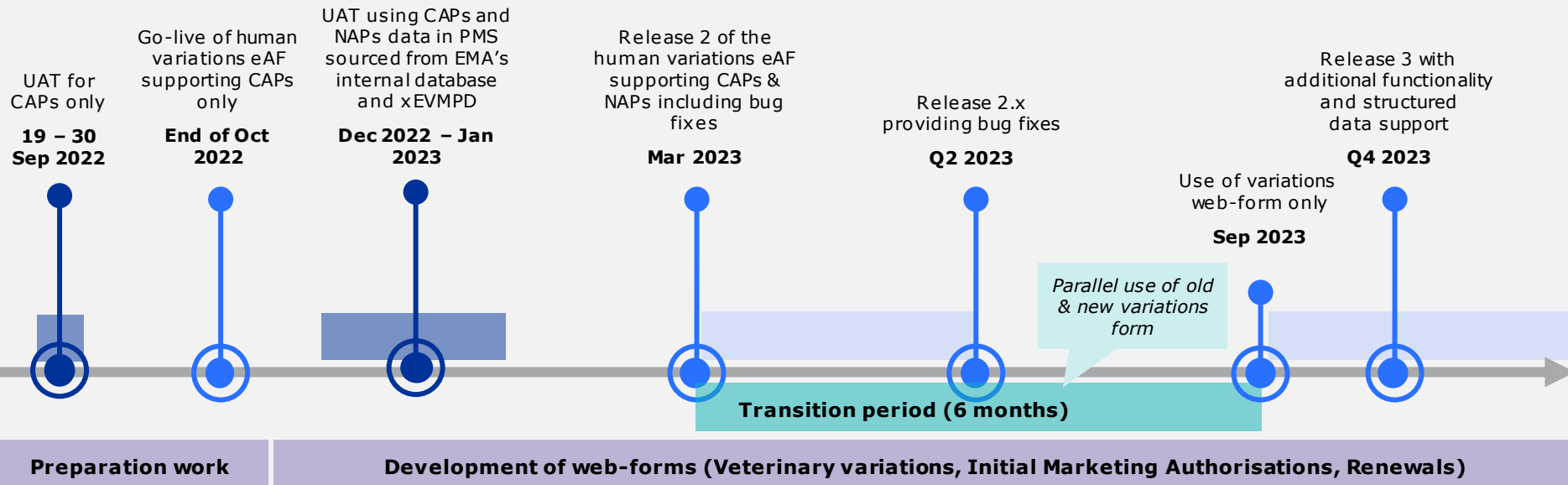


Progressive release model following the EMA Agile development approach

DADI Human Variation Form Timeline (Sep 2022)



EUROPEAN MEDICINES AGENCY



Applicants

Consultancies



Ways of working

- › Register to access application forms
- › Choose the level of access for users

- › Engage with MAH to ensure access is provided to necessary medicinal products



Training

- › New web application functionalities

- › New web application functionalities



Technology

- › Compliant web browsers & optional quality of life plugins
- › Manage webforms online instead of document management systems & email

- › Compliant web browsers & optional quality of life plugins
- › Manage webforms online instead of document management systems & email



Data

- › Available data for CAPs coming from EMA's internal database
- › Users of an MAH may only select products of their organisation

- › Need to be associated to all MAHs in EMA IAM with an appropriate role to draft applications for them



Procedural

- › Web-based forms to be used only for CAPs
- › CAPs and NAPs worksharing procedures should use PDF forms

- › Web-based forms to be used only for CAPs
- › CAPs and NAPs worksharing procedures should use PDF forms









Access Management demonstration

Noel Diamant, *DADI Product Owner, AGES/UNICOM**



João Costa, *DADI Product Manager, EMA*



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EMA	Administrators	Applicants
 EMA User Admin	 IRIS / eAF Industry User Admin	 (UAT_) eAF Applicant Contributor <ul style="list-style-type: none"> Be added as co-author Edit applications Select classifications
	 External Organisation Administrator <i>(optional)</i>	 (UAT_) eAF Applicant Manager <ul style="list-style-type: none"> Privileges of eAF Applicant Contributor Select products of my organisation Create, finalise and delete my applications Add co-authors
		 (UAT_) eAF Applicant Coordinator <ul style="list-style-type: none"> Privileges of eAF Applicant Manager Full access to all applications of my organisation
<p>Approve/Deny Administrators access requests</p>	<p>Approve/Deny Applicants access requests</p>	<p>Access to the eAF Portal Create / access / edit / manage electronic Application Forms</p>

To be an Applicant or an Administrator, you are required to have:

-  an active **EMA user account** (*external e-mail address*)
-  signed [proof of authority](#) (*only applicable to Administrators*)
-  **role(s)** assigned to that account



User Guide for registration
Request now: IRIS - eAF Industry User
Admin

The **EMA Account Management** is the online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

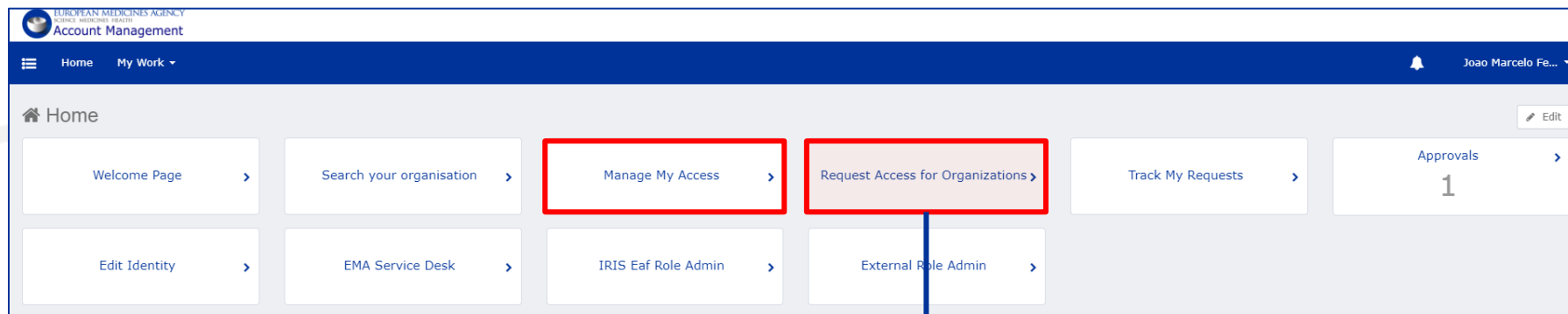
- [Look up whether you already have an EMA account](#)
- [Re-activate your EMA account](#)
- [Recover your credentials](#)
- [Retrieve your username](#)
- [Reset your password](#)
- [Create an EMA account](#)
- **[Request a user access role](#)**
- [Manage users' access for your organisation as an "User Admin"](#)
- [FAQs](#)

Note that the **organisation** on whose behalf you will be acting must be listed in the EMA's **[Organisation Management Service \(OMS\)](#)**

Disclaimer: new way to request roles

A new release of the [EMA Account Management](#) portal went recently live

- A new access request workflow has been deployed – **Request Access for Organisations** – allowing to submit in one go, user access role request(s) for more than one organisation




**New access
request workflow**

A new release of the [EMA Account Management](#) portal went recently live

- A new access request workflow has been deployed – **Request Access for Organisations** – allowing to submit in one go, user access role request(s) for more than one organisation

Up until end-
September
2022

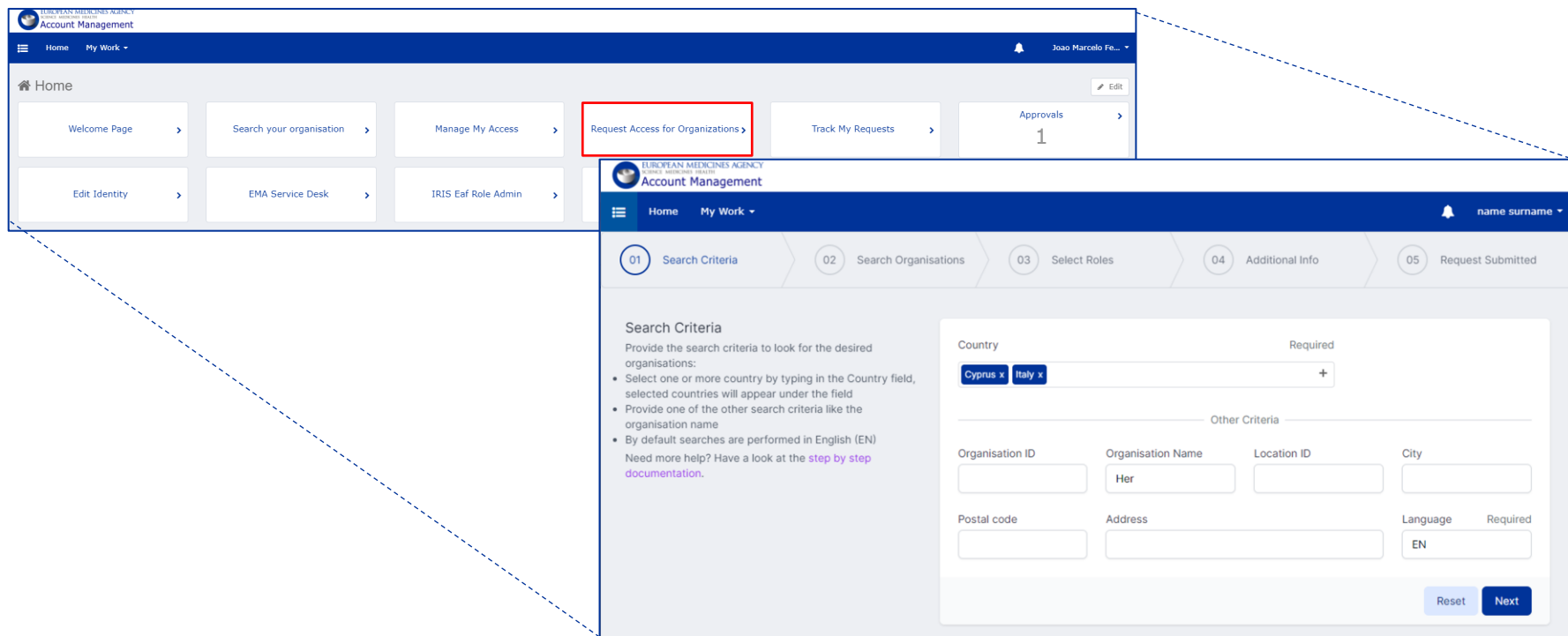
From October
2022 onwards



	Manage My Access	Request Access for Organisations
<i>Request:</i>		
1 or several role(s) for 1 Organisation	✓	✓
1 or several role(s) for n Organisations	✗	✓
1 or several role(s) for 1 Organisation	✗	✓
1 or several role(s) for n Organisations	✗	✓

Steps to request a role

[EMA Account Management](#) > Login > 'Request Access for Organisations' >
01 Search Criteria (Add at least one *Country* and one *Other Criteria*) > 'Next'



The screenshot displays the EMA Account Management interface. The top navigation bar includes 'Home' and 'My Work' menus, a user profile for 'Joao Marcelo Fe...', and a notification bell. The main dashboard features several tiles: 'Welcome Page', 'Search your organisation', 'Manage My Access', 'Request Access for Organizations' (highlighted with a red box), 'Track My Requests', 'Approvals' (showing 1), 'Edit Identity', 'EMA Service Desk', and 'IRIS Eaf Role Admin'.

The 'Request Access for Organizations' tile is expanded, showing a multi-step process: 01 Search Criteria, 02 Search Organisations, 03 Select Roles, 04 Additional Info, and 05 Request Submitted. The '01 Search Criteria' step is active, displaying instructions and a form.

Search Criteria
Provide the search criteria to look for the desired organisations:

- Select one or more country by typing in the Country field, selected countries will appear under the field.
- Provide one of the other search criteria like the organisation name
- By default searches are performed in English (EN)
Need more help? Have a look at the [step by step documentation](#).

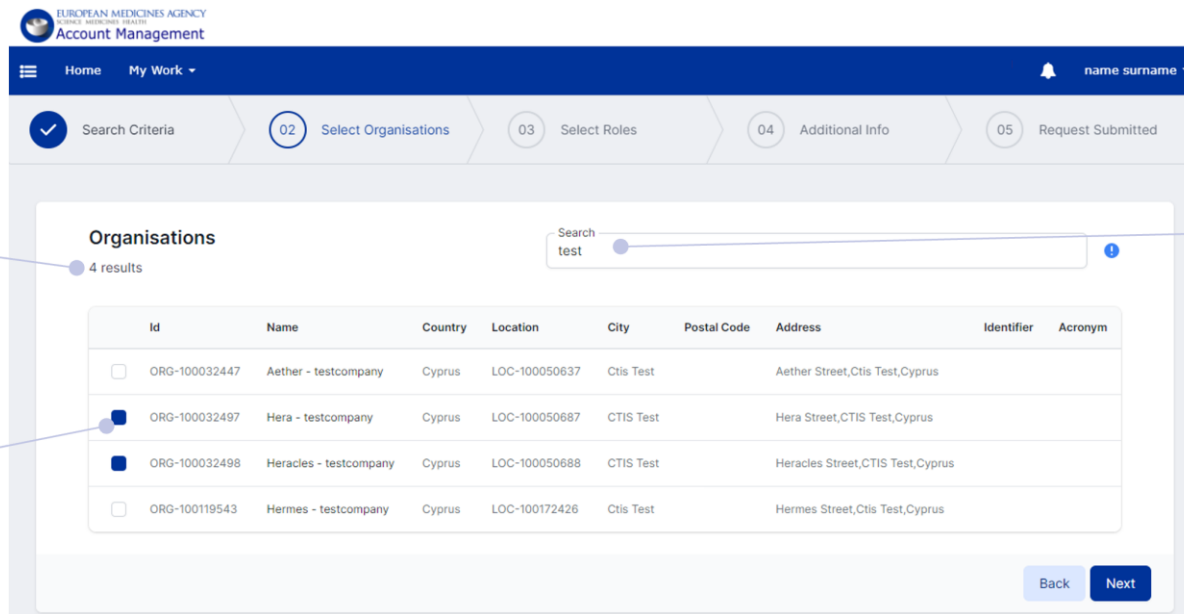
Country (Required)
Cyprus x Italy x +

Other Criteria

Organisation ID	Organisation Name	Location ID	City
<input type="text"/>	Her	<input type="text"/>	<input type="text"/>
Postal code	Address	Language	Required
<input type="text"/>	<input type="text"/>	EN	<input type="text"/>

Reset Next

02 Select Organisations (Tick-mark the organisation(s) you want to select) > 'Next'



The screenshot shows the 'Account Management' interface with a progress bar at the top indicating five steps: 01 Search Criteria, 02 Select Organisations (current step), 03 Select Roles, 04 Additional Info, and 05 Request Submitted. The main content area is titled 'Organisations' and shows '4 results'. A search bar with the text 'test' is present. Below the search bar is a table with columns: Id, Name, Country, Location, City, Postal Code, Address, Identifier, and Acronym. The table contains four rows of data, each with a checkbox in the first column. The second and third rows have their checkboxes selected. At the bottom right of the table area are 'Back' and 'Next' buttons.

	Id	Name	Country	Location	City	Postal Code	Address	Identifier	Acronym
<input type="checkbox"/>	ORG-100032447	Aether - testcompany	Cyprus	LOC-100050637	Ctis Test		Aether Street,Ctis Test,Cyprus		
<input checked="" type="checkbox"/>	ORG-100032497	Hera - testcompany	Cyprus	LOC-100050687	CTIS Test		Hera Street,CTIS Test,Cyprus		
<input checked="" type="checkbox"/>	ORG-100032498	Heracles - testcompany	Cyprus	LOC-100050688	CTIS Test		Heracles Street,CTIS Test,Cyprus		
<input type="checkbox"/>	ORG-100119543	Hermes - testcompany	Cyprus	LOC-100172426	Ctis Test		Hermes Street,Ctis Test,Cyprus		

Up to **200 results** are shown, narrow down your research if you hit this limit

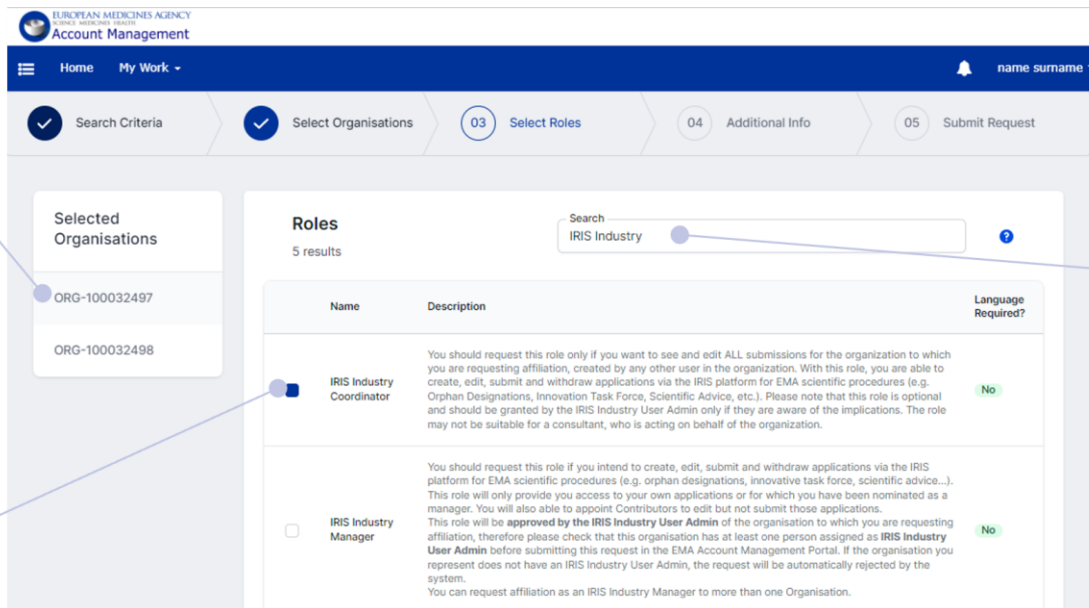
Use the **checkbox** close to each organisation to select them.

Use the Search field to restrict further your search

03 Select Roles (Tick-mark the roles(s) you want to select) > 'Next'

Selected **organisations** are shown here.
The **selected roles** will be requested **for all displayed organisations**

Use the **checkbox** close to each role to select them.



EUROPEAN MEDICINES AGENCY
Account Management

Home My Work

Search Criteria Select Organisations **03 Select Roles** 04 Additional Info 05 Submit Request

Selected Organisations

- ORG-100032497
- ORG-100032498

Roles
5 results

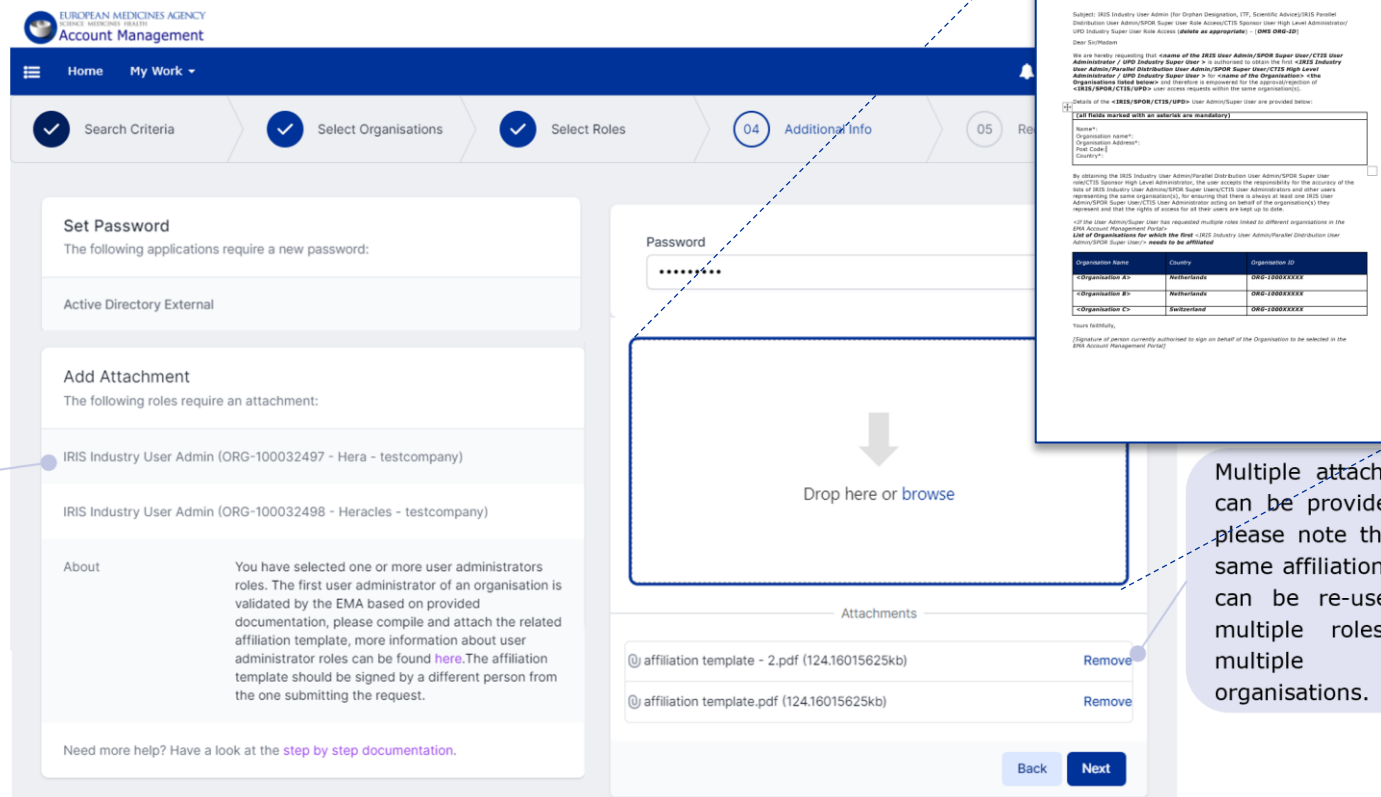
Search IRIS Industry

Name	Description	Language Required?
<input checked="" type="checkbox"/> IRIS Industry Coordinator	You should request this role only if you want to see and edit ALL submissions for the organization to which you are requesting affiliation, created by any other user in the organization. With this role, you are able to create, edit, submit and withdraw applications via the IRIS platform for EMA scientific procedures (e.g. Orphan Designations, Innovation Task Force, Scientific Advice, etc.). Please note that this role is optional and should be granted by the IRIS Industry User Admin only if they are aware of the implications. The role may not be suitable for a consultant, who is acting on behalf of the organization.	No
<input type="checkbox"/> IRIS Industry Manager	You should request this role if you intend to create, edit, submit and withdraw applications via the IRIS platform for EMA scientific procedures (e.g. orphan designations, innovative task force, scientific advice...). This role will only provide you access to your own applications or for which you have been nominated as a manager. You will also be able to appoint Contributors to edit but not submit those applications. This role will be approved by the IRIS Industry User Admin of the organisation to which you are requesting affiliation, therefore please check that this organisation has at least one person assigned as IRIS Industry User Admin before submitting this request in the EMA Account Management Portal. If the organisation you represent does not have an IRIS Industry User Admin, the request will be automatically rejected by the system. You can request affiliation as an IRIS Industry Manager to more than one Organisation.	No

Use the **Search** field to look for desired roles

Steps to request a role (*only applicable to Administrators*)

04 Additional Info (Attach signed affiliation letter) > 'Next'



Set Password
The following applications require a new password:

Active Directory External

Add Attachment
The following roles require an attachment:

- IRIS Industry User Admin (ORG-100032497 - Hera - testcompany)
- IRIS Industry User Admin (ORG-100032498 - Heracles - testcompany)

About
You have selected one or more user administrators roles. The first user administrator of an organisation is validated by the EMA based on provided documentation, please compile and attach the related affiliation template, more information about user administrator roles can be found [here](#). The affiliation template should be signed by a different person from the one submitting the request.

Need more help? Have a look at the [step by step documentation](#).

Drop here or browse

Attachments

- affiliation template - 2.pdf (124.16015625kb) [Remove](#)
- affiliation template.pdf (124.16015625kb) [Remove](#)

[Back](#) [Next](#)

Official Organisation letterhead

(Name and Surname)
(EMA Account Management Panel)

Subject: IRIS Industry User Admin (for Orphan Designation, ITT, Scientific Advice/IRIS Parallel Distribution User Admin/SPOR Super User Role Access/CTIS Sponsors user high Level Administrator/ SPOR Industry Super User Role Access) (delete as appropriate) - (ORG-000-00)

Dear Sir/Madam

We are hereby requesting that: «Name of the IRIS user Admin/SPOR Super User/CTIS User Administrator / SPOR Industry Super User >» is authorised to access the role «IRIS Industry User Admin/Parallel Distribution User Admin/SPOR Super User/CTIS High Level Administrator / SPOR Industry Super User > for «Name of the Organisation» «Name of the Organisation» and therefore is requested for the signature/initials of «Name of the Organisation» (delete as appropriate) for the signature/initials of «Name of the Organisation».

Details of the «IRIS/SPOR/CTIS/SPOR» user Admin/Super User are provided below:

List of roles required with 3rd parties and mandatory

Name*
Organisation name*
Organisation address*
Post Code*
Country*

By obtaining the IRIS Industry User Admin/Parallel Distribution User Admin/SPOR Super User role/CTIS Sponsors high Level Administrator, the user accepts the responsibility for the accuracy of the data of IRIS Industry User Admin/SPOR Super User/CTIS User Administrator and their data representing the third party organisation, by ensuring that the data is correct and valid. (delete as appropriate) for the signature/initials of «Name of the Organisation».

<If the User Admin/Super User has requested multiple roles linked to different organisations in the EMA Account Management Panel:

List of Organisations for which the first «IRIS Industry User Admin/Parallel Distribution User Admin/SPOR Super User» needs to be affiliated

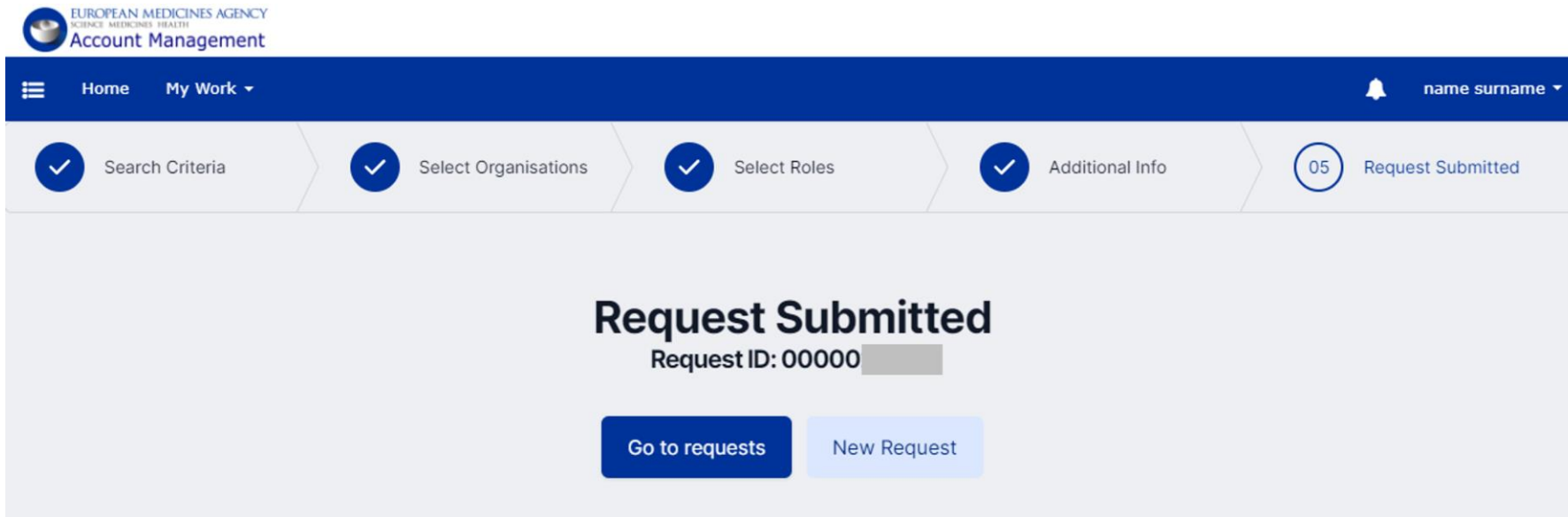
Organisation Name	Country	Organisation ID
«Organisation A»	Netherlands	ORG-1000XXXX
«Organisation B»	Netherlands	ORG-1000XXXX
«Organisation C»	Switzerland	ORG-1000XXXX

Yours faithfully,
(Signature of person authorised to sign on behalf of the Organisation to be selected in the EMA Account Management Panel)

The role requiring additional information is displayed in the righthand panel

Multiple attachments can be provided but please note that the same affiliation letter can be re-used for multiple roles and multiple organisations.

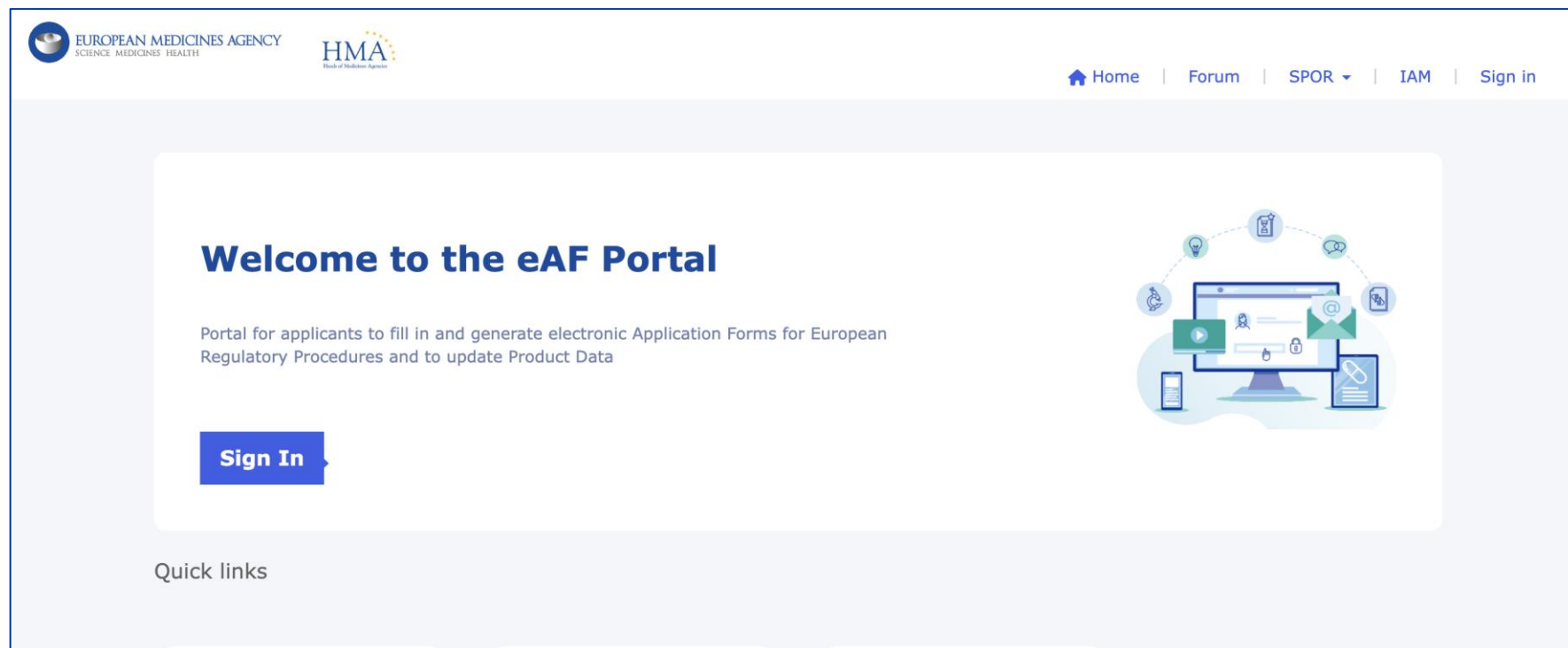
05 Request Submitted (Window confirming that the request has been submitted)



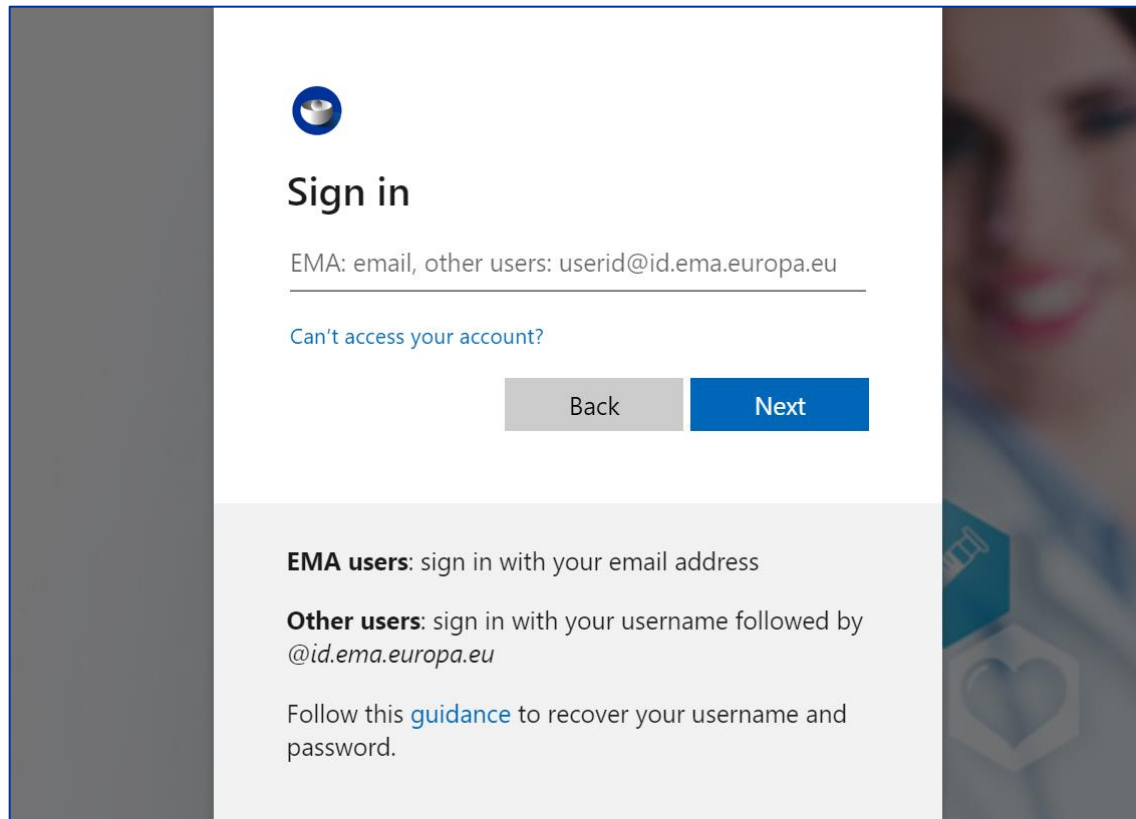
The screenshot displays the 'Account Management' interface of the European Medicines Agency. The top navigation bar includes a hamburger menu, 'Home', 'My Work', a notification bell, and a user profile dropdown labeled 'name surname'. Below this is a progress bar with five steps: 'Search Criteria', 'Select Organisations', 'Select Roles', 'Additional Info', and '05 Request Submitted'. The 'Request Submitted' step is highlighted with a blue circle. The main content area features the heading 'Request Submitted' and the text 'Request ID: 00000' followed by a greyed-out box. At the bottom, there are two buttons: 'Go to requests' (dark blue) and 'New Request' (light blue).

Upon approval, it may take up to 45 minutes to synch with and access the eAF Portal


UAT eAF portal: <https://euema-prs-uat.powerappsportals.com/>



The screenshot shows the UAT eAF portal homepage. At the top, there are logos for the European Medicines Agency (EMA) and the Health Medicines Agency (HMA). To the right of the logos is a navigation bar with links: Home, Forum, SPOR (with a dropdown arrow), IAM, and Sign in. The main content area has a large heading "Welcome to the eAF Portal" followed by a description: "Portal for applicants to fill in and generate electronic Application Forms for European Regulatory Procedures and to update Product Data". Below this is a prominent blue "Sign In" button. To the right of the text is an illustration of a computer monitor displaying a web form, surrounded by various icons representing healthcare and technology. At the bottom left, there is a section titled "Quick links".



The screenshot shows the sign-in page of the eAF portal. It features a blue header with the EMA logo and the text 'Sign in'. Below this is a text input field with the placeholder 'EMA: email, other users: userid@id.ema.europa.eu'. A link 'Can't access your account?' is positioned below the input field. At the bottom of the form are two buttons: 'Back' and 'Next'. A grey sidebar on the left contains the following text: 'EMA users: sign in with your email address', 'Other users: sign in with your username followed by @id.ema.europa.eu', and 'Follow this guidance to recover your username and password.' The background of the page is a blurred image of a smiling woman.



Sign in

EMA: email, other users: userid@id.ema.europa.eu

[Can't access your account?](#)

[Back](#) [Next](#)

EMA users: sign in with your email address

Other users: sign in with your username followed by @id.ema.europa.eu

Follow this [guidance](#) to recover your username and password.


Please note that:

- > You must sign in with your username followed by @id.ema.europa.eu:
username@id.ema.europa.eu
- > The password is the same as in <https://register.ema.europa.eu>
- > **Multifactor authentication** is required:
 - You can use the **Microsoft Authentication app** or **SMS**


Signing in to the eAF portal



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HMA
Health of Medicines Agency

[Home](#) | [Application Forms](#) ▾ | [Forum](#) | [SPOR](#) ▾ | [IAM](#) | [Arturo Test](#) ▾

Home > Application Forms

Draft | Deactivated | Completed | All






Create New Application Form

Column visibility

Refresh

Download

Application Form ID	Friendly Name	Application Form Type	Reference MAH	Modified By (Last User)	Modified On (Access Date)	Status	
VAR/22/77	IOANNIISST	Variation Form Human	UAT ORG (ORG-200036101)	Arturo Serna Leon	7/7/2022 1:51:09 AM	Draft	
VAR/22/58	Arturo test	Variation Form Human	UAT ORG (ORG-200036101)		6/22/2022 1:07:13 AM	Draft	
VAR/22/36	2022-06-14 test	Variation Form Human	UAT ORG (ORG-200036101)		6/22/2022 1:06:07 AM	Draft	

Showing 1 to 3 of 3 entries



Demonstration of the User Interface

Kristiina Puusaari, *DADI Product Owner, EMA*

Noel Diamant, *DADI Product Owner, AGES/UNICOM**





*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.



To note:

- Although all features for the go-live are developed, there are still some **bugs** present in the system and they may 'interfere' slightly with the demo
- This is not the final version of the system
 - Additional bug-fix release(s) will be deployed prior to the UAT
 - Several bug fixes will be done after UAT – before go-live

UAT eAF portal: <https://euema-prs-uat.powerappsportals.com/>



Home | Application Forms ▾ | Forum | SPOR ▾ | IAM | Kristiina Puusaari ▾

Home > Application Forms > Draft Application Form

1 Select Application Details2 Add Co-Author

Application Form Type *

Variation Form Human

Reference MAH ⓘ *

European Medicines Agency

×

Q

Org ID

ORG-100013412

Address

Domenico Scarlattilaan 6
Amsterdam 1083 HS
Netherlands

Friendly Name *

DADI eAF session 26th July 2022

LOC ID

LOC-100020264

Customer Account Number

—

Modified On

18/07/2022 12:38 AM

Create & Next

Cancel

Demonstration of the User Interface



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HMA
Heads of Medicines Agencies

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Pending



Product Selection

Variation From Human / Application for variation to a marketing authorization

device demo test 01/09/22 KP / VAR/22/168 Last Saved : 01/09/2022 21:12:26 PM



Product Selection

Pending



Products concerned by this application

Column visibility Show 10 rows Refresh

Associate MRP Nr.

Search



+ Add Product

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
-----------	----------------------	------------------	-----------------------	-----------	--------	--------------	--------	-------	-------------------	--------------------------

No data available in table

Showing 0 to 0 of 0 entries

Save Validate Cancel Export



Type(s) of Change(s)

Pending



Procedural Information

Pending



Proposed Changes

Pending



Finalisation

Pending



EMA Service Desk | eSubmissions

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



HMA
Heads of Medicines Agencies


For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on

Demonstration of the User Interface




Pending

Product Selection




Pending

Type(s) of Change(s)




Pending

Procedural Information



Pending

Proposed Changes



Pending

Finalisation

Variation From Human / Application for variation to a marketing authorization
medical device / VAR/22/600 Last Saved : 01/09/2022 21:33:26 PM

Products concerned by this application^①

Column visibility Show 10 rows Refresh

Associate MRP Nr. Search + Add Product

	Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
	Ferriprox 1000 mg/ml - Oral solution	Oral solution	DEFERIPRONE	European Union	Abbott, Frami and Tromp	EU/1/99/111	EMEA/H/C/000236	600000573286	1229276		1/1

Showing 1 to 1 of 1 entries

Save Validate Cancel Export

Demonstration of the User Interface





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 Pending 


Type(s) of Change(s)> Add/Edit Scope


Variation From Human / Application for variation to a ma


testing inactive organisations / VAR/22/348 Last Saved : 01/0


Selected Scope











[Save](#) [Cancel](#)



Lookup records

To search on partial text, use the asterisk (*) wildcard character.

B.IV.

Choose one record and click Select to continue



Name ↑

☐

B.IV.1.a.1 Device with CE marking

☐

B.IV.1.a.3 Spacer device for metered dose inhalers or other device which may have a significant impact on the delivery of the active substance in the product (e.g. nebuliser)

☐

B.IV.1.b Deletion of a device

☐

B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging

☐

B.IV.1.z Deletion of a device that leads to substantial amendments of the product information

☐

B.IV.1.z Other variation

☐

B.IV.z Other variation

Select

Cancel

Remove value

Selected Scope

B.IV.1.a.1 Device with CE marking



Select Procedure Type



Launch lookup modal

Identifier

Select procedure type from the list

Lookup records



Search



Choose one record and click Select to continue



Name ↑



Variation Type IAIN



Variation Type IB

Select

Cancel

Remove value

Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY

Pending Type(s) of Change(s)> Add/Edit Scope Variation From Human / Application for variation to a marketing authorization
testing inactive organisations / VAR/22/348 Last Saved : 01/09/2022 13:53:54

Selected Scope

B.IV.1.a.1 Device with CE marking



Select Procedure Type

Variation Type IAIN



Implementation Date *

9/20/2022



Identifier

B.IV.1.a.1 - Variation Type IAIN - 1

Implementation Date Note

Select Conditions

☐ Conditions ↑

Note

☐ If a measuring function is intended the CE marking should cover the measuring function.



☐ The change should not lead to substantial amendments of the product information.



☐ The medical device is not used as a solvent of the medicinal product.



☐ The new device is compatible with the medicinal product.



☐ The proposed measuring device must accurately deliver the required dose for the product concerned in line with the approved posology and results of such studies should be available.



Select Documentations

☐ Documentations ↑

Note ⓘ

☐ Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate), including description, detailed drawing and composition of the device material and supplier where appropriate, and including revised product information as appropriate.



☐ Proof of CE marking and if a measuring function is intended the proof of CE marking should also include the 4 digit notified body number.



Demonstration of the User Interface



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Pending

Type(s) of Change(s)

Product Selection

Pending

Type(s) of Change(s)

Pending

Procedural Information

Pending

Proposed Changes

Pending

Finalisation

Pending

Variations included for this application^①

Refresh

Search

Add Scope

Scope	Selected	Description
^ B.IV.1.a.1 Device with CE marking	1	B.IV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
^ B.IV.1.a.1 - Variation Type IAIN - 1	Variation Type IAIN	20 / 09 / 2022		<input type="checkbox"/>

1 entries

Save

Validate

Cancel

Export

Edit Scope


Delete


View de


Demonstration of the User Interface





EUROPEAN MEDICINES AGENCY


 Pending

**Product Selection**
Pending

**Type(s) of Change(s)**
Pending

**Procedural Information**
Pending

**Proposed Changes**
Pending

**Finalisation**
Pending

Variation From Human / Application for variation to a marketing authorization
medical device / VAR/22/600 Last Saved : 01/09/2022 21:49:33 PM

Procedural Information

Domain Human use

Type of Authorisation

Variation Procedure Number + Add

Type of Application Single Regulatory Activity

Name ↑

Procedure Number ↑

Worksharing ☐

Centralised Procedure

free text here 123

IG / Supergrouping ☐

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

Name ↑

Variation Type IAIN

☒ Name

☒ Medical devices

Name and Address of MA Holder (Applicant)

Contact Person

Save

Validate

Cancel

Export



Name and Address of MA Holder (Applicant) ^

Reference MAH ⓘ
Abbott, Frami and Tromp

Org ID
ORG-100017721

Address
661 Bailey Run
Oyugis DE
Thailand

LOC ID
LOC-100026475

Customer Account Number
89124356

Modified On
19/08/2022 13:08

Phone Number
+31887818404

Email
kristina.puusaari@ema.europa.eu

Contact Person ^

Selected Contacts

+ Add

Member State	Title	First name	Surname	Telephone	E-Mail	Company ↑
European Union	Product Owner	Kristiina	Puusaari	+31887818404	kristina.puusaari@ema.europa.eu	European Medicines Agency

33


[Save](#) [Validate](#) [Cancel](#) [Export](#)

Classified as public by the European Medicines Agency

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EUROPEAN MEDICINES AGENCY




Pending

Proposed Changes




Pending

Product Selection




Pending

Type(s) of Change(s)




Pending

Procedural Information



Pending

Proposed Changes



Pending

Finalisation

Variation From Human / Application for variation to a marketing authorization
medical device / VAR/22/600 Last Saved : 01/09/2022 21:49:33

Precise Scope and Background for Change

Present and Proposed Changes

Other Applications

Save

Validate

Cancel

Export

Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY

Pending

Pending

Pending

Pending

Pending

Pending

Version From Human / Application for variation to a marketing authorization
medical device / VAR/22/600 Last Saved : 01/09/2022 21:49:33 PM

Proposed Changes

Precise Scope and Background for Change

Precise Scope for Change

The applicant would like to submit a single Type IAIN (B.U.V.1.a.1) variation application, to amend the 3.2.R dossier section due to the change on the 10 ml dosing device. A step of about 5 mm length will be added below the device push plate which increases the outer diameter. There is no change in raw materials or any other aspects, including changes to the information presented in the dossier or dosing.

After communicating with EMA, it was confirmed that the removal of the name "WonderPill" printed on the barrel of the 10ml and 20 ml syringes could be submitted under this single Type IAIN (B.U.V.1.a.1) as an editorial change. Please refer to Appendix 1 in the cover letter.

Font Size B I U

Background for Change

The applicant has also taken the opportunity to update the lorem ipsum with the latest version, which is valid until 30th August 2023. This can be found in figure 1.2.

Font Size B I U

Present and Proposed Changes

Other Applications

Save Validate Cancel Export

Present and Proposed Changes

Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation of updated.

Select Product Area

☐ Product MA Number(s) ↑ ⓘ

Scope(s)

Recommended Change(s)

☐

☒ EU/1/99/111

B.IV.1.a.1 - Variation Type IAIN - 1

Text / Org. Changes

Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation of updated.

Select Product Area

- Select Product Area
- Clinical Trial
- Genetically Modified Organisms
- Ingredient
- Ingredient Documentation
- Manufactured Item
- Manufacturer
- Marketing Authorisation Holder
- Medical Device**
- Medicinal Product
- Medicinal Product Legal Status
- Package
- Package Legal Status
- Pharmaceutical Product
- Pharmacotherapeutic Group (ATC)
- Pharmacovigilance System Master File
- Pharmacovigilance
- Route of Administration
- Shelf Life


Save

Validate

Cancel

Export

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Pending  **Proposed Changes> Present & Proposed Medical Device**

Variation from Human / Application for variation to a marketing authorisation
medical device / VMD/22/600 Last Saved: 01/09/2022 21:45

Selected Scope(s)

Medical Devices

Present Values

Device Name Parent Medicinal Product

No data available in table

Showing 0 to 0 of 0 entries

Proposed Values

Device Name Parent Medicinal Product

Add Device Remove Association(s) Delete Device(s)

Add Device

Save Delete Proposed Change Return

Medical Device & Companion Diagnostic

Change to the design or intended purpose of the device component, or introduction of a new device / device constituent part >

Device(s) identification and classification >

Manufacturer of the device >

Documentation to confirm compliance to the Medical Device Regulation (EU) 2017/745 and/or to the in vitro diagnostic Medical Device Regulation (EU) 2017/746 >

Notified Body (NB) >

Save Cancel

Medical Device & Companion Diagnostic

Change to the design or intended purpose of the device component, or introduction of a new device / device constituent part

- ☒ a change to the design or intended purpose of a device component previously listed in the marketing authorisation of the medical product. Please explain the purposed changed in present/purposed section
- ☐ a new device introduced in the marketing authorisation of the medical product

Device(s) identification and classification

Name of the Device

Oral syringe

Device Quantity

1

Classification *

Class I

Sterile ☐

With Measuring Function ☒

Reusable Surgical Instrument ☐

Intended Purpose of the Device *

Lorem ipsum

Type of Combination ⓘ *

Co-packaged

Device Type *

Oral syringe

Serial number / unique device identifier (UDI) or other indications necessary to delimit precisely the device incorporated, if applicable *

Serial number (10ml) syringe: 678900

Brief Description of the Device *

Lorem ipsum device lorem ipsum dosing lorem ipsum



Manufacturer of the device



Function *

Manufacturer of medical device



Manufacturer *

European Medicines Agency



Org ID

ORG-100006175

Address

30 Churchill Place
London E14 5EU
United Kingdom

LOC ID

LOC-100010800

Modified On

13/07/2022 19:07

Title *

PO

First Name *

Kristina

Last Name *

Puusaari

Telephone

+31887818404

E-Mail

kristina.puusaari@ema.europa.eu

Documentation to confirm compliance to the Medical Device Regulation (EU) 2017/745 and/or to the in vitro diagnostic Medical Device Regulation (EU) 2017/746



Does this application include a Manufacturer's EU declaration of conformity, an EU certificate issued by a Notified Body or a Notified Body opinion, if applicable?

EU certificate issued by a Notified Body



Please note, the above mentioned documents (as applicable) should be provided in module 3.2.R of the EU-CTD.

Notified Body (NB)

Notified Body Number *

4567

Name of the Notified Body *

Austrian Agency For Health And Food Safety

x

Q

Org ID

ORG-100003912

Address

Beethovenstrasse 6
Graz 8010
Austria

LOC ID

LOC-100000001

Modified On

13/07/2022 19:07

Title *

PO

First Name *

Noel

Last Name *

Diamant

Telephone

+31887818404

E-Mail

noel@austria.com

Device Associations

Save

Cancel

Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY

Pending

Proposed Changes> Select Scope(s) and Product(s)

Variation From Human / Application for variation to a marketed product
medical device / VAR/22/600 Last Saved : 01/09/2022

Present and Proposed Changes Selected Scope(s) Selected Medicinal Product(s)

Present

Enter text...

Proposed

Enter text...


Organisation Details


+ Add

Organisation Not Selectable ↑	Organisation Name (Present Organisation)	Organisation Location (Present Organisation)	Organisation Id (Present Organisation)	Address 1 - composite (Present Organisation)	Parent Organisation ID (Present Organisation)	Modified On (Present Organisation)	Organisation Name (Proposed Organisation)	Organisation Location (Proposed Organisation)	Organisation Id (Proposed Organisation)	Address 1 - composite (Proposed Organisation)	Parent Organisation ID (Proposed Organisation)	Modified On (Proposed Organisation)
No	European Medicines Agency	LOC-100018793	ORG-100013412	Orlyplein 24 1043 DP Amsterdam Netherlands	European Medicines Agency	13/07/2022 19:07	Austrian Agency For Health And Food Safety	LOC-100000001	ORG-100003912	Beethovenstrasse 6 8010 Graz Austria	Austrian Agency For Health And Food Safety	13/07/2022 19:07

☐ In case no OMS selection is done, I declare this change does not affect organisations unless the organisation is being deleted





Pending  Variation From Human



Proposed Changes > View/Propose Changes > Add / Edit Org Change Details  medical device / VAR

☐ Organisation Not Selectable ⓘ



Present Organisation *



<input type="text" value="European Medicines Agency"/>  	Org ID ORG-100013412	LOC ID LOC-100018793
	Address Orlyplein 24 Amsterdam 1043 DP Netherlands	Modified On 13/07/2022 19:07
		Status * Active



Proposed Organisation *



<input type="text" value="Austrian Agency For Health And Food Safety"/>  	Org ID ORG-100003912	LOC ID LOC-100000001
	Address Beethovenstrasse 6 Graz 8010 Austria	Modified On 13/07/2022 19:07






**Product Selection**
Completed 

**Type(s) of change(s)**
Completed 

**Procedural Information**
Completed 


**Proposed Changes**
Completed 

**Finalisation**
Completed 

Annexed documents (where appropriate) 


The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable.


- ☒ Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation (Annex II)
- ☒ Package Leaflet
- ☐ List of all authorised presentations (Annex A)
- ☐ Labelling
- ☐ Specimens
- ☐ Mock ups
- ☐ Summary of Product Characteristics
- ☐ Restrictions posed by member states (Annex 127a)

Declaration 

I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that (Please tick appropriate declarations)

- ☒ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☒ I understand that EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder
- ☒ The individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant
- ☒ Where applicable, national fees have been prepaid or will be paid in accordance with national requirements;
- ☒ This notification/application has been submitted simultaneously in RMS and all CMSs (for products within the Mutual Recognition Procedure and worksharing) or both to EMA and (Co-)Rapporteur (for products within the Centralised Procedure) or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/ CMS (as applicable) and the EMA;
- ☒ All PIs (including annotated PIs are submitted in an anonymised format (i.e. names of the reviewers removed from the track-changes, no names in document properties and other parts of the documents)
- ☒ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- ☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.

Proof of payment 

Signatories 

Save

Validate

Cancel

Export

Finalise



Product Selection
Completed

Type(s) of change(s)
Completed

Procedural Information
Completed

Proposed Changes
Completed

Finalisation
Completed

PMS Update was successful. Please refresh the page to see the latest value.

Annexed documents (where appropriate)

The following annexed product information documents are provided in the annexed sections of the EDCTP format as PDF volume 3P format, where applicable.

Prefilled syringe test VAR/22/319

25/07/2022 21:40:16 PM

Export typically takes less than a minute but can take longer to complete, depending on the size of your Application. You'll get an email to notify you when the process is complete and ready to download.

Completed

FHIR xml Validation Failed

Download

Column visibility

Show 10 rows

Search

Refresh

Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
25/07/2022 23:11:04 PM	25/07/2022 23:11:04 PM	Kristiina Puusaari	Active			
25/07/2022 21:41:13 PM	25/07/2022 21:40:50 PM	Kristiina Puusaari	Completed			

Showing 1 to 2 of 2 entries

Close



4 / 20 99.9%

Bookmarks

- TABLE OF CONTENTS
- 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORIZATION
- 2. PRODUCTS CONCERNED BY THIS APPLICATION⁷
- 3. TYPES OF CHANGE(S)
- 4.a Type IB and Type II variation - new indication - orphan medicinal product information
- 4.b Type IB and Type II variation - Paediatric requirements
- 4.d Change to the design or intended purpose of the medical device component, or introduction of a new
- ANNEXED DOCUMENTS (WHERE APPROPRIATE)
- DECLARATION OF THE APPLICANT
- SIGNATURE
- NOTES
- FORM VALIDATION

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORIZATION

☒ Human ☐ Veterinary

Type of authorization:

☐ National Authorization in MRP/DCP
☒ EU Authorization
☐ National Authorization

Variation procedure number(s)¹:

Type of application (tick all applicable options)

☐ Single variation
☒ Grouping of variations
☐ Including a line extension³
☐ Worksharing

☐ Type IA_{IN}
☐ Type IA
☐ Type IB unforeseen²
☒ Type IB
☐ Type II
☐ Type II Art. 29⁴

Change(s) concern(s)

☒ Medical Device

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☐ Indication
☐ Paediatric requirements
☐ Safety
☒ Quality
☐ Annual variation for human influenza vaccines



Q&A session

Moderator: Cristina Pepato, *DADI & PMS Change Manager*



Closing

Joris Wiemer, *EMA Change Management Lead*



- Publication of the **Q&A Documents** from the 1st and 2nd eAF training webinars (26 July and 2 September 2022)
- Publication of the **Joint DADI-PMS Q&A Document**
- **UAT** between 19-30 September 2022
- **System demo** scheduled for September 2022



Further information

<http://esubmission.ema.europa.eu/cessp/cessp.htm>

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Telephone +31 (0)88 781 6000

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