

A light blue background featuring silhouettes of various healthcare professionals, including doctors, nurses, and a person in a lab coat, arranged in a row.

MANAGEMENT OF MEDICINES IN SPECIAL SITUATIONS

User Manual

Spanish Agency for Medicines and Health Products (AEMPS)



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1. INTRODUCTION

With the entry into force of Royal Decree 1015/2009 of 19 June, regulating the availability of medicines in special situations, all existing regulations concerning the use of investigational medicinal products outside clinical trials, medicines not authorised in Spain, and access to medicines under conditions other than those authorised have been updated and consolidated.

A key innovation introduced by this Royal Decree is the streamlining of procedures and the reduction of administrative burdens within the framework of the Administrative Burden Reduction and Better Regulation Plan. To this end, an electronic application process was introduced through the creation of an application called Management of Medicines in Special Situations (MSE), available on the website of the Spanish Agency for Medicines and Health Products (AEMPS) at the following address:

<https://mse.aemps.es/mse>

In addition to the aforementioned simplification of procedures, the application offers a number of other advantages, including:

- **Enhanced safety guarantees** for medicines used in special situations, allowing the electronic reporting, through the application, of suspected serious adverse reactions associated with investigational medicinal products used outside clinical trials.
- Improved information and transparency guarantees provided by the AEMPS to citizens, healthcare professionals and health authorities, through online access to information on these medicines.
- Ensures equity in access to medicines in special situations while safeguarding compliance with data protection legislation.
- Provides a single, standardised platform for individual access to all medicines available in special situations.

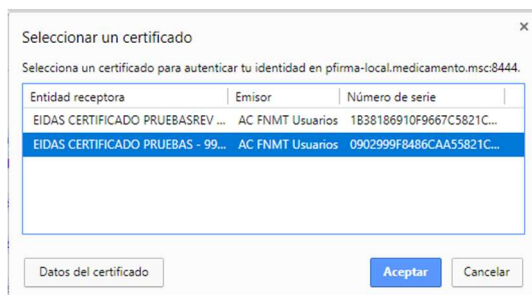
2. SYSTEM ACCESS

Access to the application requires two-factor authentication. Therefore, besides the username and password provided by the AEMPS, users must authenticate using either a **valid personal electronic certificate** or a **verification code**.

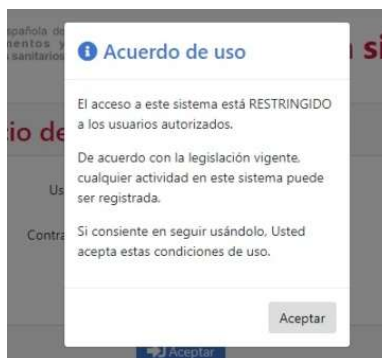
To access the application using an electronic certificate, please use the following link:

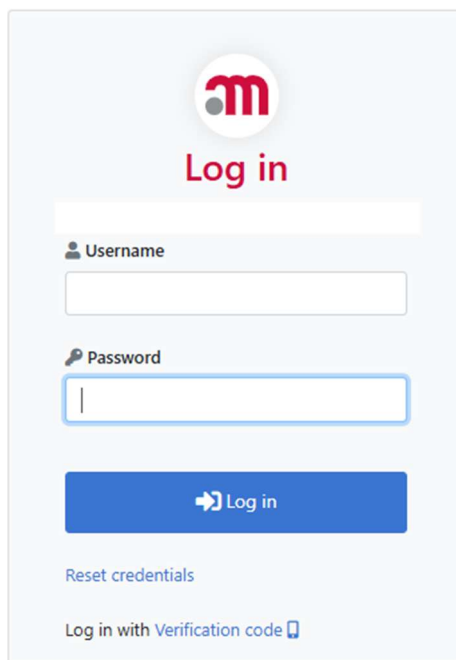
<https://mse.aemps.es>

By clicking on this link, or by entering the above address in any web browser, you will be prompted to select your digital certificate:



Once the certificate has been selected, the application will open the home page and display a notice regarding the cookie policy. After accepting the policy, users will be prompted to enter their access credentials:





The login form is centered on a light blue background. At the top is the AEMPS logo (a red 'm' with a grey dot) and the text 'Log in' in red. Below this are two input fields: 'Username' with a person icon and 'Password' with a key icon. A blue 'Log in' button with a right-pointing arrow is positioned below the password field. At the bottom, there are two links: 'Reset credentials' and 'Log in with Verification code' accompanied by a QR code icon.

To access the application using a **verification code**, please use the following link:

<https://mse-info.aemps.es>

When using the verification code option, a brief guide explaining how to configure it can be accessed from the home page via the [“What is it?”](#) link.

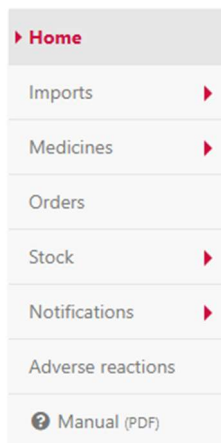
The application requires that any user wishing to access the system be registered as an authorised user by the AEMPS.

Once logged into the system, the information relating to the currently connected user will be displayed at the top of the screen, together with the date of the last access to the application and the option to log out of the current session.

The application is available in both Spanish and English, and users may switch between languages at any time during navigation.



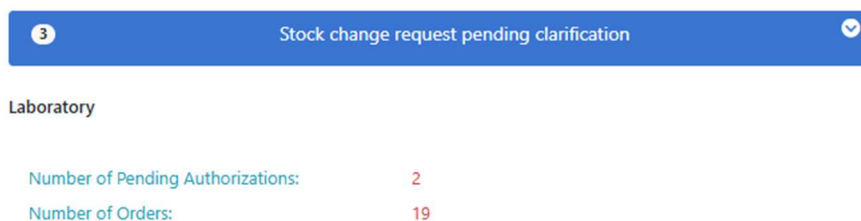
On the left-hand side of the window, the menu displays the following options:



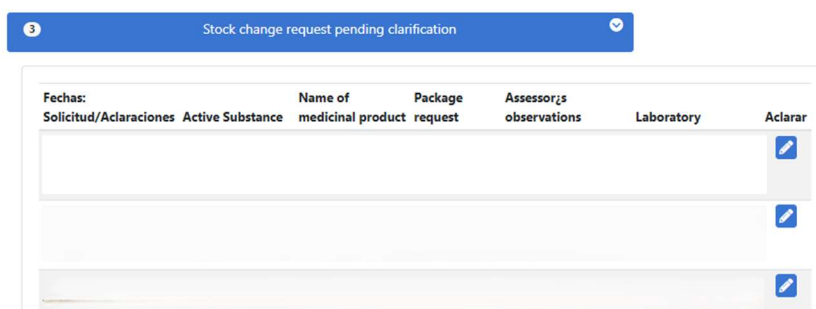
z

2.1.1. Home page

The Home page displays, under the **Pending Tasks** section, any stock change requests that are awaiting clarification, as well as the number of pending authorisations awaiting receipt and the number of orders pending fulfilment. When there are stock change requests awaiting clarification, the total number of records associated with this task will be displayed to the left of the task title.



Clicking the title button will display the list of results, as shown below.



3. IMPORTS

3.1. List

To access this functionality, click on the **List** option under the **Imports** section in the left-hand menu.

This list provides information related to imports, including the authorisation code, active substance, trade name, authorised units, issue date, request code (if applicable), and the current status of the authorisation.

In addition, a document icon is displayed, allowing users to download a PDF file containing the authorisation details.

Home
Imports
List
Medicines
Orders
Stock
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Manual (PDF)

Import Authorisation

Search Criteria

From date
15/07/2025

To date
15/07/2026

Request Code

Status *
Pending

Active Substance

Trade name

Medicine Code

Laboratory

Find

Found 1 resultados

Search results

Authorisation number	Laboratory	Active Substance	Medicine	Units	Issue date	Request Code	Status	Actions
AUT337600029540		FRESINO EXTO ALCOHOLICO	LCMMEDI EQUIVAL 2 10 mg CÁPSULA	110	2025-11-07 06:59:01.0		AUTORIZADA	

Import searches can be performed using the issue date range (by default, the last two months will be selected), request code, status, active substance, trade name, or medicine code. If none of these criteria are entered, the application will display a list of all import authorisations sorted in alphabetical order.

By clicking on the authorisation code, users can access all information relating to the import authorisation, as shown in the screen below:

Import Authorisation Detail

Authorisation number	Creation Date	Status
		AUTORIZADA
Laboratory		
Name of medicinal product		
Active Substance		
Authorised units		
110		
Observations *		
Laboratory observations *		

Found 1 resultados

Receipt date	Delivered	Pending	Batch number	Expiry date	Notifier	Observations

Found 1 resultados

4. MEDICINAL PRODUCTS

To access this functionality, click on the **Guide** option under the **Medicines** section in the left-hand menu.

The Medicine Guide provides information relating to the medicine, including the medicine code, active substance(s), trade name, supplier, billing price, whether the medicine is for hospital use only, whether it is subject to a special study, whether it is covered by a treatment protocol or a Temporary Authorisation for Use (TAU), the current status of the medicine, whether explicit approval is required, any relevant observations, and the date of the last update.

- **AVAILABLE:** The medicine can be requested for both treatment initiations (**New**) and treatment continuations (with a previously authorized TRT).
- **INITIATION CONTROL:** Healthcare centres may submit treatment continuation requests provided they have an authorized TRT. If a treatment initiation is required for that product record, they must contact **medicamentosospeciales@aemps.es** so that the record can be enabled once it has been confirmed that treatment initiation may be authorized.
- **CONTINUATION CONTROL:** Healthcare centres may submit treatment initiation requests (**New**), but they cannot submit treatment continuation requests linked to an already authorized TRT. If a treatment continuation is required for that product record, they must contact **medicamentosospeciales@aemps.es** so that the record can be enabled once it has been confirmed that a new request may be authorized for the specific patient and medicine.
- **AUTHORIZED/MARKETED:** The medicine is effectively marketed and therefore is not accessible through the **Medicines in Special Situations** procedure.

If, for any reason, healthcare centres contact the pharmaceutical company because they are unable to request a medicine that is visible in the application, they should be referred to **medicamentosospeciales@aemps.es**. The Special Access Medicines Office will inform them of the reason why access to the medicine is restricted and of the requirements that must be met for access to be enabled.

5. ORDERS

When the Orders menu option is selected, information on the orders associated with the company may be consulted. Specifically, the following data will be displayed: request code, active substance, brand name, requesting healthcare centre, request date, number of packs, and order status.

The following search criteria may be used to retrieve the information: order creation date (from/to), request code, treatment code, active substance, brand name, medicine code, healthcare centre name, and order status.

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Order list

Search Criteria

From date
To date
Request Code
Treatment Code

Active Substance
Trade name
Medicine Code

Centre
Laboratory
Status *

Found 1 resultados

Search results
Exportar

Application code	Active Substance	Trade name	Laboratory	Centre	Date	Package request	Status

Found 1 resultados

By clicking on the request code in the results list, the user will be taken to the order details screen, shown below:

Order details

Application

Center Details

Deliveries

Request Code	Treatment Code	Order date	Status
		30/06/2026	PENDIENTE

Laboratory

Name of medicinal product

TAURO 250,0 mg SOLUCIÓN ORAL, 20 cápsulas

Active Substance

TAUOURSODESOXICOLICO ACIDO

Quantity

1

Treatment indication

Anemia

Underlying condition

Anemia congénita

Laboratory observations

Return

Save comments

6. STOCK

Under the **Stock** section, the **List** menu option provides access to all stock change requests submitted by the company.

Through this list, users can view information related to the stock change requests submitted by the company, including the authorization code, active substance, medicine name, authorized units, issue date, request code (where applicable), and current status. In addition, a document icon will be available, allowing users to download the PDF file containing the authorization details.

- Home
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- Medicines
- Orders
- Stock
 - Requests for changes
- Notifications
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List of stock change requests

Search Criteria

From date: To date: Laboratory:

Active Substance: Trade name:

Found 1 resultados

Request/Resolution Date	Active Substance	Name of medicinal product	Provider	Package request	Reason	Assessor's observations	Applicant's comments	Status	Aclarar
Found 1 resultados Return + New									

To request a stock adjustment, go to the **Stock** section of the menu and click on **Requests for changes**. The following screen will then be displayed, as shown in the image below.

Next, select the relevant medicine from the drop-down list located under the Medicine field.

- Home
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- Stock
 - Requests for changes
- Notifications
- Adverse reactions
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Stock change request

Laboratory *

Medicine *

Active Substance

Number of units * ☐ Add ☒ Delete

Reason *

Observations

Real stock

Virtual stock

Pending stock

Safety stock

Units assigned to the authorisation

Next, enter the number of packs and select either *Add* or *Delete*, depending on whether the stock shown in the MSE application is lower or higher than the actual stock held in the warehouse.

7. NOTIFICATIONS

7.1. Deliveries

Access to order delivery notifications is available through the **Deliveries** menu option located under the Notifications section.

This functionality allows users to notify full or partial deliveries of orders sent to healthcare centres.

The search results will display the following information: request code, treatment code, active substance, brand name of the medicinal product, recipient healthcare centre, order authorization date, number of authorized packs, and number of packs still pending delivery.

Order delivery notifications can be accessed through the **Deliveries** menu option.

The search results will display the following information: request and treatment codes, active substance, trade name of the medicinal product, the healthcare centre to which the medicine is to be supplied, the date on which the order was authorized, the number of authorized packs, and the number of packs still pending deliver.

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Medicines ▶
Orders
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▶ Deliveries
Receipts
Adverse reactions
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Pending deliveries list

Search Criteria

Request Code

Treatment Code

Centre

Active Substance

Trade name

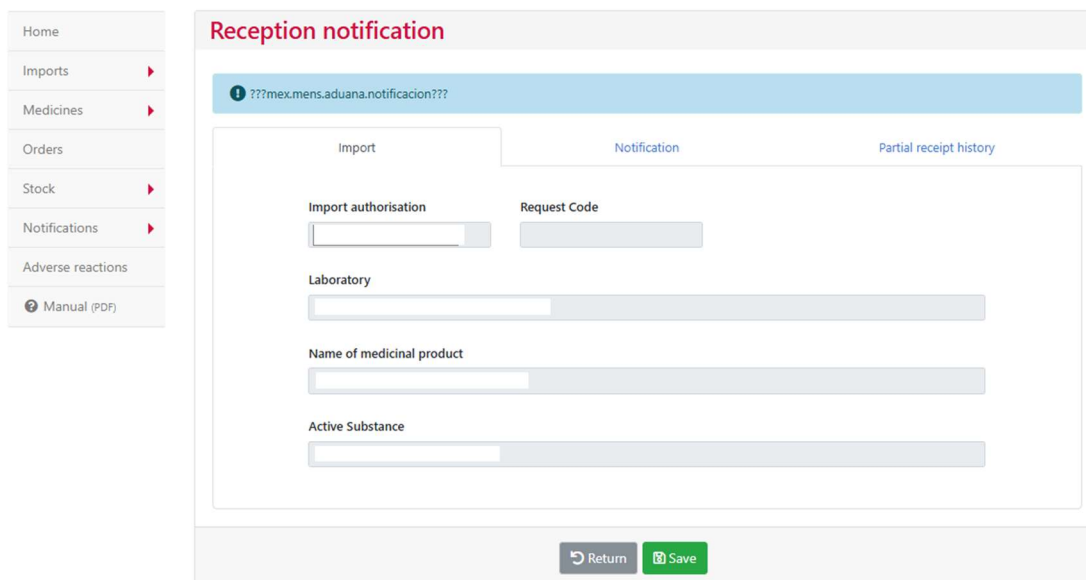
Laboratory

Find

Found 19 resultados

Search results Export							
Codes	Active Substance	Trade name	Centre	Date	Units authorised	Pending	Laboratory

Access the delivery notification screen, click on either the request code or the treatment code. The following screen will then be displayed::



In this form, the order details will be displayed under the **Order** tab, while the details of any partial deliveries will be shown under the **Partial receipt history** tab. Under the **Notification** tab, the fields in which the information related to the order delivery notification must be entered will be displayed.

7.2. Receptions

An import receipt may be notified through the **Receipts** menu option located under the **Notifications** section.

This functionality allows users to notify the receipt, whether total or partial, of import authorizations.

The search results will display the following fields: import authorization codes, active substance, medicinal product trade name, marketing authorization holder (company name), date on which the import was authorized, authorized packs, and the number of packs pending receipt.

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List of Pending Receptions

Search Criteria

Active Substance

Trade name

Authorisation number

Laboratory

Find

Found 1 resultados

Search results

Export

Authorisation number	Active Substance	Trade name	Laboratory	Date	Units authorised	Pending
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Found 1 resultados

Return

To access the receipt notification screen, click on the **authorization code**. The following screen will then be displayed:

Reception notification

Please verify that Customs has not already submitted the notification you intend to make

Import

Notification

Partial receipt history

Import authorisation

Request Code

AUT337600029540

Laboratory

Name of medicinal product

LCMMEDI EQUIVAL 2 10 mg CÁPSULA

Active Substance

FRESNO EXTO ALCOHOLICO

Return

Save

In this form, the importation details will be displayed under the **Importation** tab, while the details of any partial receipts will be shown under the **Receipt History** tab. Under the **Notification** tab, the fields in which the information related to the receipt notification must be entered will be displayed.

Reception notification

Please verify that Customs has not already submitted the notification you intend to make

Import

Notification

Partial receipt history

Quantity

110

Pending

70

Receipt date *

Package request *

Batch number *

Expired date *

Observations

Return

Save