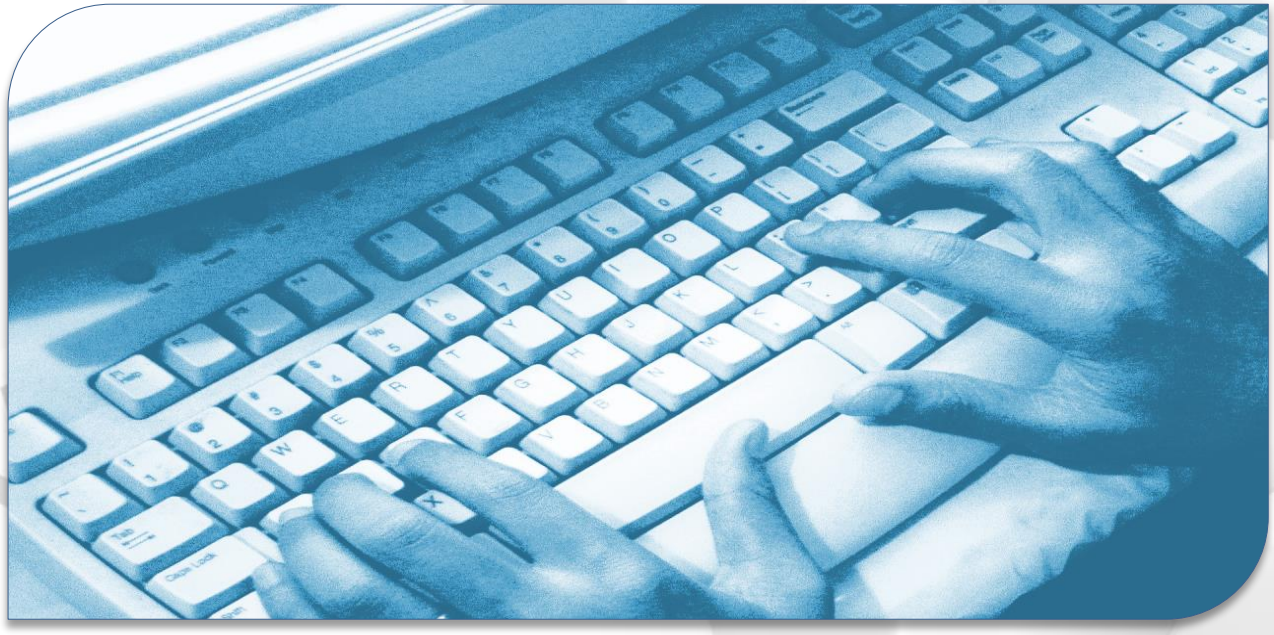
RECOPS – REGISTER FOR MAKING MEDICAL DEVICES AVAILABLE ON THE SPANISH MARKET



Reporting profile

Version 1.1
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GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

RECOPS – AEMPS Medical Devices Register

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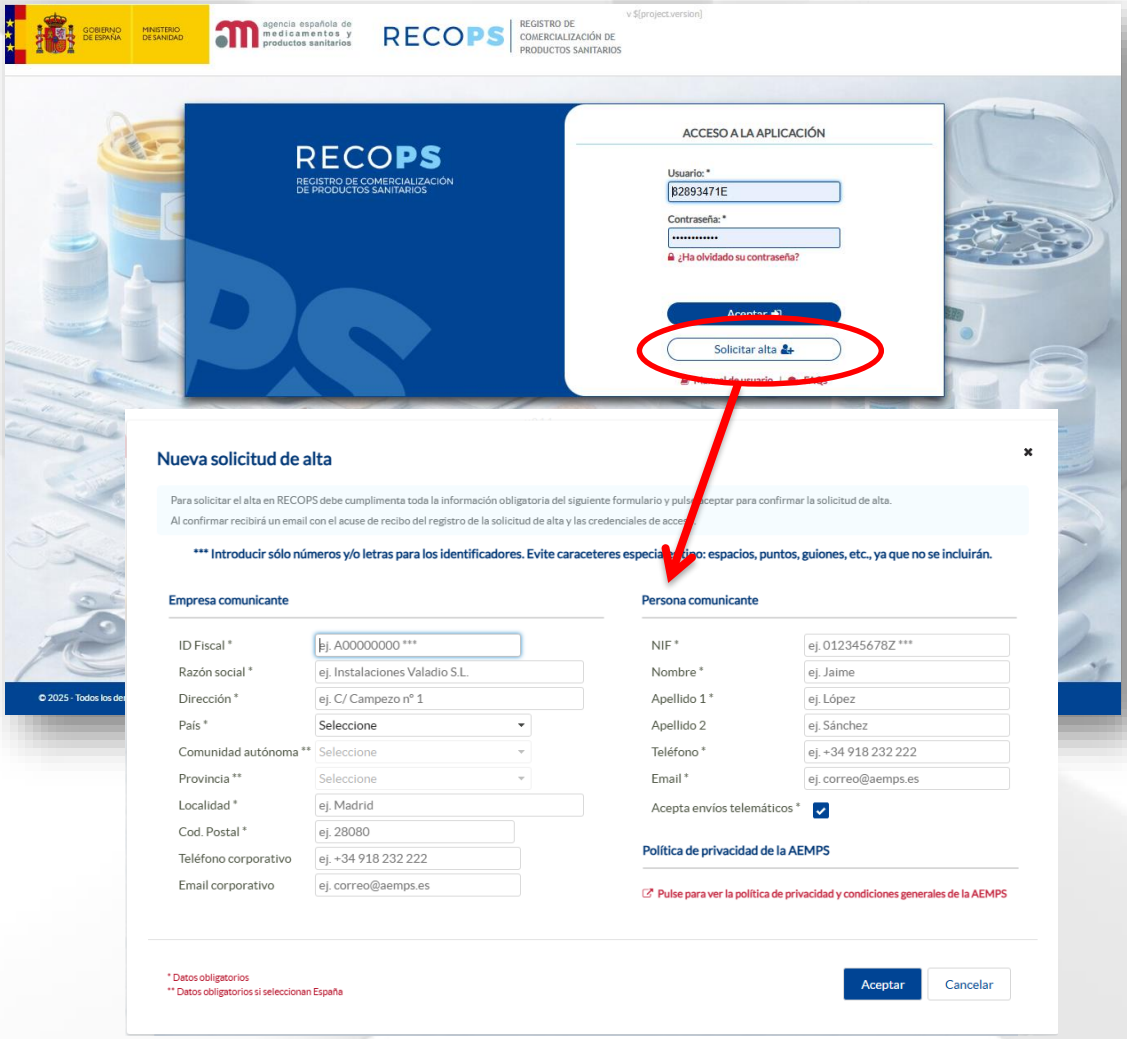
Accessing the Application - New user registration

- Before starting any other process, you need to register in the application. To do so, complete the mandatory "New Registration Request" form, where you will be asked to provide your company's current information and the details of a designated contact person.
- User accounts are personal and individual. Therefore, a separate user account is required for each person who will access on behalf of the same company.
- If a person works for more than one company, a separate registration request is required for each company they work for.
- If the data provided meets the required formats and validation criteria, the system will register your your registration request, validates the submitted data and sends an email confirming the process and providing the login credentials.



A modern, up-to-date web browser such as Edge, Chrome, Firefox, Safari or similar should be used.
The use of Internet Explorer is not recommended.

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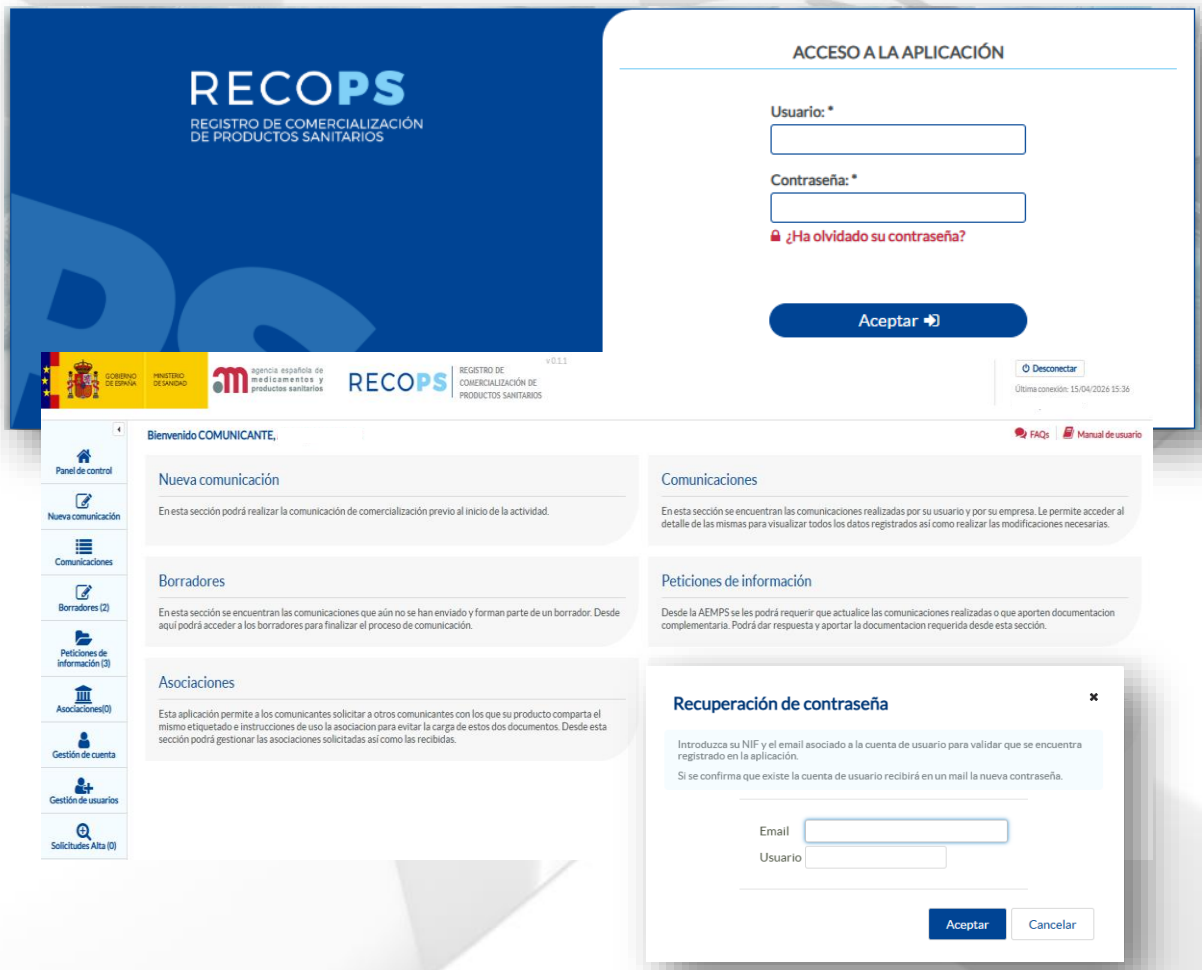
Accessing the Application - New user registration

- To access the application, enter the credentials provided by the AEMPS after the registration request has been processed:
  - User name, your National Identification Number (NIF/NIE)
  - Password
- After entering the credentials, click **OK**.
- If you cannot remember your password, you can request a new one by clicking the Forgot your password? Link.



RECOPS – AEMPS Medical Devices Register

Accessing the Application – First Login

- Once your login credentials have been activated, you can access the application.
- The first time you sign in, you will be required to :
  - Accept the application's Terms of Use.
  - Change the password received by email to a new one.

- After accepting the Terms of Use and setting your new password, your will be taken to RECOPS home page.

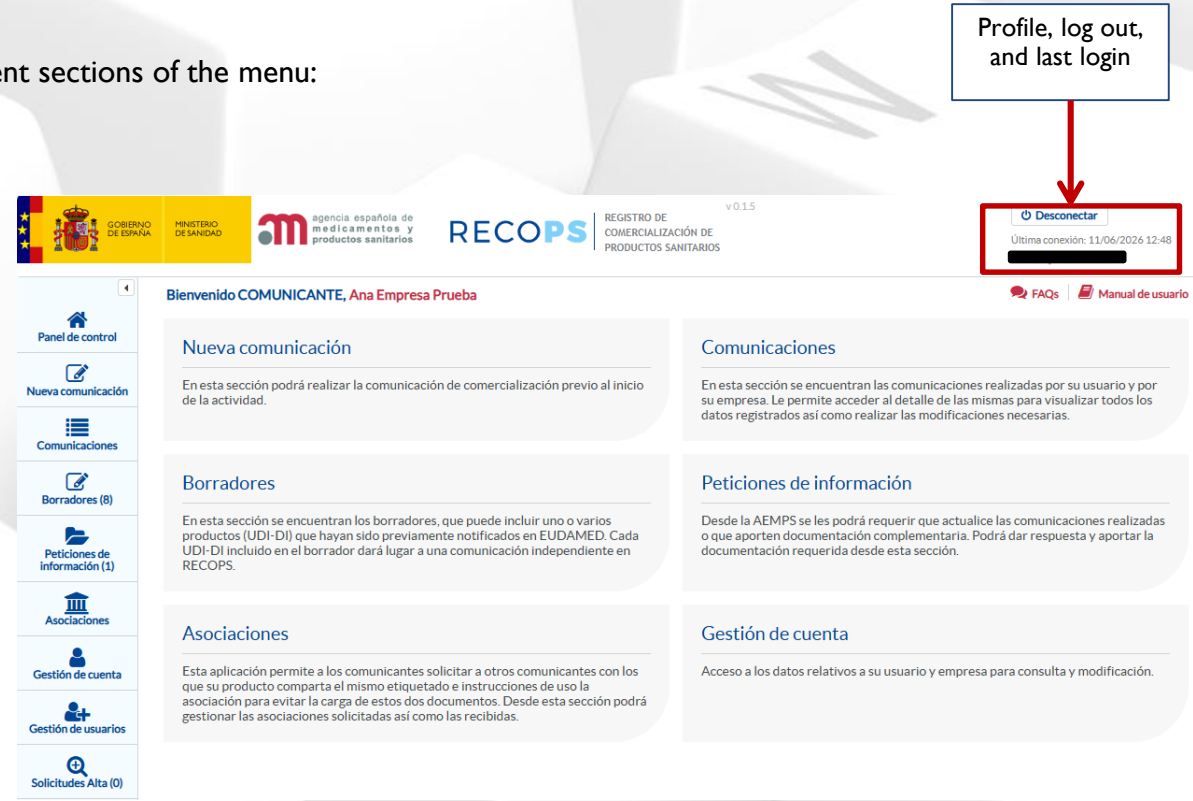
The password must contain at least one uppercase letter, one lowercase letter, one number and one punctuation mark. The minimum length is eight characters.

If you already have access to other AEMPS applications and choose a password that is different from the one you currently use for other applications, it will be updated across all AEMPS applications.

RECOPS – AEMPS Medical Devices Register
Home page

- From the home page, you can access the different sections of the menu:

- **Dashboard**: Quick access to the menu sections that require your attention.
- **New notification**: submit the notification before making the device available on the Spanish market.
- **Drafts**: Access draft notifications to complete and submit them.
- **Notifications**: View the details of notifications to review the recorded information, and make any necessary changes.
- **Requests for information**: Respond the requests from the AEMPS and provide the required documentation.
- **Associations**: Manage both requested and received associations.
- **Account management**: Access your user and company information.
- **User management**: Users assigned the "Coordinator" role can revoke access to other users.
- **Registration requests:** Users assigned the "Coordinator" role can manage registration requests from this section.

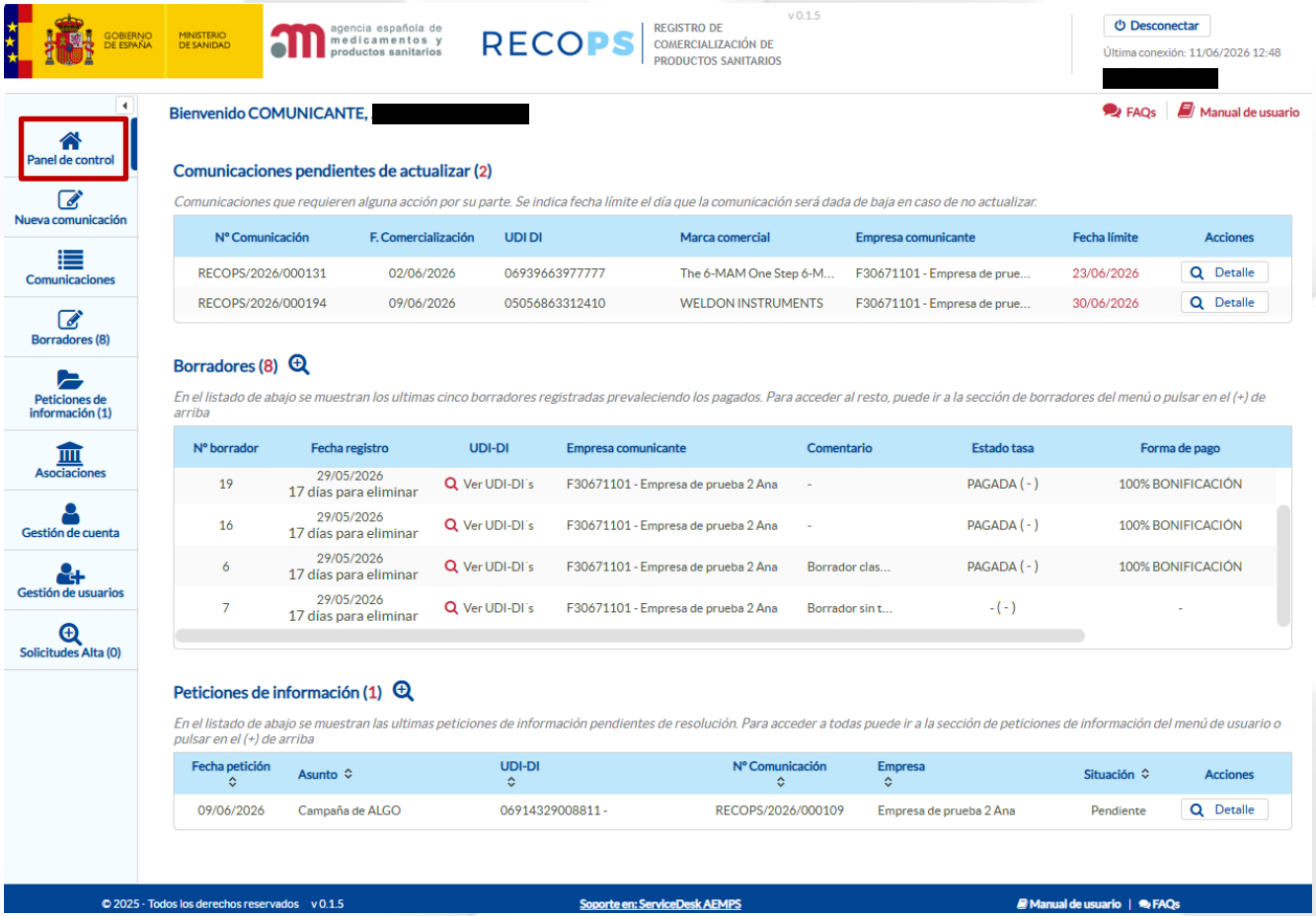


RECOPS –AEMPS Medical Devices Register
Dashboard

- The dashboard provides quick access to the four main sections of the application, allowing you to easily identify and review any items that require your attention.

The number displayed next to each section name on both dashboard and menu indicates the number of items that require your attention:

- **Notifications pending update**: List of notifications that require any action on you part.
- **Drafts**: Total number of drafts awaiting completition.
- **Requests for Information**: requests awaiting a response.
- **Associations**: Associations requests pending your acceptance or the other party's acceptance.



Menu – New Notification

- Click "**New notification**" to open the page where you can search for products notified in EUDAMED and submit their notification for making them available on the Spanish market.
- Notifications can be submitted either by uploading your own labels and instructions for use or by using documents provided by a company that has previously authorized their use through an association (see page 22 of this guide).
- A search tool is provided to help you locate the products you wish to notify.

Products need to be registered in EUDAMED and visible in the database before they can be notified.

- Once the list of products matching the search criteria is displayed, select one or more products by clicking "**Add Products**".
- The selected products are added to a temporary list called "**Added Products List**", which can be accessed by clicking "**View Added Products"**.
- You can perform different searches by repeating the search, select, and add process. All products are added to the same temporary list.

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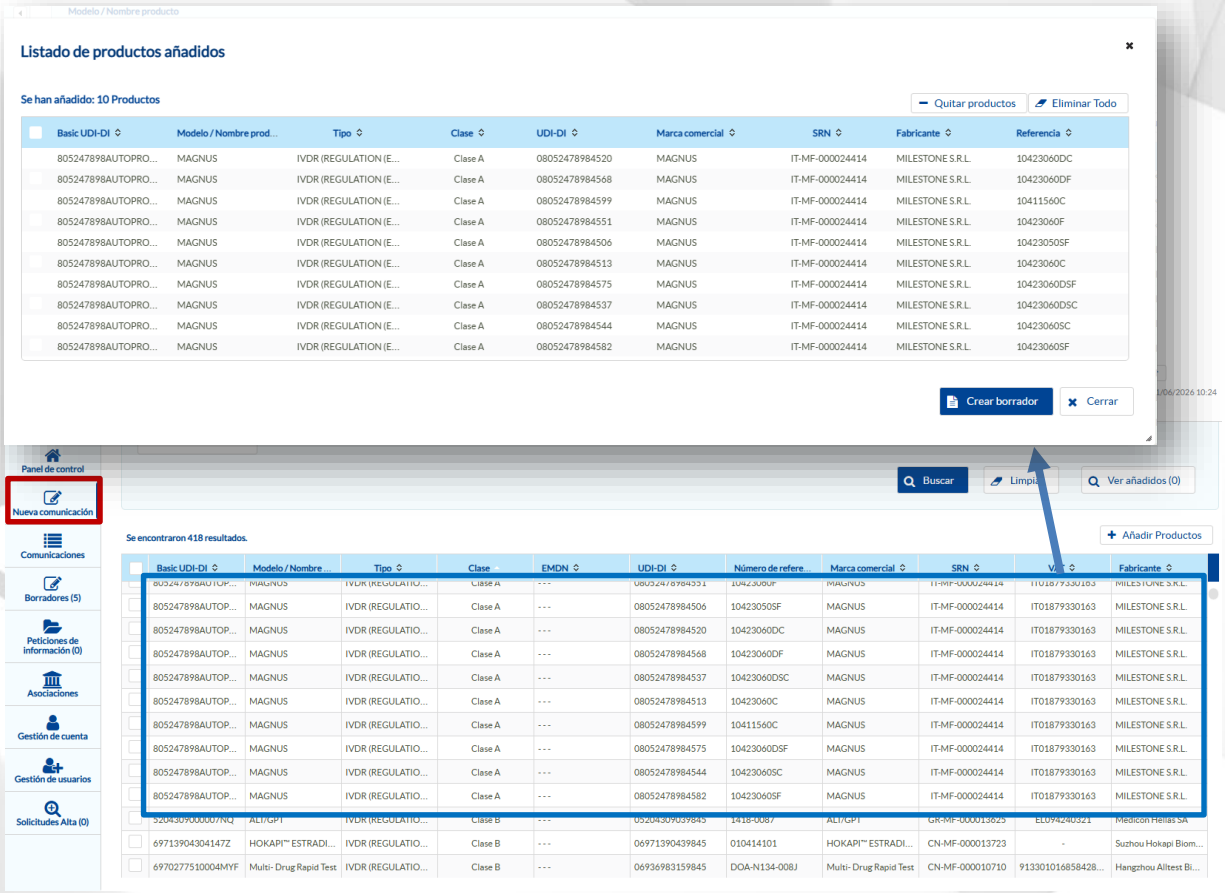
Menu – New Notification



- A single draft can include all products that share the same label, instructions for use, and making available on the market date.
- Each making-available-on-the-market notification in RECOPS corresponds to a single UDI-DI registered in EUDAMED. Therefore, a separate notification is created in RECOPS for each product (UDI-DI) included in the draft.

If a draft is not created, the temporary list is automatically deleted 30 days after the first product is added.

Only one temporary list is allowed at the same time.

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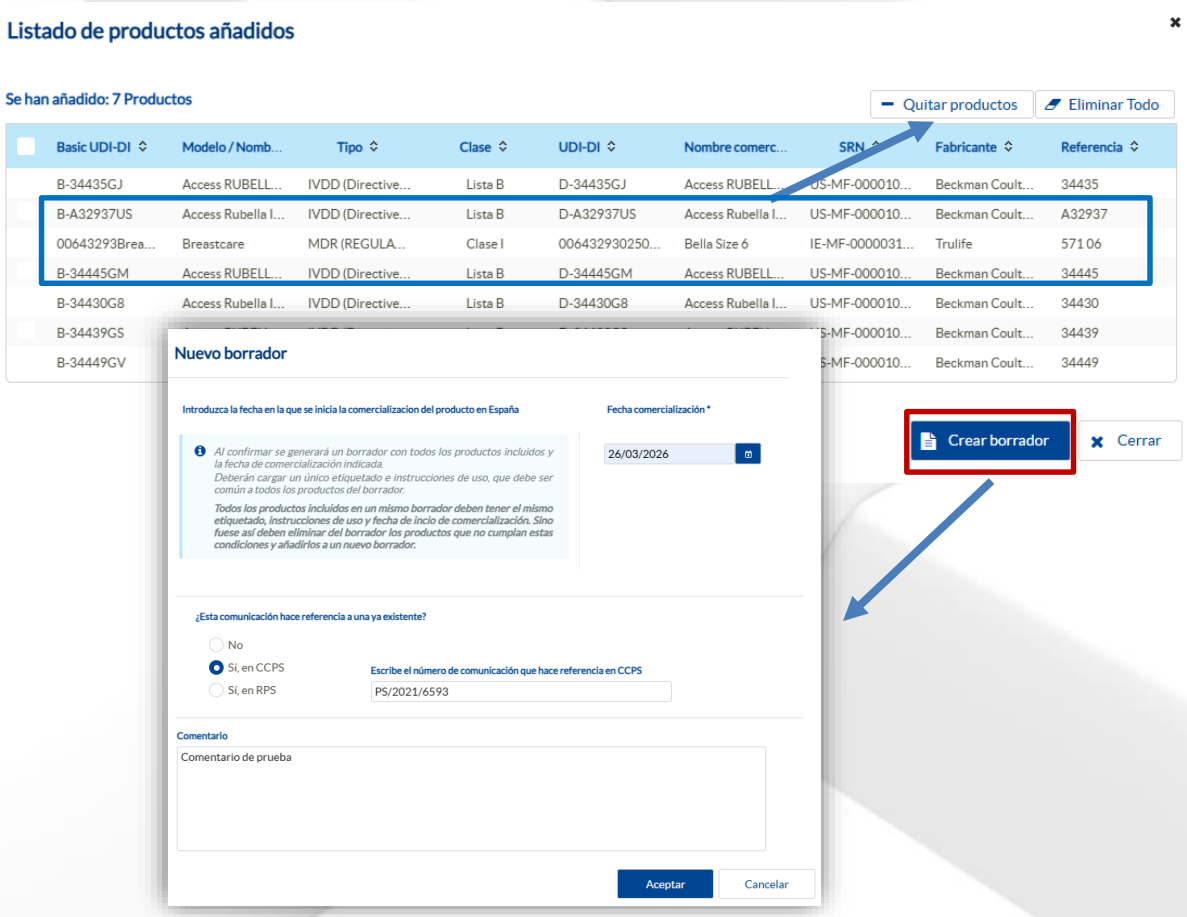
Menu – New Notification

- From the "**Added Products List**" you can remove individual products, clear the list or click "**Create draft**".
- Once you click "**Create draft**" the temporary list is cleared and no additional products can be added to that draft.

- After clicking "**Create draft",** complete the information requested in the pop-up window:
  - The **making available on the market date** for the products included in the list.
  - If the products come from a notification submitted through CCPS or RPS, enter the original notification number so the system can perform the necessary validation checks.
  - Optionally, enter a comment to help you identify the draft.
  - If the notification was previously submitted through CCPS or RPS, select validate.



Notifications for previously submitted products through CCPS or RPS are exempt from the initial fee. All products included in the draft are required to be notified under the same CCPS or RPS notification.

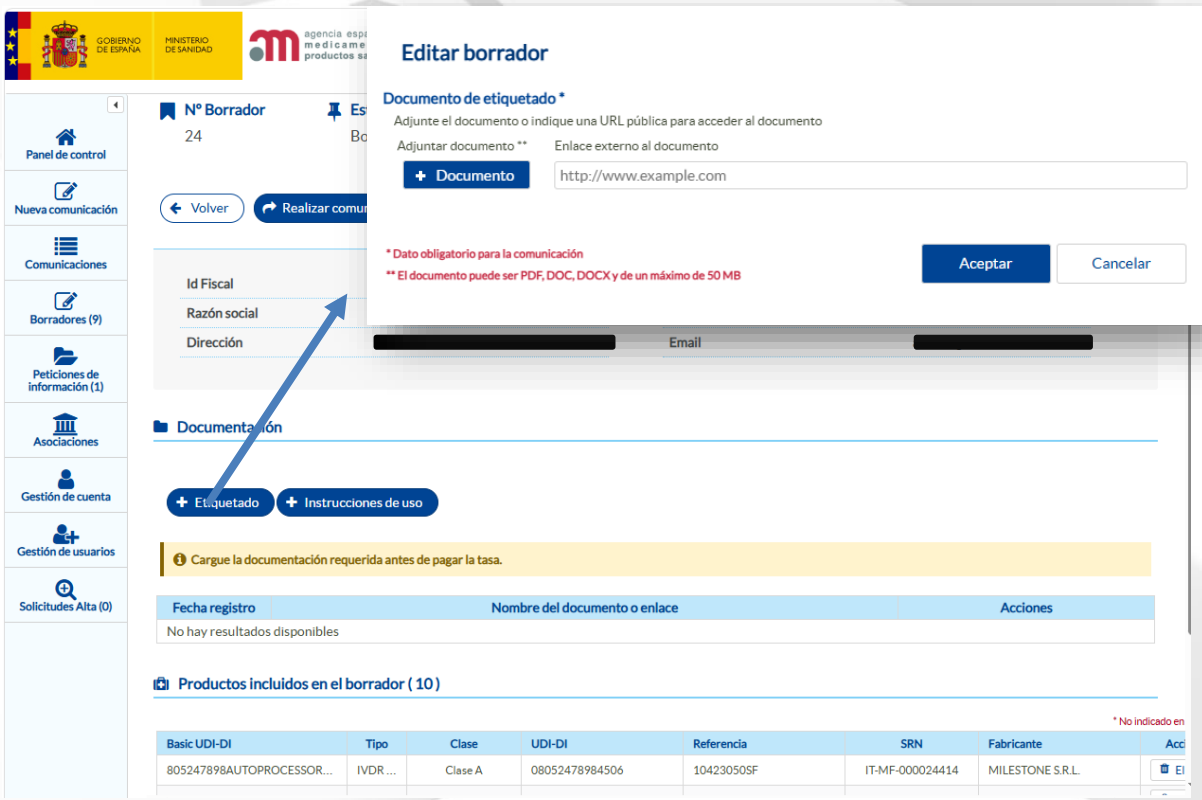
Documentation (Label and Instructions For Use)

You can either upload the document or provide a public URL where the document can be accessed.

- Clicking the buttoms to upload the documents opens a pop-up where you can either upload a document or provide an external link. You can upload more than one document for both the label and the instructions for use.

- After clicking "**Ok**" the list of uploaded documents is displayed. Documents can be removed from the list until the fee is payed.

- The list of documents is displayed at the end of the draft. Once the notification has been submitted, the documents are linked to all products (UDI-DI) included in the draft.



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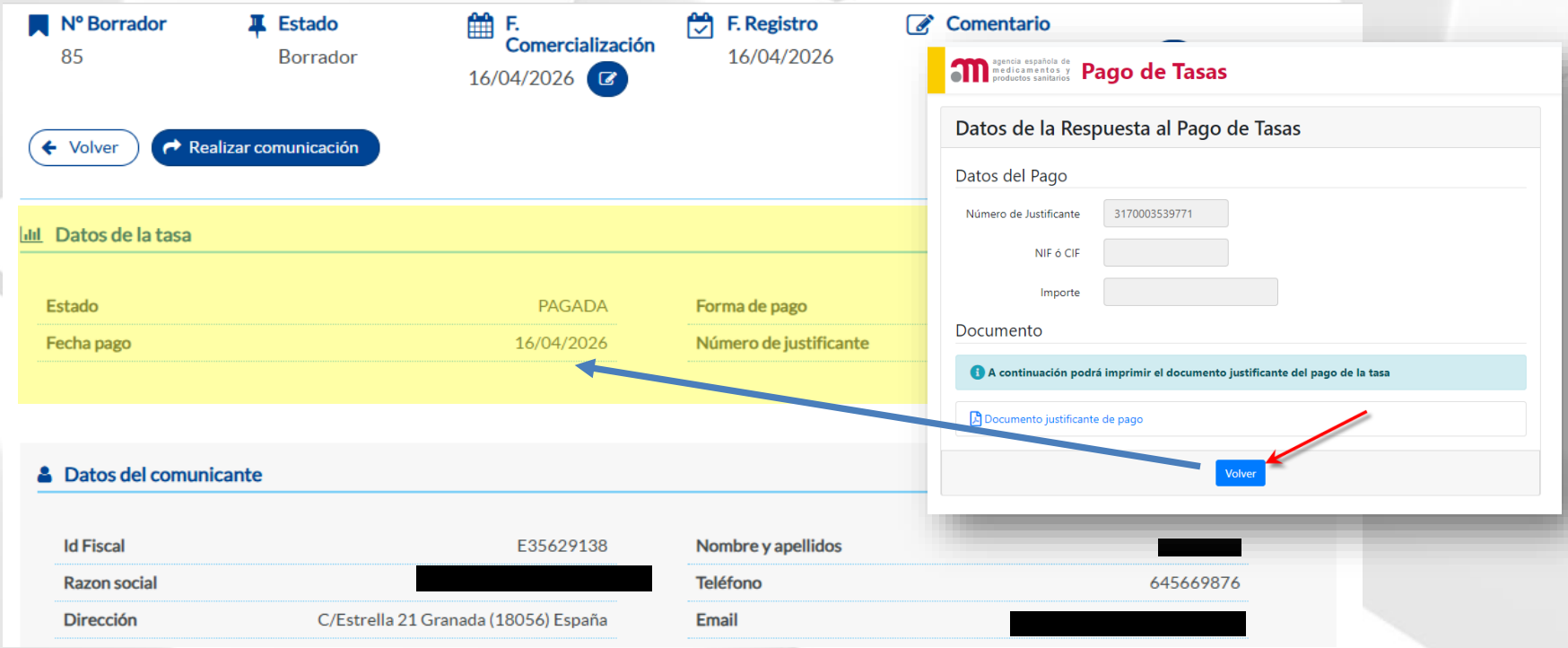
Menu – New Notification

Fee payment

- Detailed information about the fee payment process is available within the application.
- Once the fee status is PAID, you can submit the notification. While the fee status is PENDING, you will need to wait until the payment is automatically confirmed in RECOPS using the payment information provided by the Accounting Department.



Important: After completing the fee payment, click **Return** to go back to RECOPS and submit the notification from the draft.

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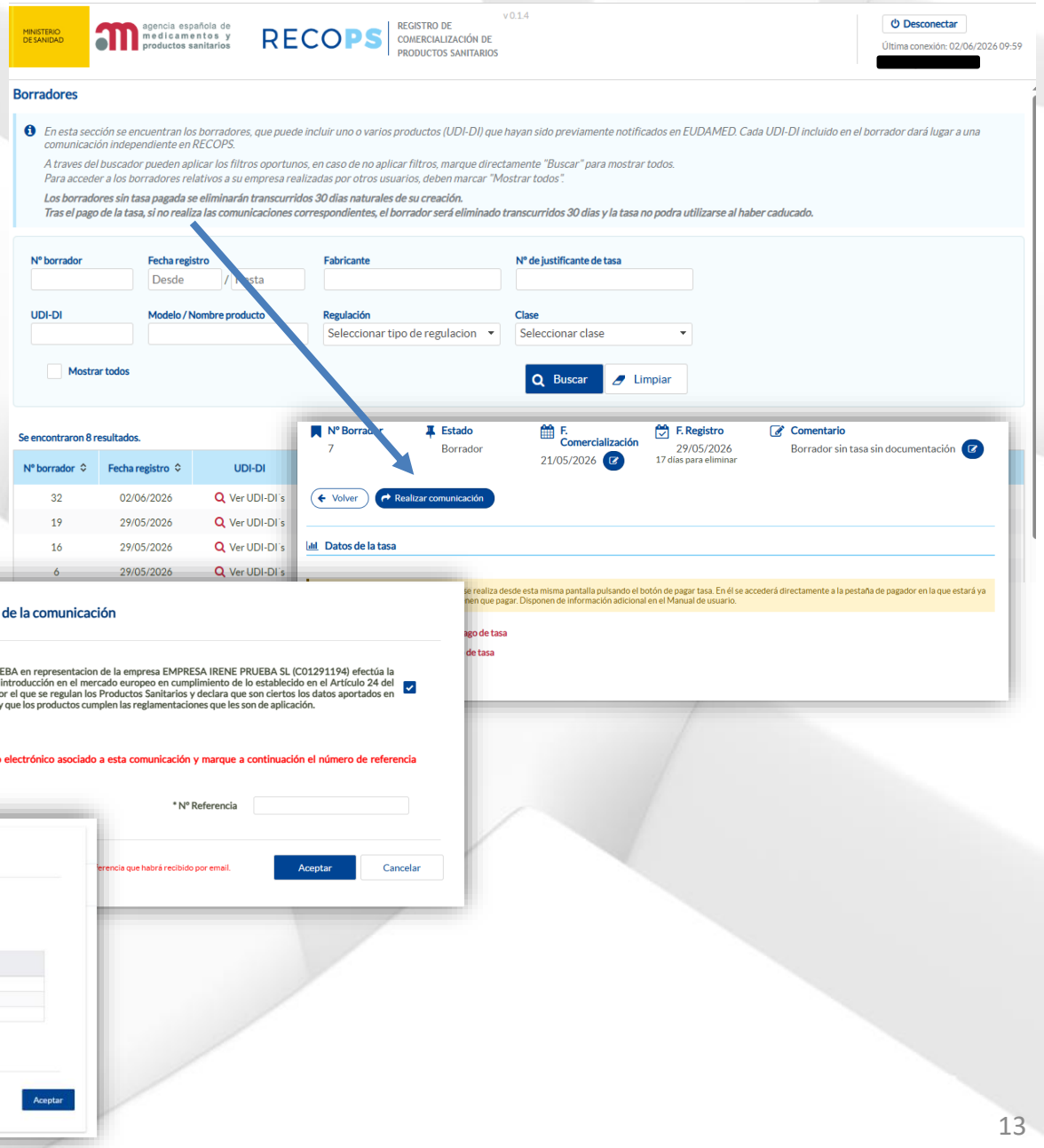
Menu – New Notification

Submit notification

- Once you have completed the process, click "**Submit notification**".
- You will receive an email containing a reference code, which needs to be entered in the new pop-up window.
- Select the checkbox, enter the reference code, and click "**Ok**".
- The notifications will then be submitted.
- Click "Ok" and you will be able to access the newly submitted notifications from the "**Notifications**" section of the menu.



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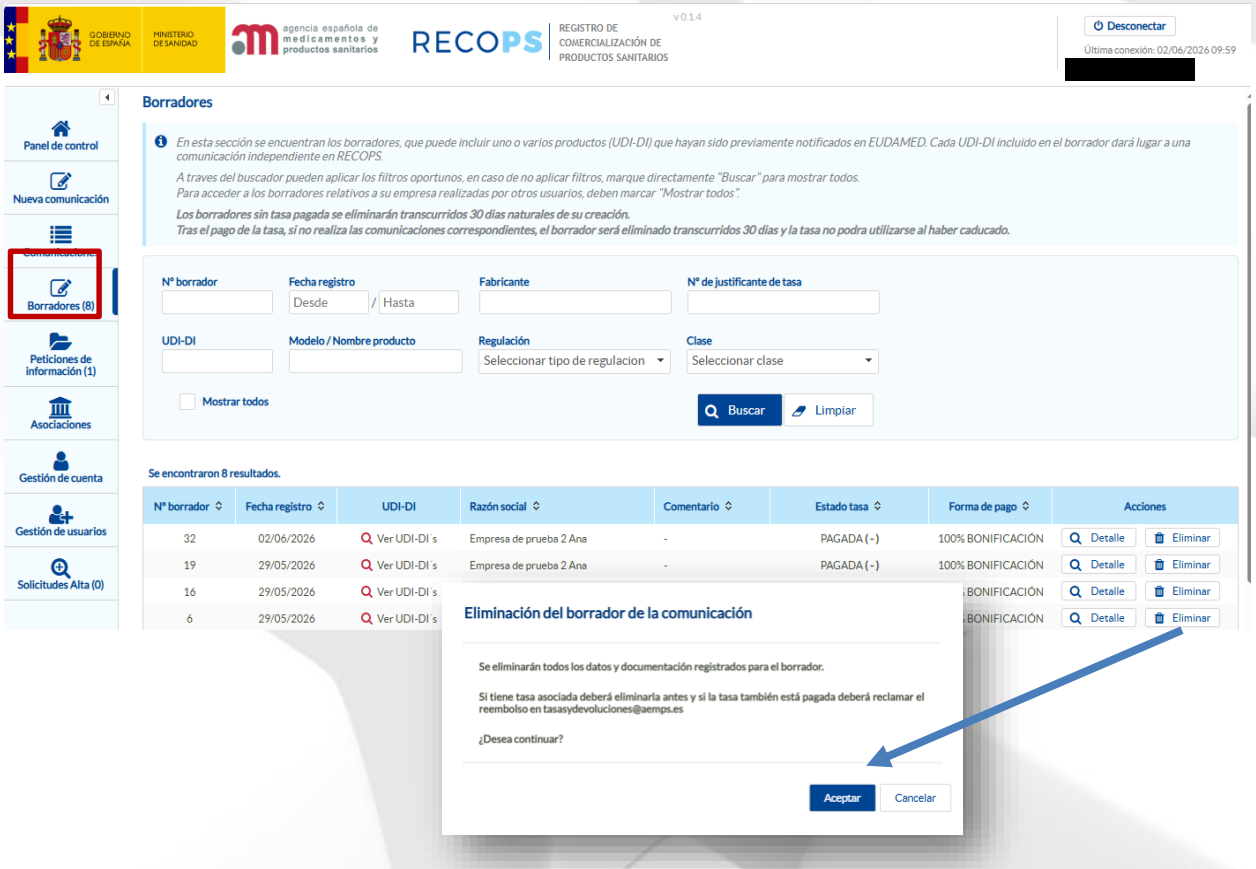
Menu – Drafts

- This section allows you to view draft notifications that have not yet been completed and continue the process of submitting the corresponding notifications.
- To display all drafts, click "**Search**" without entering any search criteria.
- The search tool allows you to view drafts created by your user account as well as by other users in your company. To view drafts created by other users, select "**Show All**".
- In the list of drafts, click "**Detail**" to view the content of the draft.
- You can also view the draft registration date, the payment date, and the number of days remaining before the draft expires if the corresponding notification is not submitted.

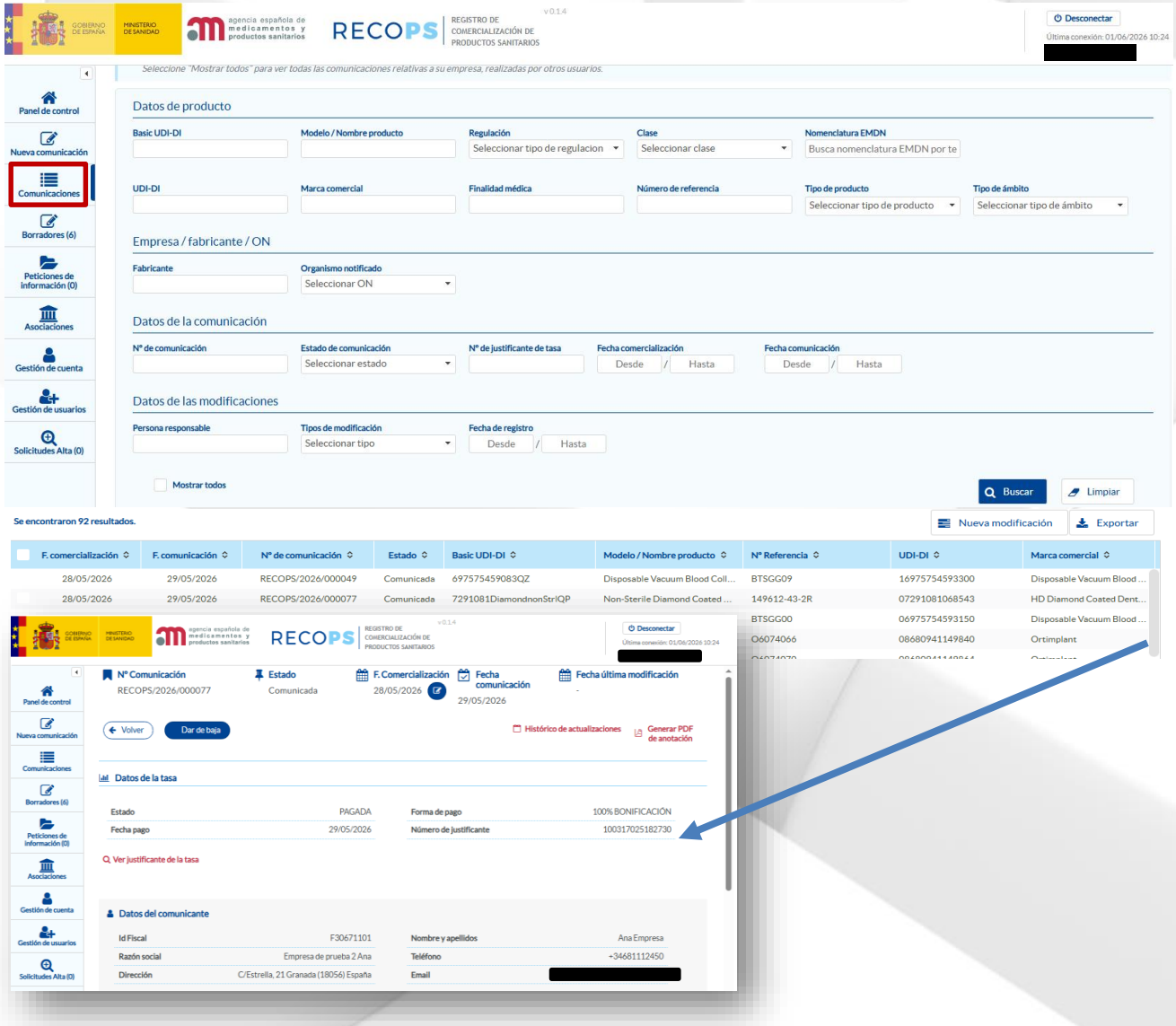


- Drafts can be deleted by clicking "**Delete**" and confirming the action. Drafts with a fee cannot be deleted.
- Drafts for which fee has not been payed are automatically deleted 30 calendar days after they are created.
- If the fee has been paid but the corresponding notifications are not submitted within 30 days, the fee expires and can no longer be used. In this case, you can delete the fee and pay it again if you wish to submit the notifications included in the draft.

RECOPS – AEMPS Medical Devices Register

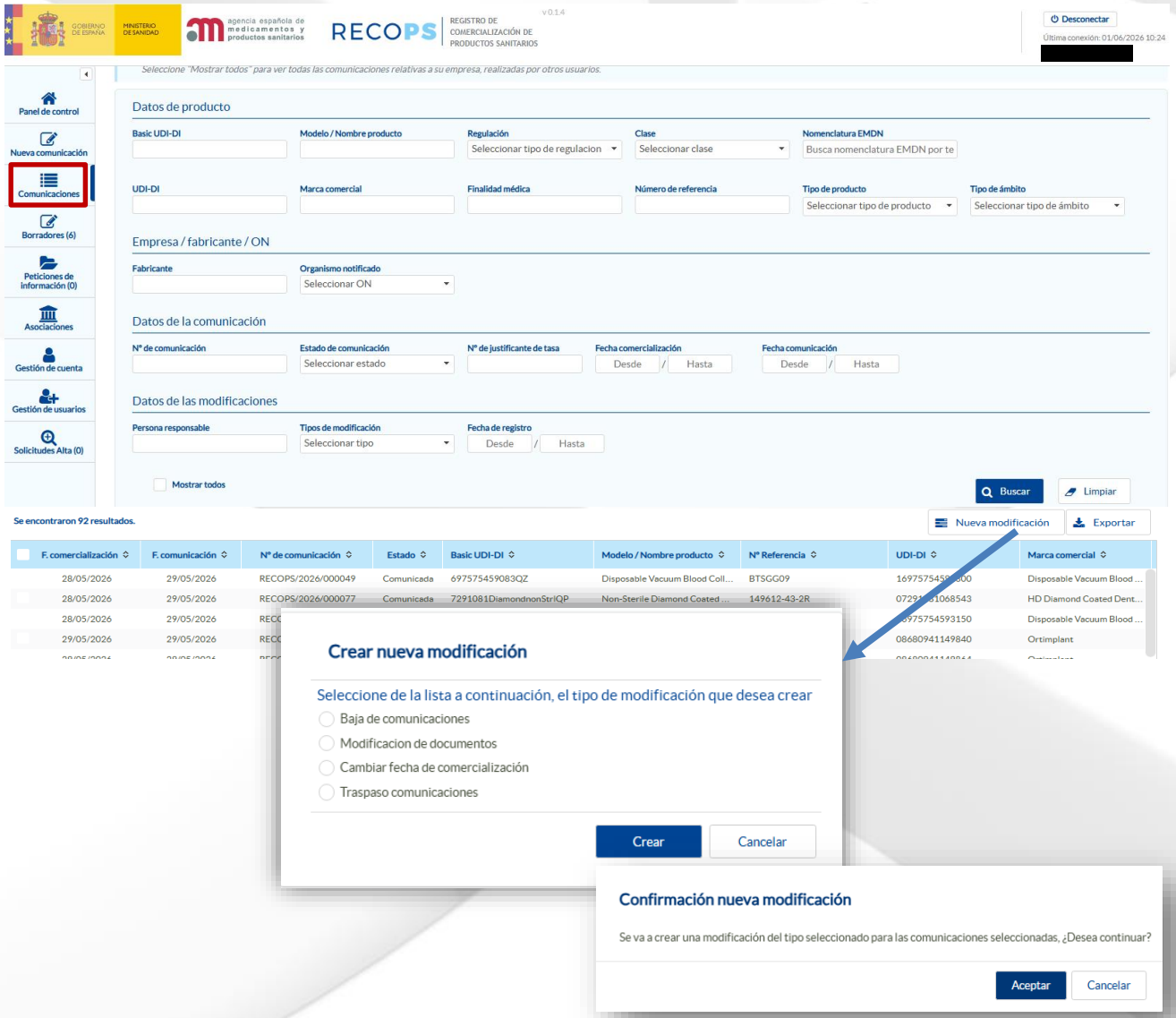
Menu – Notifications

- The notifications menu allows you to view notifications submitted by your user account as well as by other users in your company.
- To display all notifications, click "**Search**" without entering any search criteria. To view notifications submitted by other users in your company, select "**Show all**".
- To view the details of a communication, click "**Details**", in the rightmost column.



RECOPS – AEMPS Medical Devices Register
Menu – Notifications

- To make changes, you can either open the "Detail" of an individual notification or select multiple notifications and click "**New change**".
- A pop-up window opens, allowing you to select one of the following changes types:
  - **Withdrawal**
  - **Document update**
  - **Change Date of Place on the Market**
  - **Transfer notifications**



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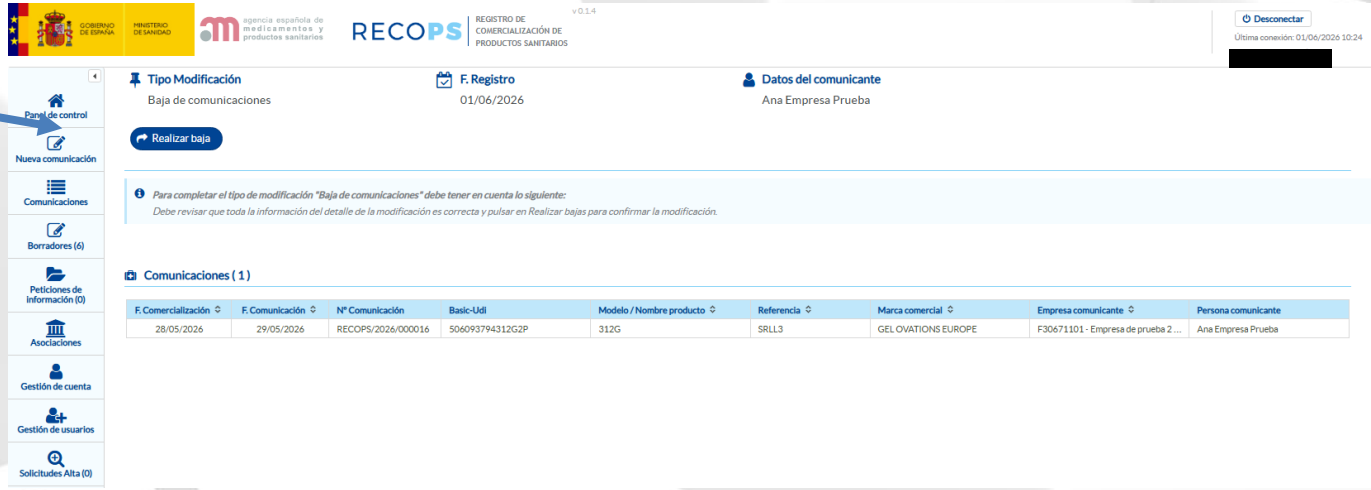
Menu – Notifications

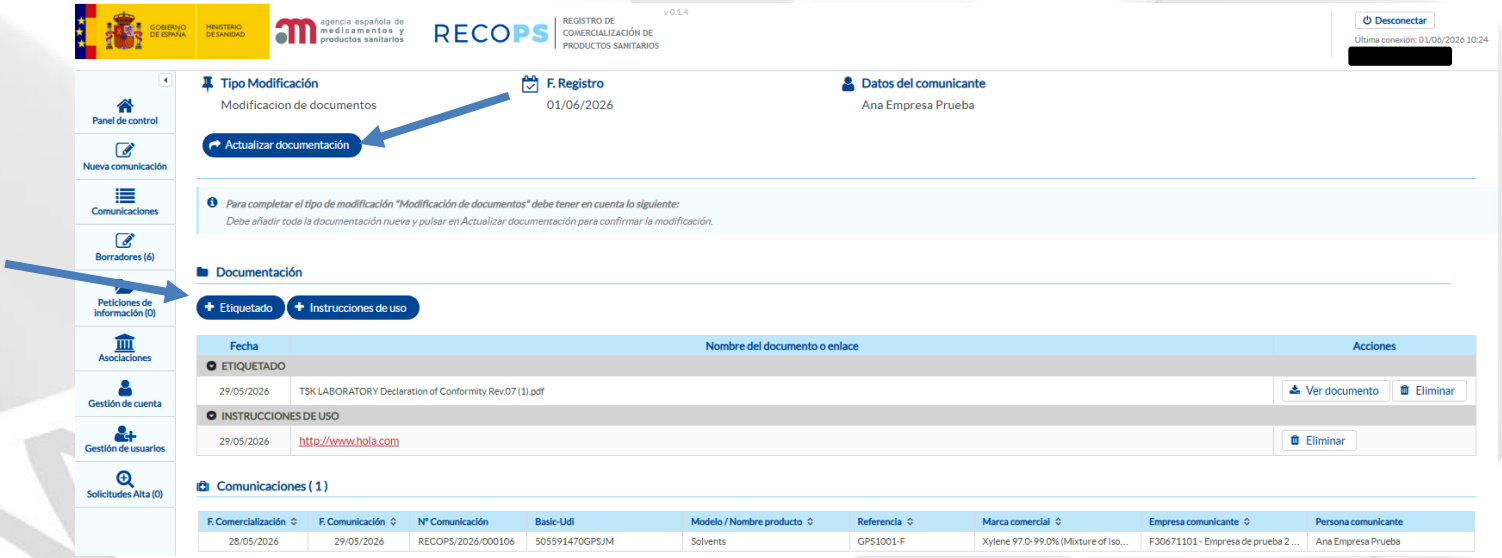
- **Withdrawal**



- Select **Submit withdrawal.** You will receive an email containing a reference code, which needs to be entered in the new pop-up window. Select the checkbox, enter the reference code you received, and click "**Ok**".

  The notification will then be withdrawn.

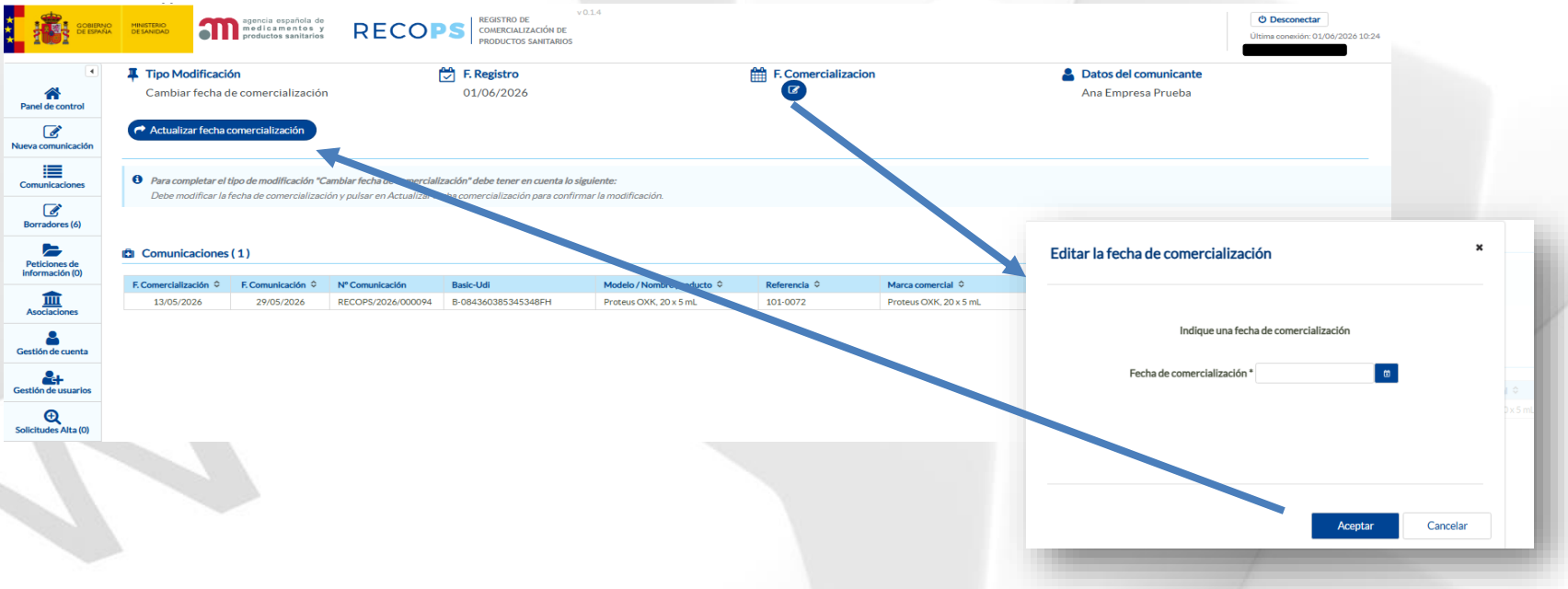
- **Document update**
  - Add or remove the documentation for the selected notifications.



- Select **"Update documentation".** You will receive an email containing a reference code, which needs to be entered in the new pop-up window. Select the checkbox, enter the reference code you received, and click "**Ok**".
- The documentation will then be updated

To update the documentation for multiple notifications, they must all have the same label and instructions for use.

- **Change Placing-on-the-Market Date**
  - Change the date and select "**Update Placing-on-the-Market Date**"



You will receive an email containing a reference code, which needs to be entered in the new pop-up window. Select the checkbox, enter the reference code you received, and click "**Ok**".

The notification will then be updated.

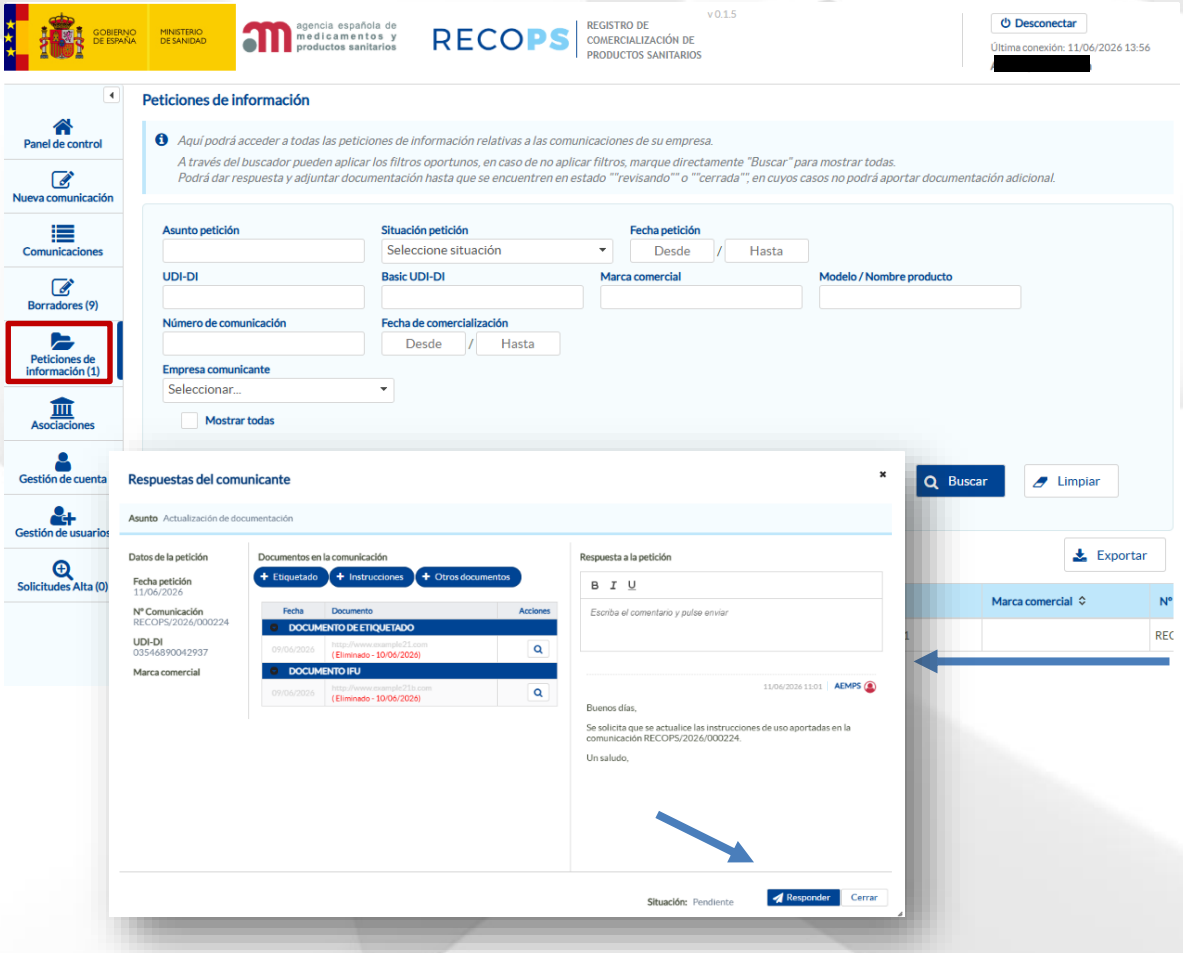
The placing-on-the-market date can only be updated for multiple notifications if they all have the same placing-on-the-market date.

- **Transfer notifications**
  - Select the user account to which you want to transfer the notification.

  - Select "**Transfer notifications"**. You will receive an email containing a reference code, which needs to be entered in the new pop-up window. Select the checkbox, enter the reference code you received, and click "**Ok**".
  - The notification will then be updated.

RECOPS – AEMPS Medical Devices Register
Menu – Requests for Information

- The AEMPS may ask you to update submitted notifications or provide additional documentation.
- You can respond to this requests and upload the required documentation from this section. Click "**Details**" to open a request.
- The search tool enables you to view requests for information, which may have one of the following statuses **("status")**:
  - **Pending**: no response has been submitted yet.
  - **Responded**: a response has been submitted, but it can still be modified.
  - **Under review**: the AEMPS is reviewing your response. At this stage, neither the response nor the supporting documentation can be edited.
  - **Closed**: the request has been closed by the AEMPS staff.

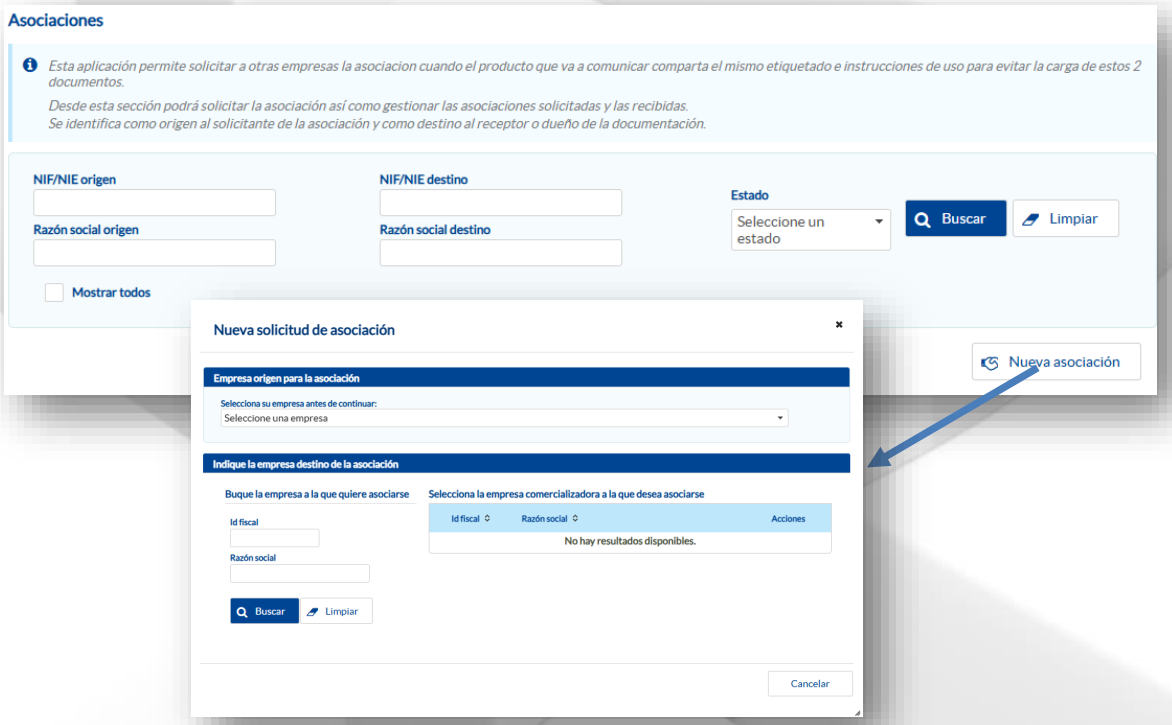


- When you have finished, click "**Submit"** to send your response to the AEMPS for review.

Association request

- From the "**Associations"** section of the menu, you can request an association with another company. An association allows you to use that company's labels and instructions for use for products that share the same documentation.

- Click "**New Association**" and, in the pop-up window, select the company you want to associate with (destination).
- If your user account is linked to more than one company, first select the company on whose behalf you are requesting the association.
- The company you want to associate with (destination) needs to have existing notifications in RECOPS. Otherwise, it will not appear in the search tool.



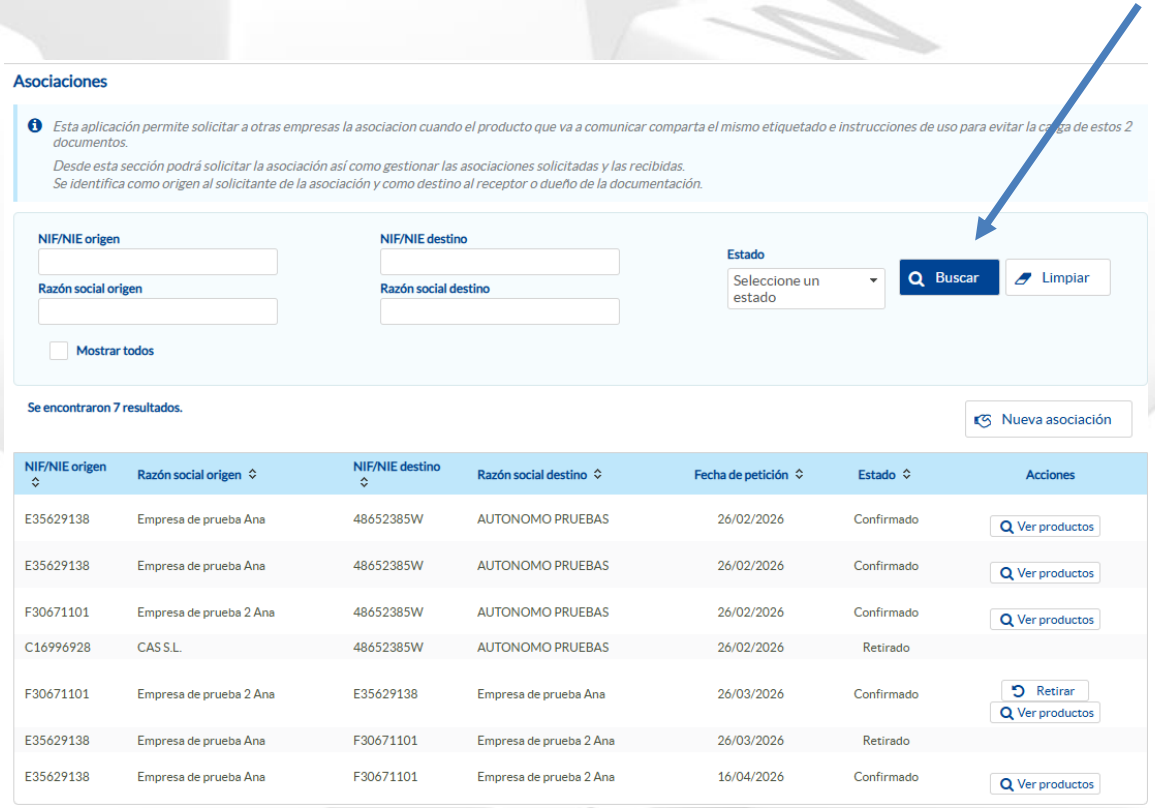
- The company that owns the labels and instructions for use (destination) receives the association request and can either approve or reject it.

If the destination company does not approve the request within 15 days, the application automatically rejects it. This does not prevent you from submitting a new association request.

- An association request needs to be in the "**Approved"** status before the requesting company (source) can use the destination company's labels and instructions for use in a new notification.

Association management

- From the search tool available in the **Association** section, you can view all your associations, whether you are the requesting company (source) or the receiving company (destination), by clicking "**Search**".
- The receiving company (destination) can withdraw an association at any time as well as view its details.
- If the receiving company (destination) withdraws the association, the requesting company (source) will need to upload its own documents or associate with another company. Otherwise, the affected notifications will be removed after 21 calendar days.
- If the receiving company (destination), which owns the documents, updates them, the updated documents are applied to all relevant notifications, including those that use the associated documents. The application notifies the requesting company (source) of the update.



- This section allows you to view and update your company and user account information.
- User accounts are personal and linked to the user's National Identification Number (NIF/NIE).
- If you need access on behalf of more than one company, submit a new registration request from the application's sign-in page (see page 3 of this guide).
- A company can have multiple registered users. All registered users can access the company's notifications, regardless of which user submitted them.
- Each company should have one or two users assigned the "**Coordinator"** role.
- The first coordinator is assigned automatically by the application to the first user who registers for the company.
- Additional coordinator assignments or changes can be managed from the User Management section (see page 25 of this guide).
- Only coordinators can update company information. Any changes are reflected across all notifications and user accounts for the company. Coordinators also have access to the additional functions available in the User Management and Registration Requests sections.
- Click **Save** when you have finished making your changes.

The Company identifier (Tax ID) and the user identifier (NIF/NIE) cannot be changed.

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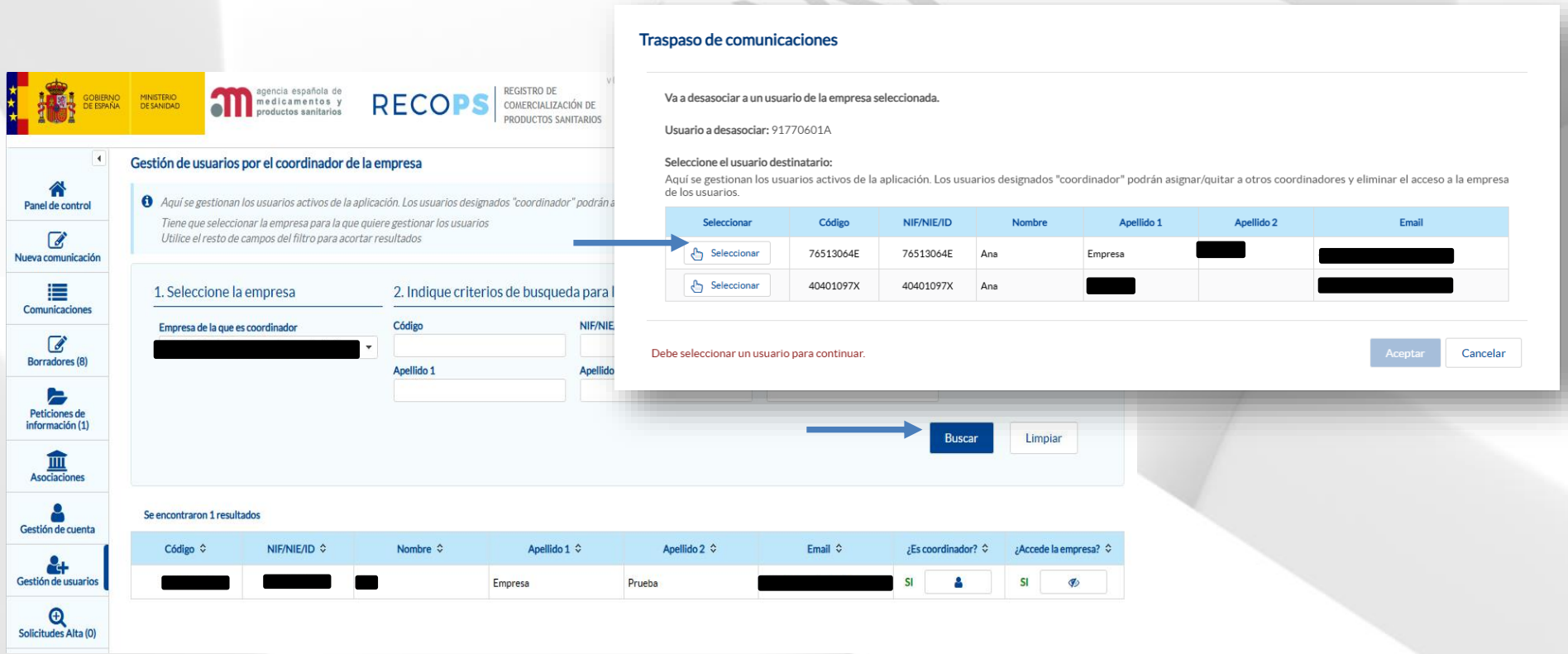
Menu – Users Management

- The **Users Management** section is availale only to users with the coordinatior role.

- From this section, coordinators can manage:
  - **Company coordinators**. Assign or revoke coordiantion permissions.
  - **Company users**. Enable or restrict user access. When a user's access is revoked, the application prompts you to transfer that user's notifications to another user in the company.



RECOPS – AEMPS Medical Devices Register

Menu – Registration Requests

- The **Registration Requests** section is available only to users with the Coordinator role.
- From this section, coordinator can approve or reject registration requests submitted by other users of their company.

RECOPS

Register for making medical devices available on the Spanish market

SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES