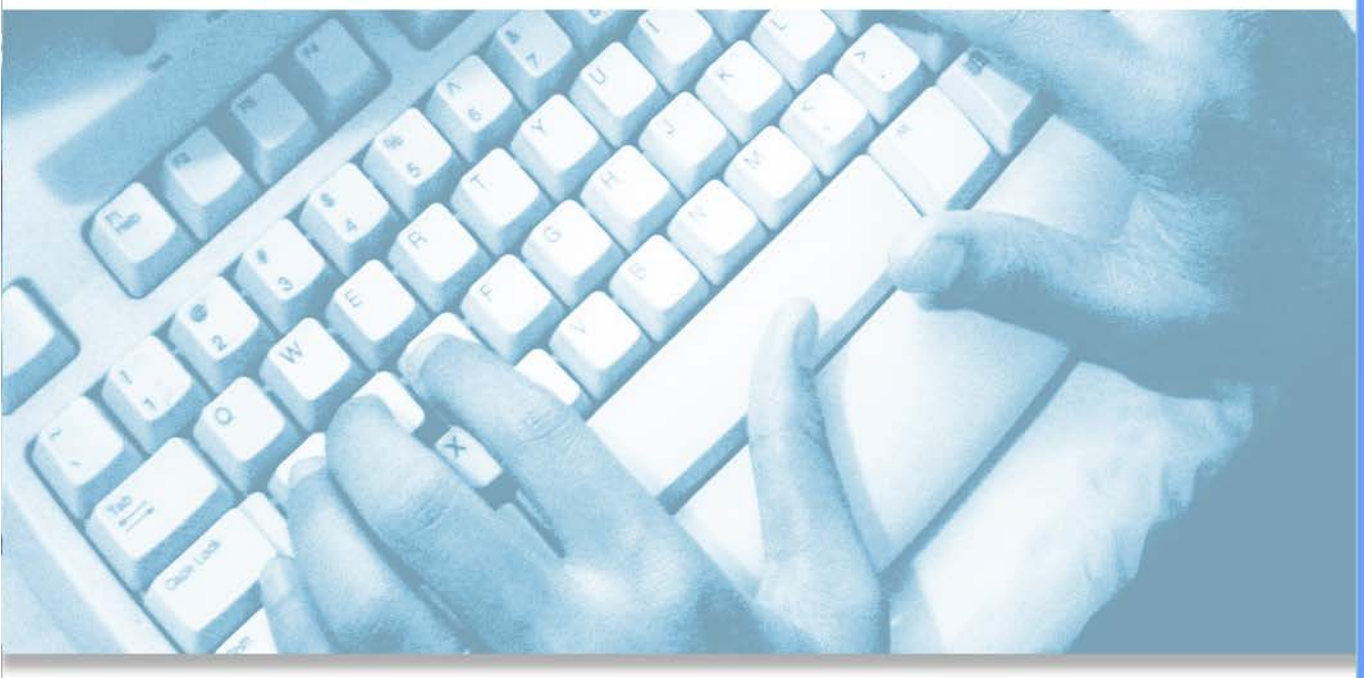
RAEFAR II – Centralized Procedures Guide Application for National Code & Notification of changes for medicines authorized by centralized procedure.

Version 1.0.0

Spanish Agency of Medicines and Health Products



MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Sede Electrónica

Publication date: 19 september 2017

IT systems division

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1. INTRODUCTION

The Spanish Agency of Medicines and Health Products (AEMPS), has adopted an initiative so that, once the Committee on Medicines of Use Human (CHMP), of the European Agency of Medicines (EMA), has given Positive Opinion for a medication authorized for centralized procedure, the lab owner of the authorization of marketing (TAC), may voluntarily present telematics "Application National Code and Packaging Material for marketing in Spain" through the application of registration of medicinal products for human use (RAEFAR II).

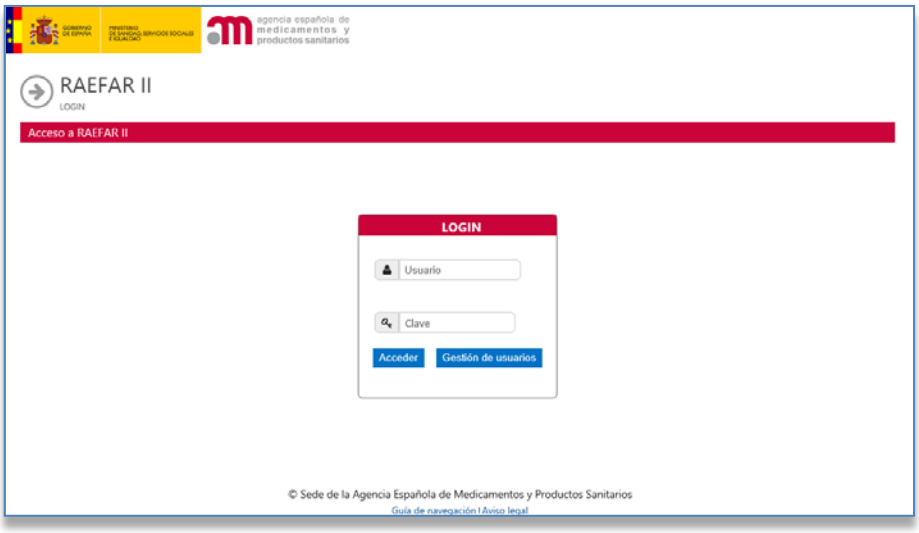
You can also report the changes which had taken place on the state of medicine centralized after the positive opinion from the CHMP of the EMA.

2. GETTING ACCESS

The application requires that all users who will access, must be registered as a user authorized for a company in our database. If you don´t currently have credentials for access, you have to application for them at AEMPS USER MANAGEMENT application https://sinaem.agemed.es/registroaemps/Pages/acceso.aspx, or take contact with application admin user assigned for your laboratory.

2.1. Access portal

For getting access to the application use the following link: https://sinaem.agemed.es/RAEFAR.



In the gateway should indicate their credentials (username and password). Once inside, the user will have access, to manage applications for medicines, laboratories for which you have permissions.

In case of not remembering the password or want to change it, you can reset it from the own welcome screen, by clicking on the button "Users management".

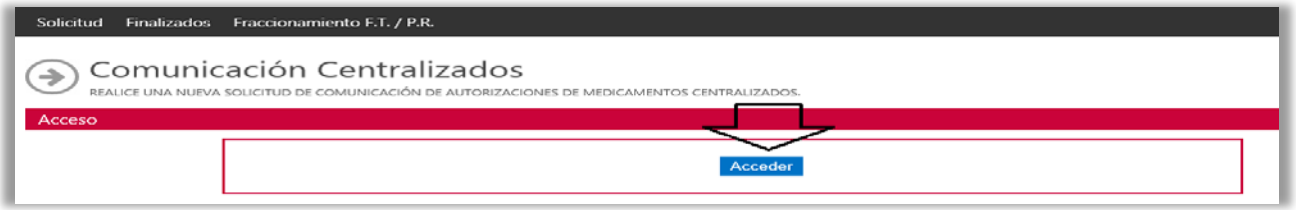
3. INITIATE APPLICATION FOR CENTRALIZED MEDICINES

3.1. Communication of centralized medicines

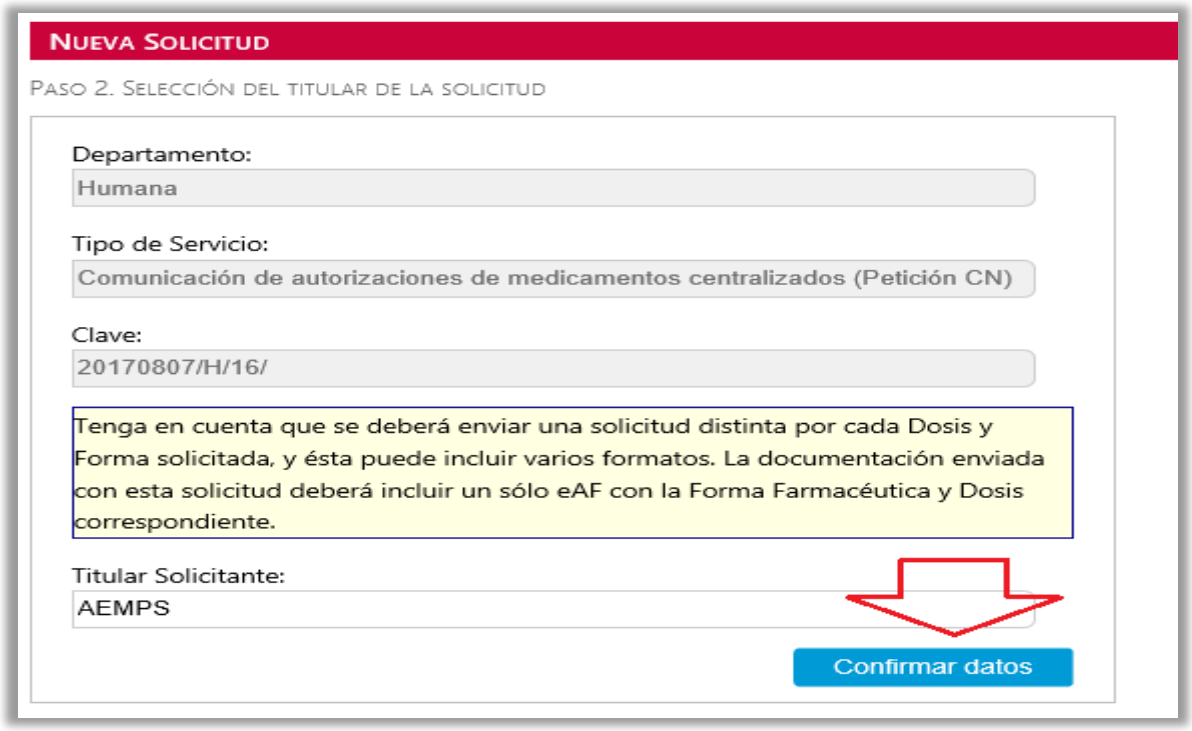
To apply for a national code to a centralized medicine, you have to send an application form and some documents by RAEFAR, according the Informative Note MUH, 8/2017 (https://www.aemps.gob.es/informa/notasInformativas/industria/2017/NI-MUH_08-2017-Raefar-II.htm).

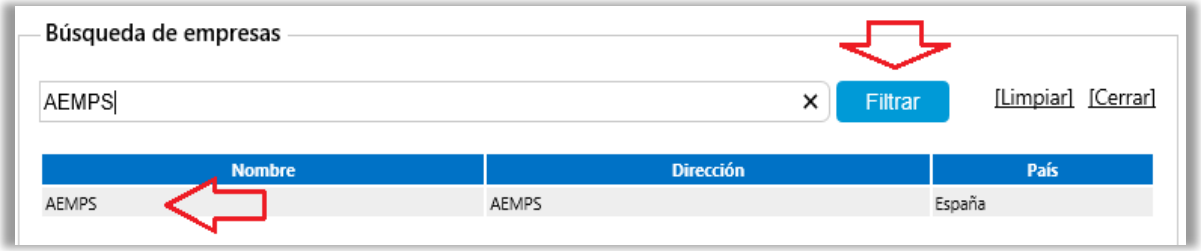
For this, you have to click on **"SOLICITUD"** in the top menu, then choose **"Comunicación Med. Centralizados"** and **NUEVA SOLICITUD** in the drop-down menu. In case we want check the status of previously submitted applications or make any additional information (required or not applicationed by the AEMPS, as the case), choose **"Consulta mis solicutudes/Inf adicional"**.

After you select the type of application, click on **"ACCEDER"**.



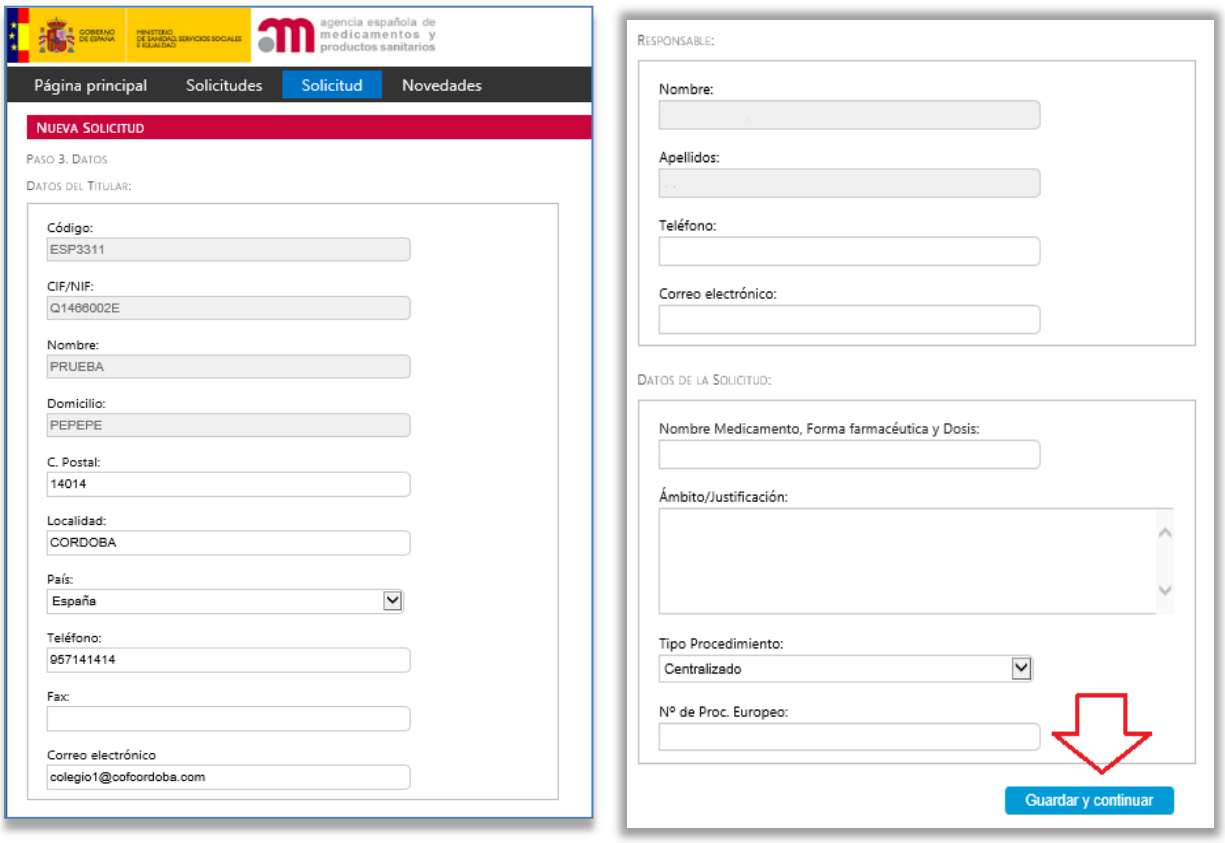
Once inside, the application will assign an application number (key), and you must indicate and select the laboratory owner of the medicine you wish to apply for the national code. Don't forget to click on **"CONFIRMAR DATOS"** to confirm the data.





NOTE: Please note that a separate application must be submitted for each dose and applicationed form, and may include several formats. The documentation sent with this application must include a single eAF with the corresponding Pharmaceutical Form and Dose.

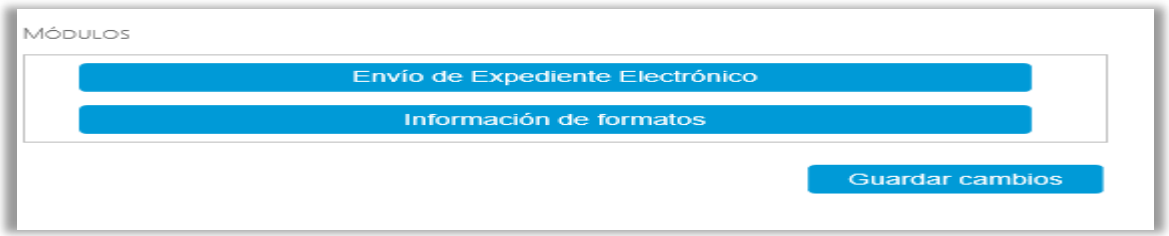
Once we confirm the data, it will give us access to the own application form, where we fill the holder laboratory data (**Datos del Titular),** contact person data (**Responsable**), and the application details (**Datos de la Solicitud**). In the latter field, you should indicate the medicine name, reason for sending, type of procedure and number of European procedure. Once completed, don't forget click on "save and follow" (**GUARDAR Y CONTINUAR**).



- **MODULES**

Once click on the "**GUARDAR Y CONTINUAR"** button, will have access to the modules (**MODULOS**).

From here you can attach the necessary documentation in electronic format (only sequences Nees will be accepted for applications of national code for centralized medicines), and specify the data of the medicine for which applicationed the national code.



Electronic file submission (Envio de Expediente Electronico)

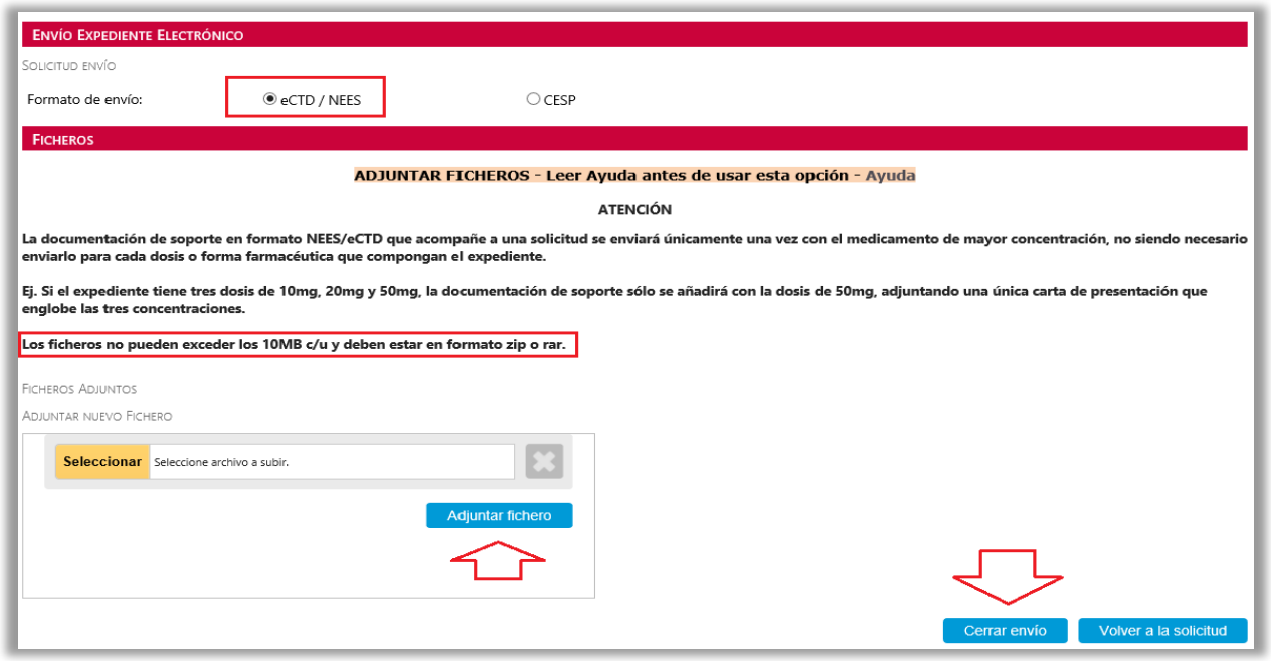
From the module **ELECTRONIC FILE SUBMISSION** you can attach the Nees sequence with the support documentation for the application (according to information note https://www.aemps.gob.es/informa/notasInformativas/industria/2017/NI-MUH_08-2017-Raefar-II.htm).

The sequence with the supporting documentation, must be under format NeeS [(Non-eCTD Electronic Submissions).] You can find information related to this type of sequence, validation rules, and help in the Electronic Site of the AEMPS and/or eSubmission guides.

Please note that a separate application for each dose and/or pharmaceutical form must be sent, and this may include various formats. The documentation sent with this application must include just one eAF with the dose and corresponding pharmaceutical form.

Once you create the sequence, it has to be zipped in ZIP or RAR format. Tick the **eCTD/NEES** option, select and attach the zip file (the zip file has to be 10 Mb as maximum, if it has more than 10Mb, you have to divide it and attach them). Finally, don't forget to close the sending form clicking at "**CERRAR ENVIO**".

IMPORTANT: By the moment, we don't accept CESP sendings for medicines authorized by centralized procedure.



SUPPORT DOCUMENTATION TO BE INCLUDED IN THE SEQUENCE

The application must be accompanied by the following information and documents:

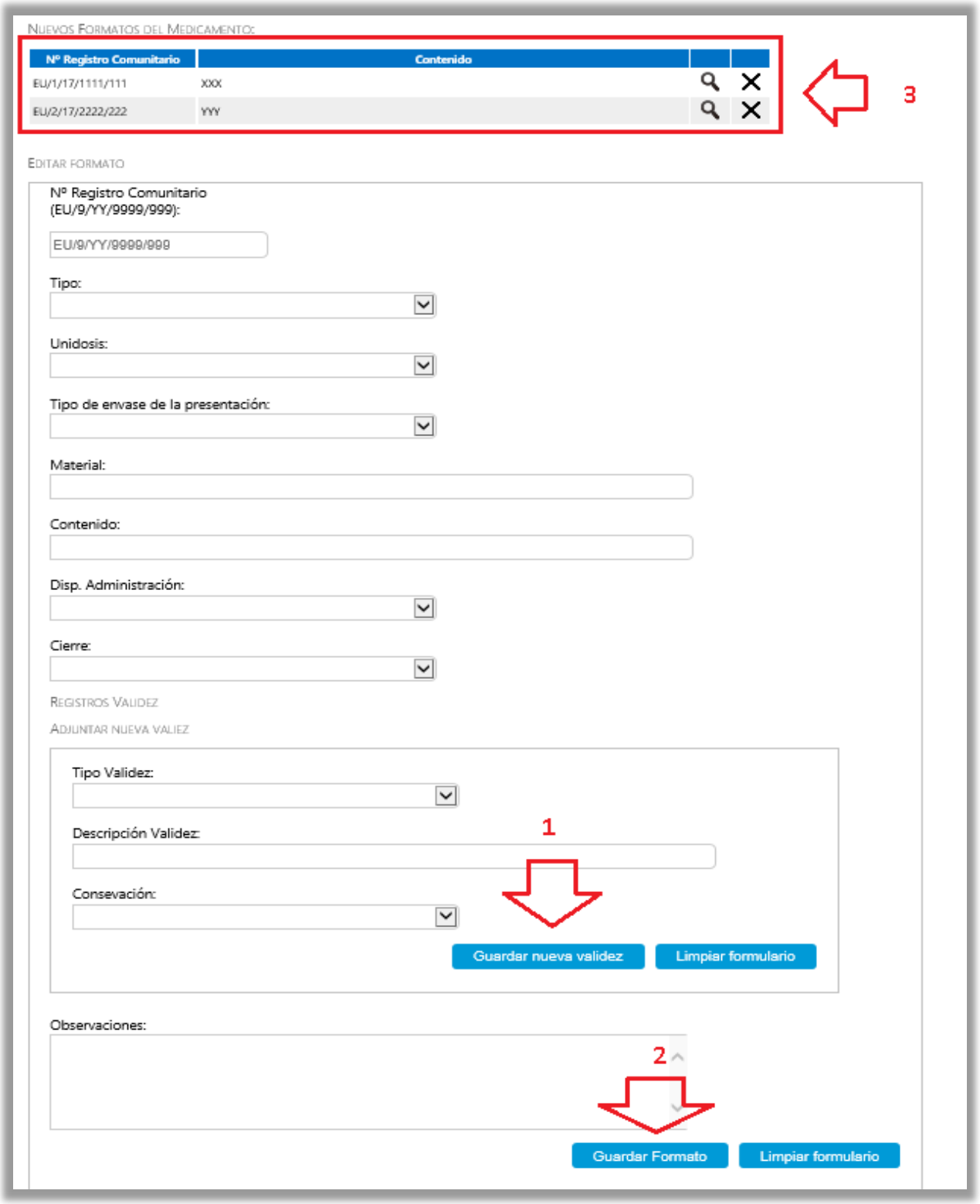
- Photocopy (in Spanish), the authorization of the Decision of the EC.
- Copy of the current version of European Administrative Data (obtained from record eCTD European dossier of registration for this medicine).
- eAF duly completed, locked and stored in digital format.
- English and Spanish texts agreed after the stage review of linguistic reviews (237 day EMA Post-opinion procedure).
- Proposal of the mock-ups of the outer packaging to presentations that are intended to be marketed in Spain. The national code must appear as XXXXXX. X. In case, at the time of this presentation the laboratory does not know even the number of European register for each submission, this can be noted in the mock-ups as EU/1/XX/XXXX/XXX.
- If applicable, certified Braille corresponding to these presentations.

This documentation will be included in the sending of the application (s), in Raefar II; and will it be structured as a sequence NeeS, including all these in module 1.

Format Information (Información de formatos)

From the module of **INFORMACION DE FORMATOS**, , indicate the European approval number "**EU/1/XX/XXXX**" (Nº De Autorización EU), the number of European procedure assigned by EMA "**EMEA/H/XXXXXX**" (Nº EMEA), data details of the Local Representative (Representante Local), and Contact Person (Persona de Contacto); as well as the new format (s) you want to market (Nuevos Formatos del Medicamento), and for which we application National Code, and indicating the validity of the same (Registros Validez). It is very important that the order of inclusion of formats, follow the same order of appearance than of the eAF.

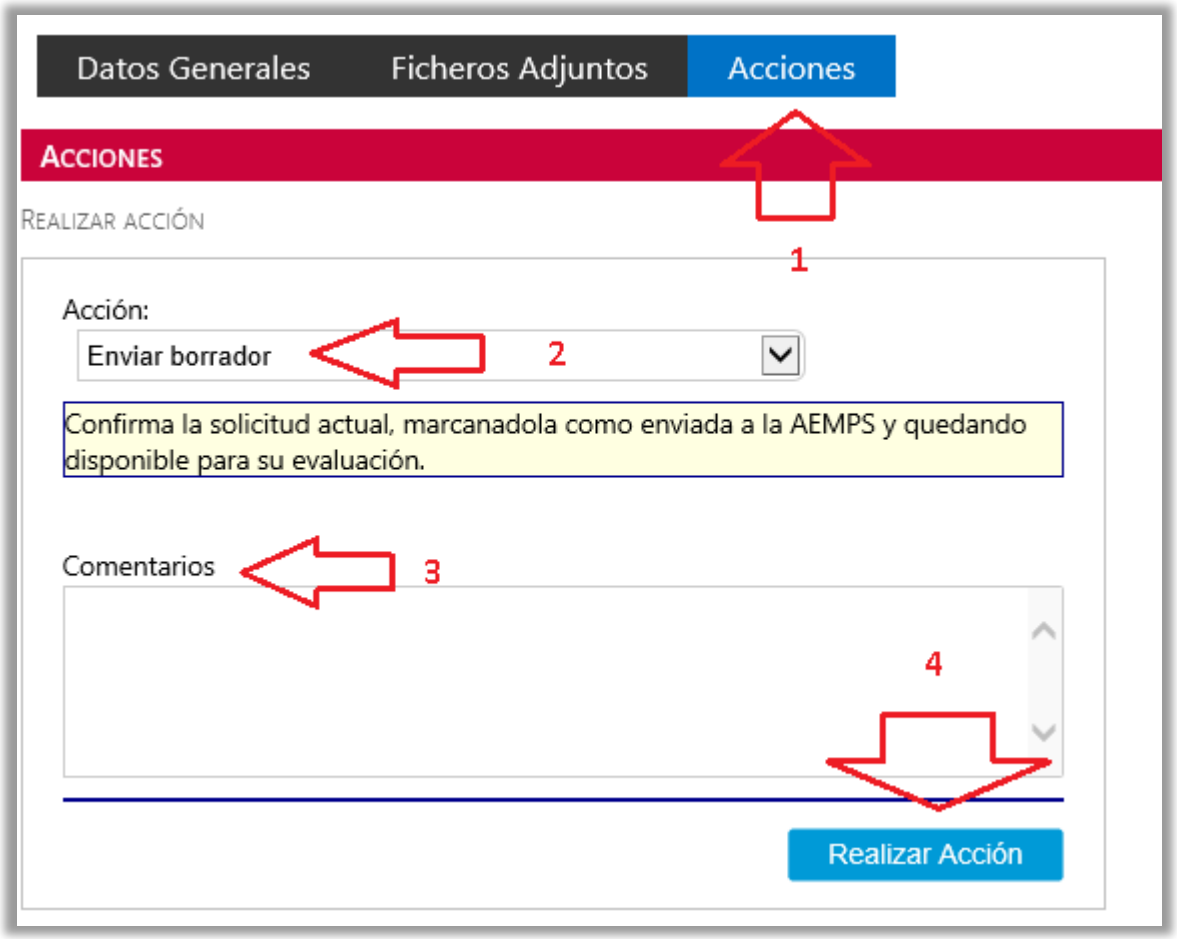
For each format and validity, click GUARDAR NUEVA VALIDEZ (**1**), y GUARDAR FORMATO (**2**), according to the case, of this way we can indicate more than one (**3**).



IMPORTANT: Until this moment the status of your application is the **DRAFT** (Borrador); that means, the applicant can modify it as desired. Once this is sent, the state will be changed and the application will be locked to the applicant, taking control on the AEMPS for the evaluation and authorisation.

- **SUBMITING THE APPLICATION FORM**

The application will be sent, once completed, since the tab "**ACCIONES**". You have to choose "ENVIAR BORRADOR" from drop down list in **ACCION**, write a comment about your application at the field **COMENTARIOS**, and click over **REALIZAR ACCION** button. In this way you will have sent the application to be evaluated.



In case you want to delete the submission, whatever the reason is, you have to choose **DESCARTAR BORRADOR**, put a reason at the field **MOTIVOS**, and click on **REALIZAR ACCION** button.

4. MODIFICATION OF CENTRALIZED MEDICINES.

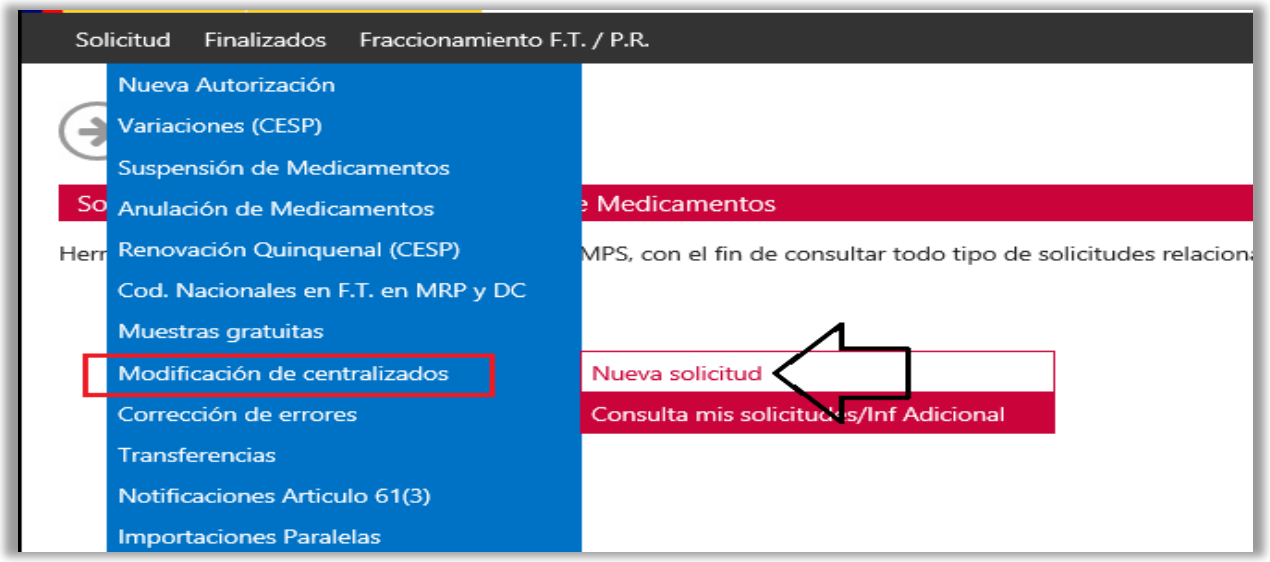
The **MODIFICACION DE CENTRALIZADOS** option, is used to communicate to the AEMPS, those changes approved by the EMA with respect to authorization of a medicinal product authorized by centralised procedure; also you can application new CN for a new format (s) of a CN already authorized in Spain, not being necessary include eAF in that case.

4.1. New Application (Nueva Solicitud)

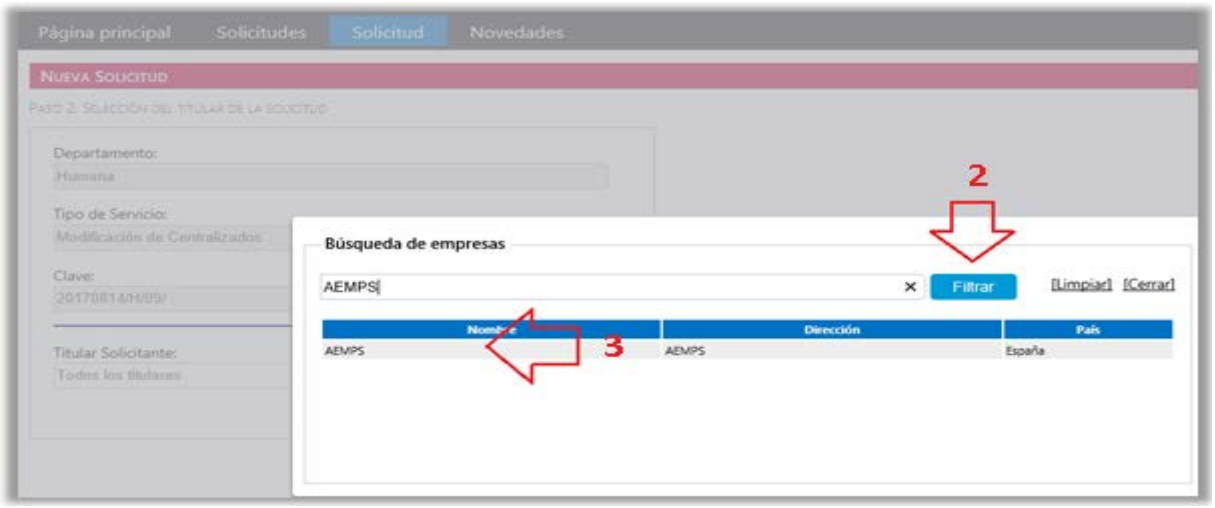
If you want to communicate a new change in a centralised medicine, you have to click on "SOLICITUD" and select MODIFICACION DE CENTRALIZADOS and NUEVA SOLICITUD from the drop down menu. Then

you have to click on **ACCEDER** button to get the application form.

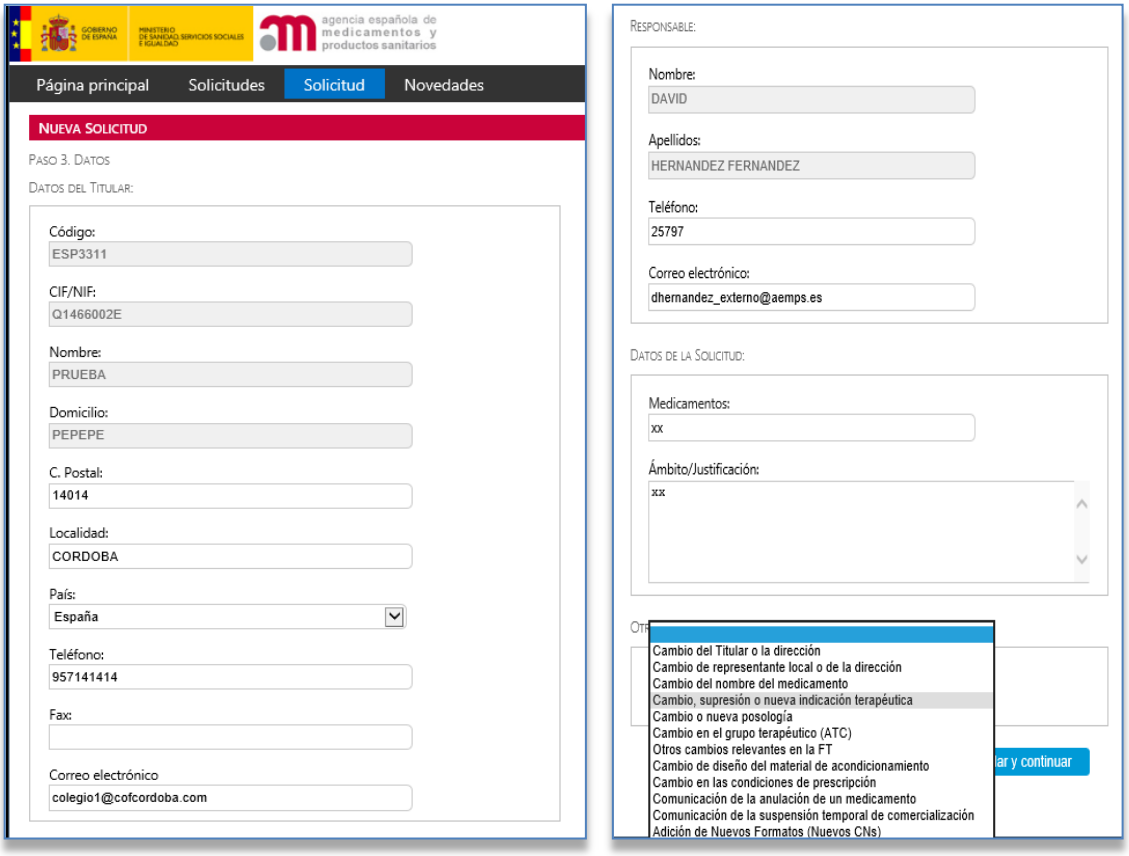
IMPORTANT: You have to submit one application form for each pharmaceutical Form/Dose



At this point, you have to indicate the laboratory holder of the medicine to be modified/updated.

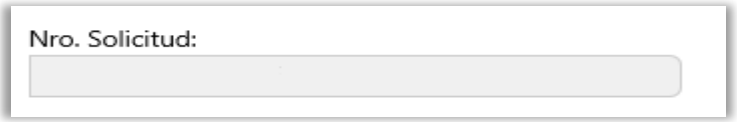


After selecting the laboratory holder, confirm it by clicking on the button “CONFIRMAR DATOS”. Then, you have to fill in the fields available in Datos del Titular , Persona Responsable and Datos de la Solicitud.

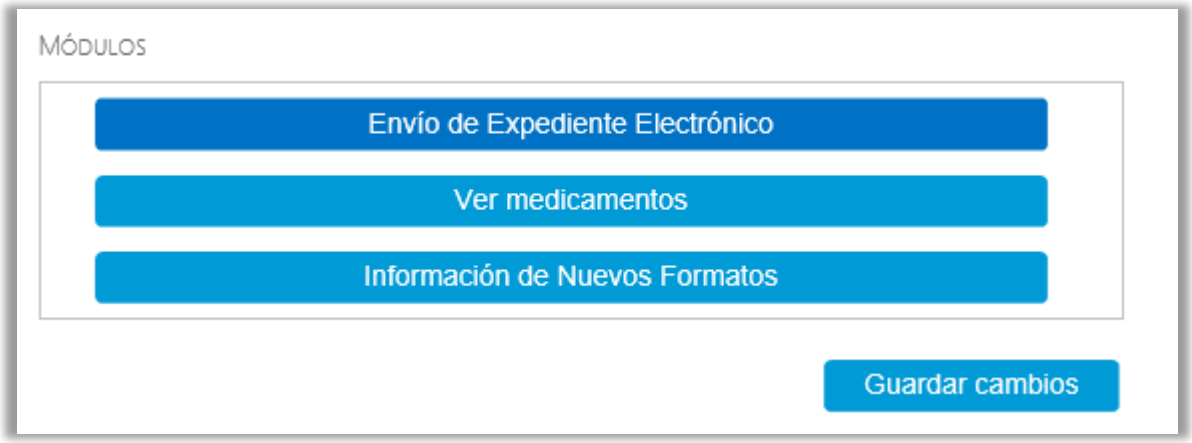


Then, you must complete the fields DATOS DE LA SOLICITUD indicating the name of the medication and detailing the reason for the application in the field ÁMBITO/JUSTIFICACIÓN.

In OTROS DATOS, you must indicate the type of changes that you want to notify. For this must click in the TIPO DE MODIFICACION field and select it from the drop-down list. Finally, you must click GUARDAR Y CONTINUAR to save the information entered and that the number of your application (Nro. Solicitud), to be generated.



Once information entered into the form is saved, will appear at the bottom of this, the modules where you can attach the corresponding sequence in Nees (ENVIO EXPEDIENTE ELECTRONICO), indicate the affected medicines (VER MEDICAMENTOS), and indicate the formats in the case of addition of new formats (INFORMACION DE NUEVOS FORMATOS). This last choice will only be used when you are asking for National Code for new formats of a medicine with National Code previously authorized in Spain.

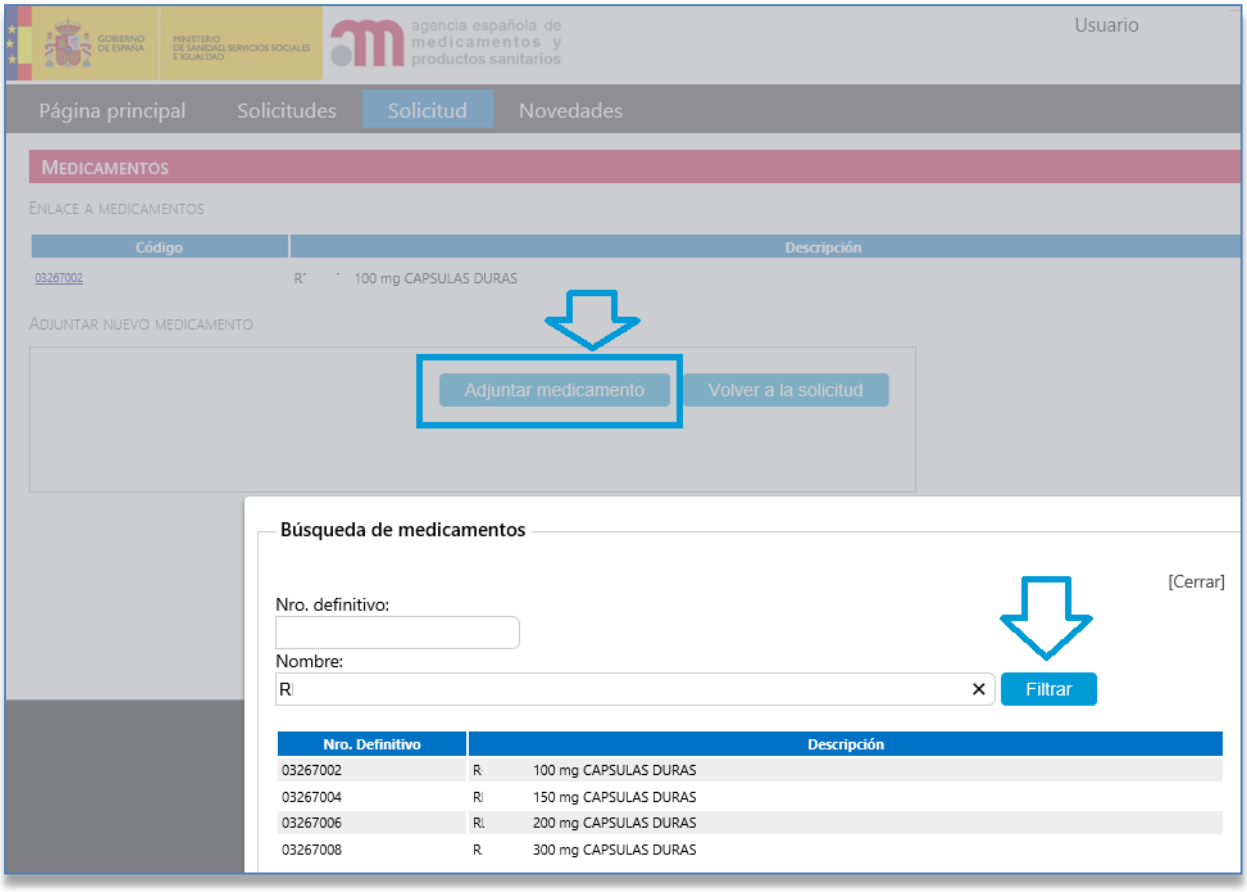


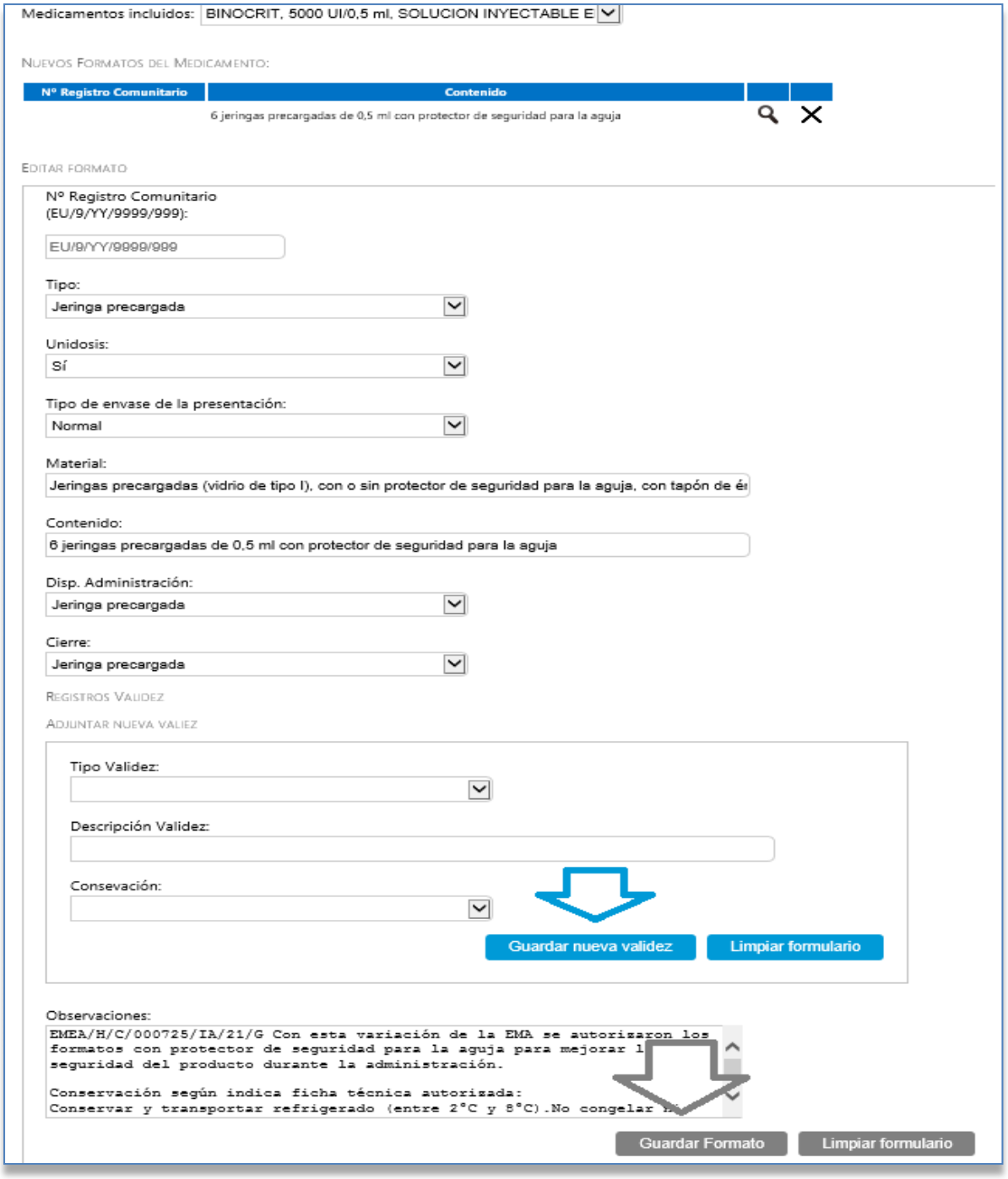
Electronic file submission (Envio de Expediente Electronico)……(see page 6)

Add Medicines (Ver medicamentos)

From here, you can indicate the medicines affected by the application. You only have to click on "ADJUNTAR MEDICAMENTO" buttom, write the name of the medicine in the field "NOMBRE", click on "FILTRAR" buttom to show the medicines and select it. You can add more than one medicine in case is necessary.

IMPORTANT: In case the medicine is not shown at drop down list, you have to confirm if you have indicated the right laboratory holder for this medicine, at the begin the application form.



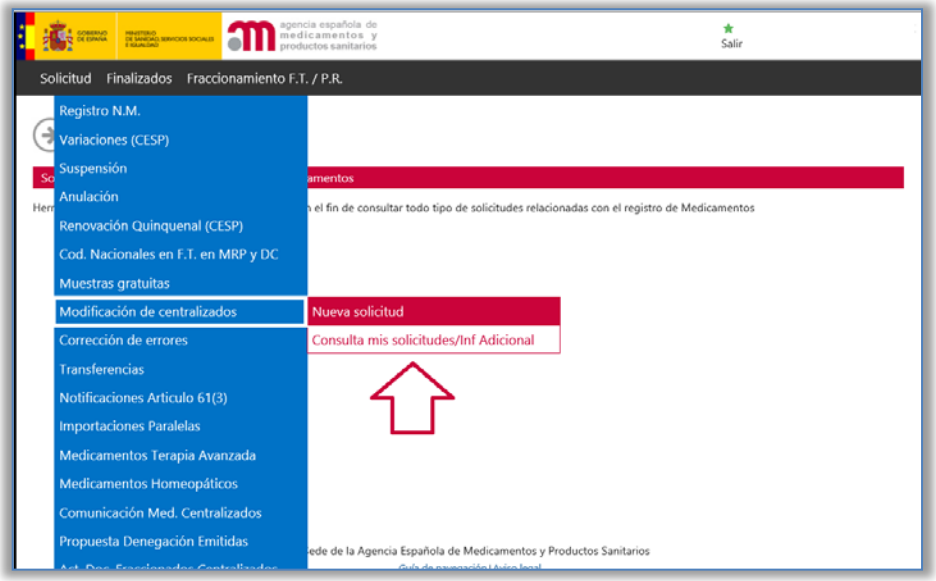


Format Information (Información de formatos)…….(see page 8)

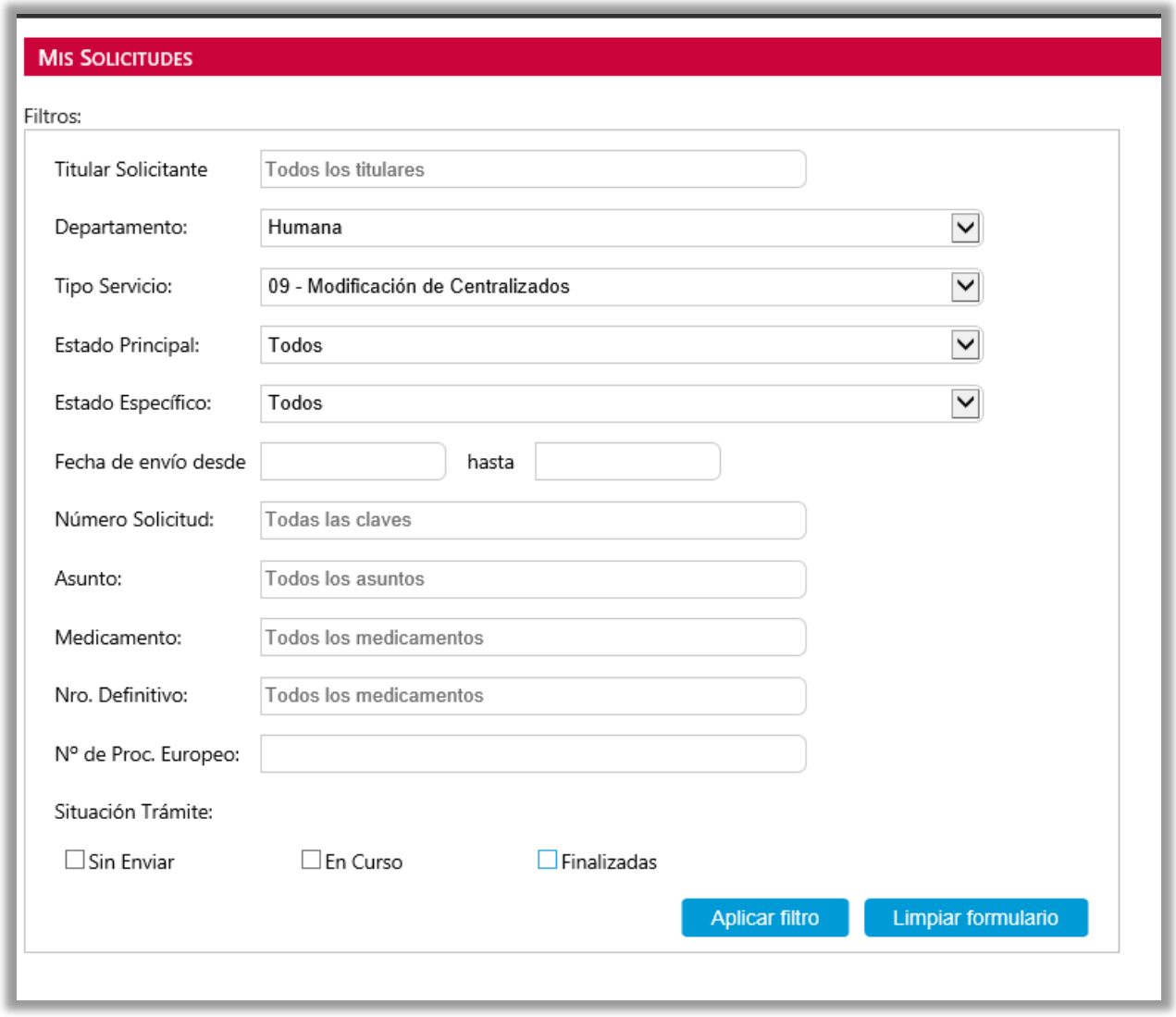
IMPORTANT: In case of selecting "Add New Formats (New CNs)", for asking for a National Code for a new medicine format that has a National Code previously authorized, you have to include the information of this new format here.

4.2. Query of my applications/additional information (Consulta mis solicitudes/Inf. Adicional)

If you want to find a register of a submit previously sent or sending an additional information for an application (required or not by evaluator), you have to click on "SOLICITUD" and select MODIFICACION DE CENTRALIZADOS and **Consulta mis solicitudes/Inf. Adicional** from the drop down menu. Then you have to click on **ACCEDER** button to get the query form.



You can use multiple search criteria depending on the Type of Service /Submit date / Application number / Subject /Medication name / Process State.



Note: We can find three types of Process State available for query.

☐ Sin Enviar (In Draft)

☐ En Curso (In progress)

☐ Finalizadas (Finalized)

When you apply the filter (s), the result will be displayed, based on the criterial selected.

From the icon 🔍 on the right of the register, we can get the application form details.

Nº Solicitud	Titular	Asunto	Estado	F. Estado	Comunicación	Situacion	F.Situación	
20170814/H/09/0006	AEMPS	XXX	En borrador	14/08/2017		Sin iniciar		🔍
20170816/H/09/0001	AEMPS	XXX	En borrador	16/08/2017		Sin iniciar		🔍

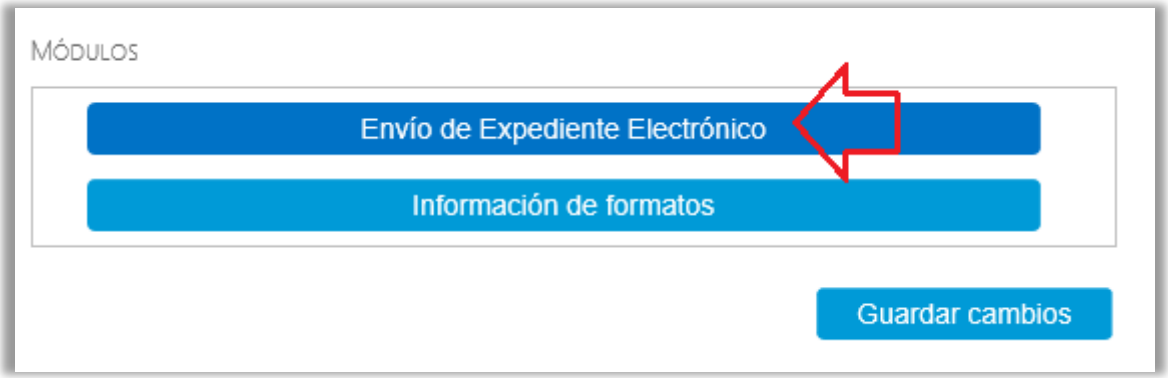
Note: If necessary, we also have the option to export our applications to a XLS file (compatible with Microsoft Excel). For this we must click the "EXPORTAR EXCEL" button, and choose a place to save it.

5. SUBMIT OF ADDITIONAL INFORMATION (ENVIOS DE INFORMACION ADICIONAL)

We can find two ways of submit additional information: Applicationed (by AEMPS), and Not Applicationed.

5.1. Applicationed Additional Information

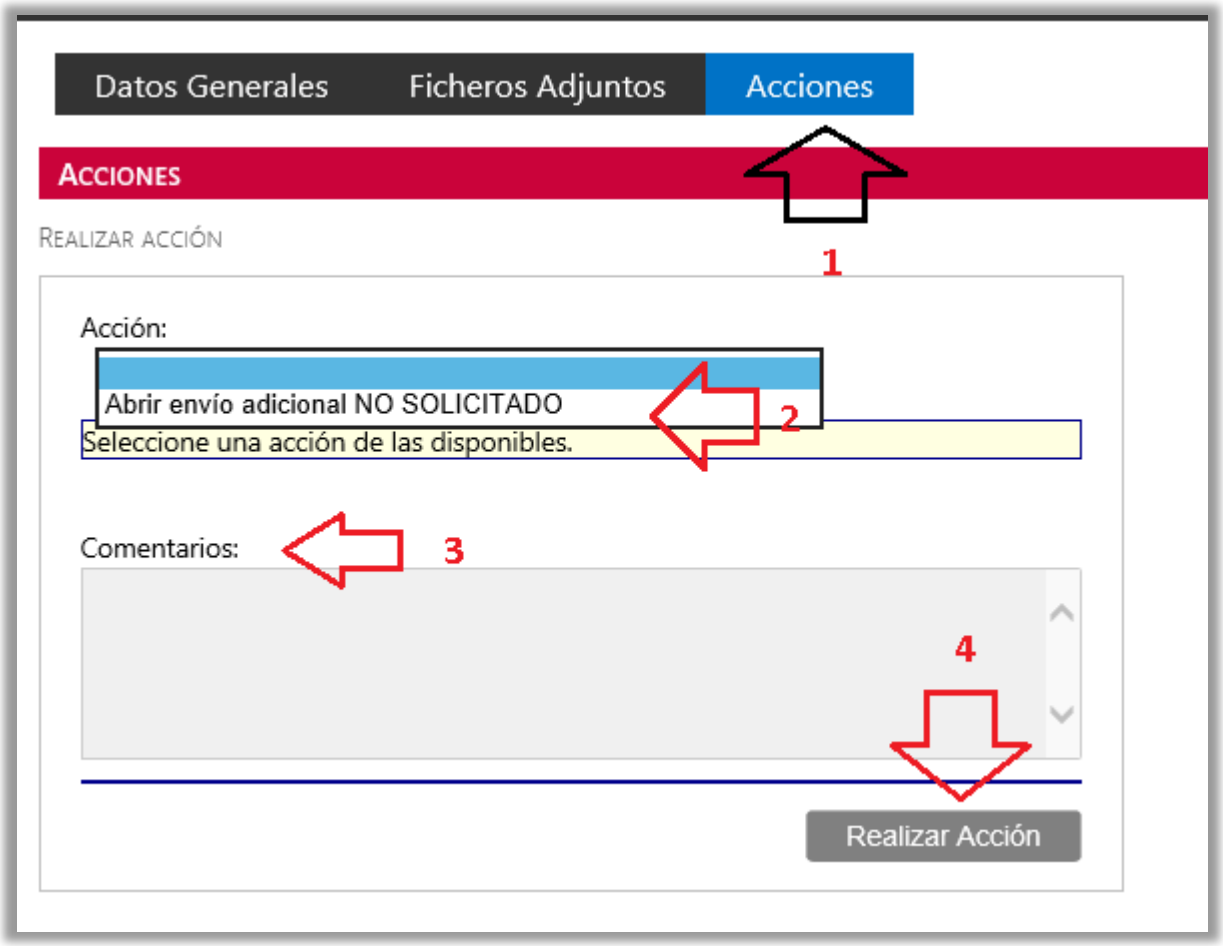
This kind of submit is applicationed by the AEMPS evaluator and it is activated for him/her. You only have to use the module “ENVIO FORMATO ELECTRONICO” at the menu tab “DATOS GENERALES”.



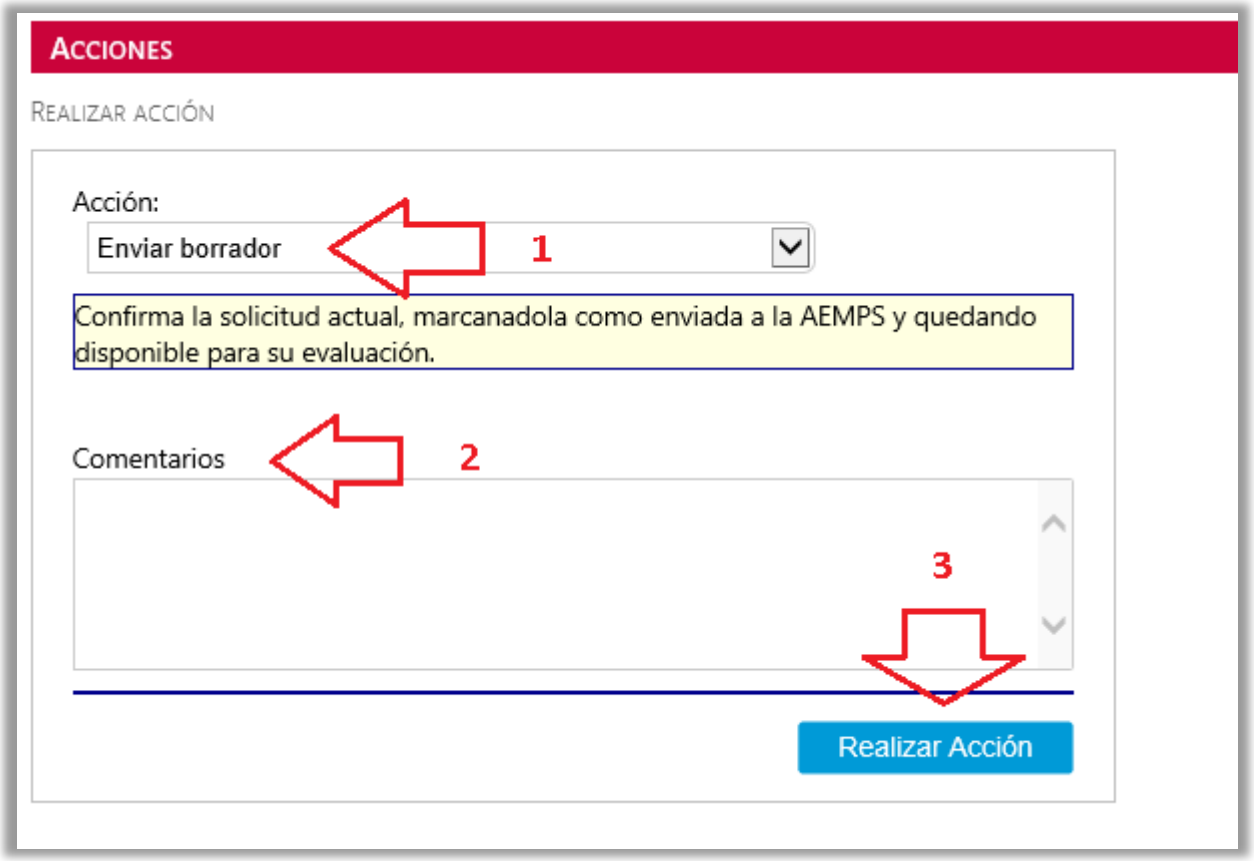
For more information about **Electronic File Submission** (Envio de Expediente Electronico),go to page 6 of this manual

5.2. Not applicationed – Additional Information Submit

If you need to add additional information to your application form after this have been sent, go to ACCIONES, choose “ABRIR ENVIO ADICIONAL NO SOLICITADO” at ACCION drop down list, write a little comment about the content of the additional information and click on “REALIZAR ACCION” button.



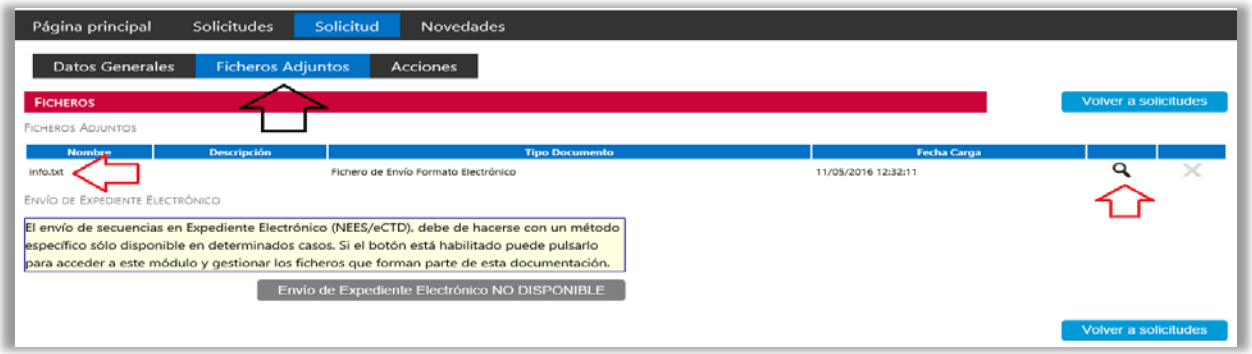
Then, go to “ENVIO FORMATO ELECTRONICO” and proceed to upload the zip file with the additional information. To finish, you have to return to “ACCIONES” at the top menu, and proceed to send it.



6. OTHER FUNCTIONALITIES

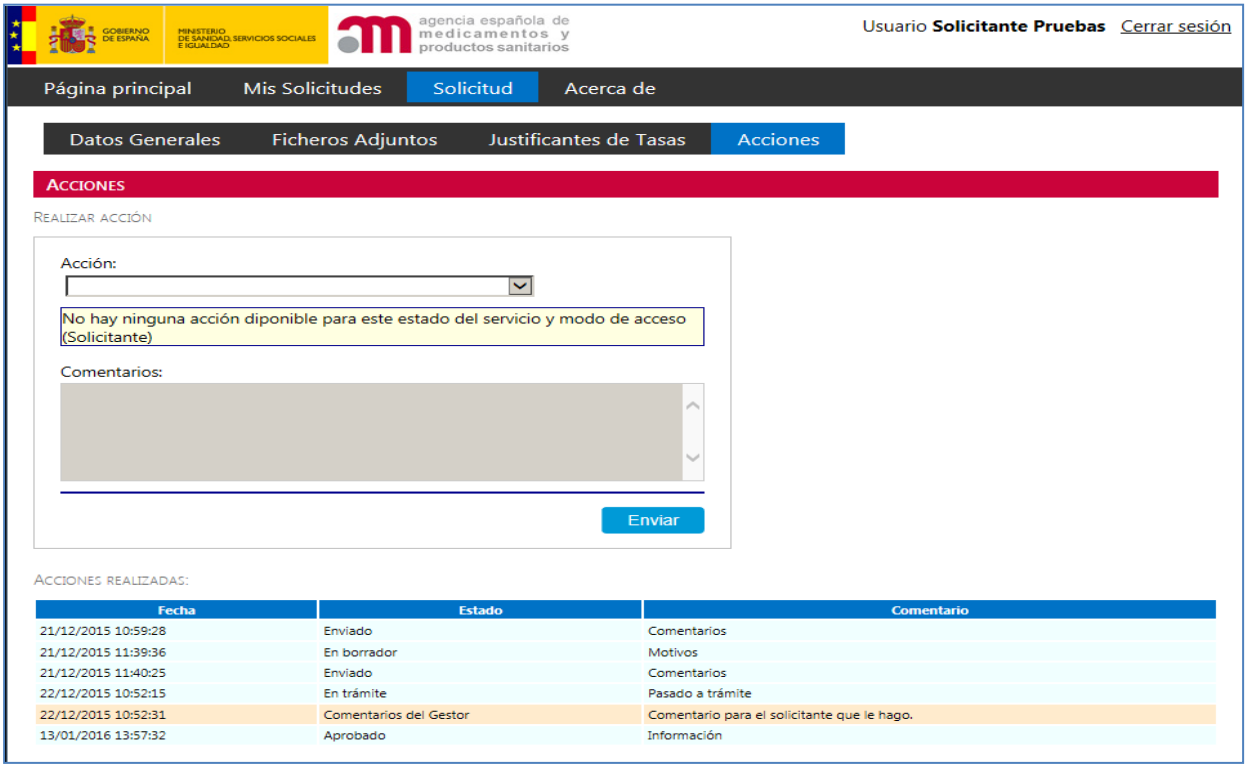
6.1. **Attached Files** (Ficheros Adjuntos)

Here we can get information details about your submits sent by "ENVIO FORMATO ELECTRONICO".



6.2. **Actions** (Acciones)

Here we can get information about the life record of the submission, as well as the comments of the AEMPS evaluator. Besides, you can get access to Resolution Office when the submission procedure has been approved and officied.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agencia española de medicamentos y productos sanitarios
Usuario Solicitante Pruebas Cerrar sesión
Página principal
Mis Solicitudes
Solicitud
Acerca de
Datos Generales
Ficheros Adjuntos
Justificantes de Tasas
Acciones
ACCIONES
REALIZAR ACCIÓN
Acción:
No hay ninguna acción diponible para este estado del servicio y modo de acceso (Solicitante)
Comentarios:
Enviar
ACCIONES REALIZADAS:
Fecha
Estado
Comentario
21/12/2015 10:59:28
Enviado
Comentarios
21/12/2015 11:39:36
En borrador
Motivos
21/12/2015 11:40:25
Enviado
Comentarios
22/12/2015 10:52:15
En trámite
Pasado a trámite
22/12/2015 10:52:31
Comentarios del Gestor
Comentario para el solicitante que le hago.
13/01/2016 13:57:32
Aprobado
Información