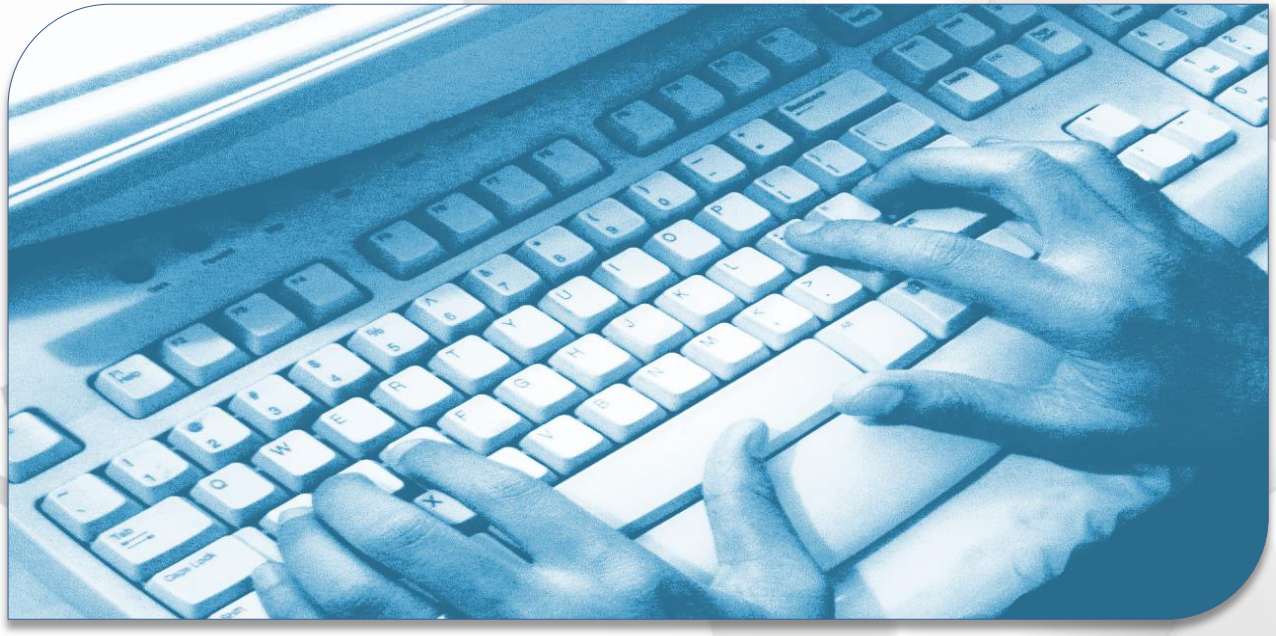
SUBMITTING OF COMMERCIALIZATION INFORMATION OF HUMAN MEDICINAL PRODUCTS

User guide



Version 5.7

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

Sede Electrónica

Submitting of commercialization information of Human Medicinal products

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Sede Electrónica

HOW TO ACCESS TO THE APPLICATION

The user credentials to get access to this application are the same of the RAEFAR II software application.

In order to access the commercialization software application, please click on the link below, complete the fields USUARIO (user) and CONTRASEÑA (password) and click on the button INICIO DE SESION (login).

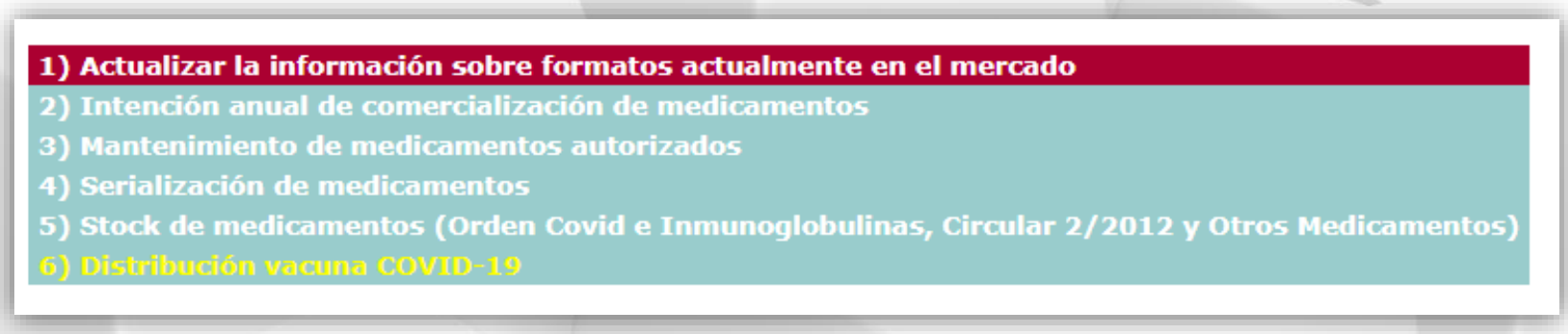
https://sinaem.aemps.es/WebComercializacion/login.aspx?opc=humana

- **IMPORTANT**: Users who does not have RAEFAR II access credentials have to submit a request from our Service Desk application.

Sede Electrónica

MAIN MENU – TYPES OF SUBMISSION

The main menu offers five different types of submissions:



- **IMPORTANT!!**

The CIMA database is updated daily with the information indicated in “point 1”. Therefore, it is mandatory to complete “option 1” with the current status of your products at the market.

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Application for submitting information on commercialization of Human Medicinal Products

OPTION 1: UPDATING OF THE CURRENT STATUS OF MEDICINE PRODUCTS ON THE MARKET

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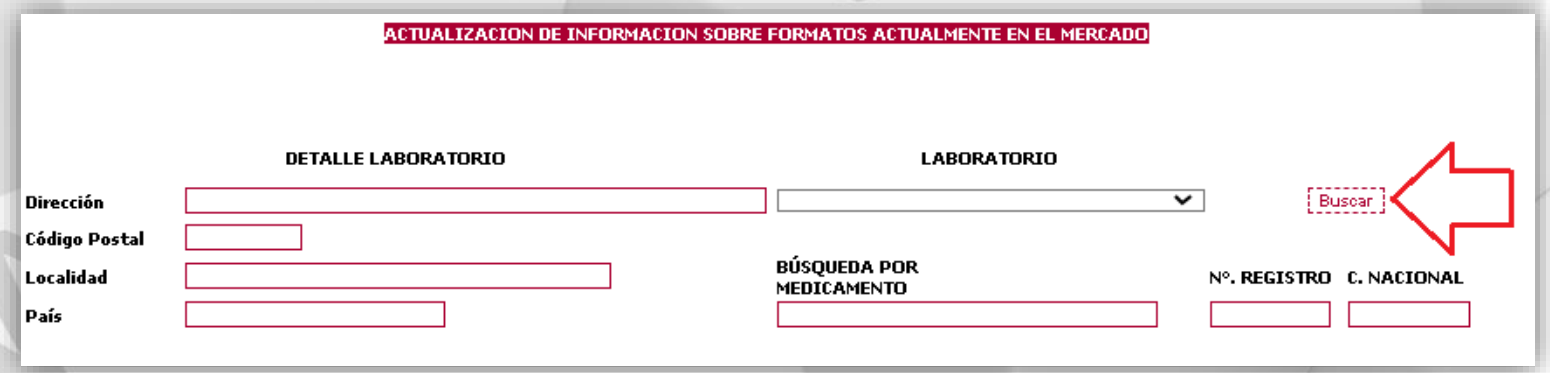
Marketing Authorization Holder (MAH) information

At this screen, the user may choose the MAH of the medicine products whose **market situation needs to be updated**. The name of the MAH appears on a drop-down menu. If the user has permissions on more than one MAH, he/she may choose which one of them to work with.



Once a MAH has been selected, click on "**Buscar**" (Search) button to show all the human medicinal products that laboratory holds.

Option 1: UPDATING OF THE CURRENT STATUS OF MEDICINE PRODUCTS ON THE MARKET

This section shows the human medicinal products formats that are held by the MAH that was previously selected:

Nº REGISTRO	F. PRIMER LOTE MED	COD. NACIONAL	PRESENTACION	SITUACIÓN	F. PRIMER LOTE CN	F. AUTORIZACIÓN	COMERCIALIZADO	NO COMERCIALIZADO	FECHA PARA ENTRADA EN NOMENCLATOR (1-15 o 16-30)	SOLICITUDES

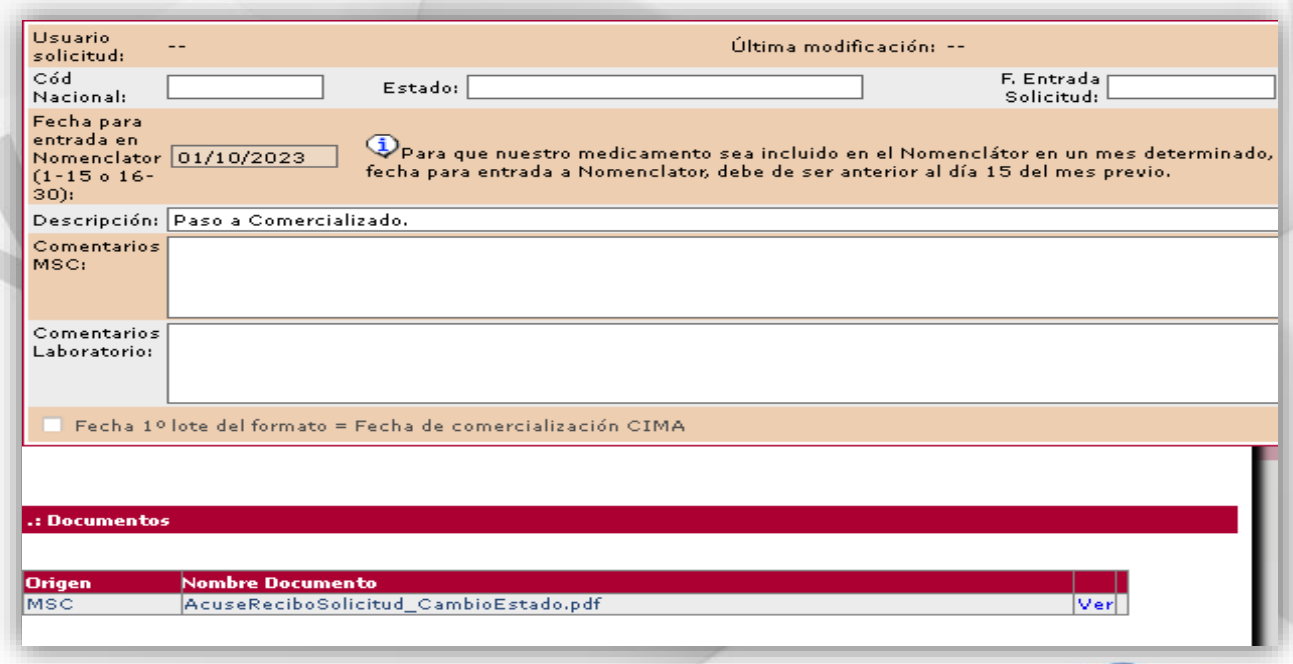
- In order to change the current status on the market of a human medicinal format (from “Commercialized” to “Not commercialized”, or vice versa), please tick the check box on the correspond column (“Comercializado” or “No comercializado”). In case of MAH has a lot of medicine formats, to view them click on the page numbers at the bottom of the list.
- All mandatory fields indicated in the application must be completed, such as: **F. PRIMER LOTE MED** (to indicate the date on which the first batch of the drug was placed on the market), as well as in column **F.PRIMER LOTE CN** (to indicate the date of the first batch of each format).
- Once you have indicated the current status changes of the medicinal formats on the market, please click on the “**Enviar a AEMPS**” (Send to AEMPS) button.
- In case of error corrections (and always at the same day of submission), you can cancel the application clicking on **VER** button at the column **SOLICITUDES,** delete the application and do it again.

❑ **IMPORTANT**: The icon ⚠, means that before you request the change of status on the market of a product, you have to complete the serialization of it(option 4).

Sede Electrónica

Option 1: UPDATING OF THE CURRENT STATUS OF MEDICINE PRODUCTS ON THE MARKET

- Requesting the change of the status on the market of a product to "**COMERCIALIZADO**", generates an "inception date of apply" (**F. Entrada Solicitud**). This date will be used as a reference to be included in the AEMPS monthly list of commercialized medicines (**Nomenclator database**); and if it is applicable, in the **Financing List developed by the SN**S and **Pharmacy Basic Services Portfolio Departmen**t.
- In case of you decide to change the "Reference date to enter to the "**Nomenclator database**" (Fecha para entrada en Nomenclator), once the application has been sent to the AEMPS, click on the **VER** button. Then, at the application form below, enter the new reference date.



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FIELDS IN THE APPLICATION FORM:

- **National Code** (Cód. Nacional) : indicates the national code of the drug.
- **Status (Estado):** Indicates the current status of our application.
- **Date for entry to the Nomenclator** (Fecha para entrada a Nomenclátor) : This field indicates the day on which it will be taken as reference for the entry to the Nomenclator.
- **Description** (Descripción): Indicates what type of change we are requesting.
- **MSC Comments** (Comentarios MSC): This field is used for the evaluator in case of any additional document or clarification is needed.
- **Laboratory Comments** (Comentarios Laboratorio): This field allow you to respond any query to the evaluator.
- **Documents** (Documentos): This section allow you upload documentation requested and/or download the acknowledgement of the status change request.

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Aplicación para el envío de información sobre comercialización de medicamentos de uso humano.
Opción 1 - UPDATING OF THE CURRENT STATUS OF MEDICINE PRODUCTS ON THE MARKET

In order to request the status change on the market of a product to NOT MARKETED, you have to check the box at the correspond column. Besides, you have to consider the next:

- In case of a NOT FUNDED medicine product and/or authorized by CENTRALIZED PROCEDURE, the change of status request will be approved **24 hours after** has been submitted to the AEMPS (taking as reference the "Date of request") and the new status on the market will be showing at CIMA like this.
- In the case of FINANCED medicine product and authorized by DCP/MRP/NATIONAL procedure, the change of status request will be evaluated by the General Directorate of Common Portfolio of Services of the SNS and Pharmacy, with a **maximum response time of 2 months**.

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Application for submitting information on commercialization of Human Medicinal Products

OPTION 2: ANNUAL INTENTION OF COMMERCIALIZATION

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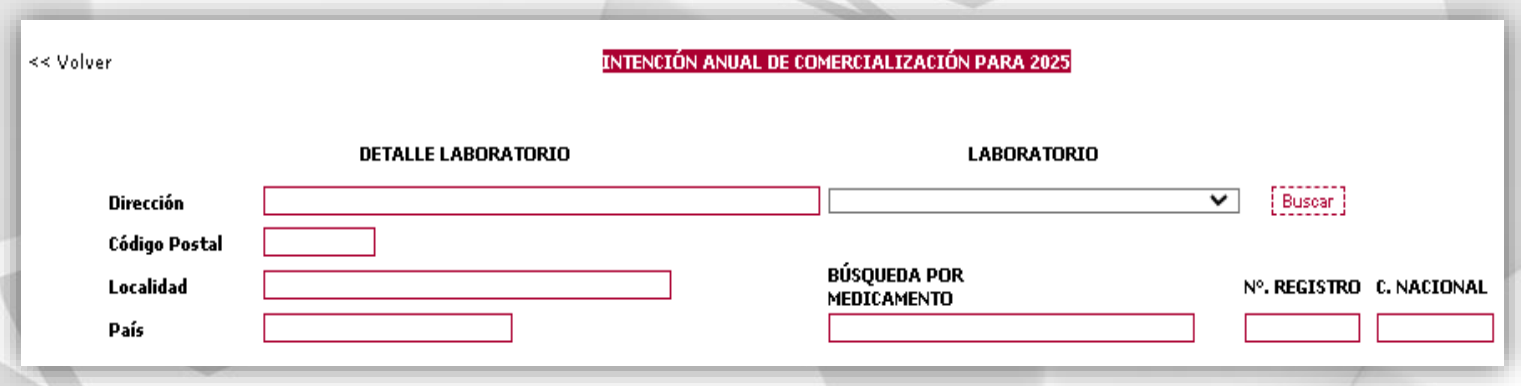
Option 2: ANNUAL INTENTION OF COMMERCIALIZATION

Marketing Authorization Holder (MAH) information

At this screen, the user may choose the MAH. The company name appears on a drop-down menu. If the user has permissions on more than one MAH, he/she may choose which one of them to work with.



Once a MAH has been selected, click on "**Buscar**" (Search) button to show all the medicinal products that laboratory holds.

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Option 2: ANNUAL INTENTION OF COMMERCIALIZATION

The medicines product information will be shown according the column names:
Nº registro – Cód. Nacional – Presentación – Situación – Fecha autorización
(Register number – National Code – Product Name – Status – Authorization Date)

The annual intention of commercialization will be indicated checking the box below to the columns (*) and (**), as per the next instructions:

- (*) Check the box in order to indicate your intention of commercialize the product the nex year.
- (**) Check the box in order to indicate your intention of withdrawing the product.
- In case of the current status product is “Not commercialized”, but you have the intention to commercialize it after the next year, not check any boxes.

Buttons available:

- **GUARDAR** (SAVE): In case of a lot of registers, clicking this button help you save the work advanced until the moment and continue later.
- **ENVIAR AEM** (SUBMIT APPLICATION): Once the annual intention of all products is finished, clicking this button to submit the application to the Spanish Agency of Medicines (AEMPS).

Application for submitting information on commercialization of Human Medicinal Products

OPTION 3: ANNUAL FEE PAYMENT FOR AUTHORIZED MEDICINES

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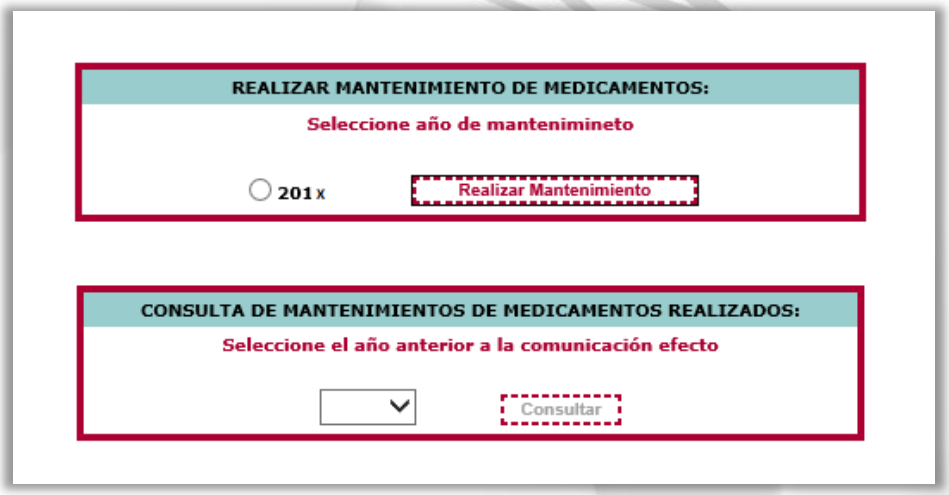
Option 3 – ANNUAL FEE PAYMENT FOR AUTHORIZED MEDICINES

At this option, you can find two sections:

1. **REALIZAR MANTENIMIENTO DE MEDICAMENTOS** (Making the annual fee payment of the products): In this section, you have to check the corresponding year and click on "**Realizar Mantenimiento**" button.



2. **CONSULTA DE MANTENIMIENTO DE MEDICAMENTOS REALIZADOS** (Consult of previous annual fee payments): In this section, you have to select, at the drop down list, the previous year of the annual statement. Then, click on "**Consultar** (Search) button.

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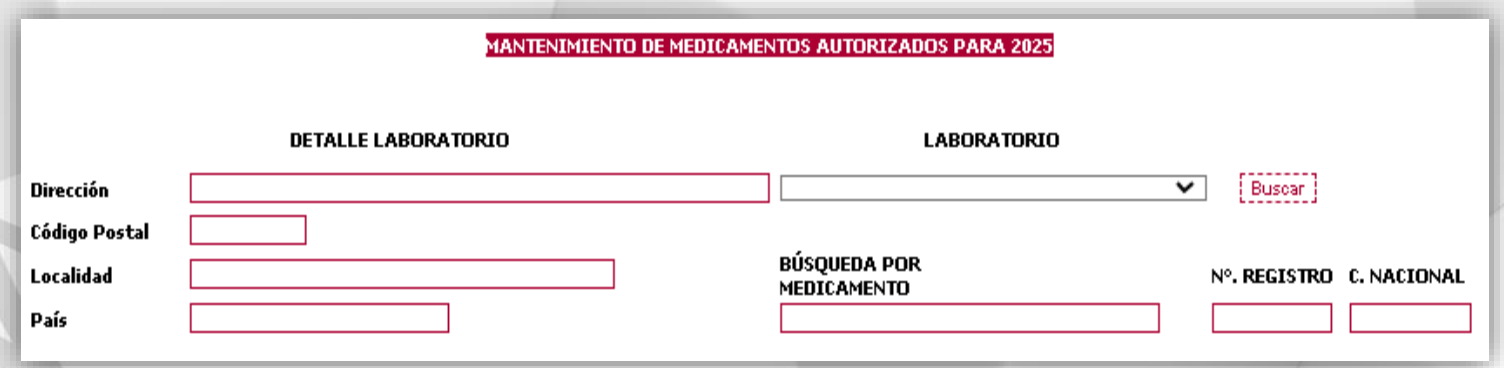
Marketing Authorization Holder (MAH) information

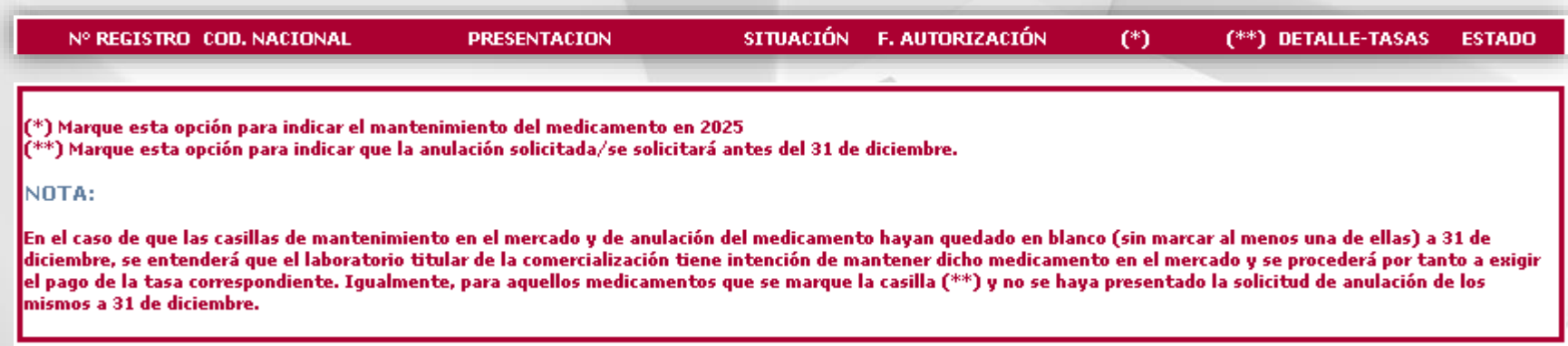
At this screen, the user may choose the MAH. The company name appears on a drop-down menu. If the user has permissions on more than one MAH, he/she may choose which one of them to work with.



Once a MAH has been selected, click on "**Buscar**" (Search) button to show all the medicinal products that laboratory holds.

Option 3 – ANNUAL FEE PAYMENT FOR AUTHORIZED MEDICINES

Only will be shown the medicines products which the applicant is the MAH (the withdrawn medicines and CENTRALIZED being exempted).
The annual fee payment will be indicated checking the box below to the columns (*) and (**), as per the next instructions:



(*) Check this box in order to indicate the annual fee payment of the register.
(**) Check this box in order to indicate the marketing authorization withdrawal of the register (it has to be requested before 31 December.

IMPORTANT:
In the case of (on 31 December) both boxes (*)(**) stayed empty (blank), the Spanish Agency of Medicines (AEMPS) will understand that the MAH has the intention to keep the commercialization of the correspond medicine product, so the annual fee payment of this register will be required. The same for the registers checked with (**), but whose marketing authorization withdrawal application has not been received until 31 December.

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Option 3 – ANNUAL FEE PAYMENT FOR AUTHORIZED MEDICINES

Buttons available:

- **Guardar** (Save): In case of a lot of medicine formats, this button allow us to save the advanced work and continue later.
- **Tramitar Solicitud** (Create the annual fee payment application): Clicking this button groups all the medicine registers checked together into an one payment application form and changes the status of the fee payment application to “PENDIENTE” (Pending to complete). In order to proceed with the fee payment, you have to click on the “eye” icon that appear in the “Detalle-Tasas” column.

- **IMPORTANT**:
  - The annual fee payment must be set for all the authorized medicines listed, whether they are marketed or not. Only the withdrawn medicines and CENTRALIZED being exempted.
  - Do not forget the annual fee payment is made for register number, no for national code.
  - In the case of error in the annual fee payment form, you have to delete it. For this, click on the “eye” icon to open the application form, and then click on the “**Eliminar Solicitud**” (Delete application form) button.

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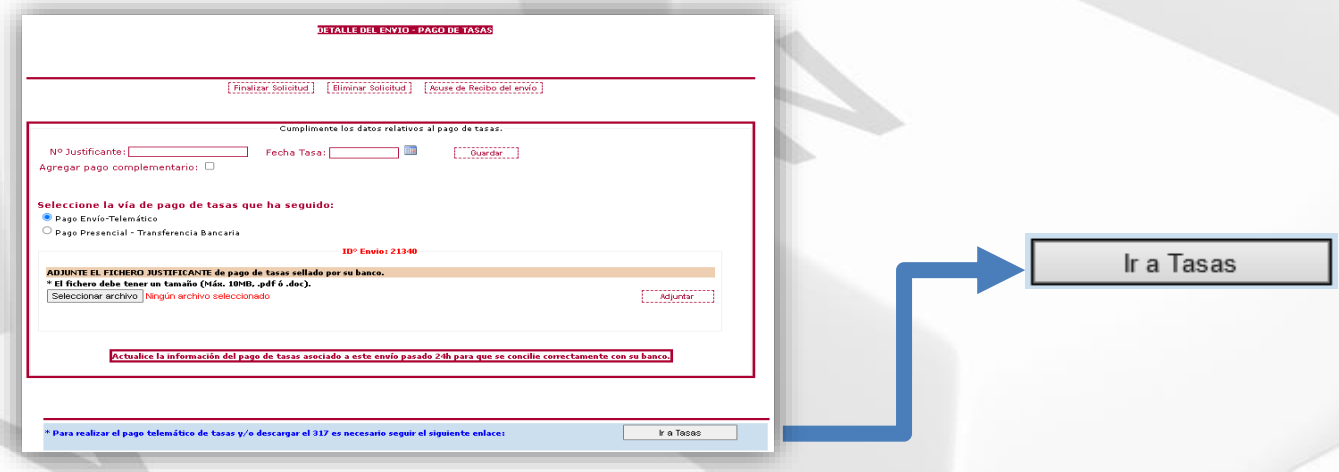
Option 3 – ANNUAL FEE PAYMENT FOR AUTHORIZED MEDICINES

How to pay annual fee maintenance of the medicine products:

Clicking on the "EYE" icon at the "DETALLE-TASAS" column in order to enter to the annual maintenance application form from where you can proceed to the payment. For this, you have to click on **IR A TASAS** (Go to the Fee Payments application) button. Once into the application, you only have to follow the instructions.



- Once the payment has been made, it has to be confirmed by our bank (in case of payments by card the confirmation is **immediate** and in case of bank transfer, it could late between **48 to 72 hours)**.
- Once the payment has been confirmed, return to this application form in order to indicate the proof of payment number and the date of payment. Then ,click on GUARDAR (Save) button.
- Finally, clicking on the "**FINALIZAR SOLICITUD**" button in order to finish the annual maintenance application.
- **UPLOAD THE PROOF OF PAYMENT (317 MODEL) IS NOT MANDATORY**.

❑ **IMPORTANT: In case of error, please take contact with our IT support team at Service Desk**

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Application for submitting information on commercialization of Human Medicinal Products

OPTION 4 : SERIALIZATION OF MEDICINES

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Option 4 – SERIALIZATION OF MEDICINES

This step is mandatory only for medicines that must to use safety features in accordance with **Regulation (UE) 2016/161**, (October 2nd 2015) and codified them using the unique identifier code "**GTIN"** (Global Trade Item Number), and **NTIN** (National Trade Item Number). No matter which type of procedure are (National, MRP, DCP or Centralized).

Attention: The "Prescription Nomenclator" database published by AEMPS, will include the information relative to the mandatory use of safety features according to the Regulation (UE) 2016/161 at the field "Serialización" for each National Code. In case of it is mandatory to use it, the field contains the number "1", otherwise contains "0".

- **IMPORTANT**: Only the medicines products exempt to carry safety features must not complete this point.

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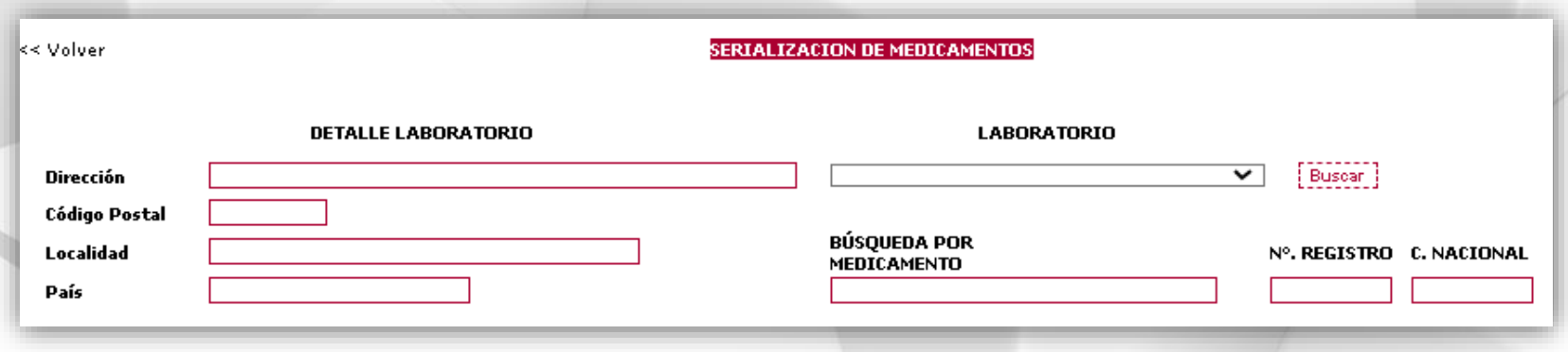
Marketing Authorization Holder (MAH) information

At this screen, the user may choose the MAH. The company name appears on a drop-down menu. If the user has permissions on more than one MAH, he/she may choose which one of them to work with.



Once a MAH has been selected, click on "**Buscar**" (Search) button to show all the medicinal products that laboratory holds.

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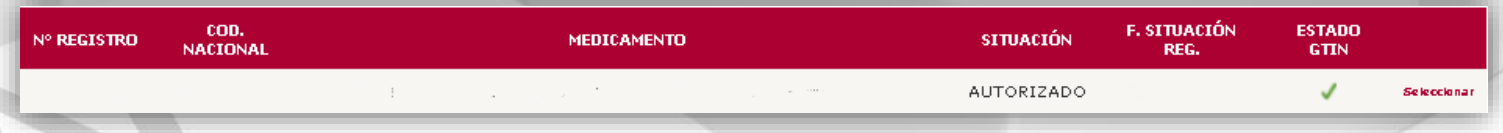
- This declaration is made per **national code** (i.e. per each authorized drug format, including not commercialized drugs), and it has to be made per each drugs that require serialization and been encode the unique identifier using the GTIN or NTIN code indistinctly.

- At the "**ESTADO GTIN**" (GTIN Status) column will appear a **green tick** to confirm the serialization information of the drug format has been completed (i.e. at least a GTIN or NTIN code has been indicated).



- Once the drug format has been selected, you can indicate all GTIN codes as many as the national code has.

- The **GTIN** codes entered will be validated by algorithm and control code.

- For drug formats encoded via **NTIN**, only a single code may be included.

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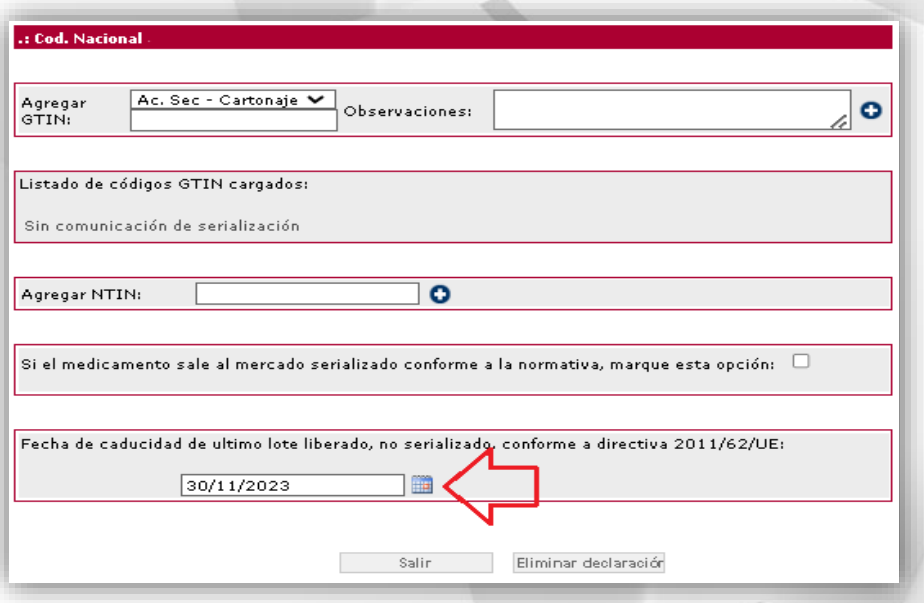
Option 4 – SERIALIZATION OF MEDICINES

For those medicines that are affected by the **Regulation (UE) 2016/161**, and must use safety features and **have been released before February 9, 2019** (date of entry into force of the regulation), the "*Fecha de caducidad de último lote liberado, no serializado, conforme a la Directiva 2011/62/UE*" (Expiration date of the last released, non-encodeded batch, according to the Directive 2011/62/UE) field must be completed. For more information, go to the informative note **MUH, 04/2022**



- **IMPORTANT**: The field "Fecha de caducidad de ultimo lote liberado" permit us to know the last date until the unencoded medicines can be dispensed without safety features, even if they are affected by the regulation. From this date, must be dispensed with safety features.

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Application for submitting information on commercialization of Human Medicinal Products

OPCIÓN 5 : STOCK OF MEDICINES

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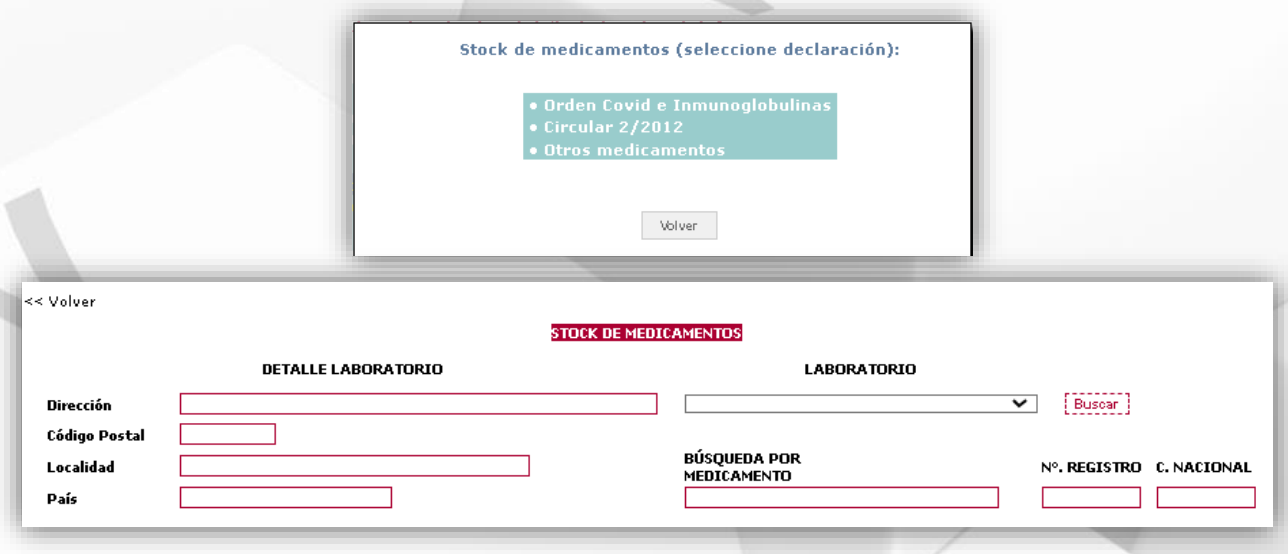
Opción 5 : STOCK OF MEDICINES

- To start the stock declaration, you has to choose the type of declaration: **Orden Covid e Inmunoglobulinas – Circular 2/2012 – Otros medicamentos**
- Next, you will select the **MAH** for which have to report the sales, available units and planned manufacturing. This report must be made per authorized and commercialized national code (Código Nacional).



Once a MAH has been selected, click on "**Buscar**" (search) button to show all the medicines that MAH holds.

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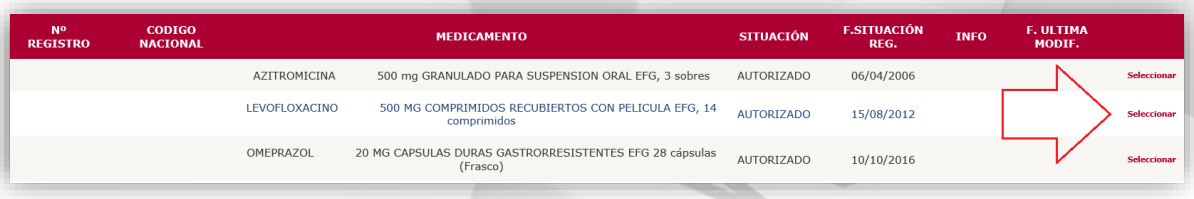
Opción 5 : STOCK OF MEDICINES

At this section, you may find all the medicines the stock must be reported:



Nº REGISTRO	CODIGO NACIONAL	MEDICAMENTO		SITUACIÓN	F.SITUACIÓN REG.	INFO	F. ULTIMA MODIF.	
		AZITROMICINA	500 mg GRANULADO PARA SUSPENSION ORAL EFG, 3 sobres	AUTORIZADO	06/04/2006			Seleccionar
		LEVOFLOXACINO	500 MG COMPRIMIDOS RECUBIERTOS CON PELICULA EFG, 14 comprimidos	AUTORIZADO	15/08/2012			Seleccionar
		OMEPRAZOL	20 MG CAPSULAS DURAS GASTRORRESISTENTES EFG 28 cápsulas (Frasco)	AUTORIZADO	10/10/2016			Seleccionar

Only click on the **SELECCIONAR** (Choose) button in order to select the medicine. Then, you have to complete the next information requested:

- **Venta envases:** Packages sold in january and february.
- **Ventas de envases por semana:** Packages sold by weeks. This information declared has to be made only once and it could not be modified.
- **Stock diario** (number of packages on daily stock): This information must be updated daily and the form will show the information of the reported stocks for the last 3 days.
- **Previsión de stock** (planned new package stock): At this section, you may enter several scheduled dates indicating the number of planned stock packages.

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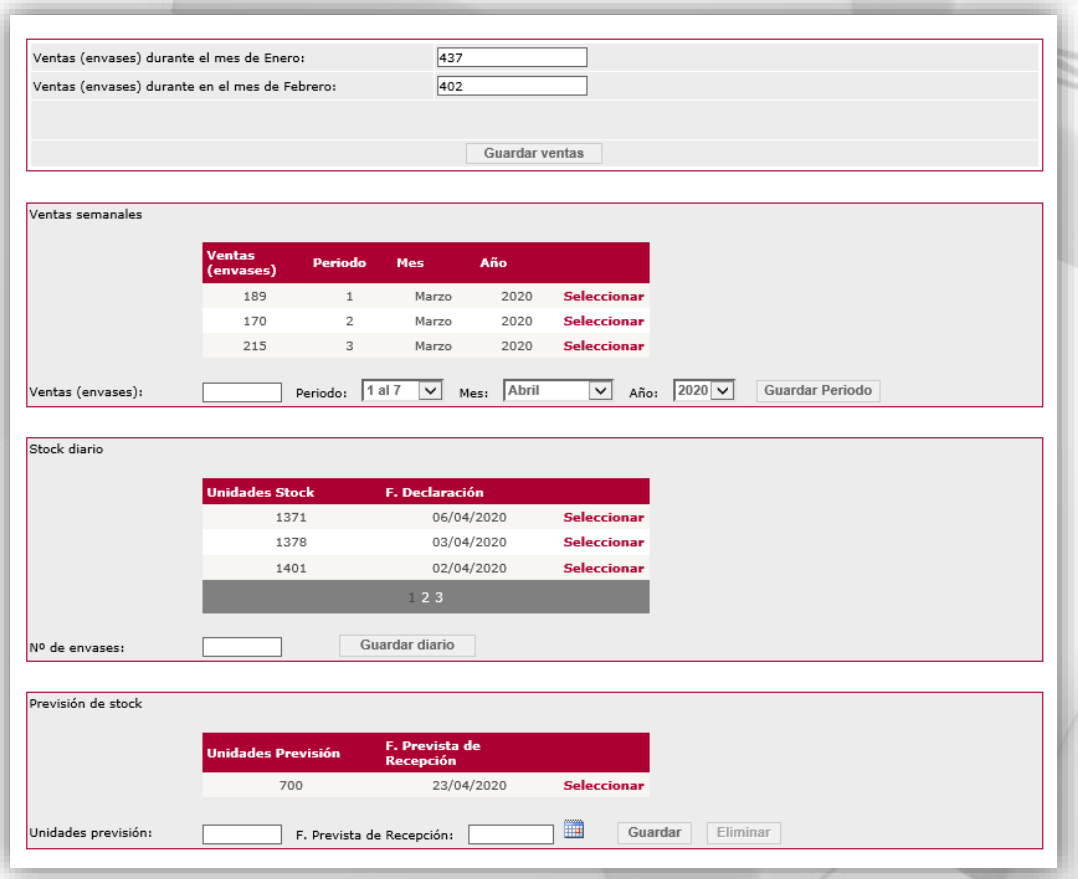
Application for submitting information on commercialization of Human Medicinal Products.

Opción 5 : STOCK OF MEDICINES



- **IMPORTANT**: In case of error in the data entered, it could be corrected before 12 noon of the day of the report.

Sede Electrónica