SECRETARÍA EJECUTIVA
COMISCA
CONSEJO DE MINISTROS DE SALUD DE CENTROAMÉRICA Y REPÚBLICA DOMINICANA

SICA
Sistema de la Integración Centroamericana

USER MANUAL

PHARMACEUTICAL INDUSTRY NOTIFICATION

Noti-FACEDRA

Portal Regional de notificación en línea de sospecha de reacciones adversas a medicamentos y vacunas de uso humano.

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Introduction

The **Noti-FACEDRA** portal is part of the FACEDRA Regional System (Central American Pharmacovigilance Data on Adverse Reactions to Drugs and Vaccines for Human Use) which is administered by the Executive Secretary of the Council of Ministers of Health of Central America and the Dominican Republic (SE-COMISCA) in coordination with the National Centers, National Units or National Programs competent in matters of pharmacovigilance in the Drug Regulatory Authorities of the Member States of the Region of the Central American Integration System (SICA), as part of the strengthening of capacities and "consolidation of the Regional Pharmacovigilance Program of Central America" and the strengthening of national pharmacovigilance actions for Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and the Dominican Republic.

Noti-FACEDRA is an informatic application that will allow online notification process of suspected adverse reactions to drugs and vaccines to the National Pharmacovigilance Centers in Central America and the Dominican Republic. This is why it is important for patients to inform their doctor, pharmacist or other health professional about possible adverse reactions resulting from the use of medications and vaccines; considering that they can also do it themselves directly through **Noti-FACEDRA**.

With this electronic notification tool, is contributed to knowing in an agile and timely manner the adverse reactions of drugs and vaccines that are used in the private sector as well as in national health systems.

The implementation of **Noti-FACEDRA** 2.0 will strengthen national capacities for vigilance the safety and effectiveness of drugs and particularly for the vigilance of vaccines that are authorized by the Drugs Regulatory Authorities of the SICA region.

General conditions

All drugs can cause, on more than one occasion, an undesirable effect, also known as adverse reactions to drugs and vaccines (ADRs). Sometimes, ADRs can appear after a person has stopped using the drug, while some ADRs may not be discovered until many people have used the drug or vaccines for a long period of time.

If you believe that a patient has experienced an adverse reaction to a drug or vaccine under your company's vigilance responsibility, you can also notify it through the electronic form that is available through the link www.notificacentroamerica.net.

The use of the electronic form is intended to be a simpler and quick way to a pharmaceutical company can notify to the National Drug Regulatory Authority of the SICA Region a possible adverse reaction presented with the use of a drug or vaccine.

WHAT TO NOTIFY?

Please complete the **Noti-FACEDRA** electronic form if you suspect that a drug or vaccine has caused an adverse reaction in a patient.

Mainly you must notify:

- Drugs and vaccines
- Suspected serious adverse reactions identify whit any drug, with any of the following situations being considered serious:

i. Cause death.
ii. Threaten the patient's life.
iii. Cause hospitalization, or prolong it.
iv. Cause incapacity for work or school.
v. Induce congenital defects.
vi. ADRs that are clinically relevant.

If you are not sure of the severity of the reaction, notify it anyway.

Do not limit yourself because the adverse reaction is common or apparently insignificant, since your report can help identify safety problems with drugs or vaccines authorized for use in the SICA Region.

Do not wait to notify if you missing any data or information, however, it is essential to analyze the adverse reaction, that you always provide all possible information and all the data you have about the drug(s) or vaccine that you suspect may be causing an ADR, including products you have received and that may contain substances with pharmacological effects (e.g.: nutritional supplements, macrobiotics, medicinal plants).

Be aware to indicate the brand name and presentation of the suspected drug or vaccine, as well as the lot number printed on the product package, this information is especially important when it comes to biological medicines.

What to include in the notification? The **Noti-FACEDRA** electronic form includes four fundamental sections of information that are necessary for the notification process:

Suspected medications(s)

The name of the drug(s) or vaccine, which is suspected of causing the reaction. If the commercial name is known, the complete denomination (brand, concentration and presentation) must be communicated. You should also add this information if known:

- Route of administration.
- Daily dose, dose frequency and posology.
- Dates of administration.
- If it is a vaccine or other biological drug, the name of the brand with the complete denomination, lot number and expiring date.

Adverse Reaction(s)

Describe the adverse reaction that you detected and include main diagnosis and the following:

- When the adverse reaction occurred, establishing the start and end dates.
- Severity of the reaction.
- Any treatment used concomitantly.
- Result of the reaction or its outcome.

If the reaction has already been reported (for example, by another healthcare professional or the patient), but you have additional information to report, please tell us in the notification so that we can identify the previous notification and add that information.

Patient details

Basic information about the patient is vital for the cases assessment and to obtain additional information. Please provide, if possible, the following information:

- Patient sex.
- Age of patient at the moment of reaction.
- If known, indicate weigh of patient.
- Names and surnames of patient, and in case of having the medical history number, this can help to identify the patient in case of future notification.

Notifier details

This information must be completed in all cases. Please include your name and email so we can acknowledge receipt of your notice and contact you for additional information if necessary.

Only if ADRs associated with 'medication errors' are reported (by selecting the corresponding field), your personal data will not be admitted to the form.

Other additional information

It is very useful that you notify us of any additional information that you consider relevant to the analysis of the reported case, such as:

- Other drugs used in the last three months before the reaction occurred, including prescription, non-prescription medication, promotional, or herbal medications.
- Any information about re-exposure with the suspected drug, at other times.
- Medical history of interest, including allergies.
- Results of medical or laboratory tests.
- For congenital anomalies, please list all other medications taken during

pregnancy and the date of last menstruation.
- You can attach additional documents or test reports if necessary, as well as images or photos.
- If the patient was not taking other medications, or if no other information is available, please indicate so.

All the information you provide will help us interpret the case and facilitate its evaluation. Please provide as much information as you can, but do not delay reporting the case because you do not know some details of the notification.

ADVERSE DRUG REACTIONS

How to identify ADR's?

Patients can tell you about the symptoms they have experienced since using a new medication or after receiving a vaccine. However, as some adverse reactions may not be evident to the patient, you will need to be alert to the possible occurrence of adverse reactions. Other information that should be considered for inclusion:

- Abnormal clinical measurements (for example, temperature, pulse, blood pressure, blood glucose, body weight), during drug treatment.
- Abnormal biochemical or analytical results during drug treatment. For example, plasma drug concentrations or liver biopsy in drug-induced hepatitis.
- If a new pharmacological therapy is instituted to treat AMR symptoms.

HOW TO COMPLETE THE FORM?

To fill out the form you will need to provide information on four important aspects:

1) Details of possible adverse reaction.
2) Provide the name of the drug you suspect caused the adverse reaction.
3) The information of the person who had the adverse reaction.
4) Information about the person making the notification will also be needed.

The electronic form in **Noti-FACEDRA** has "help" elements that are presented as a question mark or an asterisk.

If you require this help, place the cursor over those elements, a drop-down menu will appear with the help text.

Keep in mind that the form fields are dynamic and will provide you with some suggestions as you enter the information.

ABOUT THE PROTECTION OF DATA INCLUDED IN Noti-FACEDRA

All the information provided will be protected and will not be disclosed to third parties, in order to comply with national provisions on confidentiality of information.

¿ HOW THE INFORMATION PROVIDED BY THE REPORTING OF SUSPECTED ADVERSE REACTIONS IS USED TO IMPROVE DRUG SAFETY?

The National Pharmacovigilance Centers of Central America and the Dominican

Republic evaluate these data, along with the information collected from clinical studies and other sources on the use of medicines or vaccines authorized for marketing.

When there is sufficient information to determine that a group of similar cases of suspected adverse reactions are likely caused by a drug or vaccine, this information is moved to the safety information for the drug and the package insert.

On other occasions this information is used for communication with the use of some medications or vaccines, for medical prescription to certain specialists, or its use is recommended as a second choice.

The Drug Regulatory Agencies of Central America and the Dominican Republic also use this information to issue Information Alerts that are available on institutional websites or to prepare and distribute information bulletins.

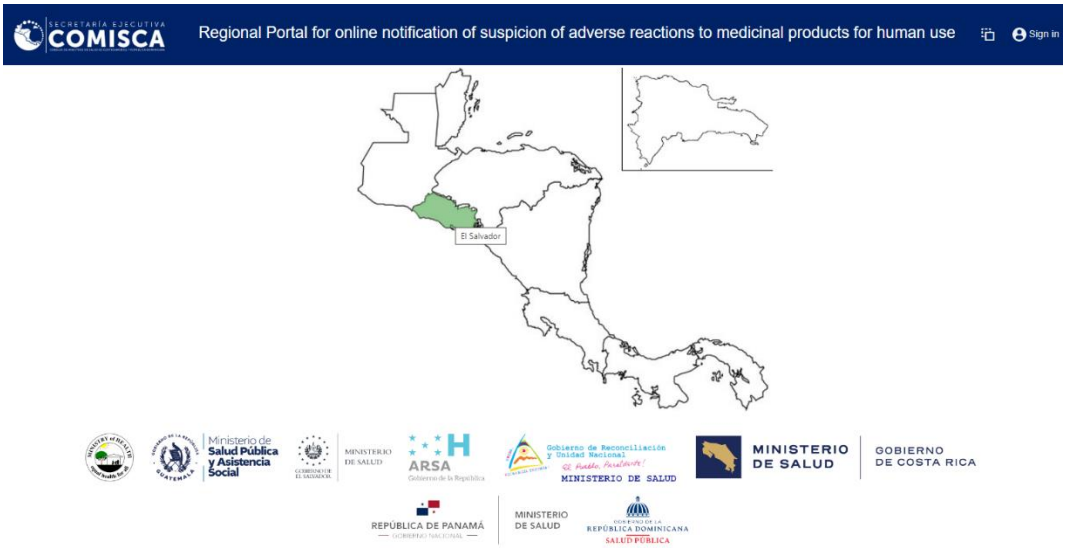
How to access the platform?

Regional Portal for Online Notification of Suspected Adverse Reactions to Drugs and Vaccines for Human Use, called **Noti-FACEDRA**, is available through an internet address www.Notificacentroamerica.net. The online notification portal aims to facilitate the online notification of suspected adverse reactions to drugs or vaccines that are detected by health professionals, citizens themselves and the pharmaceutical industry, so that they are reported in an agile and timely manner to the National Pharmacovigilance Centers of the country where they reside. To access the platform, you must follow these steps:

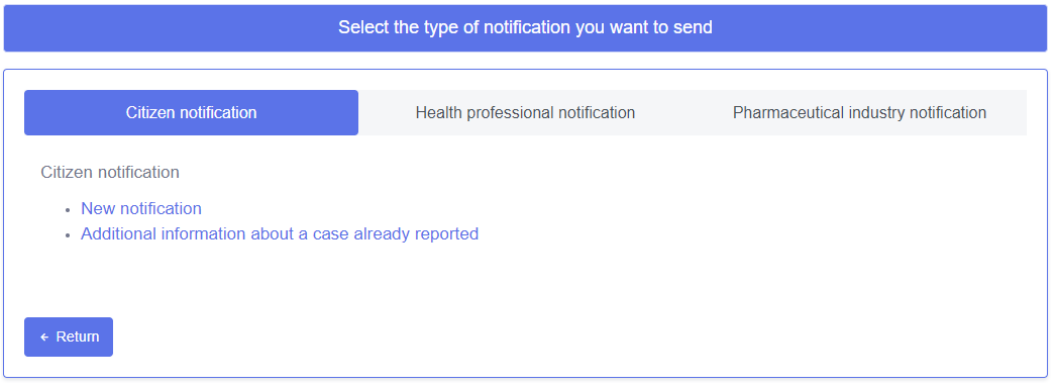
1

Enter the following in the address bar of your preferred browser: www.notificacentroamerica.net where the welcome screen shown below will be displayed

2 Next, you must click on the map to select your country of residence.



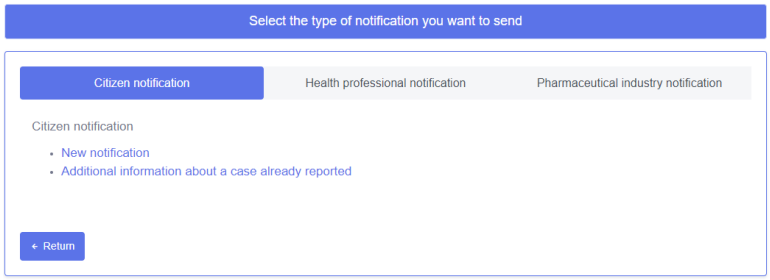
Then the **Main Menu** will be displayed for the online reporting of suspected adverse reactions to medications through **Noti-FACEDRA**, either as a Citizen or as a Health Professional.



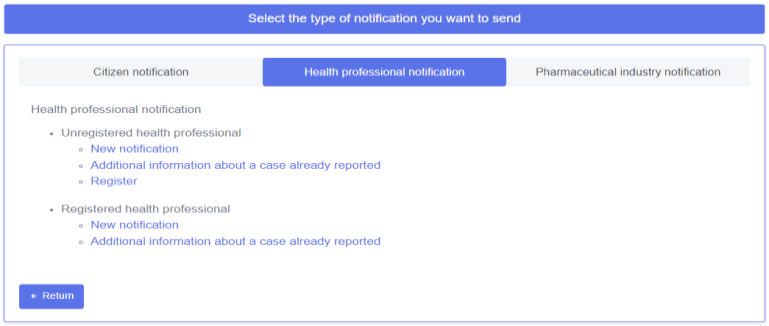
Main Menu

The **Main Menu** screen of **Noti-FACEDRA** consists of three options for selecting the type of notifier that will carry out the process of filling out the electronic form of suspected adverse reactions to drugs or vaccines, these being the following

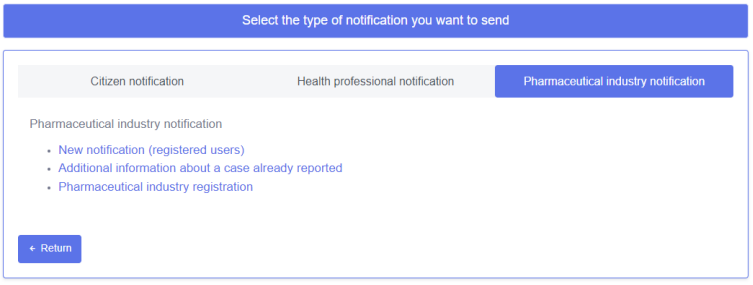
1. The first corresponds to access to the form called **Citizen Notification**, in which access is given to Citizens to directly notify suspected adverse reactions that are detected by them, this includes patients or their caregivers, in case of that the patient cannot do it directly.



2. The second option gives access to the form called **Health Professionals Notification**, which makes it possible to report suspected adverse reactions that may be detected by Health Professionals during their usual practice.



3. The third option gives access to the form called **Pharmaceutical Industry Notification**, so that industries that register on the platform can report adverse reactions to their medications.



Pharmaceutical industry notification process

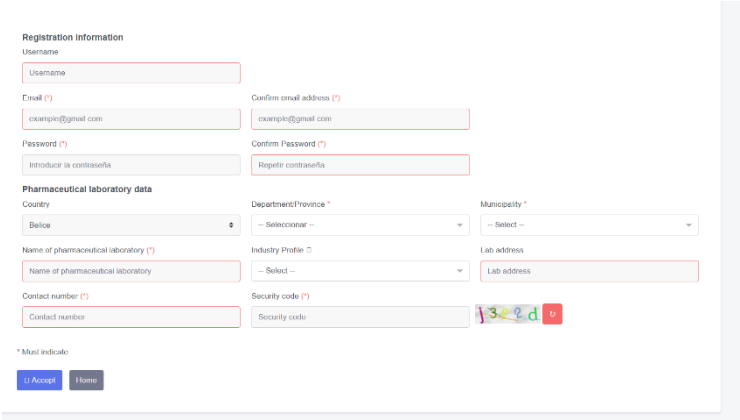
Regional Portal for Online Notification of Suspected Adverse Reactions to Drugs and Vaccines for Human Use, called **Noti-FACEDRA** is available through an internet address www.notificacentroamerica.net

The portal for online notification seeks to facilitate the online notification of suspected adverse reactions to drugs and vaccines, which are detected by the Pharmaceutical Industry so that they are reported in an agile and timely manner to the National Pharmacovigilance Centers of the country where they reside.

Access to the electronic form requires that a health professional trained in pharmacovigilance issues in the pharmaceutical industry register as a ***Notifier***. This registration process will facilitate the process in future reports of suspected adverse reactions to drugs or vaccines of the pharmaceutical products that they are responsible for monitoring the safety and use of the patients to whom their medications or vaccines are prescribed or acquired.

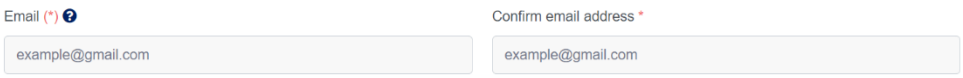
Registration Process

a) Select the **"Register"** option to complete the general information of the Notifier, displaying the following image:

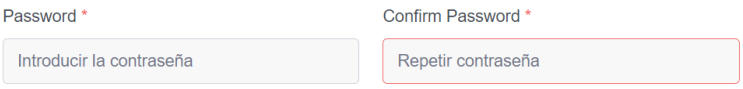


b) The Health Professional of the Pharmaceutical Industry to register must complete the information requested in the fields corresponding to **"Registration Data"** as follows:

- Detail a valid **"Email Address"** (*), which will serve to send the acknowledgment of receipt of the notification, for this you must confirm the email address, as shown in the following figure:



- Next, set a **"Password"** that will give you access to **Noti-FACEDRA** as a **Registered Notifier**, the password must be confirmed for it to be accepted, as shown below:



c) To complete the **"Pharmaceutical Laboratory Data"** information, the laboratory must follow the following steps:

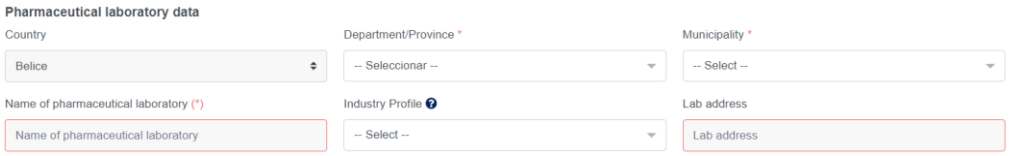
- **Department/Province:** You must select an option from the list that is displayed and you must indicate the department where the laboratory is located. This list will depend on the country chosen on the initial screen of the platform.

- **Municipality:** you should select one of the options to refer to the municipality where the laboratory is located, the list will depend of the selection made in the previous field.

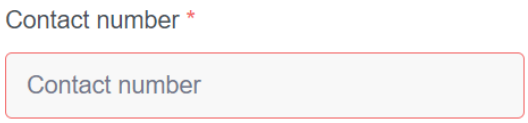
- **Name of pharmaceutical laboratory (*):** You must enter the name of the laboratory that is reporting adverse reactions to your medications.

- **Industry Profile:** Select one of three options in the list.

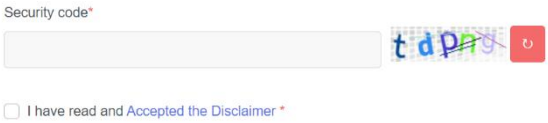
- **Lab Address:** enter the exact address where the laboratory facilities are located.



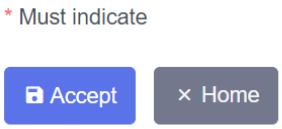
- **Contact number (*),** the notifier must establish the contact telephone number in the Service Center; if desired, the mobile telephone number can be detailed.



- The notifier must enter the random key shown as an image in the field called **"Security Code",** as shown in the figure:



- Once you complete all fields to make the register, click on **"Accept"** to finish the register process.



For the Pharmaceutical Industry to have access to the **Noti-FACEDRA** electronic form, it must register and must have the necessary information for the process of reporting suspected adverse reactions to a medication or vaccines, including prescription, non-prescription, or herbal medicines, do not hesitate to do so if you suspect any problems with the use of these products. To fill out the form you will need to provide information on four important aspects:

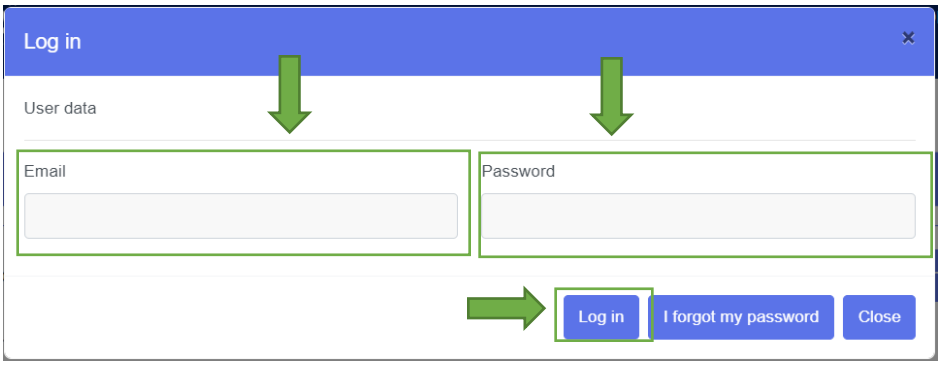
I. Details of possible adverse reaction.
II. Provide the name of the drug you suspect caused the adverse reaction.
III. The information of the person who had the adverse reaction.
IV. Information about the person making the notification will also be needed.

With this information available, the Pharmaceutical Industry can carry out the process of filling out the electronic form through **Noti-FACEDRA**, following the instructions below:

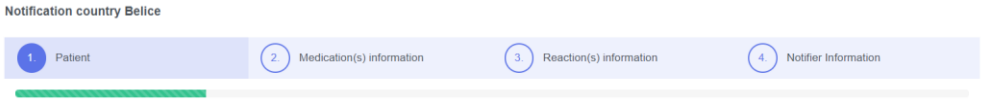
New Notification

After registering as a Notifier, begin the New Notification process by following these steps:

1. By selecting the New notification option from the main menu, a window will be displayed where you will have to enter the email address you previously registered with and the password. Then you must click on the **"Login"** button.



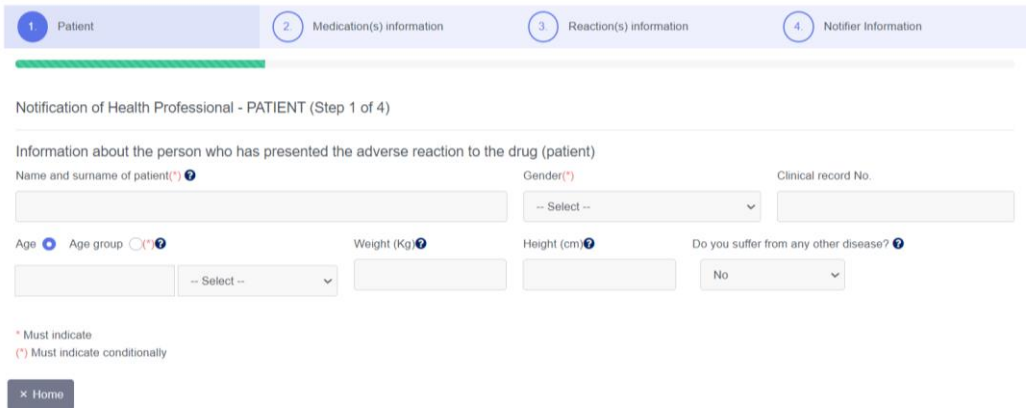
2. Then, notification form will be displayed according to the four sections shown in the following figure:



3. Below are the fields of the form corresponding to step 1, called Patient Data, in this section the information about the person who has had the adverse reaction to the medication must be detailed.

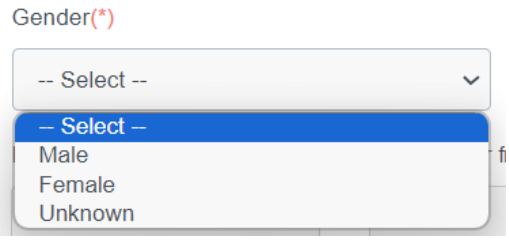
Patient Data

For step 1 of 4: related to the information about the person who has had the adverse reaction to the drug (patient), the following information must be completed:



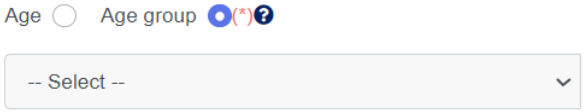
a. **Name and Surname of the Patient,** the patient's full name or initials must be entered. The information marked (*) corresponds to mandatory information.

b. **Gender,** you must select one of the options shown in the list to establish sex of the patient, Male or Female, as the following figure shown:



The information marked (*) corresponds to mandatory information.

c. To report the **Age of the patient**, there are two possibilities. The first is by selecting the **Age** option, which allows you to enter a numerical value, accompanied by the time unit in decades, years, days, hours, months or weeks, as shown in the following figure.

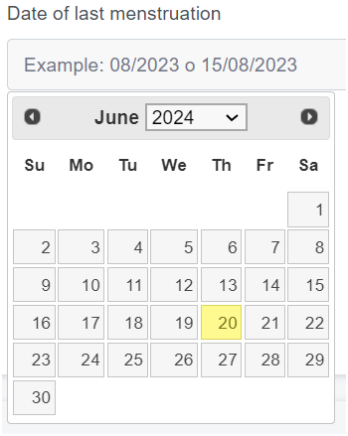


The second possibility is to select the **Age group** option, in which the patient's age is expressed by age groups, selecting one of the options Fetus, Newborn, Infant, Child, Adolescent, Adult or Elderly, as shown in the figure below:

d. **To report the Patient's Weight,** the weight expressed in kilograms must be indicated, entering only the numerical value of the weight.

e. **For the Patient's Height,** its value must be indicated in centimeters, entering only the numerical value of the height.

f. **Date of last menstruation,** this field will be displayed only if the patient is female, the patient must indicate the date in month/year or day/month/year format. Example: 08/2023 or 01/08/2023.



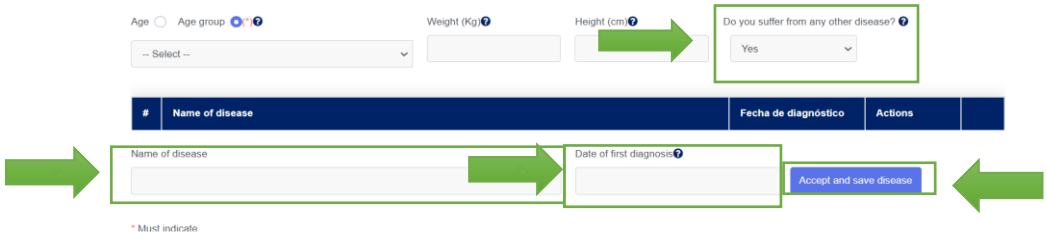
This information is not mandatory, so if you do not know or remember it, you can leave the field blank.

g. For the question, **Do you suffer from any other disease?** it is related to the presence or absence of any disease at the time the adverse reaction being reported occurs.

In the case of presenting a disease, you must select the **"YES"** option, so that two additional fields are displayed for the report of that disease.

In the **Name of disease** field, you must enter the name of the disease you suffer from, a menu of medical terminology will assist you, you can select one of these

terms to report the disease. In the second field, you must enter the **date of first diagnosis** in month/year or day/month/year format, if you do not know this information, you can leave the field blank.



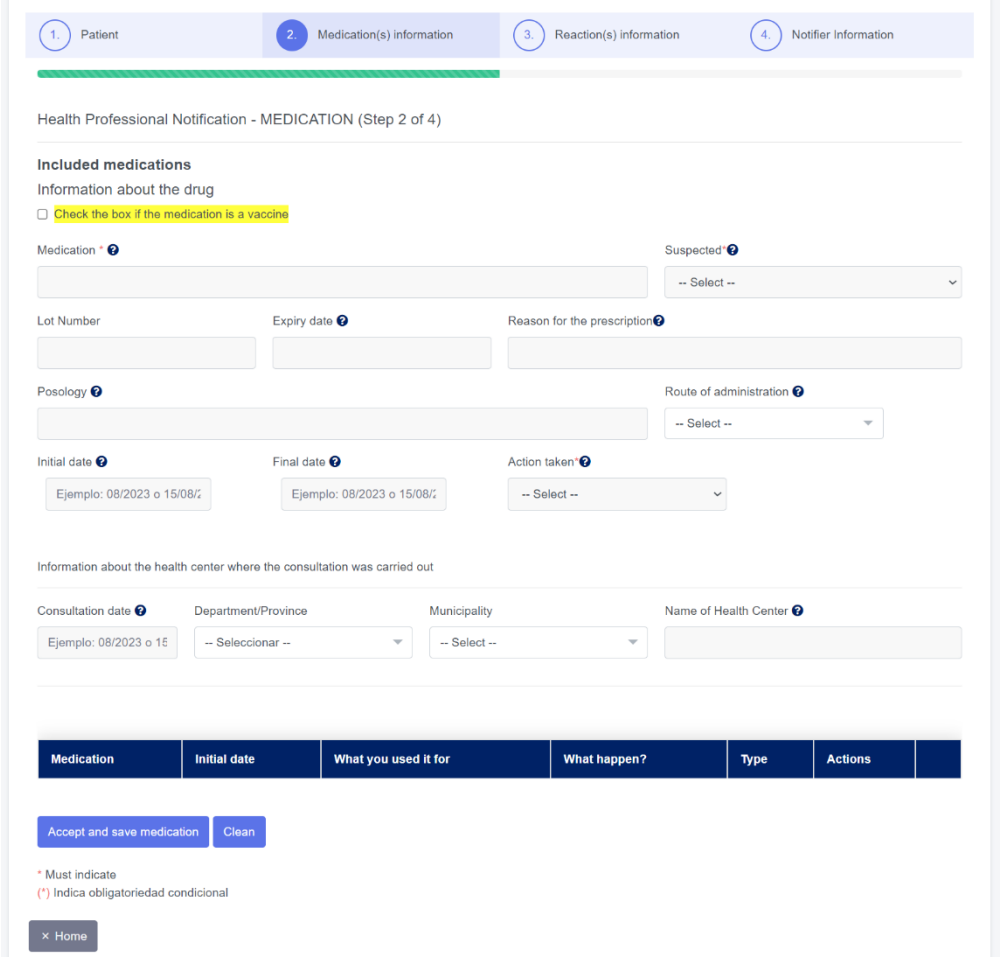
Next, you must click on the **"Accept and save disease"** button to save the information. In this field, more than one disease that the patient suffers can be reported, as long as each one of them is accepted and saved.

h. Step 1 ends when you complete the information and click the "Next" button.

Medication(s) Information

For step 2 of 4, called **"Medication(s) Information",** related to the necessary information of the medication or medications suspected to be responsible for the adverse reaction, the patient must complete the following information:

Add Medication

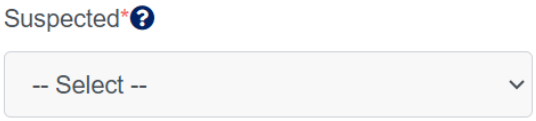


a) **Medication,** to provide information about the medication that may have caused the adverse reaction, in the field called **"Medication"**, for these, you must enter the name of the active ingredient of the medication. As you type in this space, you can select from the drop-down list the name of the active ingredient of the suspected drug, as shown in the following figure:

If you do not know or do not have available the name of the active ingredient of the medication, you can enter the commercial name of the suspected medication.

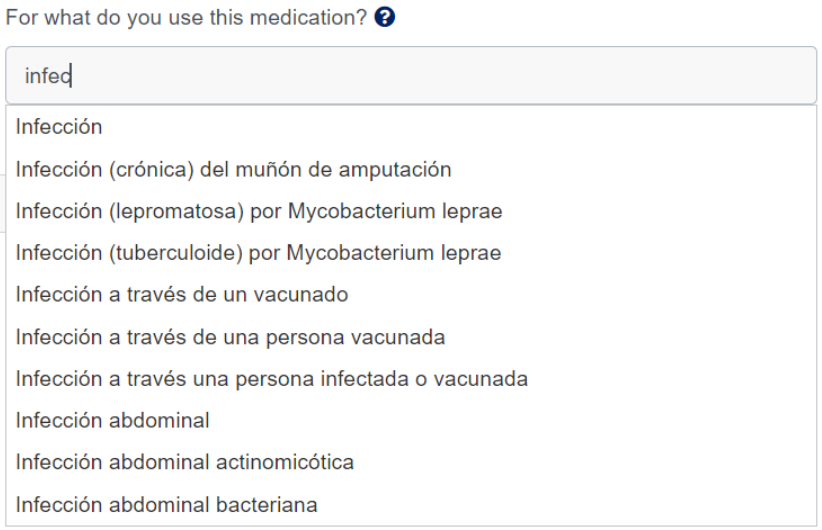
Please note that this is a field marked (*) that corresponds to mandatory information.

b) To complete the **"Suspected"** information, the Notifier must select one of the options related to whether the medication detailed in section a) corresponds to the Suspect, is a Concomitant, or presents an Interaction with the medication that has been administered, such as shown in the figure below:



c) To report the **Lot Number and Expiry Date** of the suspected medicine or vaccine, you can look for this information available on the medicine packaging. If it is not available or you do not know it, you can continue with the process of filling out the information.

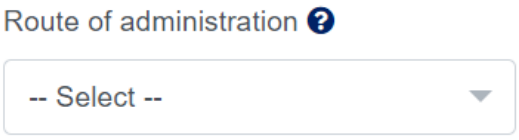
d) To specify the **"Reason for prescription"** of each of the medications or vaccines that the patient is using and that will be included in the notification, the notifier must enter the pathology for which the medication was prescribed. As you type in this space, you can select one of the options from the drop-down list as shown in the following figure:



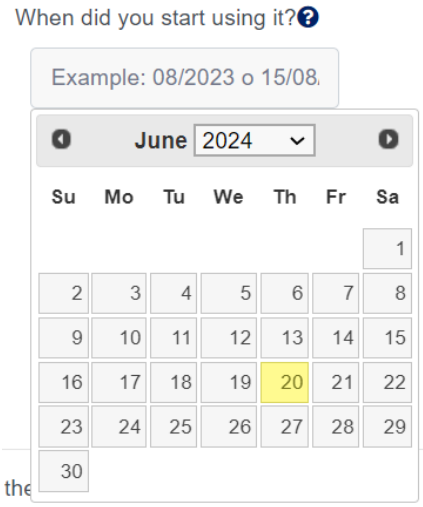
e) To complete the **"Posology"** information, the Notifier must establish for each medication that will be included in the report, the way in which the medication was

prescribed or the way in which the patient reports that he or she was taking the medication, for example: a tablet every day or 500mg twice a day.

f) To declare the **Route of Administration** in which the medication was used, the patient must select one of the options presented from a drop-down list, as shown in the following figure:



g) For the **Initial Date**, the patient must establish in as much detail as possible the date on which the use of the medication began. For this, the calendar modality shown below must be used:

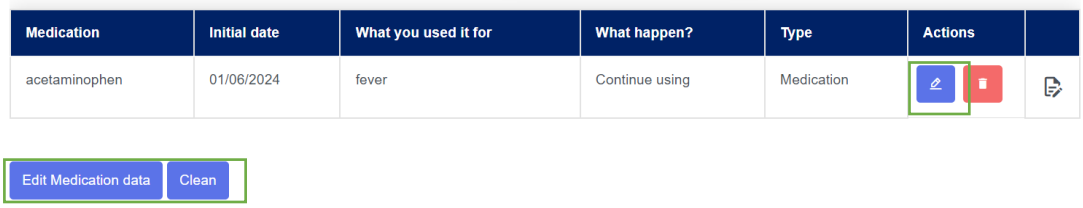


h) For the **Action taken** field, it is necessary to select one of the options shown in the list.

i) To complete the registration of the suspected medication, the patient must select the **"Accept and save medication"** button. With this action, the record of the suspected medication will be stored, presenting it in the format as follows:

Medication	Initial date	What you used it for	What happen?	Type	Actions	
acetaminophen	01/06/2024	fever	Continue using	Medication		

j) If it is necessary to make any correction, the patient can use the edit option, to make the necessary modifications, when finishing they must select the "Edit Medication data" button.

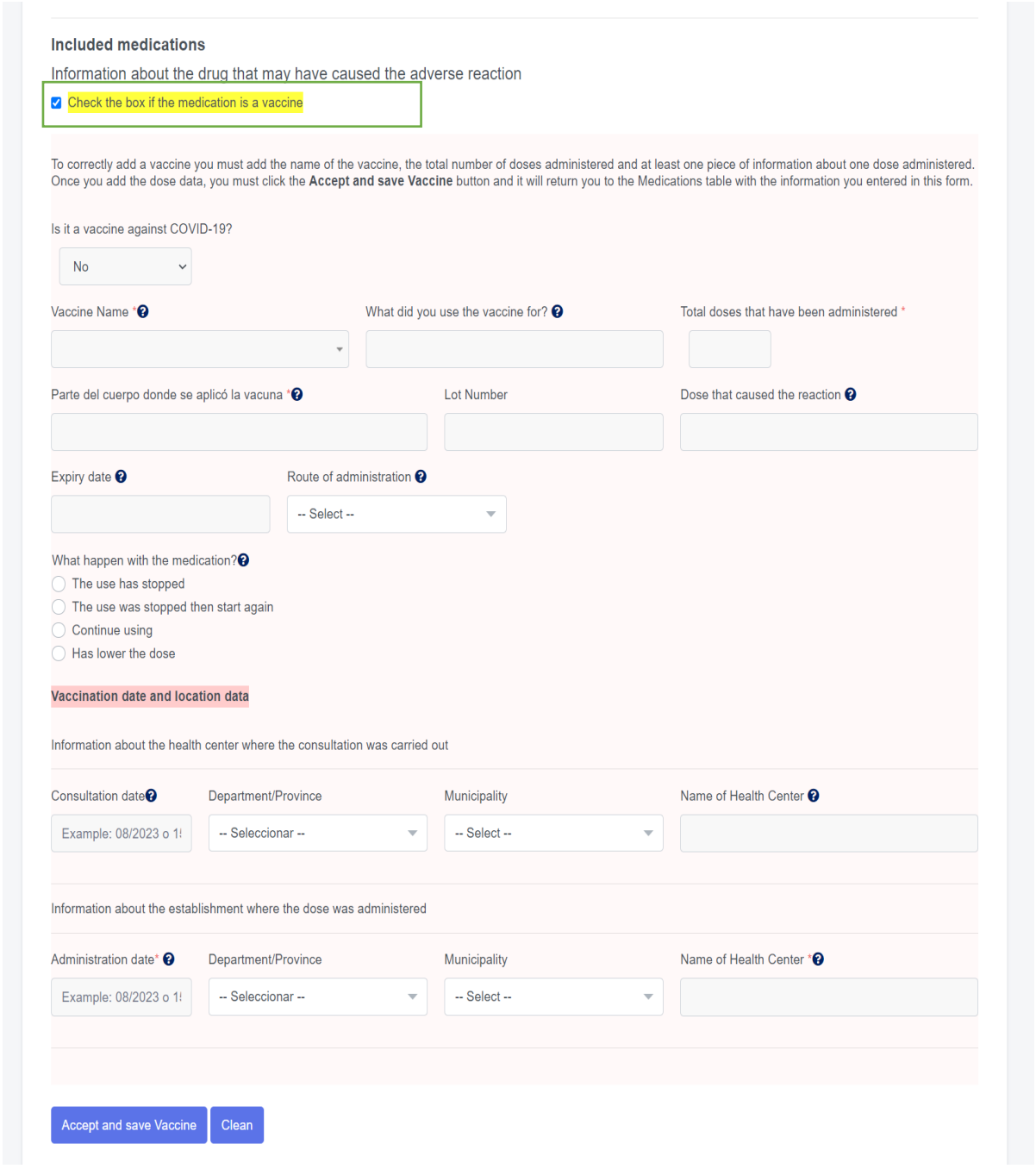


k) **Information about the health center where the consultation was carried out:** If the patient had a consultation at a health center, please provide the following information:

- Consultation Date: Detail date in format month/year or day/month/year.
- Department/Province: A list of options is displayed where you must select the department where the Health Center is located.
- Municipality: The data in this list will depend on the department selected in the previous field and must indicate the municipality where the Health Center is located.
- Name of Health Center

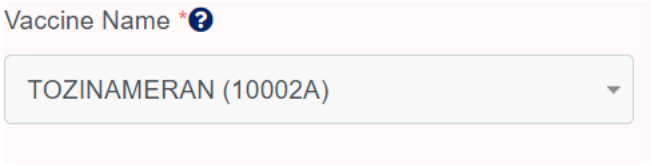
Report of suspected ADR from vaccines

If the medication that caused the adverse reaction is a vaccine, you must click in the box **"Check the box if the medication is a vaccine"**. The following form will be displayed immediately.



a) To answer the question: **Is it a vaccine against COVID-19?,** the patient must answer **Yes** or **No**.

b) **Vaccine Name,** to provide information about the vaccine that may have caused the adverse reaction, some options will be displayed that you can select. These options will be filtered depending on whether the vaccine is COVID or not.



If none of the options displayed in the list match the term you are looking for, you can type the name of the vaccine.

c) To answer the question: **What did you use the vaccine for?** the patient must type the use for which the vaccine was indicated. As you type in this space, you can select one of the options from the drop-down list.

d) To report the Lot Number and Expiry Date of the suspected vaccine, you can look for this information available on the medicine packaging. If it is not available or you do not know it, you can continue with the process of filling out the information.

e) **Total doses that have been administered,** you must indicate how many doses have been administered to the patient of the vaccine you report**.**

f) **Anatomical place where the vaccine was applied,** it must indicate where on the body the dose of the vaccine that caused the reaction was placed.

g) **Dose that caused the reaction,** refers to the specific amount and frequency with which the doses were administered. Example: 0.3 ml each dose.

h) For **Action taken,** you must select from a drop-down list one of the options presented.

i) **Vaccine dose,** in order to add the vaccine information correctly, the data of at least one applied dose must be added:

Information about the health center where the consultation was carried out: If the patient had a consultation at a health center, please provide the following information:

- Consultation Date: Detail date in format month/year or day/month/year.
- Department/Province: A list of options is displayed where you must select the department where the Health Center is located.
- Municipality: The data in this list will depend on the department selected in the previous field and must indicate the municipality where the Health Center is located.
- Name of Health Center

Information about the facility where the dose was administered: In order to save the dose data, the following information must be added:

- Consultation date: Detail the date of the patient's consultation in which they received the vaccine dose. This information is mandatory to add the dose to the vaccine.
- Department/Province: A list of options will be displayed where you must select the department where the establishment where the dose was administered is located.
- Municipality: The data in this list will depend on the department selected in the previous field and must indicate the municipality where the establishment where the dose was administered is located.
- Name of Health Center: the name of the establishment where the dose was administered must be indicated.

Once you complete the information you have to click on **"Accept and save Vaccine"**.

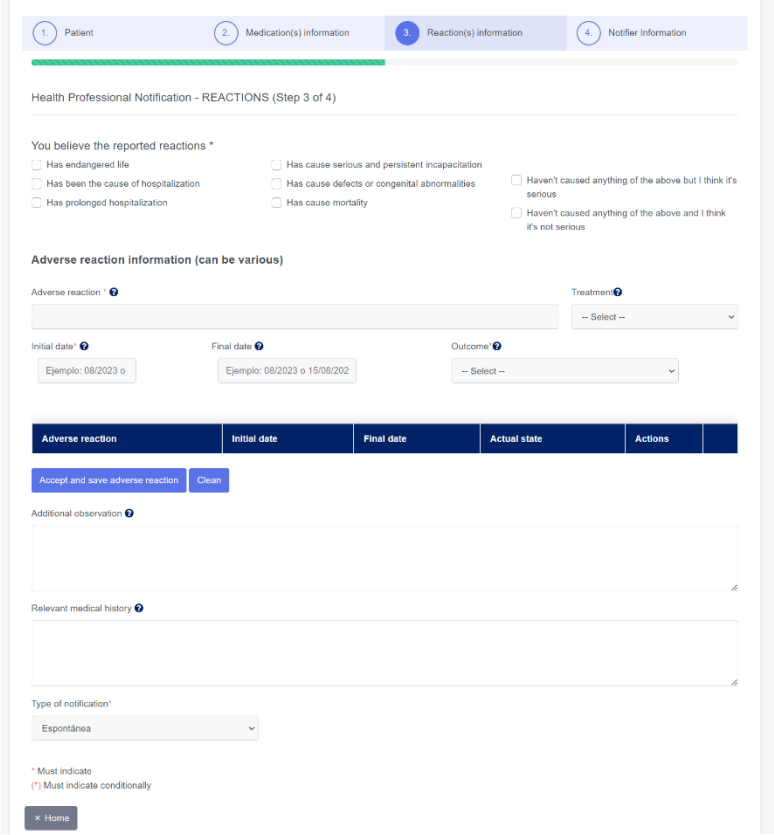
You can repeat the process to add the number of doses needed.

If it is necessary to make a correction, the patient can use the edit option, to make the necessary modifications. When finishing, they must select the **"Edit Vaccine Data"** button.

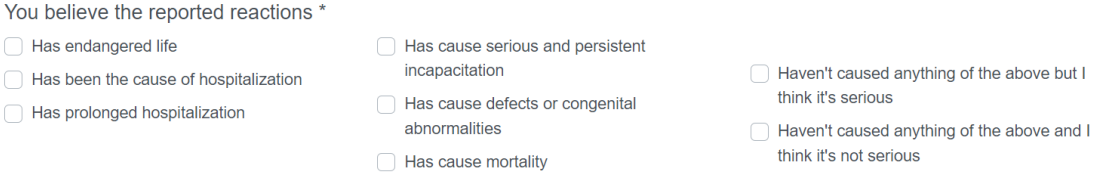
To finish the process, you must select the **"Accept and save vaccine"** button and then click the **"Next"** button.

Information of adverse reactions reported

For step 3 of 4, called **"Reaction(s) information"**, related to the necessary information on the possible adverse reactions that have been identified by the Health Professional and that are presumably linked to the medications that the patient is using. For this the following information must be completed:

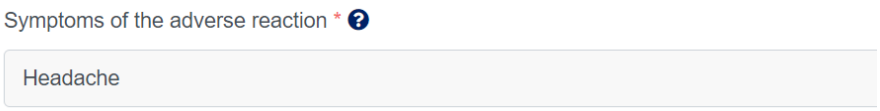


a) The Pharmaceutical Industry, according to the status of the adverse reaction that has occurred in the patient, must select one or more of the criteria shown in the following figure:



Please note that this is a field marked (*) that corresponds to mandatory information.

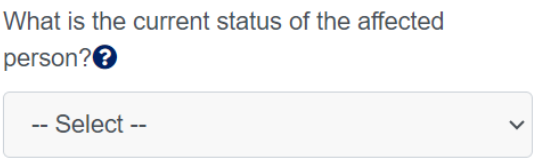
b) For the section called **"Adverse reaction information (can be various)"**, the information related to the suspected adverse reaction(s) must be completed as follows:
In the field called **"Adverse Reaction"** you must enter the adverse reaction that has occurred with the use of or medications used by the patient. As you type in this space, you can select from the drop-down list with the medical terminology that closer, as shown in the following figure:



c) To complete the information related to the **"Initial Date",** you must establish with as much detail as possible the date on which the adverse reaction appeared; for this, the calendar mode must be used. You must place at least the data in month/year format.
Please note that this is a field marked (*) that corresponds to mandatory information.

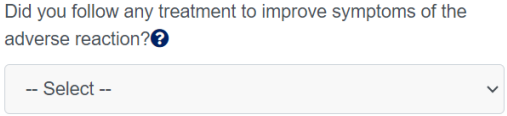
d) Next, you must provide the information on the **"Final Date"** of the adverse reaction, considering that for this information the Health Professional must establish the most exact date possible on which the symptoms have disappeared, if it has happened. To do this you must use the calendar mode and you must enter at least the data in month/year format.

e) To answer the **Outcome** question, you must select one of the options shown in the drop-down menu, as shown below:



Please note that this is a field marked (*) that corresponds to mandatory information.

f) To answer the **Treatment** question, you must select one of the options shown below. If you have not received any treatment, you must select the **"No treatment"** option.



g) To complete the recording of the adverse reaction data, the patient must select the **"Accept and save adverse reaction"** button. With this action the record of the adverse reaction will be stored, presented in the format as follows:

Symptom	Initial date	Final date	Actual state	Actions	
Headache	01/06/2024	06/06/2024	DESCONOCIDO		

h) If it is necessary to make a correction, you can use the edit option, to make the necessary modifications. When finishing, they must select the **"Modify Reaction data"** button.

Symptom	Initial date	Final date	Actual state	Actions	
Headache	01/06/2024	06/06/2024	DESCONOCIDO		

Modify Reaction data | Clean

i) If the patient is required to give more information that may provide other elements that may be necessary for the analysis of the case, a narrative of the case, results of laboratory tests or other clinical tests may be included. This information may be entered in the field called **"Additional observation",** shown below:

Additional observation

j) **Relevant medical history,** in this field enter relevant information or medical history that supports the investigation of the case

Relevant medical history

k) The Health Professional, according to the **type of notification** made in Noti-FACEDRA, must select one of the options shown in the drop-down menu, as shown in the following figure:

Type of notification*

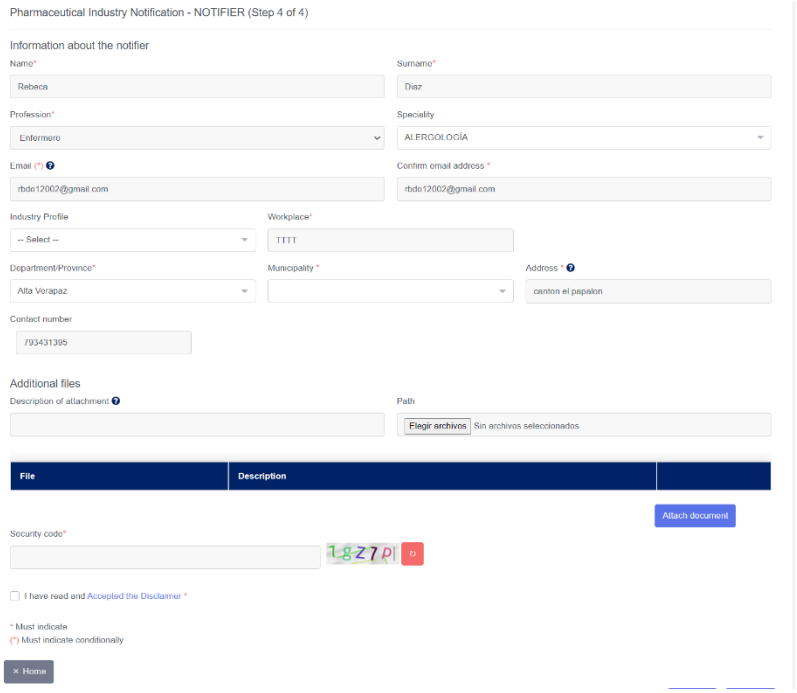
Espontánea

If it is a report of suspected adverse reaction detected during your usual practice, you must select the “Espontánea” option.
If the suspected adverse reaction(s) are identified by the Health Professional as part of a study or reported in the scientific literature and refers to cases from the Central American region, they should consider reporting them as “Estudio” cases.

Step 3 ends when you complete the information and click the **“Next”** button.

Notifier information

For step 4 of 4, called **"Notifier information"**, related to the information necessary to identify the Health Professional who is carrying out the notification process of the suspected adverse reaction that is presumably linked to the medications that the patient is using, for this the following information must be completed:



a) For the information on the person who fills out the data in the **Noti-FACEDRA** electronic form, it will be completed with the **name and surname of the notifier.**

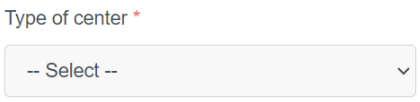
b) To identify the **"Profession"** of the notifier, you must select one of the options shown in the drop-down menu.
Please note that this is a field marked (*) that corresponds to mandatory information.

c) Detail a valid **email address**, which will be used to send the acknowledgment of receipt of the notification, for this you must confirm the email address.
Please note that this is a field marked (*) that corresponds to mandatory information.

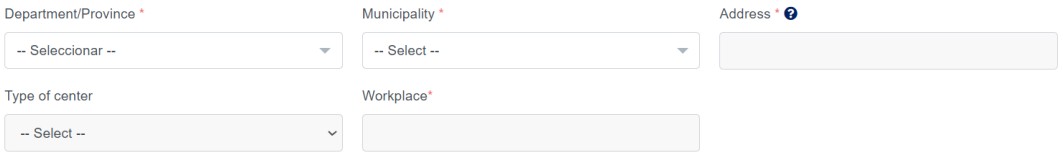
d) The notifier must detail their **"Specialty"**, specifically for Medical Professionals, select one of the options shown in the drop-down menu.

e) A **contact telephone number** must be indicated, preferably that of the Work Center. Optionally you can register a mobile phone number.

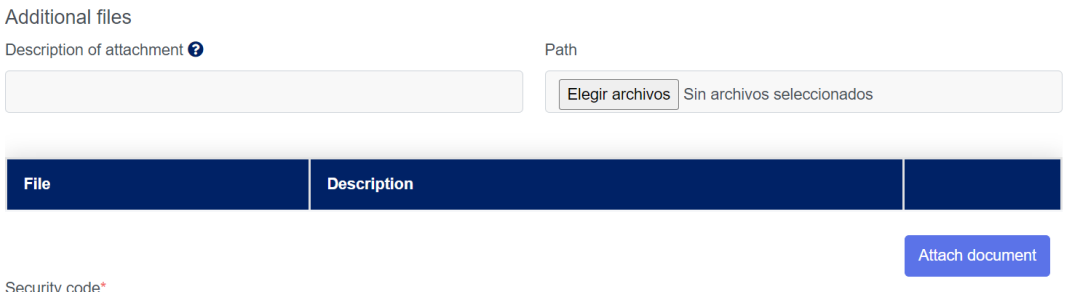
f) To detail the **type center**, the Health Professional must select one of the options shown in the drop-down menu shown below:



g) To declare the name of the **"Workplace"**, the Health Professional must enter the full name and **"Address of the workplace"** in the sections shown below:



h) If necessary to provide more information related to the case being reported, the patient can attach files as attachments to the report, as shown below.:



In the field called **"Description of attachment"**, you must establish a short description or the name of the file you want to attach.

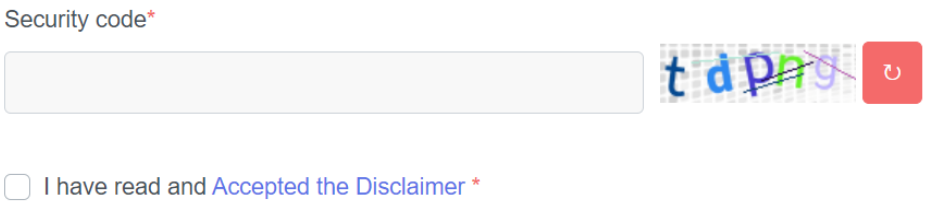
For the field called **"Path"**, you must indicate in which folder on your computer or device the file you want to attach is located.

Note: The formats supported to attach to the notification are the following:

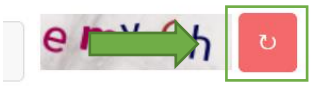
- For text files type: .DOC,
- For image files type: .JPG .GIF and .PDF type

i) To upload as an attachment, you must click on the **"Attached document"** button.

j) The notifier must enter the random key shown as an image in the field called **"Security Code",** as shown in the figure:

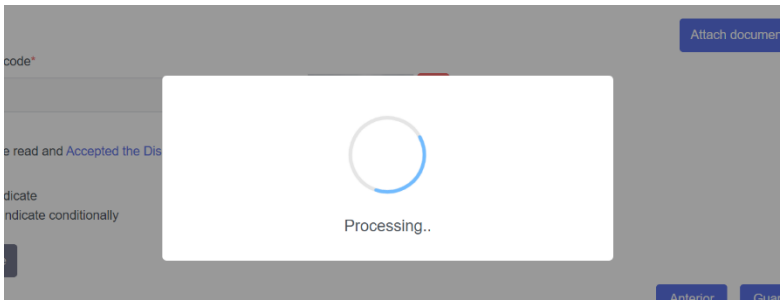


If it is not legible, you can update the image by clicking on the button



k) For information security purposes, it is necessary for the notifier to select and activate the option **"I have read and Accepted the Disclaimer"**, displaying a window in which the text of the legal notice is displayed.

l) To finish the process of filling out the form and proceed to send the information, you must click on the **"Save"** button. At that moment the platform will display the following message:



m) You will receive confirmation of sending the form.

n) To print a copy of the notification report of suspected adverse reactions that has been prepared through **Noti-FACEDRA**, you must click on the **"Download PDF"** button and the process of downloading the file with the code will begin. the notification in .PDF format, example NCA11.PDF.

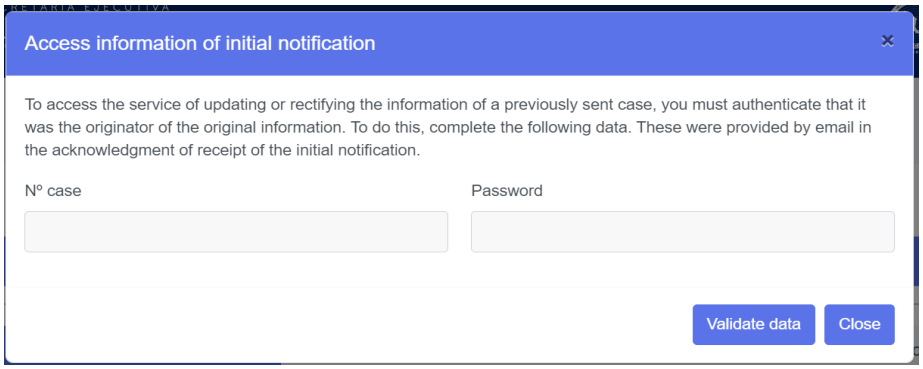
o) After downloading, the notifier will receive an acknowledgment of receipt to the email that was included in literal c), with a summary of the case, the case report code and a unique key for possible follow-up or contribution of more related information.

Follow-up of cases or provision of additional information on a reported case

This section details the steps to follow in the event that the notifier has more information about a reported case or needs to update or clarify the data provided. To do this, the following must be done:

a) The person who reported the case and provided their contact information to receive the acknowledgment of receipt generated by **Noti-FACEDRA**, must search in the email received, the following information:
   I. Reported case number
   II. Individual password of the reported case.

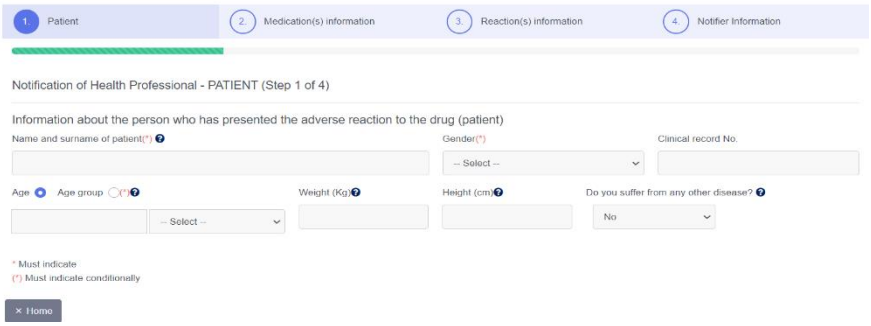
b) Upon having the information from step a), the notifier must access **Noti-FACEDRA** through the link www.notificacentroamerica.net, and click on **"Additional information about a case already reported"** in which the following screen will be displayed:



In this space you must enter the **Notification Code (No. Case) and Password** that was received in the acknowledgment of receipt email.

c) By entering the data, the notifier will access to the report and may make changes or modifications to any of the fields in the form.

When accessing the form all the fields will be blank as shown in the following figure:



Note: the notifier should only fill out the form with the information they wish to update or modify, the other fields of the form should be left blank.

d) If it is necessary to make any correction or modification in any of the steps in the form, remember that at the end you must select the **"Accept and save"** button as appropriate.

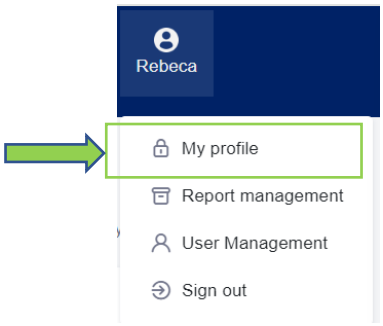
e) To save the corrections or additional information provided, you must click the **"Save"** button; if the tracking was carried out correctly, a confirmation message will appear that will give you the option to download the PDF again. In addition, you will receive an email again with the notification number and password information.

Edit my profile

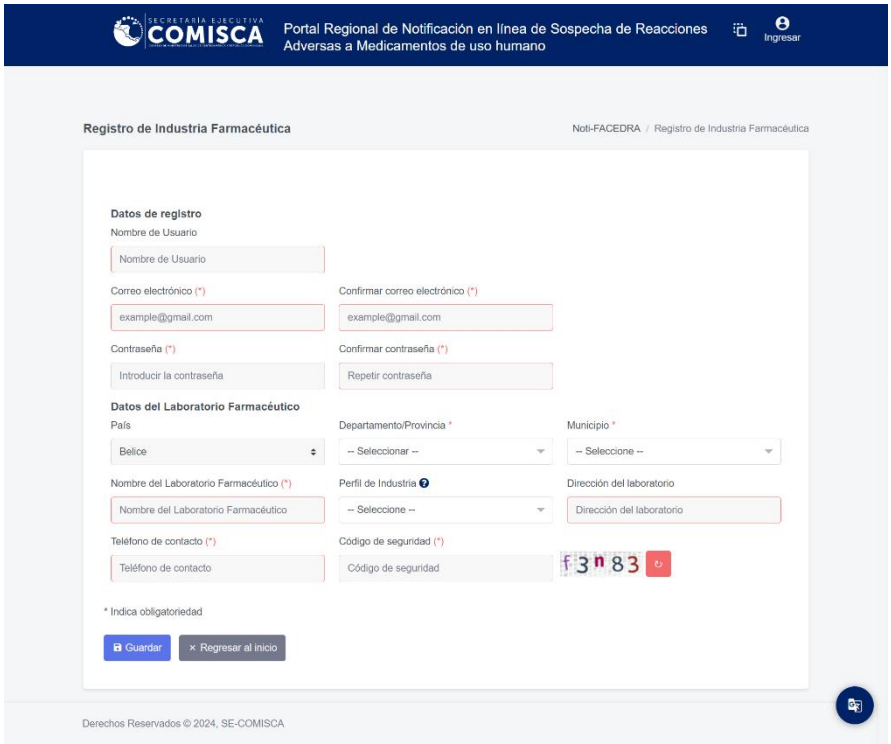
In this section you can edit your user information, the data with which you registered will be displayed.

Once you have logged in you will have the **"My Profile"** option available, to update your information follow these steps.

a) The health professional of the pharmaceutical industry who manages the profile with a logged in, must Click on "My profile"

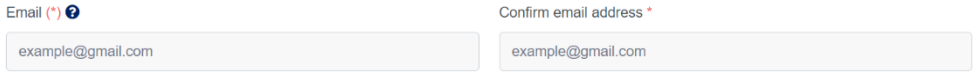


b) Select **"My profile"** option to edit your profile information, the following image will be displayed with your preloaded data:

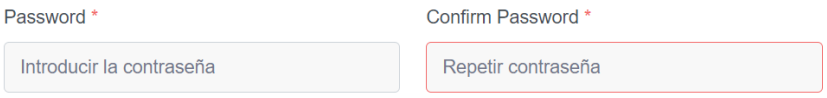


c) You must have the information requested in the fields corresponding to **"Registration Data"** as follows:

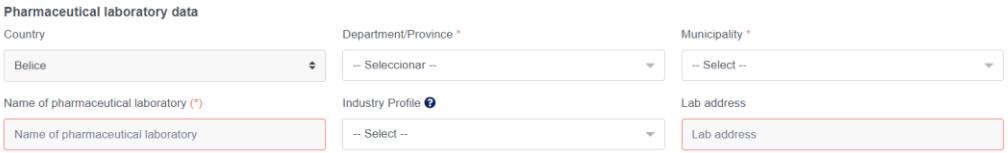
- Edit valid **Email Address (*)**, which will serve to send the acknowledgment of receipt of the notification, for this you must confirm the email address, as shown in the following figure:



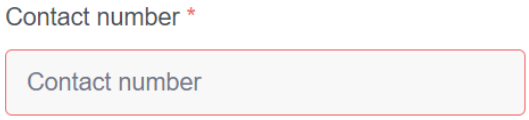
- Next, update the **Password** which will give you access to **Noti-FACEDRA** as a **Registered Notifier**, the password must be confirmed for it to be accepted, as shown below:



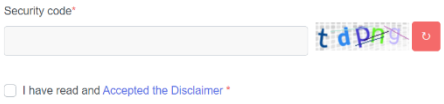
d) To edit the **Pharmaceutical Laboratory data**, you must consider that you will only be able to edit the information related to the address of the laboratory, that is: The department/Province, Municipality and the address of the laboratory. If you want to change other data, you must contact the platform administrator.



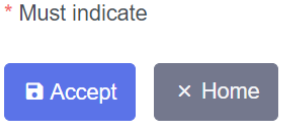
- Edit the **contact telephone number (*)**, the Notifier must establish the contact telephone number in the Service Center, if desired the mobile telephone number can be register.



- You must enter the random code shown as an image in the field called *Security Code,* as shown in the figure:



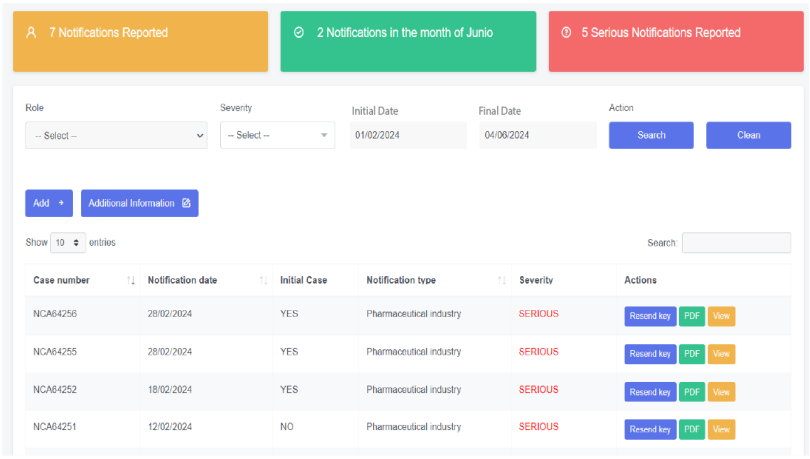
- Once you edit all the fields to update, you must click on **"Accept"** to complete the updating process.



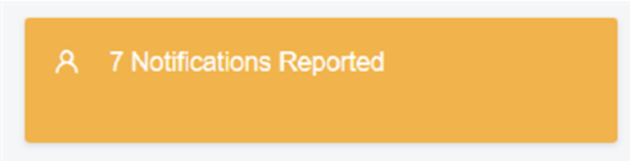
- You will receive a message confirming the successful modification.

Report management

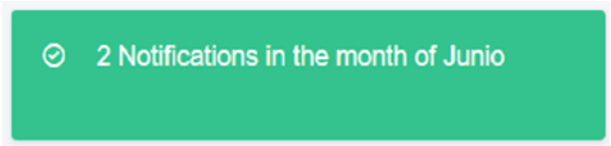
In this section you will be able to manage the notifications that have been reported through the **Noti-FACEDRA** platform, you will have information on the number of notifications accumulated in the current month, in addition to the option to identify the serious cases reported, as shown below.



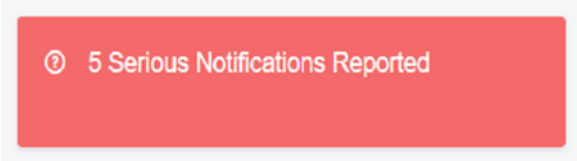
a) Information on the number of notifications reported.



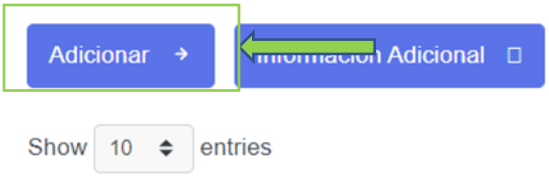
b) Information on the number of notifications made in the current month.



c) Information on the number of serious notifications reported.

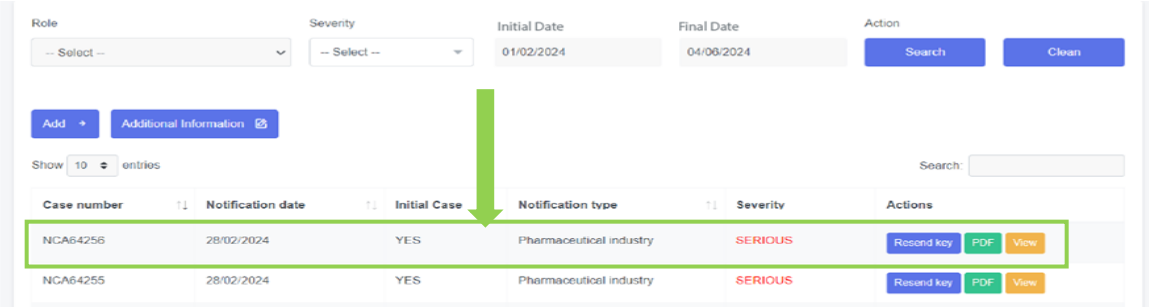


d) To make a new notification you must click on the **"Add"** Button

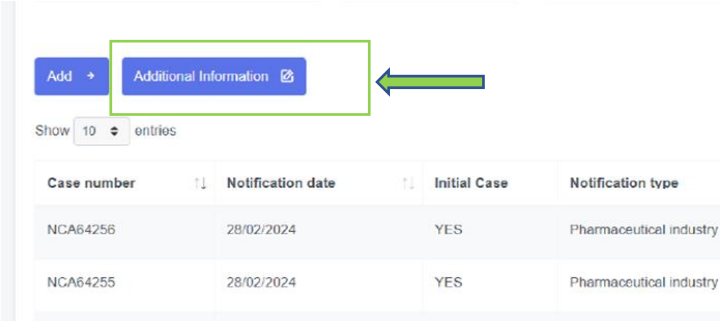


e) To add additional information to a notification, follow these steps:

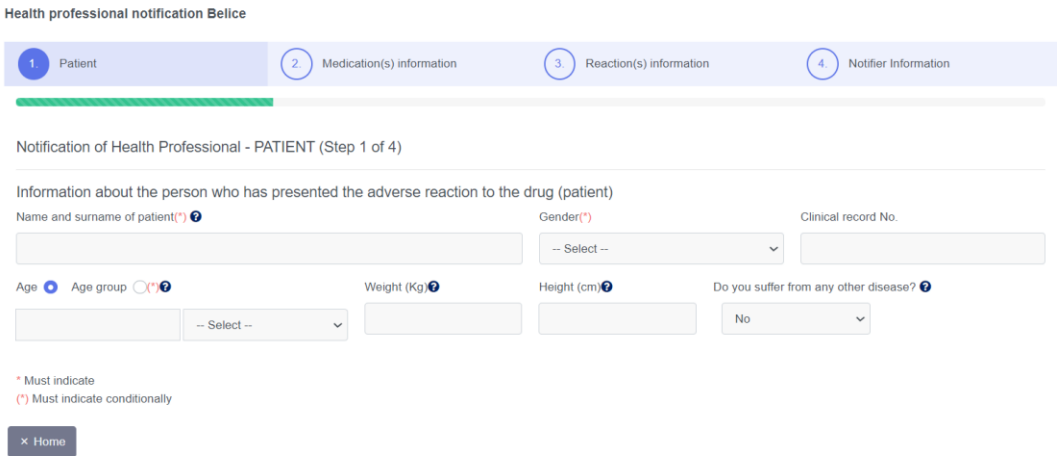
a. Select a record by clicking on it.



b. Click on the "Additional Information" button.

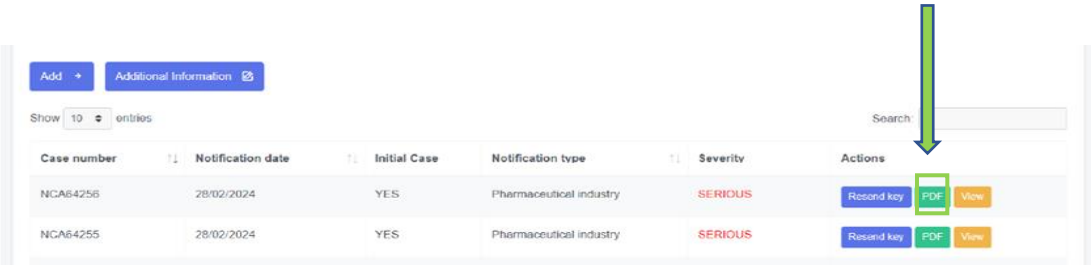


c. This way, you can add information to an existing notification.



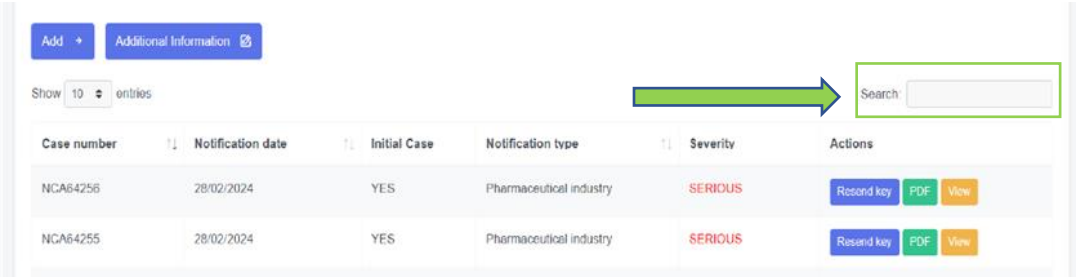
f) Resend notification password, you must click on the **"Resend key"** button of the corresponding case.

g) To download the pdf of the notification you must click on the “PDF” Button.



h) See detailed information about the notification, click on the “View” button.

i) Search or filter notifications.

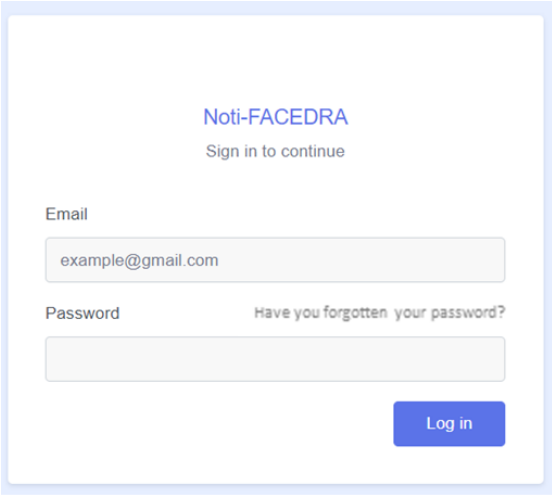


Process to recover password

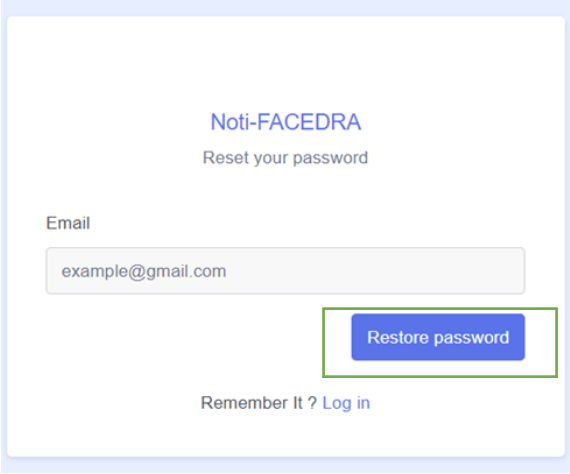
The **Noti-FACEDRA** User also has an option that allows them to recover their password in case it has been forgotten or lost.

On the login screen you will find an option to help you reset your password, follow these steps:

a) On the login screen, click on the question **"Have you forgotten your password?"**



b) Enter your email and click on the "Restore password" button.



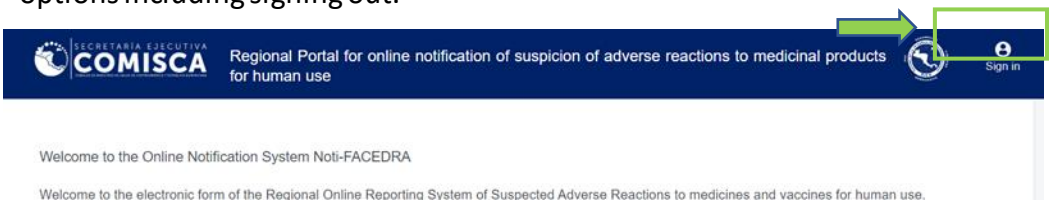
c) Once you have clicked on the "Reset" button you will have a response, which tells you to check your inbox or spam email.

d) Check your email and you will be able to enter with the new password, do not forget to update it once you have logged in.

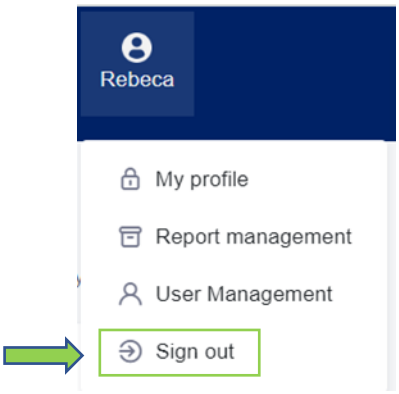
Sign out of the portal

Remember to log out when you finish your activities in Noti-FACEDRA. To carry out this process, follow these steps:

a) In the menu located in the upper right part of the screen you will find several options including signing out.



b) Look for the **"Sing out"** option and click, with this action the active session finished



Frequent Questions

1. **If all medications can cause adverse reactions, does this mean that no medication or vaccine is safe?**

   No medication or vaccine is completely free from producing one or more adverse reactions, but the benefit obtained from the use of the medication outweighs its potential risks.

   In general, most people who use a medication or are given a vaccine do not experience any adverse reactions. Even adverse reactions that are described as common occur in only a small percentage of people who use the medication.

2. **Since I have started using the medication, I have noticed a number of new symptoms that I believe may be due to the medication. What should I do?**

   If you are concerned about a suspected adverse reaction, you should discuss it with your doctor or pharmacist or you can use the mechanisms used by the manufacturing company to report problems with use or patient monitoring. If you think that a medicine, vaccine or herbal medicine has caused you an adverse reaction, talk to your doctor or pharmacist.

   If you want to communicate it directly, please fill out the **Noti-FACEDRA** electronic form available through the link www.notificacentroamerica.net.

   When deciding whether the new medication could have caused the symptoms you are experiencing, a number of factors should be considered.

   If symptoms start after starting treatment with the new medicine, they could be related to this medicine, but this will not always be the case.

   Your symptoms may be related to a disease or medical problem you have, or it may simply be a coincidence, especially if you have symptoms that commonly affect a large number of people in the population, for example, headache.

   It is also possible that the symptoms could be the result of an interaction between the new medication and another one you are using, or even a certain food.

   If your symptoms go away when you stop using the medication, this may suggest that they were probably caused by the medication.

   Your doctor is in the best position to advise you about the symptoms you are experiencing, whether or not they are associated with the medication you are taking. It will even tell you how to avoid some potential adverse reactions.

3. **What will happen to the notification sent through the Noti-FACEDRA portal?** Notifications are collected and uploaded to a specialized database that allows them to be quickly analyzed and evaluated.

   Your notification will be considered in the context of all other notifications received from patients or healthcare professionals. The Drug Regulatory Authority in your country may use your notification in different ways:

   - Carry out a targeted analysis of similar notifications to identify new information on drug safety.
   - Consider the patient's perspective, to better understand the impact of adverse reactions on people who use medications.
   - Request additional information from other sources.
   - Discuss the adverse reaction with the other Drug Regulatory Authorities of Central America and the Dominican Republic, to take joint actions against these possible problems.

4. **What happens to the personal data in the notification that is placed in the form?** Personal data are managed in such a way that they are not incorporated into the adverse reactions database in an anonymized manner, only the patient's sex and age data are handled.

   The confidentiality of sensitive data is expressly protected by current legislation and will not be transmitted to any person or organization outside the National Pharmacovigilance Center of your country.

5. **If I fill out a form through the Noti-FACEDRA portal, will a treating doctor or other health professional receive a copy?** No, in no case. At the end of sending the notification, only the company that notified will receive a copy of the report and the respective identification number.