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

SICA
Sistema de la Integración Centroamericana

# USER MANUAL

## HEALTH PROFESSIONAL NOTIFICATION

## Noti-FACEDRA

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

# Content

# Introduction

The Noti-FACEDRA portal is part of the FACEDRA Regional System (Central American Pharmacovigilance Data of Adverse Reactions to Medicines and Vaccines for Human Use), which is managed by the Executive Secretariat of the Council of Ministers of Health of Central America and the Dominican Republic (SE-COMISCA) in coordination with the National Centers/ Units/ Programs competent in the pharmacovigilance field in the Medicines Regulatory Authorities of the Member States of the Central American Integration System (SICA) region, as part of the capacity building and consolidation of the Central American Regional Pharmacovigilance Program and of the national pharmacovigilance actions for Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and the Dominican Republic.

**Noti-FACEDRA** is an Information tool that allows the online notification process of suspected adverse reactions to medicines and vaccines (for human use) to the National Pharmacovigilance Centers in Central America and the Dominican Republic. Therefore, it is important for patients to inform their doctor, pharmacist or other health professional about possible adverse reactions derived from the use of medications and vaccines; taking into account that citizens can do so directly through the regional portal **Noti-FACEDRA 2.1.**

This electronic notification tool contributes to knowing in a prompt and timely manner, the adverse reactions of medicines and vaccines used in both the private sector and in national health systems.

With **Noti-FACEDRA 2.1**, national capacities will be strengthened for the surveillance of the safety and effectiveness of medicines and vaccines authorized by the drug regulatory authorities of the SICA region.

# General considerations

All medications can occasionally cause unwanted effects, also known as adverse drug and vaccine reactions (ADRs). Sometimes, ADRs can appear after a person has stopped using the medication, or, even after a vaccine has been administered, while some ADRs may not be discovered until many people have used the medication over a long period of time.

If you believe your patient has experienced an adverse reaction to a medication or vaccine, you can also report it using the electronic form we provide at the following link: www.notificacentroamerica.net

The electronic form is intended to be a simpler and faster way to notify your National Regulatory Authority of a possible adverse reaction that occurs with the use of a medicine or after the administration of a vaccine.

### WHAT SHOULD YOU NOTIFY?

Please complete the **Noti-FACEDRA 2.1 electronic form** if you have detected a suspected adverse reaction to a medication or vaccine in a patient.

### Mainly you must report:

- Medicines and vaccines
- One or more suspected serious adverse reactions that are identified with any medication or vaccine, with any of the following situations being considered serious:
  i. Cause death.
  ii. Threaten the patient's life.
  iii. Cause or prolong hospitalization.
  iv. Cause inability to work or study.
  v. Induce birth defects.
  vi. Be clinically relevant.

If there is an uncertainty of the severity of the reaction, please report it anyway.

Don't be limited by whether the adverse reaction is common or seemingly insignificant, as reporting it can help identify safety issues with medications and vaccine use.

Don't wait to report if you're missing any information or data. It is essential for the analysis of the adverse reaction that you always provide as much information as possible including all the data you have on the medication(s) being reported, including any products that they may have consumed that may contain substances with pharmacological effects (e.g., nutritional supplements, macrobiotics, medicinal plants).

Be careful to indicate the brand name and presentation of the suspected medication(s) or vaccine, as well as the Lot number printed on the product packaging. This information is especially important when it comes to biological medications.

### What should be included in the report?

**The Noti-FACEDRA 2.1** electronic form includes four key sections of information that are necessary for the reporting process:

### Suspected drug(s)

The name of the medication(s) suspected of causing the reaction. If the brand name is known, the complete name (brand, strength, and presentation) should be provided. This information should also be included, if known:

- The route of administration.
- Daily dose, dose frequency and dosage.
- Administration dates.
- If it is a vaccine or other biological medicine, the brand name with the complete name, batch number, and expiration date.

### Adverse reaction(s)

Describe the adverse reaction detected, including the main diagnosis, as well as the following:

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

If the reaction has already been reported (for example, by another healthcare professional or the patient), but you have additional information to report, please let it be known in the report so that the previously reported case can be identified and the information added.

### Patient details

Basic patient information is vital for evaluating cases and obtaining additional information. Please provide the following information, if possible:

- Patient's sex.
- The patient's age at the time of the reaction.
- If known, indicate the patient's weight.
- Patient's first and last name, if available, the medical record number to help identify the patient in any future notifications.

### Notifier Details

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

Only if you report ADRs associated with "medication errors" (by selecting the corresponding field), your personal data will not be included in the form.

### Other additional information

It is very helpful to include any additional information you consider relevant to the analysis of the reported case, such as:

- Other medications used in the last three months before the reaction occurred, including prescription, non-prescription, branded, or herbal medications.
- Any information on re-exposure to the suspected drug at other times.
- Relevant medical history, including allergies.
- Results of medical or laboratory tests.
- For congenital anomalies, please indicate all other medications taken during pregnancy and the date of the last menstrual period.

- 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 this.

All the information you provide will help us interpret the case and facilitate its evaluation. Please provide as much information as possible, but do not delay reporting the case because you are unfamiliar with certain details.

## ADVERSE REACTIONS TO MEDICINES

### How to identify ADR?

Patients can tell you about the symptoms they've experienced since using a new medication. However, since some adverse reactions may not be obvious to the patient, you'll need to be alert to the potential for adverse reactions.

Other information that should be considered for inclusion:

- Abnormal clinical measurements (e.g., temperature, pulse, blood pressure, blood glucose, body weight) during drug treatment.
- Abnormal biochemical or laboratory results during drug treatment. For example, plasma drug concentrations or liver biopsy in drug-induced hepatitis.
- If a new drug therapy is started to treat the symptoms of the ADR.

**HOW TO COMPLETE THE FORM?** To complete the form, you'll need to provide information on four important aspects:

1) Details of the possible adverse reaction.
2) Provide the name of the medication or vaccine that you suspect caused the adverse reaction.
3) The data of the person who had the adverse reaction.
4) Information about the person making the notification will also be required.

The electronic form in **Noti-FACEDRA 2.1** has "help" elements that appear as a question mark or an asterisk.

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

Please note that the form fields are dynamic and will provide suggestions as you enter information.

## ON THE PROTECTION OF DATA INCLUDED IN *Noti-FACEDRA*

All information provided will be protected and not disclosed, in order to comply with national information confidentiality provisions.

**HOW IS THE INFORMATION PROVIDED BY REPORTING SUSPECTED ADVERSE REACTIONS USED TO IMPROVE DRUG SAFETY?** The National Pharmacovigilance Centers of Central America and the Dominican Republic evaluate this data, along with information collected from clinical studies and other sources on drug use.

When there is sufficient information to determine that a group of similar cases of

suspected adverse reactions are likely caused by a medicine or vaccine, this information is provided in the medicine's safety information and leaflet included in the package.

In other cases, this information is used to communicate the use of certain prescription medications to certain specialists, or to recommend their use as a second choice and not a primary choice.

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

# How to access the platform?

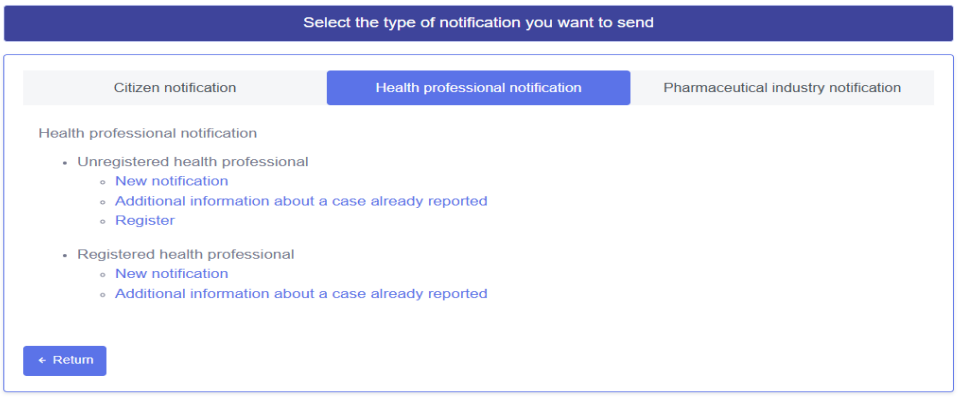
The Regional Online Reporting Portal for Suspected Adverse Reactions to Medicinal Products for Human Use, known as **Noti-FACEDRA,** is available at www.notificacentroamerica.net. The online reporting portal aims to facilitate the reporting of suspected adverse reactions to medications or vaccines detected by healthcare professionals, citizens, and the pharmaceutical industry, so that they can be promptly reported to the National Pharmacovigilance Centers in their country of residence, so that the respective analysis can be conducted.

To access the platform, you must follow these steps:

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

2 You will then need to click on the map to select your country of residence.

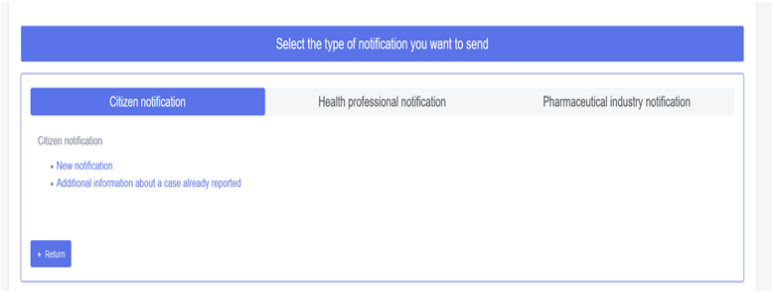

3 Then the **Main Menu** will be displayed, which consists of three options for the type of report to be sent. You must select the "**Health Professional Notification**" form to start the online report of suspected adverse reactions to medicines or vaccines through Noti-FACEDRA.



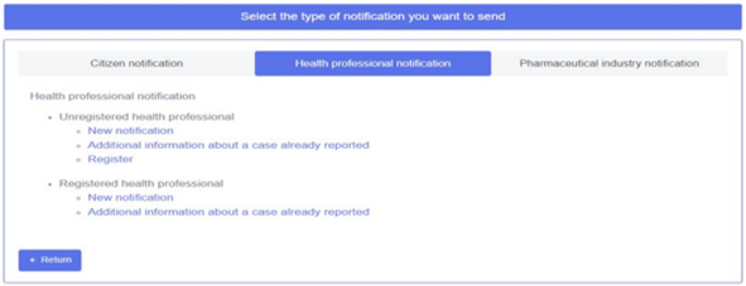
# Main Menu Overview

**Noti-FACEDRA** Main Menu screen consists of three options for selecting the type of reporter that will complete the electronic form for suspected adverse drug reactions, these being the following:

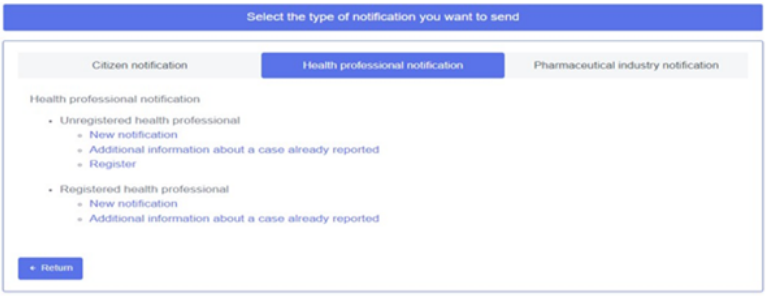
1. The first corresponds to access to the form called **Citizen Notification**, which is given access to "citizens" so that they can directly report suspected adverse reactions that are detected by them. This includes patients or their caregivers, in case the patient cannot do so directly.




2. The second option provides access to the **Health Professional Notification** form, which enables the reporting of suspected adverse reactions that may be detected by health professionals during their routine practice.




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



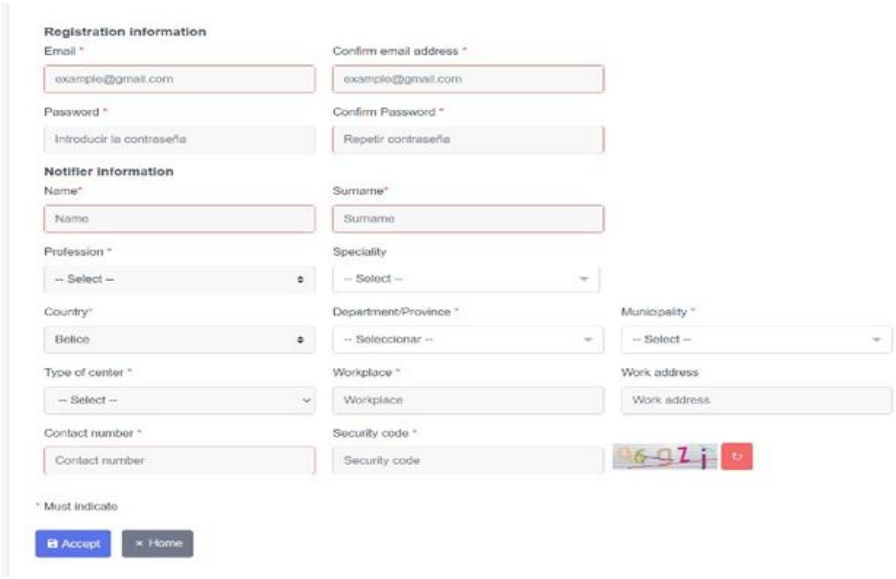
# Health Professional Notification

**Noti-FACEDRA 2.1** online reporting portal aims to facilitate the online reporting of suspected adverse reactions to medications or vaccines detected by healthcare professionals, the pharmaceutical industry, and citizens themselves, so that they can be promptly reported to the National Pharmacovigilance Centers in their countries of residence.

Access to the electronic form requires that the healthcare professional preferably register as a Notifier. This registration process will facilitate the process for future reports of suspected adverse drug reactions that you wish to report.

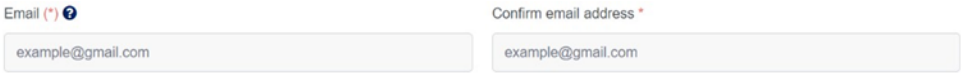
## Registration Process

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

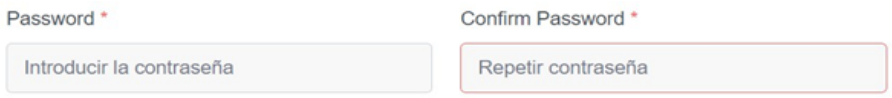



b) The Health Professional to register must complete the information requested in the fields corresponding to **"Registration Data"** as follows:

- **"Email"** address (*), which will be used to send the acknowledgment of receipt of the report. To do this, you must confirm the email address, as shown in the following figure:

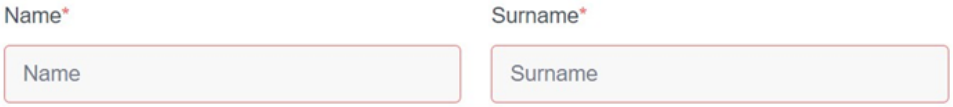


- Next, set a **"Password"** that will give you access to **Noti-FACEDRA 2.1** as a Registered Reporter. The password must be confirmed for it to be accepted, as shown below:

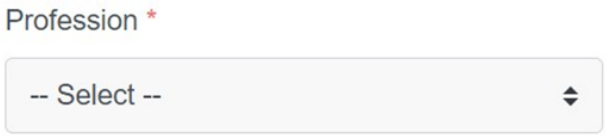



c) To complete the **"Reporter Data"** information, the Health Professional must follow the following steps:

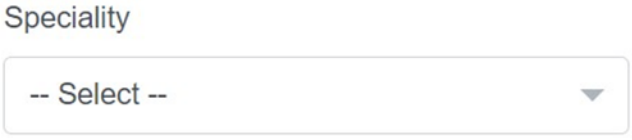
- Please provide your full name (*), preferably your full name (both your first and last names)



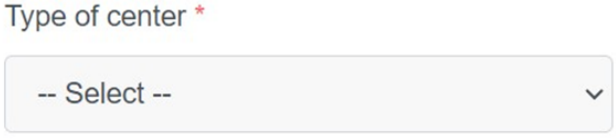

- In the **"Profession"** field, select one of the options from the drop-down menu as appropriate, as shown below:




- Select one of the drop-down options in the **"Specialty"** field, as appropriate, as shown below:



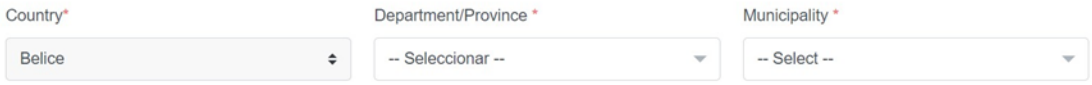

- To detail the "**Type of Center"**, select one of the options from the drop-down menu, as appropriate, as shown below:



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

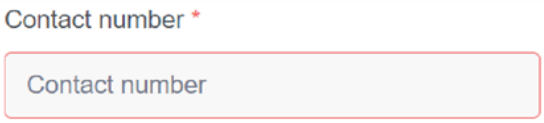
d) For details of the health professional's "**Work Center",** you must complete the information requested below:

You must select one of the options shown in the drop-down menu for each of the following fields:

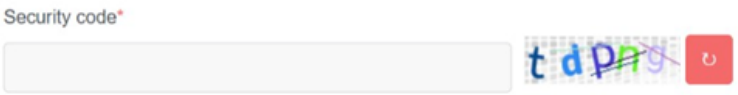



- **"Workplace"** field, enter the full name of the service center and also enter the address of the workplace as clearly as possible.


- **"Contact number"**, the reporter must establish the contact telephone number at the Service Center. if desired a mobile cellphone number can be used.




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




- Once all the fields are completed to register, click "**Accept"** to complete the registration process.

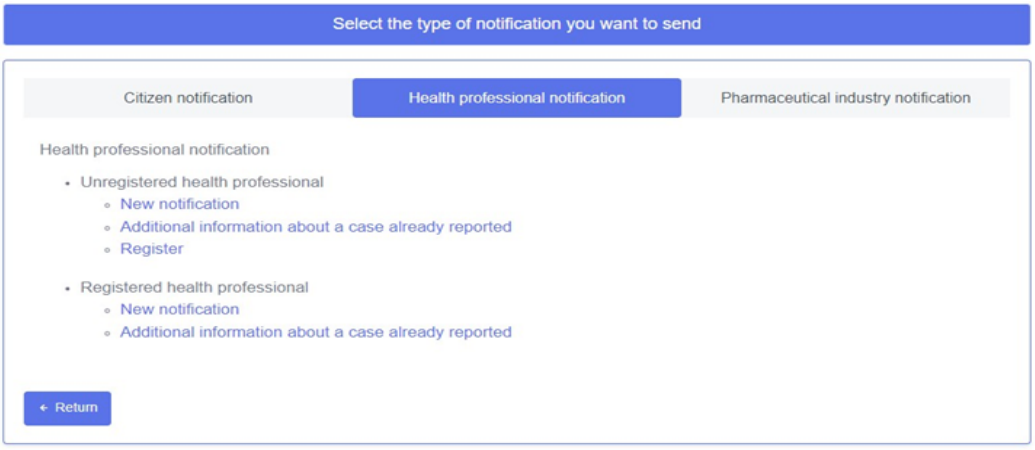
# Health Professionals Notification Process

In order for Health Professionals to have access to the **Noti-FACEDRA 2.1 electronic form,** they must have the necessary information for the process of reporting suspected adverse reactions to a medicine or vaccine, including prescription, non-prescription, or herbal medicines. Do not hesitate to do so if you suspect any problem with the use of these products.

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

i. Details of the possible adverse reaction.
ii. Provide the name of the medication you suspect caused the adverse reaction.
iii. The information of the person who had the adverse reaction.
iv. Information about the person making the report will also be required.

With this information available, Health Professionals can complete the electronic form through **Noti-FACEDRA 2.1,** following the instructions below:

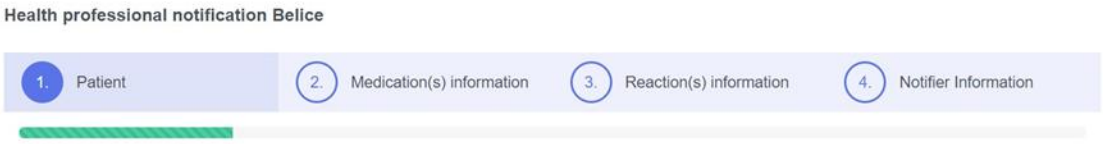


# New Notification

After registering as a new notifier, the process of filling out a **New Notification** begins by following the steps below:

1. Selecting the **New notification** option from the main menu, the notification form fields will be displayed according to the 4 sections shown in the following figure:

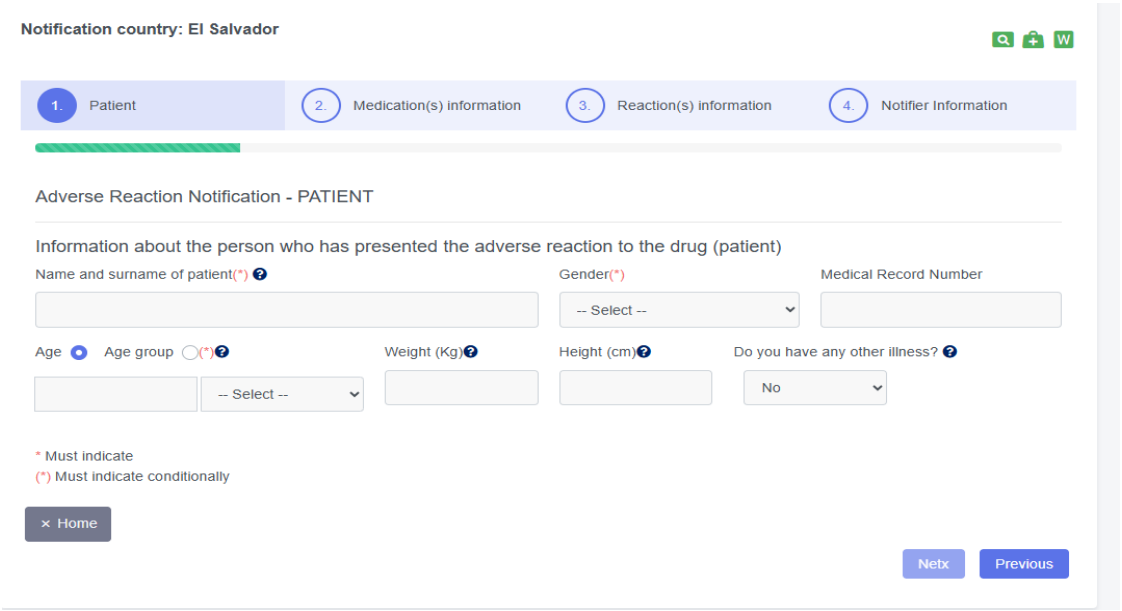
Information marked (*) corresponds to mandatory information




2. Below are the form fields 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.

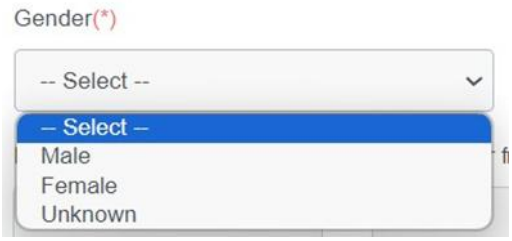
# Patient Data

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

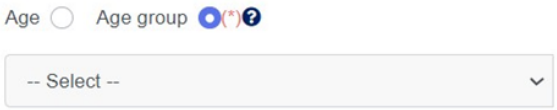


a. **Patient's Name and Surname,** the patient's full name or initials must be entered, this corresponds to information marked (*) which corresponds to mandatory information.

b. **"Gender",** the patient's sex must be established by choosing one of the options shown, **Male, Female or Unknow** as shown in the figure.

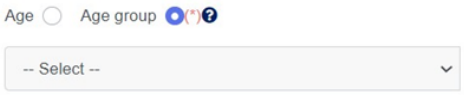



c. For the reporting of **Patient Age** there are two possibilities. The first is selecting the "**Age"** option, allows you to enter a numerical value, accompanied by the time unit in decades, years, days, hours, months or weeks, as shown in the following figure:




Information marked (*) corresponds to mandatory information and cannot be left blank.
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: Newborn, Infant, Child, Adolescent, Adult or Elderly.

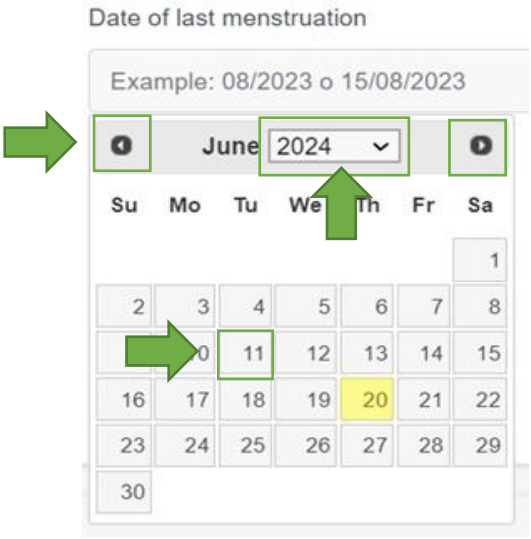
d. For the reporting of **Patient Weight,** the weight, expressed in kilograms, must be indicated, placing only the numerical value of the weight.



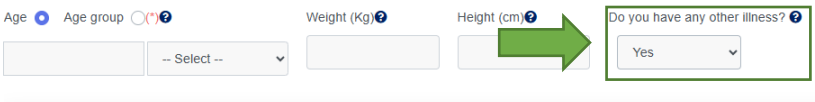

e. **For Patient Height,** the value must be indicated in centimeters, placing only the numerical value of the height.

f. **“Date of last menstruation”,** this field will be displayed only if the patient is female. The patient must provide the date in month/year or day/month/year format. For example: 08/2023 or 01/01/2024. This information is not mandatory, if the information is not known, the filed can be left blank.

Use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.



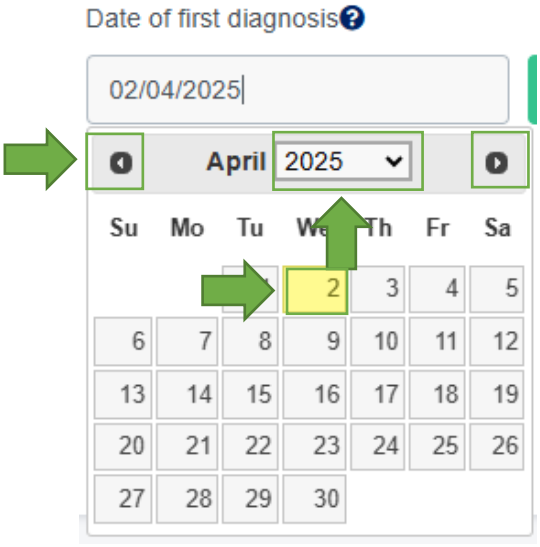

g. For the question **"Do you have any other illness?",** it refers to the presence or absence of any illness in the patient at the time the adverse reaction being reported occurs.




If the patient has any concomitant illness at the time of the report, the option "**YES**" must be selected, so that two additional fields will be displayed for reporting that illness.

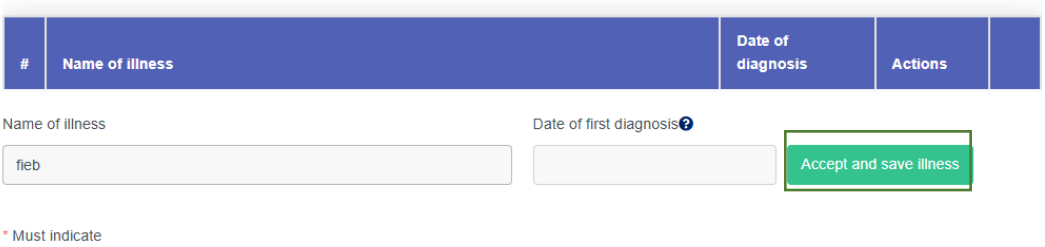
In the field “**Name of illness”,** enter the name of the disease that the patient suffers from. A menu of medical terminology will appear that will assist in filling it out.

Select one of these terms for the disease report. In the second field, enter the "**Date of first diagnosis"** in month/year or day/month/year format. If the information is unknown, the field can be left blank.




Use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

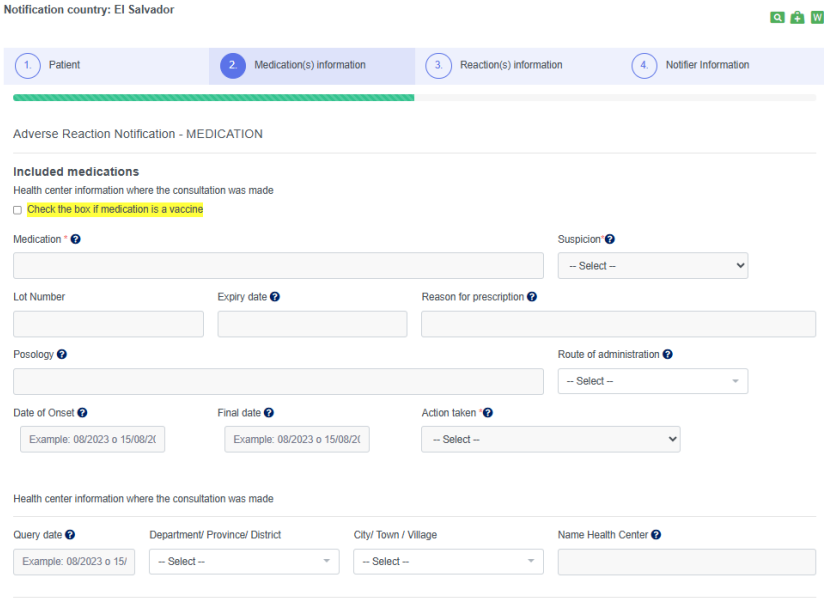
Next, click the " **Accept and Save illness**" button to save the information. More than one disease can be reported in this field, as long as each one is accepted and saved.




i) Step 1 ends by completing the information and clicking the "**Next"** button.

# Medication Information

**For step 2 of 4,** called "**Medication Information",** relates to the necessary information about the drug(s) suspected of being responsible for the adverse reaction. The patient must complete the following information:




## Add a Medication

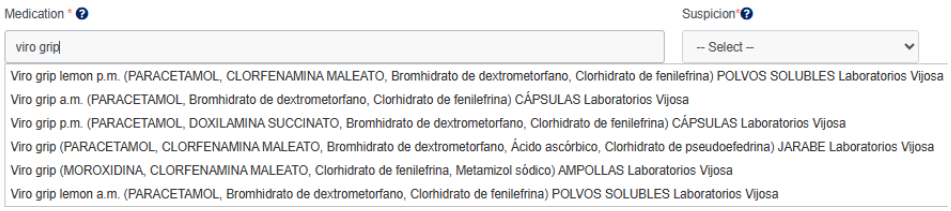
a) **Medication:** to facilitate information about the medication that may have caused the adverse reaction, in the field called "**medication**", enter the trade name or the name of the active ingredient of the medication. As you type in this space, you can select from the drop-down list the trade name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


If you do not know or do not have the brand name of the medication available, you may provide the name of the active ingredient in the suspected medication.

Please note that this is a field marked (*) that corresponds to mandatory information and cannot be left blank.

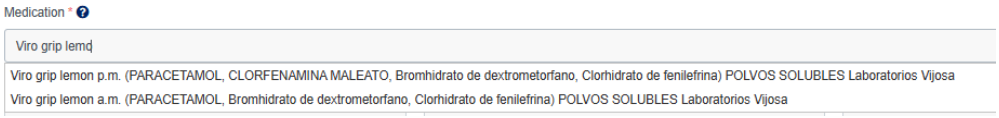
**How to correctly search for a medicine by brand name:**

I. In the Medication or Vaccine field, you must enter the **brand name** of the medication you wish to report. The options that begin with the text entered in the field will then be displayed.

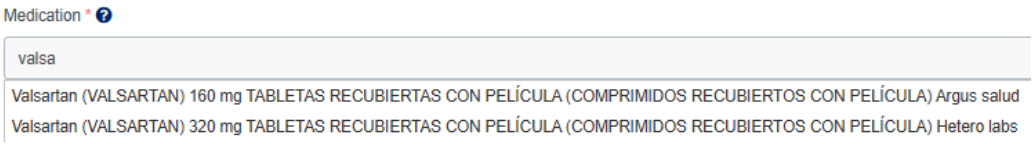



Only the brand names of medicines sold in the country where you are reporting will be displayed.

The structure of the drug options follows the following order:
***Trade name + Active ingredient + Concentration + Pharmaceutical form + Manufacturer name,*** an example is shown below:




If the medication has more than one strength, dosage form, or brand name, all available options will be displayed for more accurate notifications.

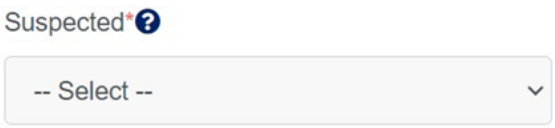



II. After having selected one of the drop-down options, you must fill in the other fields (see the section “Add medication”, paragraphs b to j “Report of a suspected ADR due to vaccines”, paragraphs c to j as appropriate).

III. If the medication you want to report isn't listed in the auto-complete options, you can still submit the report. Enter the name as you know it, add the other information, and click "Accept and Save Medication" or "Accept and Save Vaccine."

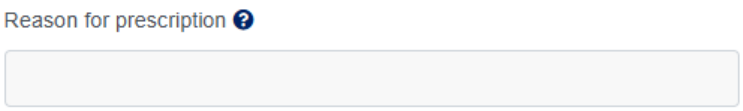
**Note:** If the medication you want to report is not among the options shown, you can enter the name as you remember it, and the platform will use the name you entered in the respective reporting field.

b) **“Suspicion”** information, the Notifier must select one of the options related to whether the medication detailed in literal a) corresponds to the **Suspected,** is a **Concomitant**, **Has an Interaction with** or the Medication has not been administered, as shown in the following figure:




c) To report the " **Lot number and Expiration Date"** of the suspected medication, you can find this information on the medication packaging. If it's not available or you don't know it, you can continue with the information completion process.

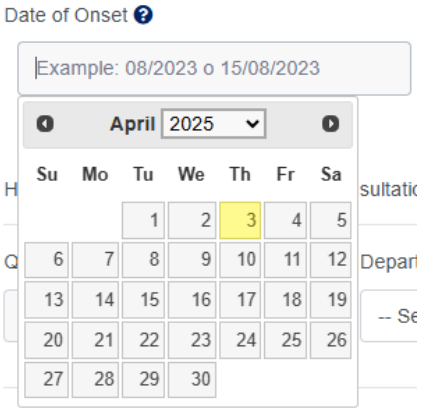
d) To specify the “**Reason for prescription”** for each of the medications that the patient is using and that will be included in the notification, the notifier must enter the pathology for which the medication was prescribed. As you type in this space, you can select one of the options from the drop-down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




e) To complete the **“Posology”** information, the Notifier must establish for each medication to be included in the report, the way in which the medication was prescribed or the way in which the patient reports that he was taking the medication, for example: one tablet each 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 "**Date of Onset",** the patient must establish in as much detail as possible the date on which he or she began using the medication. To do this, the calendar method shown below must be used:



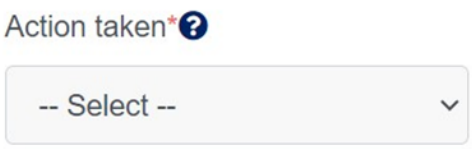

The date must be entered in day/month/year format. You can use the drop-down calendar to facilitate date entry.

To move between the different months of the year, simply click the arrows in the upper corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

h) For the "**End Date",** the patient must establish in as much detail as possible the date on which the use of the medication ended; for this, the calendar method shown below must be used:

To move between the different months of the year, simply click the arrows in the upper corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

i) **"Actions Taken"** field, you must select one of the options shown in the list.



j) To complete the registration of the suspected medication, the patient must select the "**Accept and Save Medication**" button. This action will save the suspected medication record, presented in the following format:

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

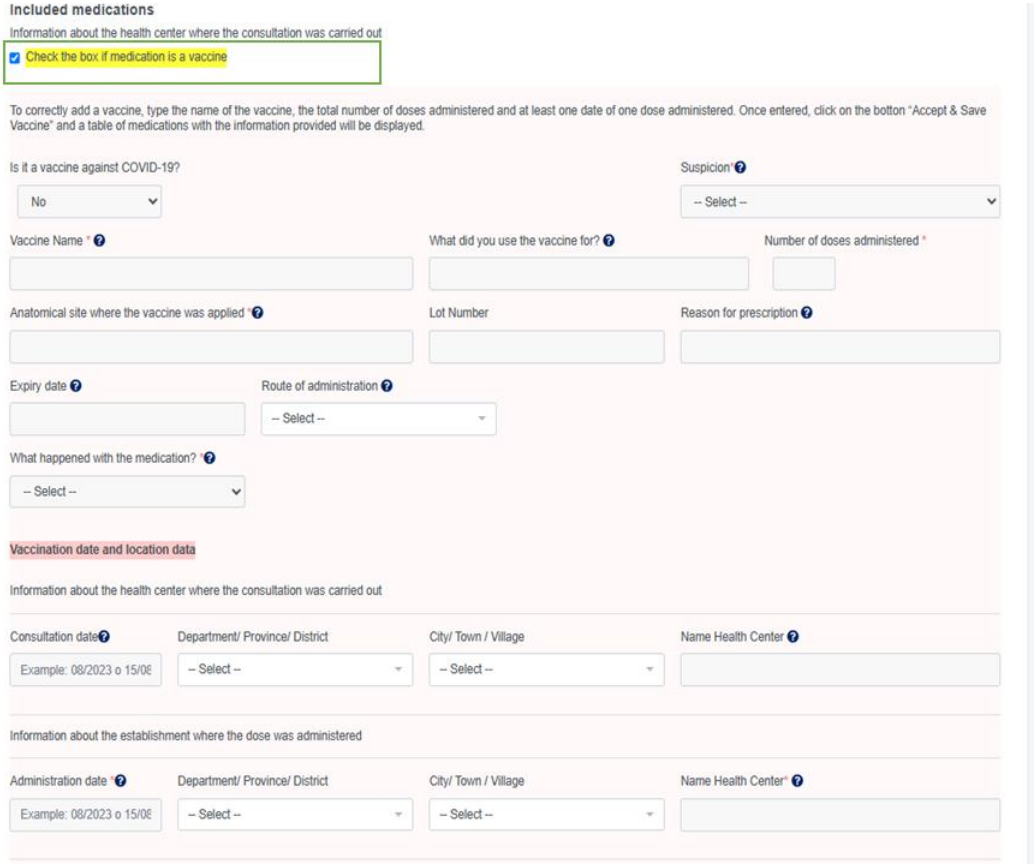
k) If any corrections are necessary, the patient can use the modify option to make the necessary modifications. Once the modifications are complete, the patient must select the "**Modify medication information**" button.


l) **Health Center Information where the consultation was made**: If the patient was consulted at a health center, please provide the following information:

- **Query date:** Specify the date in month/year or day/month/year format.
- **Department/ Province/ District:** A list of options will be displayed where you must select the department where the Health Center where the consultation was held is located.
- **City/ Town / Village:** The data in this list will depend on the department selected in the previous field and must indicate the municipality where the Health Center where the consultation was held is located.
- **Name of Health Center**

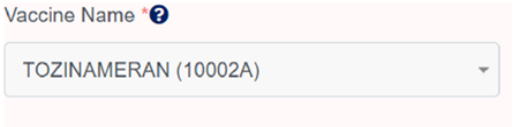
# Report of a suspected ADR due to vaccines

**"Check the box if the medication is a vaccine"** must be checked, and the following form will immediately be displayed.



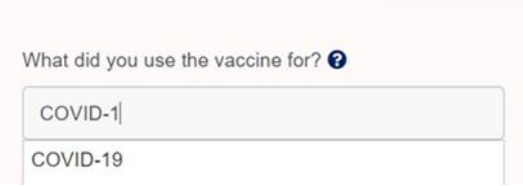

a) To answer the question: "**Is it a vaccine against COVID-19?"** The patient must answer **Yes** or **No** as appropriate**.**

b) **"Vaccine name"**: To facilitate information about the brand name of the vaccine that may have caused the adverse reaction, several options will be displayed that you can select. These options will be filtered depending on whether the vaccine is COVID-19 or not.



If none of the options match, you can freely write the name of the vaccine, you can type the name as you remember it.

c) To answer the question **"What is the vaccine used for?",** you must enter the intended use of the vaccine. As you type in this space, you can select one of the options from the drop-down list, as shown in the following figure:



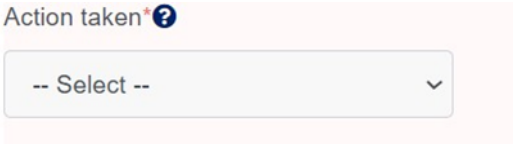

d) To report the **lot number and expiration date** of the suspect medication, you can find this information on the medication packaging. If it's not available or you don't know it, you can continue with the information completion process.

e) **"Number of doses administered",** you must indicate how many doses of the vaccine reported have been administered to the patient, for example, 1st, 2nd or 3rd dose, or as appropriate.

f) **"Anatomical site where the vaccine was administered",** must indicate in which part of the body the dose of the vaccine that caused the reaction was administered.

g) **"The dose that triggered the reaction"** refers to the specific amount and frequency with which the doses were administered. Example: 0.3 mL of each dose or the corresponding volume based on the dose administered.

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




i) **Vaccination date and location data:** To correctly add the vaccine information, you must add the Administration Date and Name of the Health Center where the dose was administered. You can also add information about where the consultation was made:

**"Health center information where the consultation was made"**: To correctly add information about the consultation where the vaccine was recommended, you

must include the consultation date and the location of the consultation. You can also add information about where the consultation was made:

- **Query date:** Specify the date in month/year or day/month/year format.
- **Department/ Province/ District**: A list of options will be displayed where you must select the department where the Health Center where the consultation was held is located.
- **City/ Town / Village**: The data in this list will depend on the department selected in the previous field and must indicate the municipality where the health center where the consultation was held is located.
- **Health Center Name:** The name of the facility where you received the consultation must be indicated.

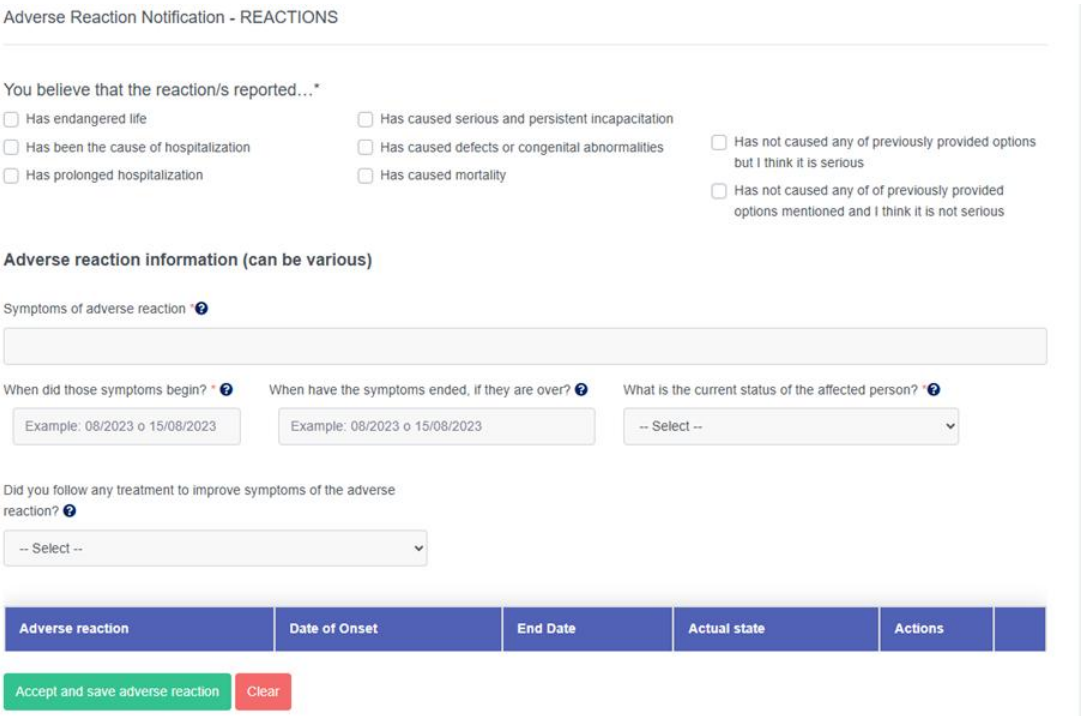
**Information about the facility where the dose was administered:** To save the dose data, the following information must be added:

- **Administration Date**: Specify the date of the patient's visit where they received the vaccine dose. This information is required to add the dose to the vaccine.
- **Department/ Province/ District**: A list of options will be displayed where you must select the department where the establishment where the dose was administered is located.
- **City/ Town / Village**: The data on 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.
- **Health Center Name**: The name of the facility where the dose was administered must be provided. This information is required to add the dose to the vaccine.

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

# Data on reported adverse reactions

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

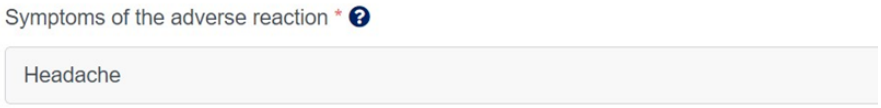



a) The Health Professional, according to the status of the adverse reaction that the patient has presented, must select one or more of the criteria shown in the following figure:


Please note that this is a field marked (*) that corresponds to mandatory information and cannot be left blank.

b) For the section entitled **"Information on adverse reactions",** 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 the medication(s) used by the patient. As you type in this space, you can select the medical terminology that most closely matches the drop-down list, as shown in the following figure:



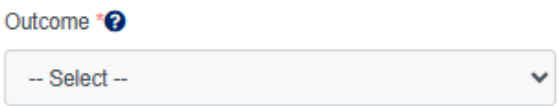

c) **"Onset Date"** information: You must specify the date on which the adverse reaction occurred in as much detail as possible. To do this, use the calendar format. To report the date, use the day/month/year format. Please note that this field is marked (*) and represents mandatory information.

You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

d) Next, you must provide the **"End Date"** information for the adverse reaction. For this information, the healthcare professional must establish the exact date on which the symptoms disappeared, using a calendar format. For reporting the date, use the day/month/year format.

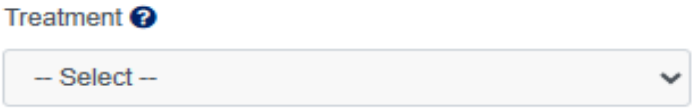
You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

e) To answer the question "**Outcome",** 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 and cannot be left blank.

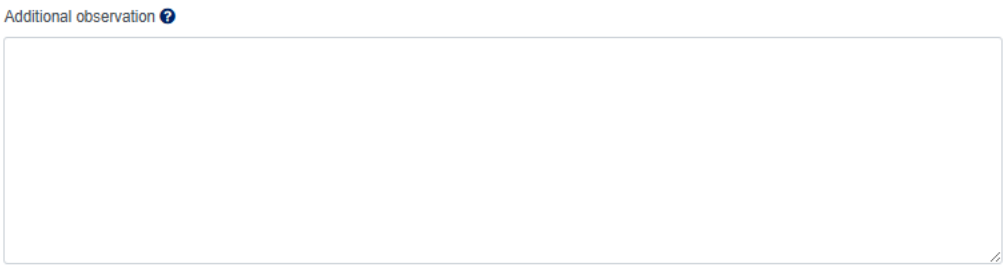
**f)** To answer the "**Treatment"** question, you must select one of the options below. If you have not received any treatment, you should select "No treatment."



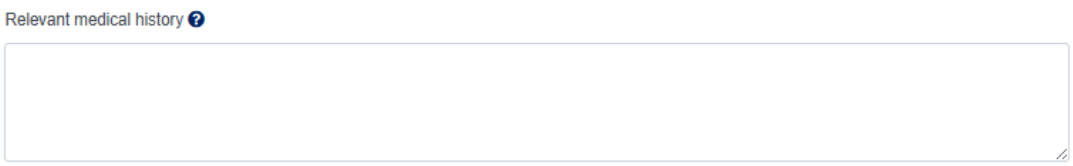

g) To complete the recording of adverse reaction data, the notifier must select the **"Accept and save adverse reaction"** button. This action will save the adverse reaction recorded and present it in the following format:


h) If you require any correction, you can use the modify option to make the necessary changes. When you finish the modifications, you must select the "**Modify Reaction Data"** button.

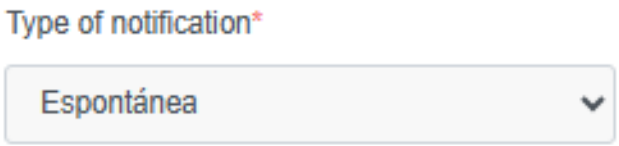

i) If you need to report any relevant aspect of the patient related to the reported case, you can provide other elements that may be necessary for the analysis of the report, through a narrative of the case or results of clinical laboratory tests or other clinical tests, this information can be entered in the field called **"Additional Observations"**, which is shown below:



j) **“Relevant medical history”**, in this field place relevant information or medical history that supports the investigation of the case.




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:



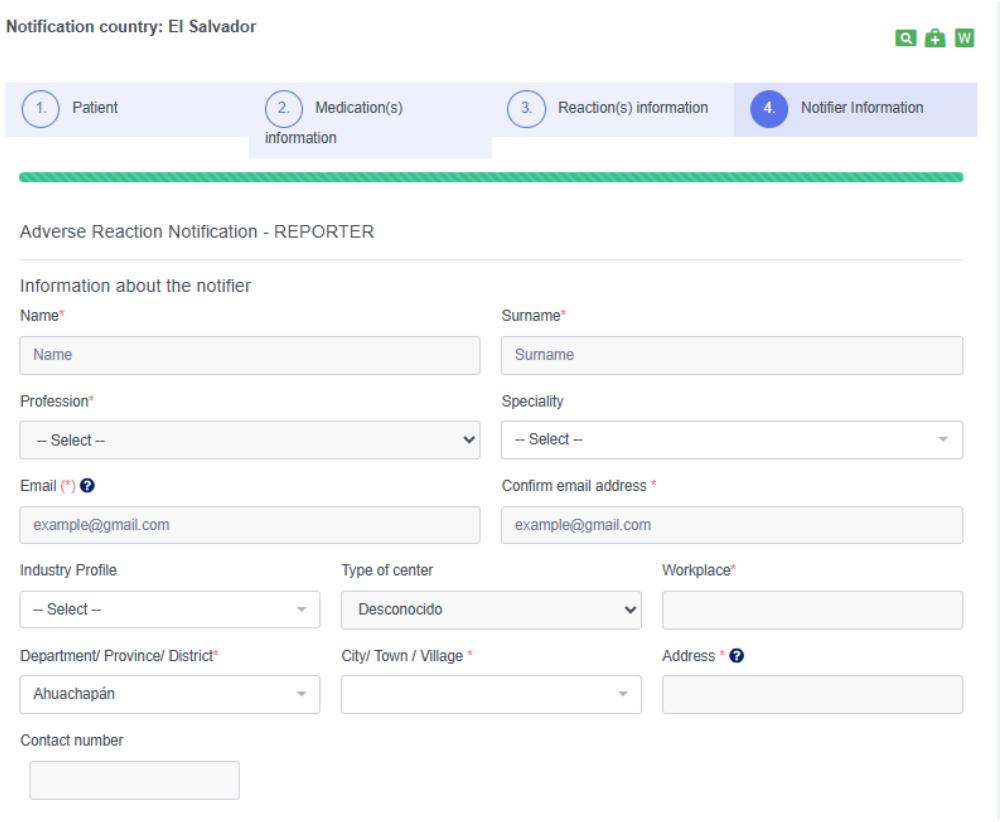

In the case of a report of a suspected adverse reaction detected during your regular practice, you must select the “**Spontaneous**” option.

If the suspected adverse reaction(s) are identified by the Healthcare Professional as part of a study or reported in the scientific literature and refer to cases from the Central American region, they should be considered for reporting as "Study" cases.

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

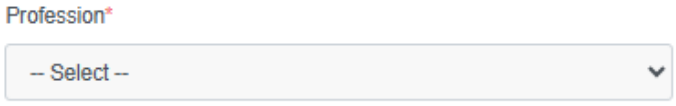
# Notifier Information

**For step 4 of 4**, called **"Notifier Information"** related to the information necessary for the identification of 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:



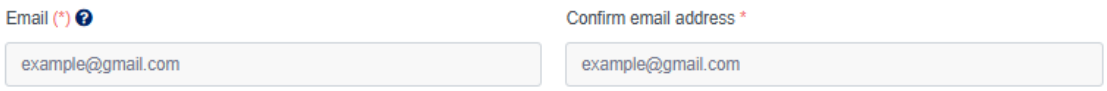

a) For the information of the person who fills out the data on the electronic form of Noti-FACEDRA 2.1, it will be completed with the name and surname of the notifier. Please note that this is a field marked (*) that corresponds to mandatory information.

b) To identify the "**Profession**" of the notifier, you must select one of the options shown in the drop-down menu, as shown in the following figure:




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

c) **“Email”** address, which will be used to send the acknowledgment of receipt of the notification. To do this, you must confirm the email address, as shown in the following figure:

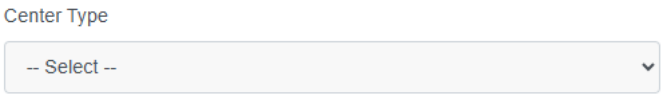



Please note that this is a field marked (*) that corresponds to mandatory information and cannot be left blank.

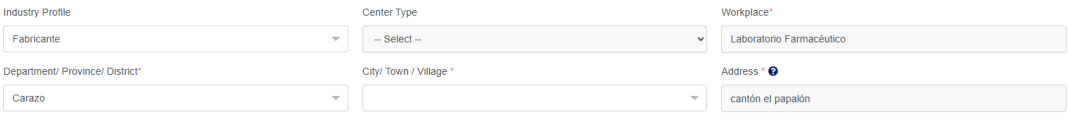
d) The notifier must detail the **"Specialty"** he or she has, specifically for Medical Professionals, selecting one of the options shown in the drop-down menu shown in the following figure:


e) **“Contact number”** must be provided , preferably that of the work center. A mobile phone number may be optional.

f) To specify the “**Center Type**”, the healthcare professional must select one of the options shown in the drop-down menu below:




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




h) If you wish to provide more information related to the reported case, the patient can attach files to the report, as shown below:


In the field called **"Description of the file you want to attach"**, you must provide 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 accepted for attachment to the notification are the following:

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

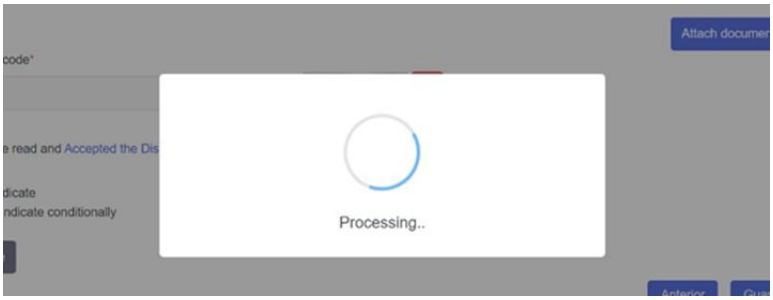
i) To upload as an attachment, you must click on the **"Add attachment"** button.

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

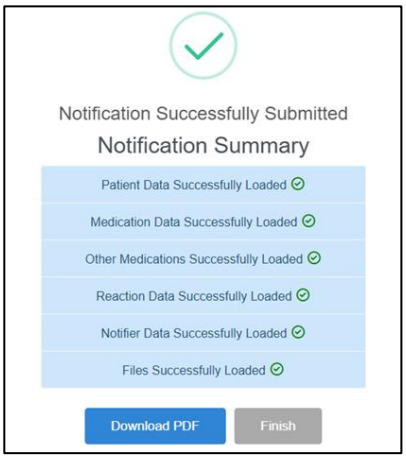

If it is not legible, the image can be updated by clicking on the button

k) For information security purposes, it is necessary for the notifier to select the option "**I have read and accept the Legal Disclaimer"**, which will display a window showing the text of the legal notice.

l) To complete the form and submit the information, click the **"Accept"** button. The platform will then display the following message:




m) Confirmation of submission of the form is presented as follows:




n) To print a copy of the report of notification 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 notification code in PDF format will begin, for example NCA11.PDF.

o) After downloading, the notifier will receive an acknowledgment of receipt to the email address included in paragraph b) of step 4 of 5, with a summary of the case, the case report code, and a unique key for possible follow-up or provision of further information. A sample of the acknowledgment of receipt is presented below:

**Noti-FACEDRA** <rbdo12002@gmail.com> 10:12 (hace 7 minutos)
para mí

Buen día,

Muchas gracias por notificar al ***Sistema Regional de Notificación en línea de Sospechas de Reacciones Adversas a Medicamentos:Noti-FACEDRA.***

Los datos del caso que ha notificado son los siguientes:
**Número de Notificación:** NCA64420
**Contraseña:** Sc30H1btApAb
**Fecha notificación:** 2024-01-15 10:12:45
**Género del Paciente:** Femenino
**Edad del Paciente:** 29 Año
**Primer Fármaco sospechoso que notificó:** CIPROFLOXACINO (2049A)
**Primera Reacción adversa que notificó:** Fiebre

Si en el futuro desea actualizar o rectificar la información enviada, deberá acceder de nuevo al formulario a través del Portal Regional de Notificación en línea Noti-FACEDRA:

**Ir a Seguimiento de Noti-FACEDRA**

Indicar que desea añadir información sobre un caso ya notificado e introducir el número de caso notificado y la contraseña proporcionados en este correo electrónico.

No es necesario que vuelva a incorporar toda la información del caso inicial aunque esta no aparezca en pantalla. Añada o rectifique únicamente la nueva información. Si fuera posible, en el campo Otros datos de interés que desee aportar comente la información añadida o rectificada.

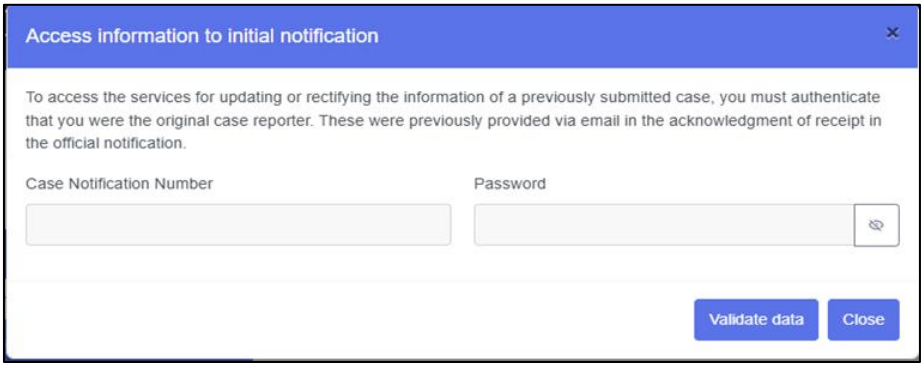
Contacto: Centro Nacional de Farmacovigilancia Guatemala, E-mail: farmacovigilanciadrcpfa@mspas.gob.gt

# Follow -up of cases or contribution of additional information of a reported case.

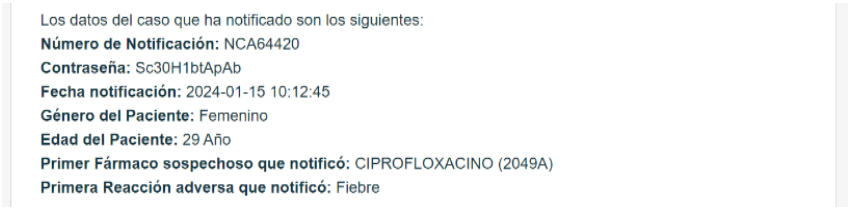
This section details the steps to follow if the reporter has more information about a reported case or needs to update or clarify the data provided. To do this, the reporter must do the following:

a) The person who reported the case and provided their contact information to receive the acknowledgment generated by **Noti-FACEDRA** should look for the following information in their email:
   I. Number of the reported case
   II. Individual password of the reported case.

b) Once the information from step a) is available, the notifier must access Noti-FACEDRA 2.1 through the link www.notificacentroamerica.net , and click on **"Additional information on a case already notified"** where the following screen will be displayed:

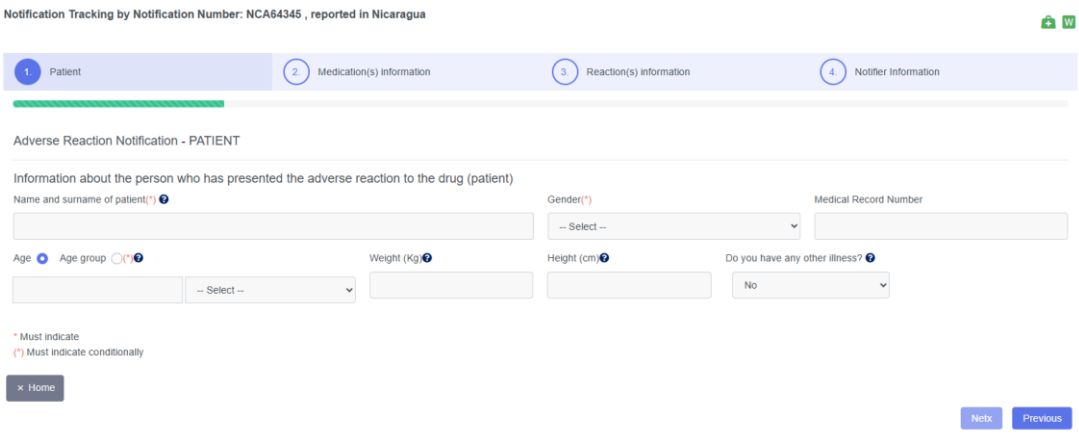



In this space, you must enter the "**Case Notification Number"** and "**Password"** that you received in the acknowledgment email.




c) Upon entering the data, the report is accessed and the notifier can make changes or modifications to any of the fields in the form.

When accessing the form, all 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 on the form should be left blank.***

d) If you need to make any corrections or modifications to any of the steps in the form, remember that at the end you must select the **"Accept and Save"** button as appropriate.

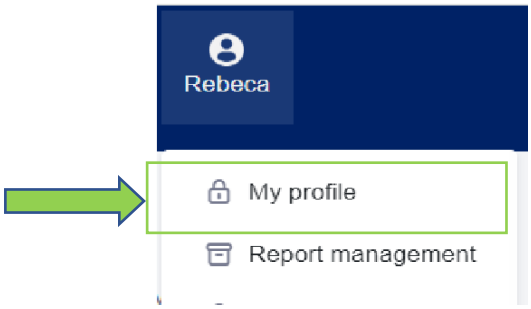
e) To save any corrections or additional information you provide, click the "**Accept**" button. If the tracking was successful, a confirmation message will appear, giving you the option to download the PDF again. You will also receive another email with your notification number and password.

# Edit My Profile

In this section, the user information can be edited, and the data which the user registered will be displayed.

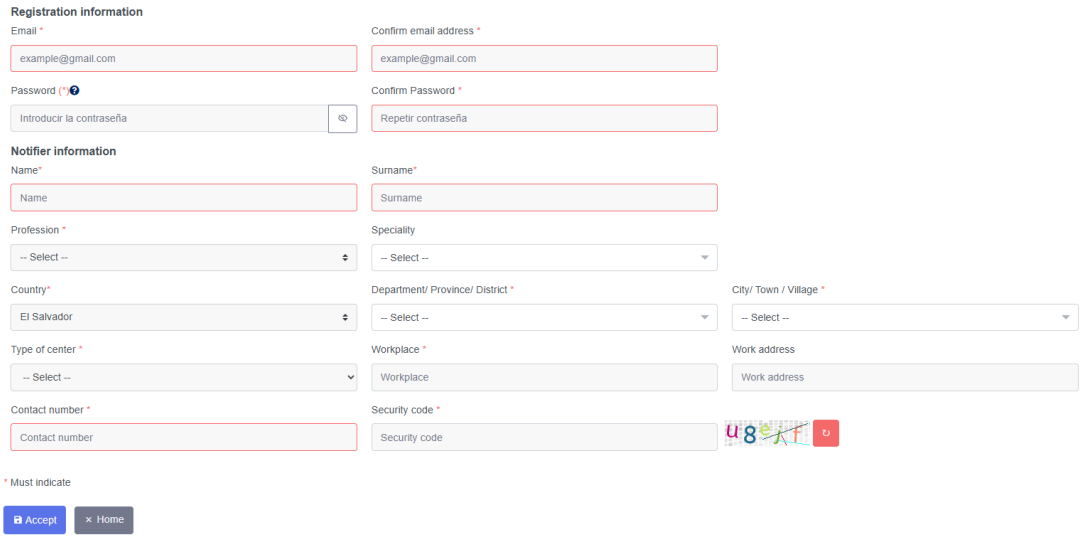
Once logged in, the option "**My Profile**" will be available. To update the information, follow these steps.

a) Health professional logged in must click on "**My profile**".

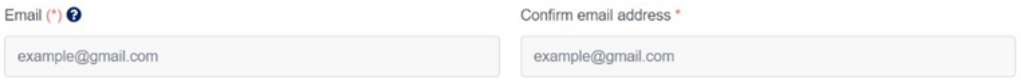



b) Select the "**My Profile**" option to edit profile information. The following image will be displayed with the data pre-filled:

e) The registered Health Professional must have the information requested in the fields corresponding to "**Registration Information**" as follows:



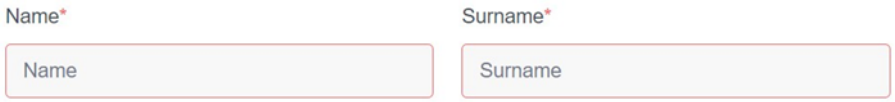
- Edit the valid **"Email",** which will be used to send the acknowledgment of receipt of the notification. To do this, the email address must be confirmed, as shown in the following figure:



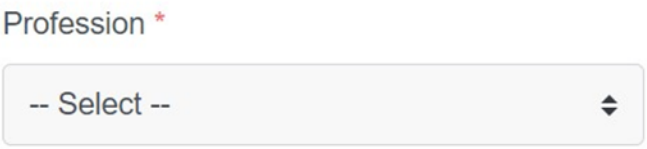

- Next, update the "**Password**" that will provide access to Noti-FACEDRA 2.1 as a Registered Notifier, the password must be confirmed to be accepted, as shown below:


f) To edit the **Notifier Data information**, the Health Professional must follow the steps below:

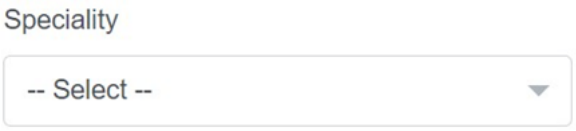
- Edit your first and last name (*), preferably set your full name (both your first and last names)



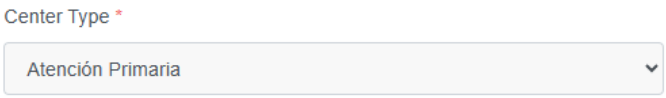

- In the **"Profession"** field, edit one of the drop-down options as appropriate, as shown below:




- Edit one of the drop-down options in the **"Specialty"** field as appropriate, as shown below:



- To Edit the "**Center Type",** select one of the options from the drop-down menu as appropriate, as shown below:

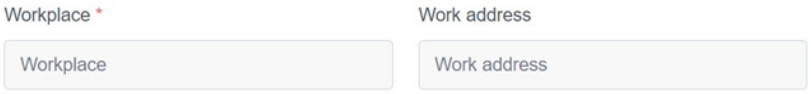



Please note that this is a field marked (*) that corresponds to mandatory information.

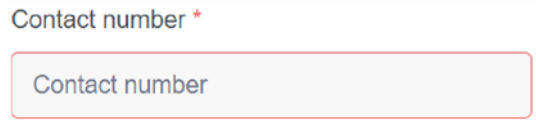
g) To edit the healthcare professional's "**Workplace"**, you must complete the following information:

- The address should be stated as clearly as possible so that it can be located as precisely as possible.
  You must select one of the options shown in the drop-down menu for each of the following fields:

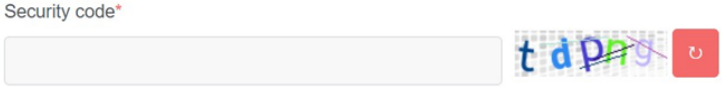

- To edit the Workplace field, you must enter the full name of the Service Center and also enter the address of the workplace as clearly as possible, so that you can locate it as precisely as possible.



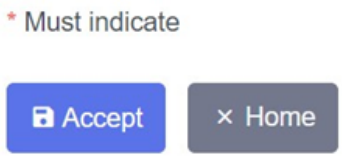

- Edit the "**Contact Number",** the Notifier must establish the contact phone number at the work center, if desired the mobile phone number can be detailed.




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



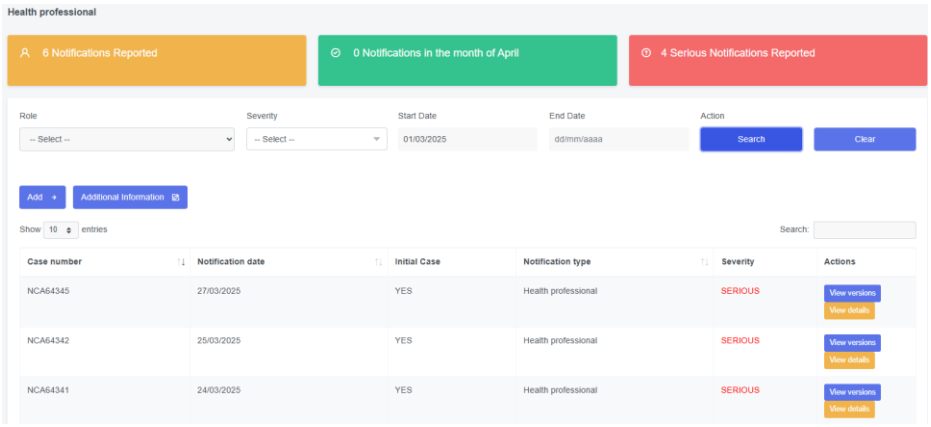
- Once you have edited all the fields to be updated, you must click **"Accept"** to complete the update process.



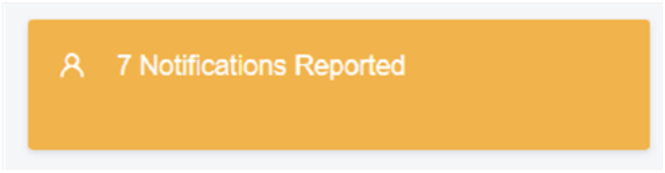

- You will receive a message confirming the successful modification.

# Report management

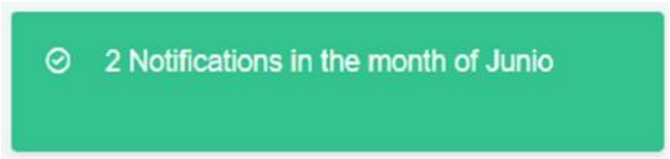
In this section you can manage the notifications that have been reported through the **Noti-FACEDRA 2.1 platform**. Information on the number of notifications accumulated in the current month will be available in addition to the option to identify the serious cases reported, as shown below:



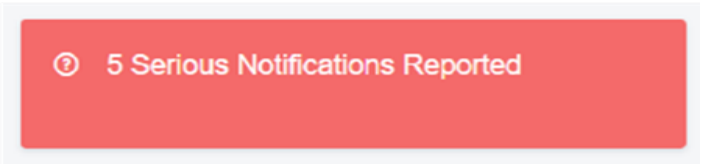

a) Information on the number of notifications made




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



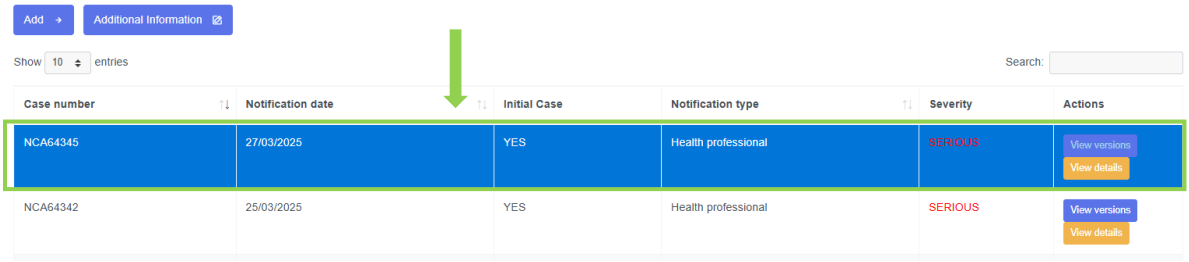

c) Information on the number of serious cases reported



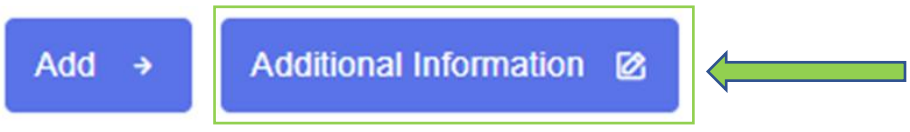

d) To make a new notification click on the **“Add”** button.


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

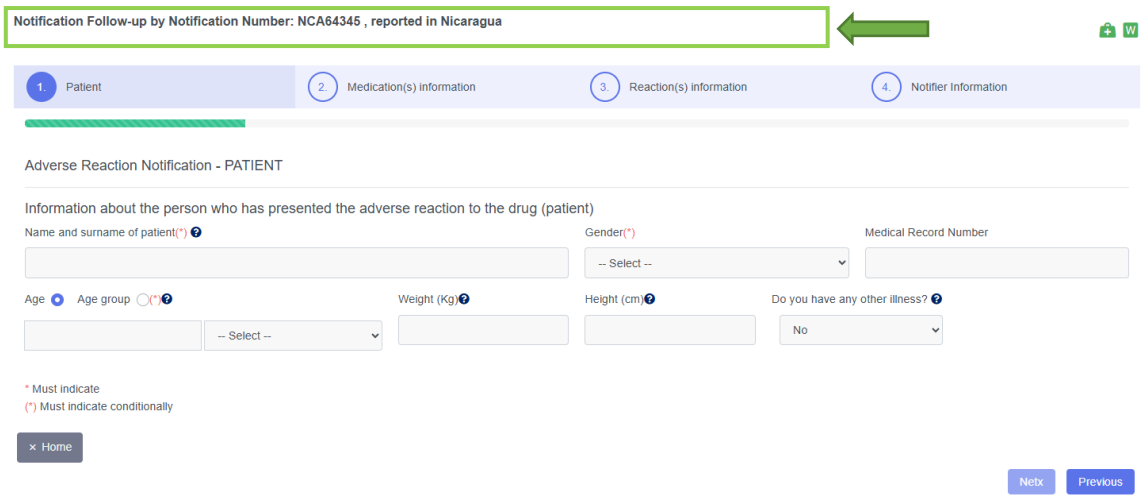
a. Select a record by clicking on it.




b. Click on the **“Additional Information”** button

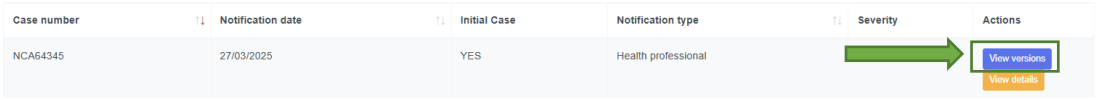



c. Additional information can be added to an existing notification.

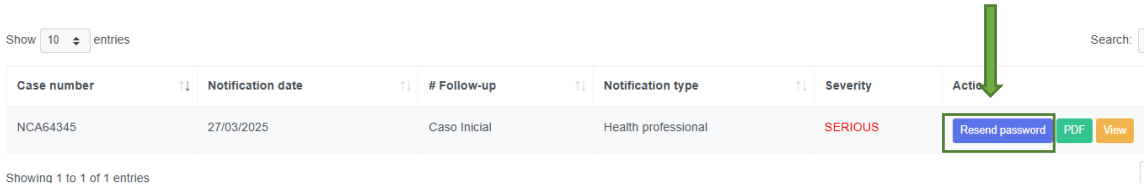



f) Resend notification password

a. Click on the "**View versions**" button of the corresponding case.

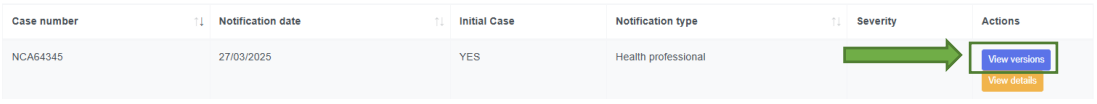



b. Click on the **"Resend password"** button in any of the case follow-ups.

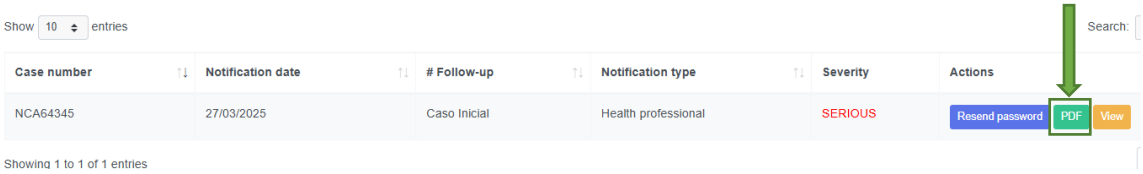



g) To download the PDF of the notification

a. Click on the **"View versions"** button for the corresponding case.

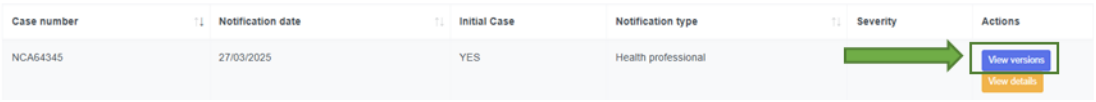



b. Click on the **"PDF"** button.

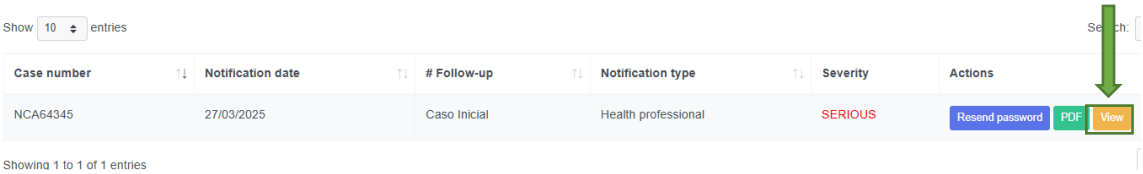



h) View detailed notification information

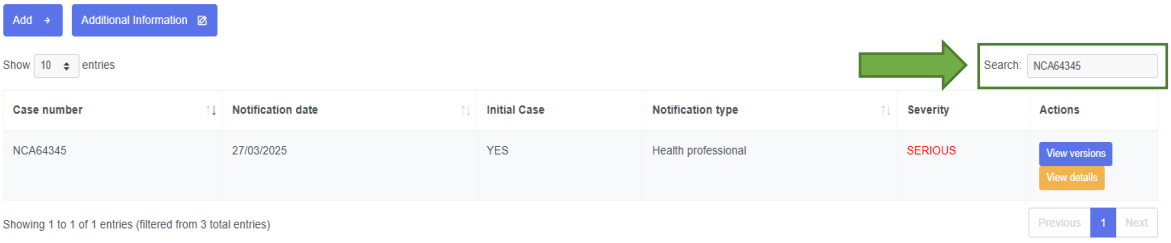
a. Click on the **"View versions"** button for the corresponding case.




b. Click on the **"View"** button.



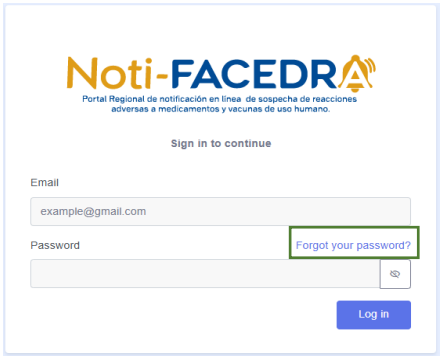

i) Search or filter notification



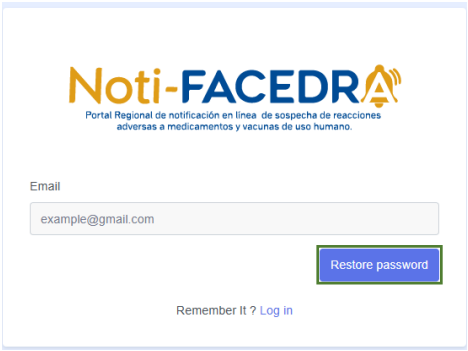
# Password recovery process

**Noti-FACEDRA 2.1** user also has an option to recover password if it has been forgotten or lost. On the login screen, an option to reset password can be located. Follow these steps:

a) On the login screen, click on the question **“Forgot your password?”**




b) Enter your email and click on the “**Restore password**” button.




c) Once you have clicked on the “**Restore password**” button, you will receive the following response, which tells you to check your inbox or spam folder for the email.

d) Check your email and you'll be able to log in with your new reset password. Don't forget to update it once you're logged in.

Buen día durjan.alvarado94@gmail.com,

Reestablecimos la contraseña de tu usuario, recuerda que debes cambiar tu contraseña una vez inicies sesión.

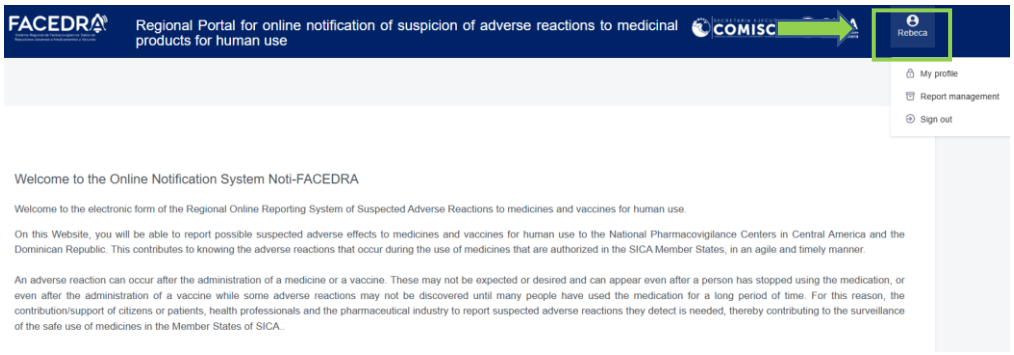
**Contraseña:** ezp^Z78FvEJd

**iniciar sesión en Noti-FACEDRA**

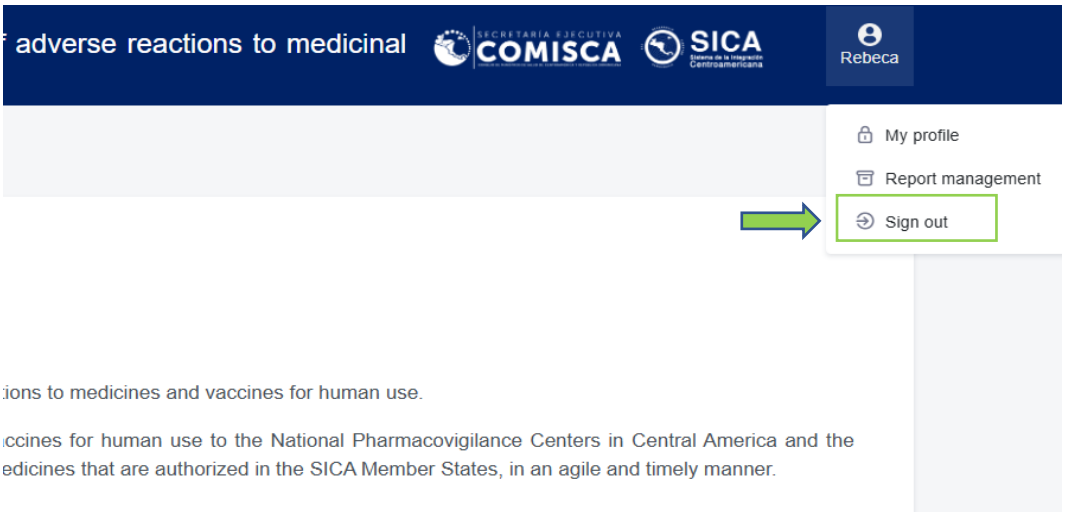
# Log out of the portal

Remember to log out when you finish your activities in **Noti-FACEDRA 2.1.** To do this, follow these steps:

a) At the top right, several options will be available including logging out.




b) Find the **"Sign out"** option and click on it, this action ends the active session.



# Frequently Asked Questions

1. **If all medications can cause adverse reactions, does this mean that no medication is safe?** No medication or vaccine is completely free from adverse reactions, but the benefits obtained from the medication outweigh its potential risks.

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

2. **Since I started using the medication, I've noticed a number of new symptoms that I think may be due to the medication. What should I do?** If you're concerned about a suspected adverse reaction, you should discuss it with your doctor or pharmacist. If you think a medication, vaccine, or herbal medicine has caused an adverse reaction, discuss it with your doctor or pharmacist.
   If you wish to report it directly, please complete the electronic form **Noti-FACEDRA 2.1** available at www.notificacentroamerica.net .

   When deciding whether the medication or vaccine you received could have caused the symptoms you are experiencing, several factors must be considered.

   If symptoms begin after starting treatment with the new medication or vaccine, they may be related to its administration, but this will not always be the case.

   Your symptoms may be related to an illness 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, headaches.

   It's also possible that your symptoms could be the result of an interaction between the new medication and another medication you're currently taking, or even a certain food.

   If your symptoms disappear when you stop using the medication, this may suggest that they were likely caused by the medication.
   Your doctor is in the best position to advise you about the symptoms you're experiencing, whether or not they're associated with the medication you're taking. They'll even tell you how to avoid some potential adverse reactions.

3. **What will happen to the notification I just completed?** Notifications are collected and uploaded to a specialized database that allows for rapid analysis and evaluation.

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

   - Conduct 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 in Central America and the Dominican Republic to take joint action to address these potential problems.

4. **Is my notification really important?** Yes, it is. It helps to better understand the actual use of the medicine or vaccine, which will contribute to the safe use of medicines.
   We need this data to identify new adverse reactions or conditions in which they occur; this will help us reduce the risk of medication and optimize treatments.

5. **What happens to my personal data in the notification I just completed?** Your personal data is managed anonymously in the adverse reaction database (FACEDRA); only the patient's sex and age are processed. The confidentiality of your data is expressly protected by current legislation, and it will not be transmitted to any person or organization outside the National Pharmacovigilance Center of your country.

6. **If I fill out a form, will my doctor or other healthcare professional receive a copy?** No, under no circumstances. Once the notification is sent, only you will receive a copy of the report and your ID number.

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

SICA
Sistema de la Integración Centroamericana

*"Solidaridad entre los pueblos para la integración regional en salud"*

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