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 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 Centres/ Units/ Programs responsible for pharmacovigilance within the Regulatory Authorities for Medicine 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 a reporting tool allows the online reporting 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 reporting tool contributes to timely reporting of the adverse reactions of medicines and vaccines used in both the private sector and in national health systems.

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

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 a patient has experienced an adverse reaction to a medication or vaccine that is under your company's surveillance responsibility, you can also report it using the electronic form available at www.notificacentroamerica.net .

The electronic form is intended to be a simpler and faster way for a pharmaceutical company to notify the National Drug Regulatory Authority of the SICA Region of a potential adverse reaction that may occur with the use of a medication or vaccine.

WHAT TO NOTIFY?

Please complete the electronic **Noti-FACEDRA 2.1** form if you suspect that a drug or vaccine registered by your company has caused an adverse reaction in a patient.

Mainly you must notify:

- Medicines and vaccines
- Suspected serious adverse reactions that are identified with any medication, with any of the following situations being considered serious:
- Causes death.
- Threatens the patient's life.
- Causes or prolongs hospitalization.
- Causes inability to work or study.
- Induces birth defects.
- ADRs that are clinically relevant.

If you are unsure of the severity of the reaction, please report it in like manner.

Do not be limited by whether the adverse reaction is common or seemingly insignificant, as reporting it can help identify safety issues with medications or vaccines authorized for use in the SICA Region.

Do not wait to report if you're missing any information; however, it is essential for analyzing the adverse reaction that you always provide as much information as possible and provide all the data you have on the medication(s) or vaccine you suspect may be causing an ADR, including any products received 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 notification? The **Noti-FACEDRA 2.1**

electronic form includes four key sections of information that are necessary for the notification process:

Suspected drug(s)

The name of the medication(s) or vaccine suspected of causing the reaction. If the brand name is known, the full name (brand, strength, and presentation) must 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 full name, batch number, and expiration date.

Adverse reaction(s)

Describe the adverse reaction detected, including the main diagnosis, including 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 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 share, please let us know in the notification so that the previous notification may be identified and updated accordingly.

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, include 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 notification and contact you for additional information if necessary.

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

Other additional information

It is very helpful if you notify us of 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, advertised 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 in the interpretation of the case and better facilitate its evaluation. Please provide as much information as possible, but do not delay reporting the case because of unfamiliarity with certain details.

ADVERSE REACTIONS TO MEDICINES

How to identify RAMs?

Patients can tell you about the symptoms they've experienced since using a new medication or after receiving a vaccine. However, since some adverse reactions may not be obvious to the patient, one should be alert to the potential for adverse reactions. Other information to consider include:

- 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 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 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 will not be disclosed to third parties, 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 the use of drugs 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 medicine or vaccine, this information is transferred to the medicine's safety information and the package insert.

On other occasions, this information is used to communicate on the use of certain medications or vaccines, to prescribe them to certain specialists, or to recommend their use as a second choice. this information is sometimes used to communicate about medications or vaccines, for prescriptions to specialists, or as a secondary option.

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.

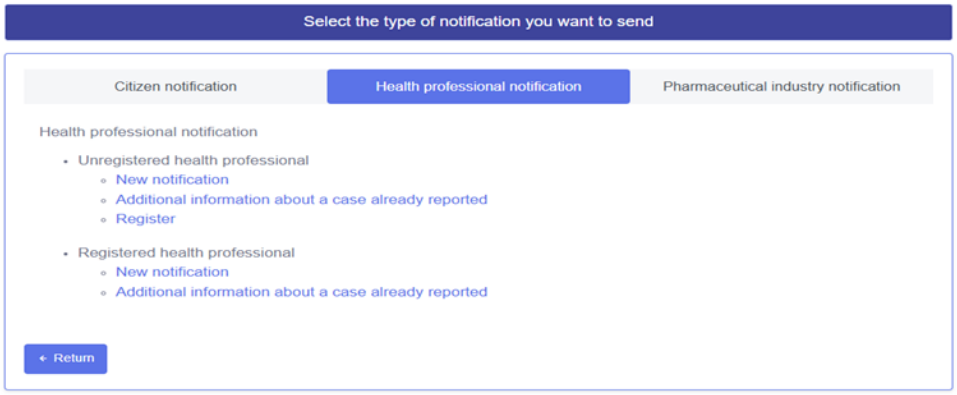
How to access the platform?

The Regional Online Reporting Portal for Suspected Adverse Reactions to Medicines and Vaccines for Human Use, known as **Noti-FACEDRA 2.1,** is available at www.notificacentroamerica.net . The online reporting portal facilitates the online reporting of suspected adverse reactions to medicines 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 countries of residence. To access the platform, please 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.

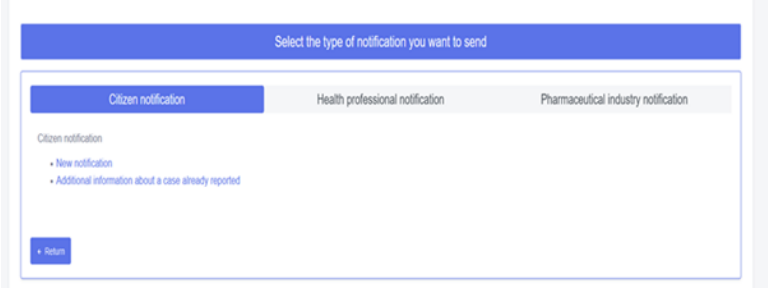
3 Then, the **Main Menu** will be displayed for the online reporting of suspected adverse reactions to medications through Noti-FACEDRA 2.1, either as a Citizen, as a Health Professional or Pharmaceutical Industry.



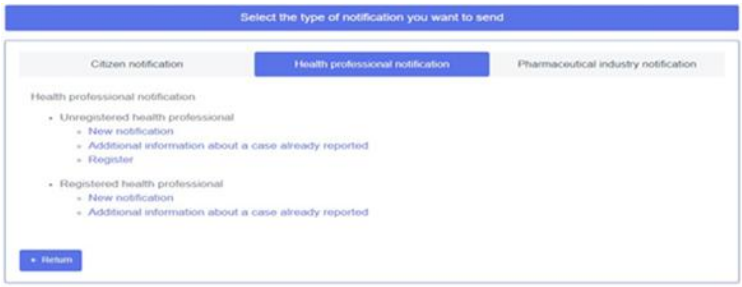
Main Menu

On the Main Menu screen of **Noti-FACEDRA 2.1,** contains three options for selecting the type of reporter that will complete the electronic form for suspected adverse reactions to medications or vaccines, and are as follows:

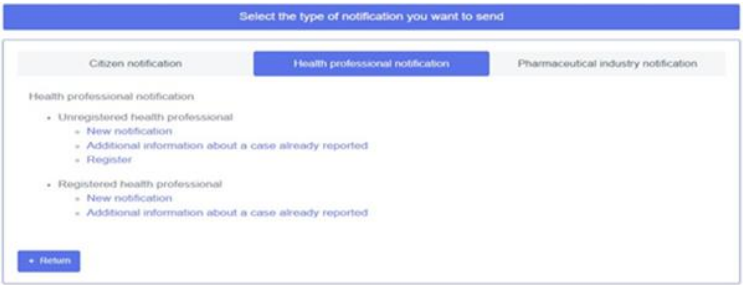
1. The first corresponds to access to the form called **Citizen Notification.** Through this, Citizens can directly report suspected adverse reactions that are detected by them. This includes patients or their caregivers, in the event that a patient cannot do so directly.



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.



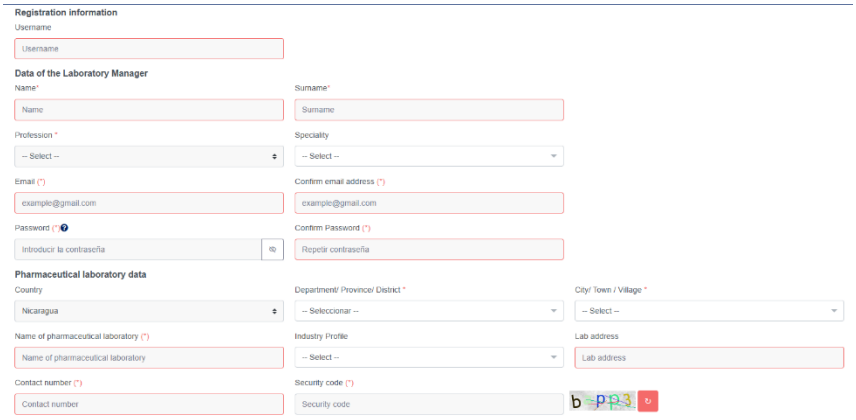
Pharmaceutical industry notification process

The Regional Online Reporting Portal for Suspected Adverse Reactions to Medicines and Vaccines for Human Use, called **Noti-FACEDRA 2.1,** is available at: www.notificacentroamerica.net. The online reporting portal aims to facilitate online reporting of suspected adverse reactions to medicines and vaccines detected by the Pharmaceutical Industry, so that they can be promptly reported to the National Pharmacovigilance Centers of the country where they are located.

Access to the electronic form requires that a Health Professional, trained in pharmacovigilance issues in the pharmaceutical industry, first register as ***a Notifier***. This registration process will facilitate future reports of suspected adverse reactions to medications or vaccines of pharmaceutical products that are under the responsibility of safety and usage monitoring for patients who are prescribed or acquire their medications or vaccines.

Registration Process

a) Select the **"Pharmaceutical industry registration"** option to complete the Notifier's general information, displayed in the following image:



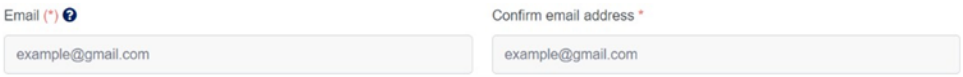
b) The Healthcare Professional responsible for the Pharmaceutical Industry to be registered must complete the information requested in the fields corresponding to **"Registration Information"** as follows:

- For **Data of the Laboratory Manager**, you must enter the representative's first name, last name, profession, and specialty. This data will only be visible when

notifications are sent from the main profile. If a notification is sent from an associated profile, the information from the associated profile will be filled in.

- You must add a **“Username”,** this should be a short name that represents the company name, this information will be displayed in the upper right corner when you log in.

- **"Email"** address (*), which will be used to send the acknowledgment of receipt of the notification. 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 Notifier,** the password must be confirmed for it to be accepted, as shown below:

c) **Pharmaceutical Laboratory Data”** information, the laboratory must follow the following steps:

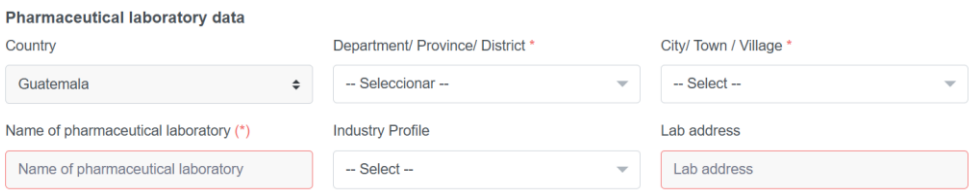
- **Department/District/ Province:** You must select an option from the drop-down list and indicate the district where the laboratory is located. This list will depend on the country selected on the platform's home screen.

- **City/ Town / Village:** You must select one of the options and must refer to the municipality where the laboratory is located. This list will depend on the selection in the previous field.

- **Pharmaceutical Laboratory Name:** You must enter the name of the Pharmaceutical Company (Laboratory) that will be reporting adverse reactions for your medications.

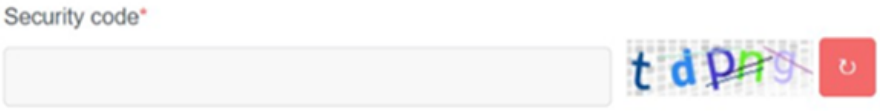
- **Industry Profile:** You must select one of the three options from the list.

- **Laboratory address:** You must enter the exact address where the pharmaceutical Laboratory facilities are located.



- **"Contact number",** the Notifier must establish the contact telephone number at the Service Center, if desired the mobile telephone number can be placed.

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



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

For the Pharmaceutical Industry to have access to the **Noti-FACEDRA 2.1 electronic form** , you must register and 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 problems with the use of these products. To complete the form, you will need to provide information on four important aspects:

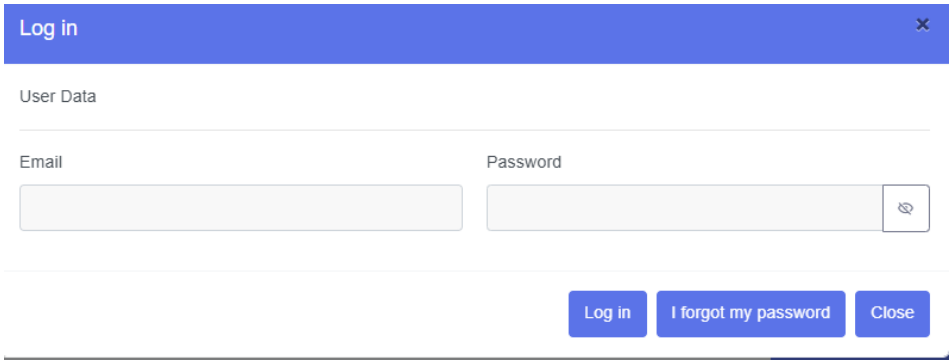
I. Details of the possible adverse reaction.
II. Provide the name of the medication you suspect caused the adverse reaction.
III. The data of the person who had the adverse reaction.
IV. Information about the person making the notification will also be required.

With this information available, the Pharmaceutical Industry can complete the electronic form through Noti-FACEDRA 2.1, following the instructions below:

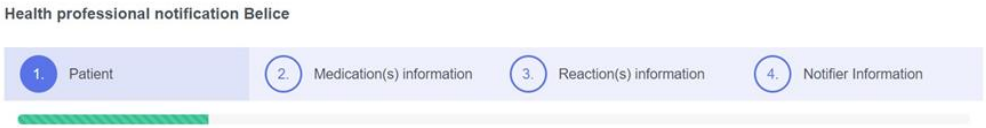
New Notification

After registering with Notifier, the New Notification process begins by following these steps:

1. Selecting the New Notification option from the main menu will display a window where you'll need to enter the email address you previously registered with and your password. Then, click the **"Log In"** button.



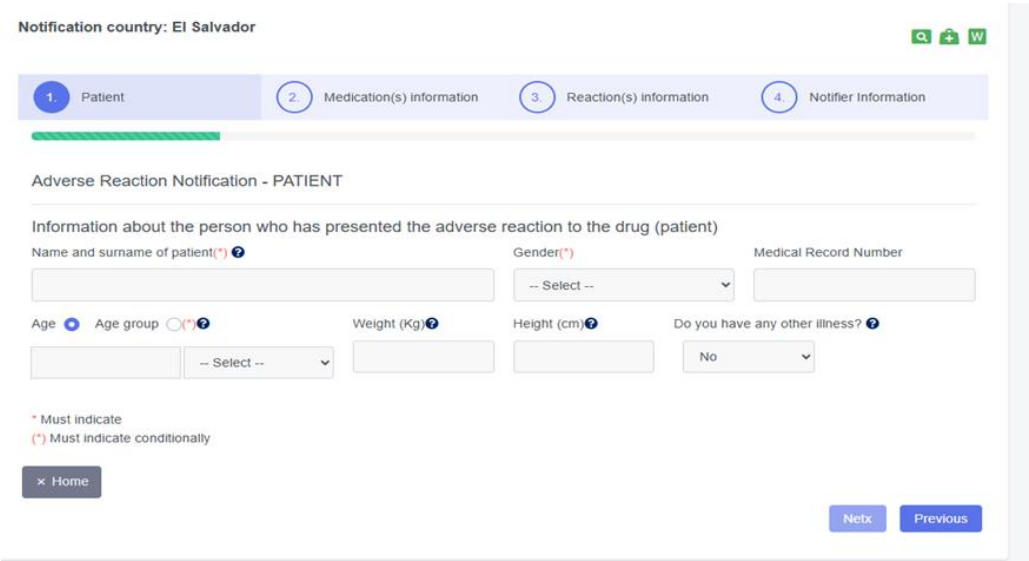
2. Upon entering, the notification form will be displayed according to the 4 sections shown in the following figure:



3. Below are the form fields corresponding to step 1, called Patient Data. In this section, you must detail the information about the person who has experienced the adverse reaction to the medication.

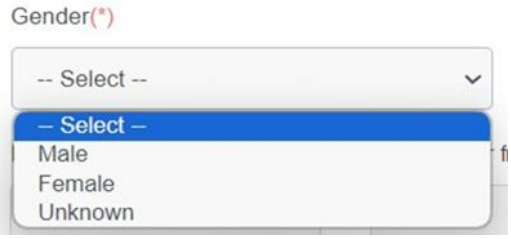
Patient Data

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, the information marked (*) that corresponds to mandatory information.

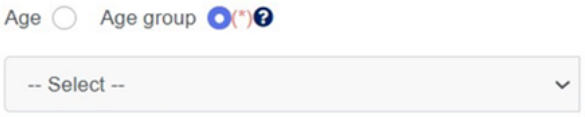
b. **Gender,** the patient's sex must be established by choosing one of the options shown, Male or Female as shown in the figure:



Information marked (*) corresponds to mandatory information and should not be left blank.

c. For the **Patient Age report,** there are two possibilities. The first is the **Age** option, which allows you to enter a numerical value, accompanied by the time unit in decades, years, days, hours, months or weeks.

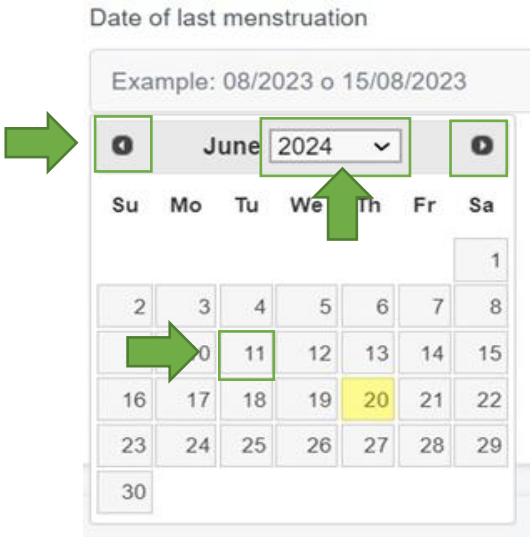
The second option is the **Age Group** option, in which the patient's age is expressed by age groups, selecting one of the options Fetus, Newborn, Infant, Child, Adolescent, Adult or Elderly, as shown in the following figure:



d. **For the Patient Weight report,** 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.

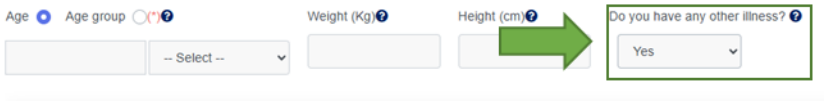
f. **Date of last menstruation,** this field will be displayed alone If the patient is female, the patient must provide the date in month/year or day/month/year format. For example: 08/2023 or 01/01/2024.



This information is not mandatory, so if you don't know it or don't remember it, you can leave it blank.

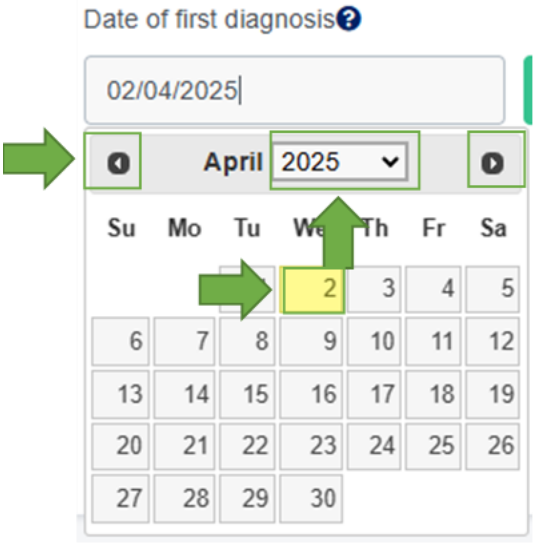
You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, 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.

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



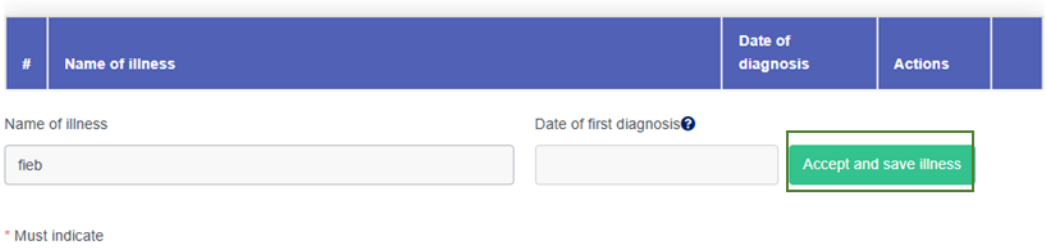
If you have a disease, you must select the "**YES**" option, so that two additional fields will be displayed for reporting that disease.

In the field "**Name of illness",** 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.



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.

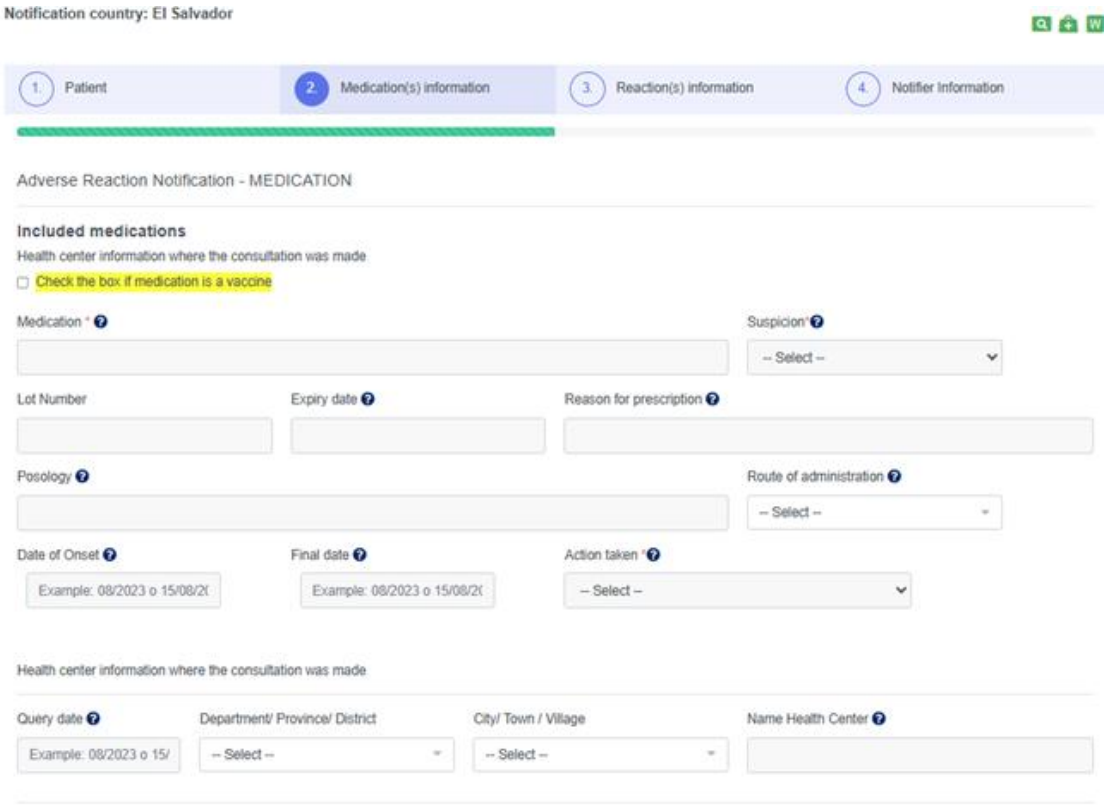
Next, you must click the "**Accept and Save Illness**" button to save the information. More than one disease can be reported in this field, as long as each one is accepted and saved.



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

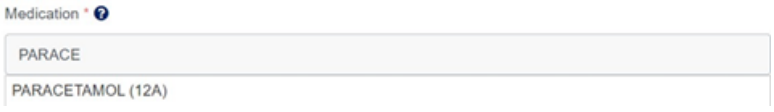
Medication Information

For step 2 of 4, called **"Medication Information",** related to the necessary information of the drug or drugs suspected of being responsible for the adverse reaction, the patient must complete the following information:



Add Medication

a) **"Medication"**, to facilitate information on the name of the medication that may have caused the adverse reaction, in the field called "medication", for these, you must enter the trade name or 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 medication, as shown in the following figure:



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

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

To report a drug by trade name, the World Health Organization's drug dictionary, WHODrug, has been made available in Noti-FACEDRA 2.1. To use this dictionary in the drug reporting process, you must meet the following requirements:

1. Have a valid WHODrug license. For more information, please visit: https://who-umc.org/whodrug/whodrug-global/

2. Include it in your registration information on the **Noti-FACEDRA 2.1 platform** (see section "Adding Drug Dictionary Licenses").

If you meet both requirements, the following icons will appear when you enter the form:

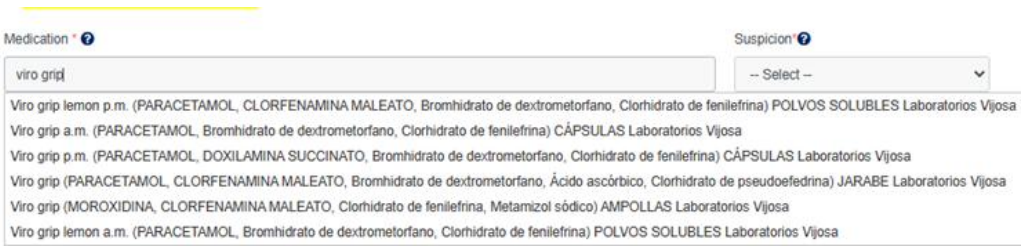
If the icon is green, it means you have an active WHODrug license.
If the icon is gray, it means you don't have a valid or expired license

If the icon is green, it means the WHODrug dictionary is enabled in your country.

If the icon is green, it means you have an active MedDRA

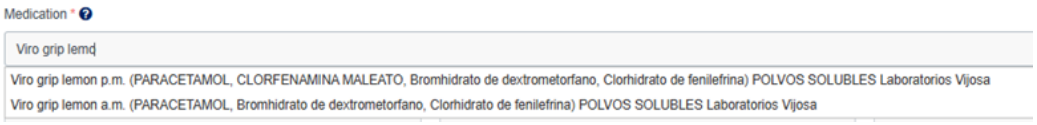
How to correctly search for a drug's brand name in the Noti-FACEDRA 2.1 form:

I. In the Medication or Vaccine field, enter the **brand name** of the suspected medication you wish to report. The options that begin with the text entered in the field will then appear. As shown in the image:



Only the brand names of medicines marketed in the country where you are reporting will be displayed. The structure of the medicine options follows the following order:

Trade name + Active ingredient + Concentration + Pharmaceutical form + Manufacturer name, as shown below:



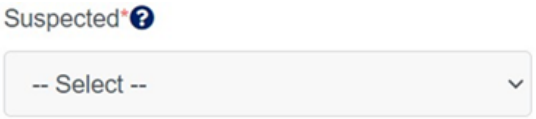
If the medication has more than one strength, dosage form, or brand name, all available options will be displayed for more accurate notifications.

II. After having selected one of the self-complementing 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 is not shown in the auto-complete options, you can still submit the report. Enter the name you know, add the other information, and click **"Accept and save medication"** or **"Accept and save vaccine".**

Note: If the medication to be reported is not among the options shown, it is possible to enter it as text, typing the name as you remember it to complete the notification process.

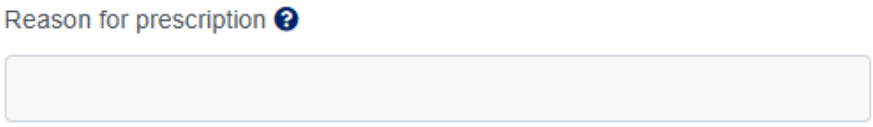
b) **"Suspicion"** information, the Notifier must select one of the options related to whether the medication detailed in literal a) corresponds to the Suspect, is a Concomitant, has an Interaction with or the Medication has not been administered, as shown in the following figure:



c) To report the **lot number and expiration date** of the suspected medication or vaccine, you can find this information on the medication packaging. If it is not

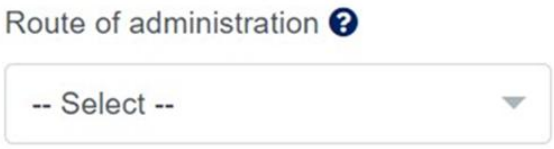
available or you do not know it, you can continue with the information completion process.

d) To specify the **"Reason for prescription"** for 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:

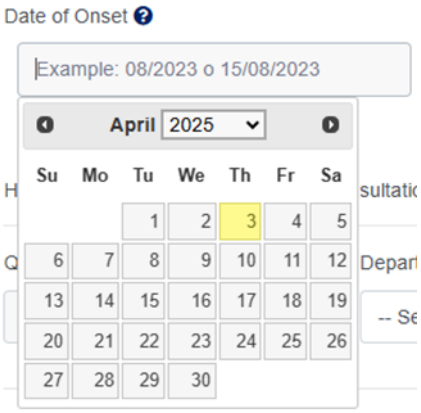


e) To complete the **"Posology"** information, the Notifier must establish for each medication to be included in the report, the way in which the medication was prescribed or the way in which the patient reports that he was taking the medication, for example: one tablet each day or 500mg twice a day.

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:

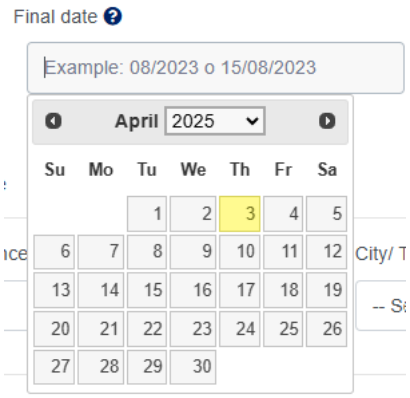


g) For the "**Date of Onset"**, the patient must establish in as much detail as possible the date on which he or she began using the medication. To do this, the calendar method shown below must be used:



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		

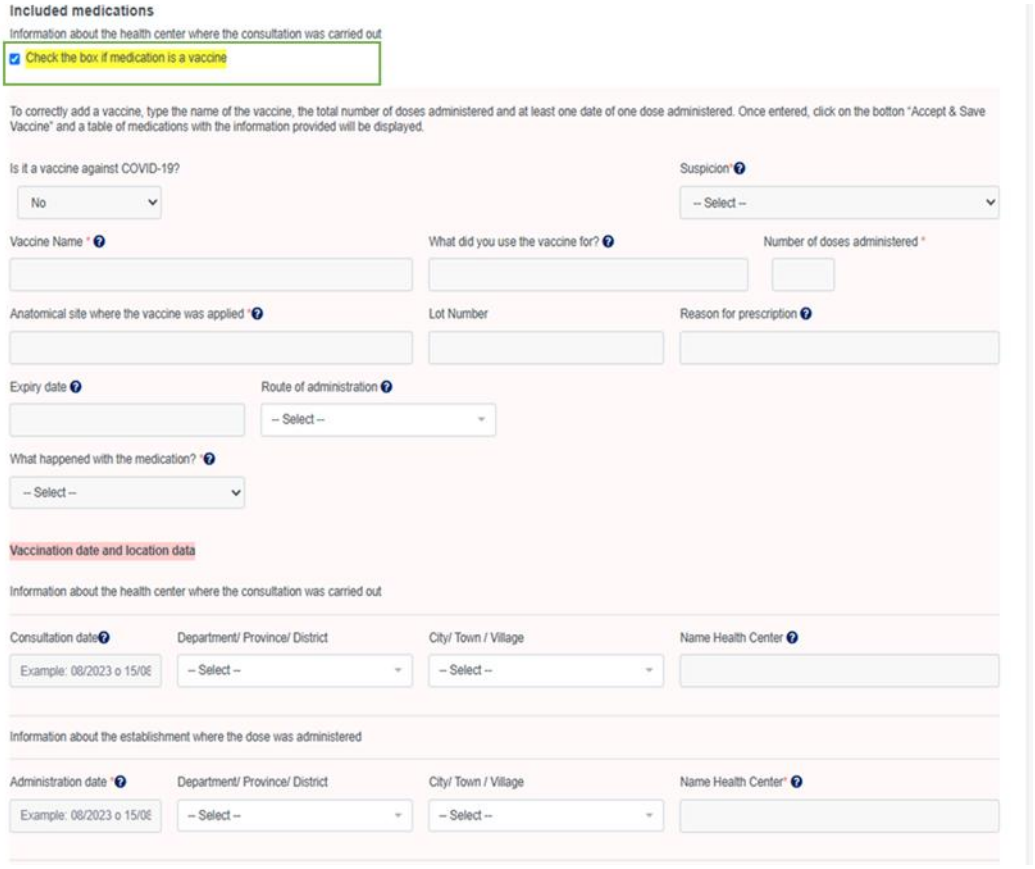
k) If any corrections are necessary, the patient can use the modify option to make the necessary modifications. Once the modifications are complete, the patient must select the "**Modify Medication Information**" button.

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 district 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

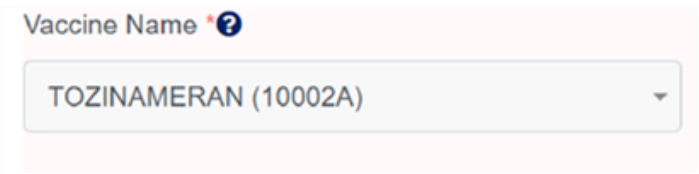
"Check the box if the medication is a vaccine" must be checked; the following form will immediately appear.



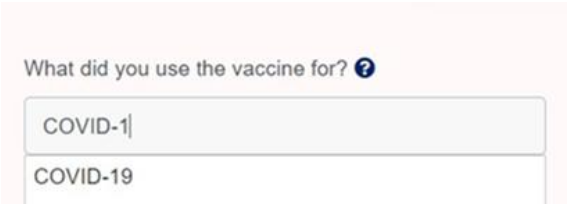
a) To answer the question: "**Is it a vaccine against COVID-19?",** The patient must answer **Yes** or **No** as appropriate**.**

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

If none of the options listed match your search term, you can freely type the name of the vaccine.



c) To answer the question " **What is the vaccine used for**?", the patient must enter 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, as shown in the following figure:



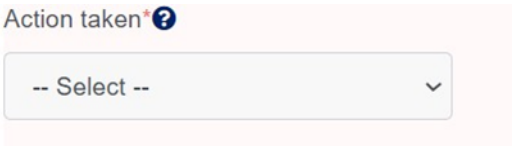
d) To report the **lot number and expiration date** of the suspected vaccine, you can find the information on the medication packaging. If it's not available or you don't know it, you can continue with the information completion process.

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",** which should indicate the part of the body where the vaccine dose 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: 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 appear, 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**

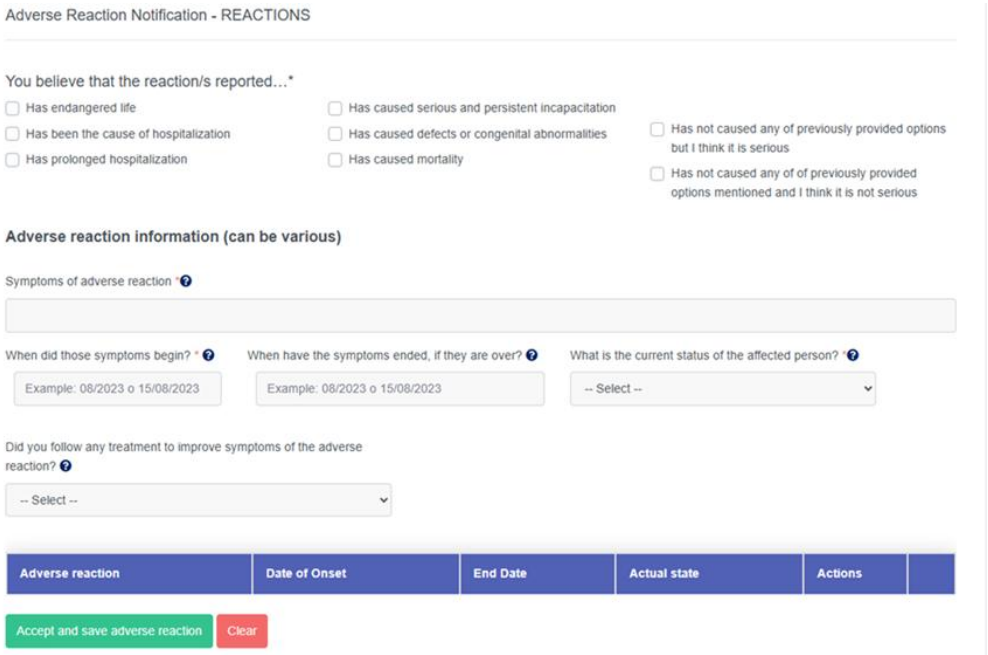
Information about the facility where the dose was administered: To save the dose data, the following information must be added:

- **Date of consultation:** Please provide the date of the patient's visit and receipt of 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 facility where the dose was administered is located.
- **Municipality:** The data on this list will depend on the department selected in the previous field and must indicate the municipality where the facility 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.

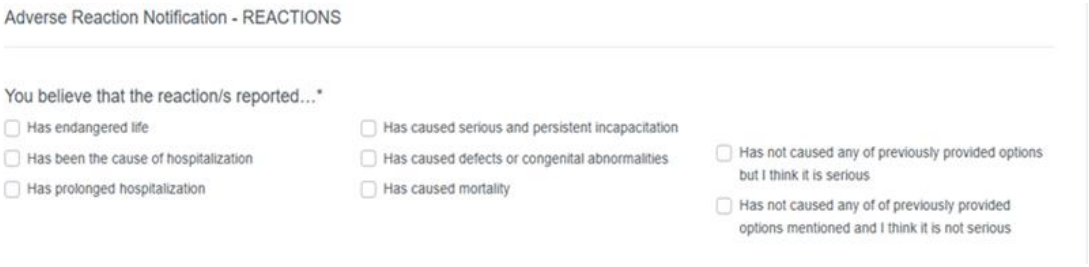
j) To complete the process, you must select the **"Accept and save vaccine"** button and then click the **"Next"** button.

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:



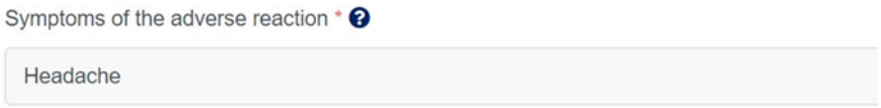
a) The Pharmaceutical Industry, depending on the status of the adverse reaction that the patient has presented, must select one or more of the criteria shown in the following figure:



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

b) For the section entitled **"Information on adverse reactions (may be several)",** 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) **"Date of Onset"** information, you must specify the date on which the adverse reaction occurred in as much detail as possible. For this, you must use the calendar format. Enter the information in month/year format, at a minimum.

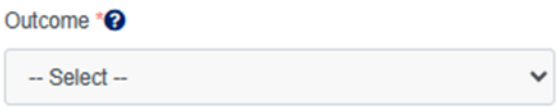
Please note that this is a field marked (*) that corresponds to mandatory information and cannot be left blank.

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, if any. To do this, they must use a calendar format. Enter the data in month/year format, at a minimum.

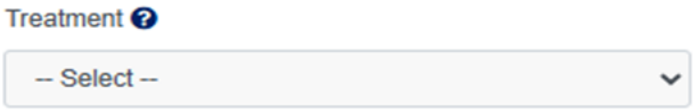
You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, 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 should be left blank.

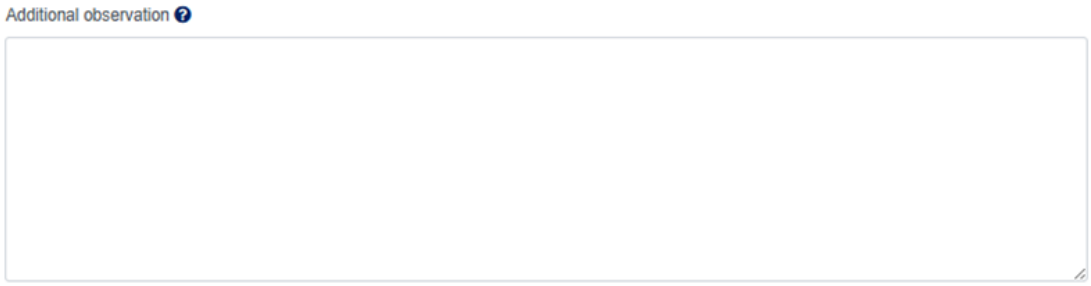
f) To answer the "**Treatment "**question, you must select one of the options below. If you have not received any treatment, you should select the **"No treatment "** option.



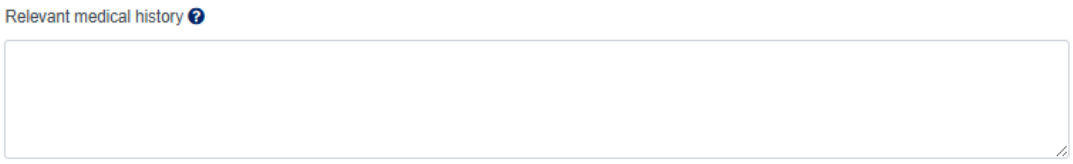
g) To complete the recording of adverse reaction data, the patient must select the **"Accept and save adverse reaction"** button**.** This action will save the adverse reaction record, presented in the following format:

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

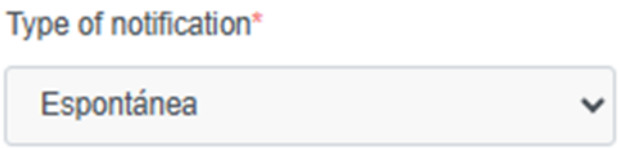
i) If the patient is required to provide more information that may provide other elements that may be necessary for the analysis of the case, a case narrative or results of clinical laboratory tests or other clinical tests may be included. This information can be entered in the field called "**Additional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

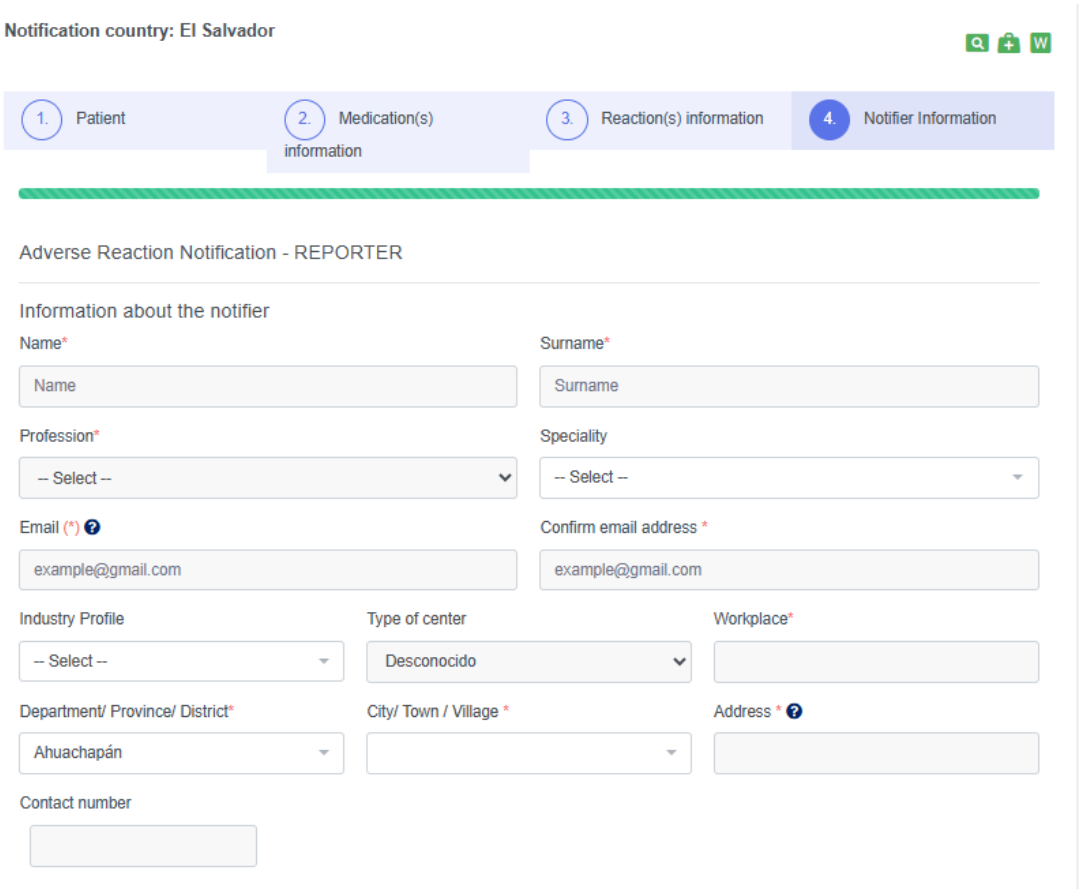


If the report is a suspected adverse reaction detected during your routine practice, you should select the "Spontaneous" option.
If the suspected adverse reaction(s) are identified by the Healthcare Professional as part of a study or reported in the scientific literature and refer to cases from the Central American region, they should be considered for reporting as "Study" cases.

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

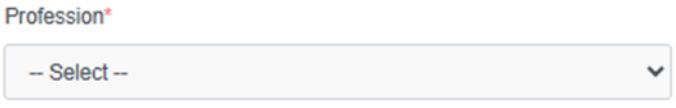
Notifier Information

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:



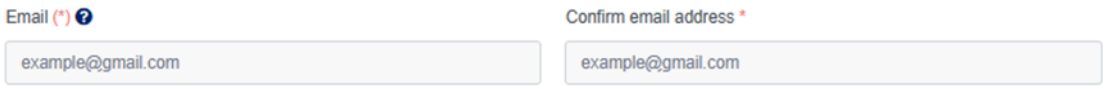
a) For the information of the person who fills out the electronic form of Noti-FACEDRA 2.1, it will be completed with the name and surname of the notifier.

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

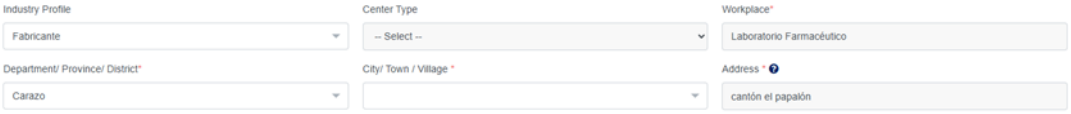


Please note that this is a field marked (*) that corresponds to mandatory information .

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 the workplace number. A mobile phone number may be optional.

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



g) If necessary, to provide more information related to the reported case, the patient may 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”**, indicate in which folder on your computer or device the file you want to attach is located.

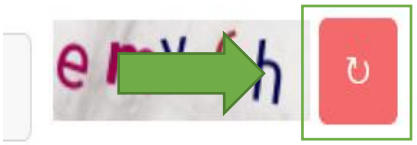
Note: The formats accepted for attachment to the notification are the following:

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

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

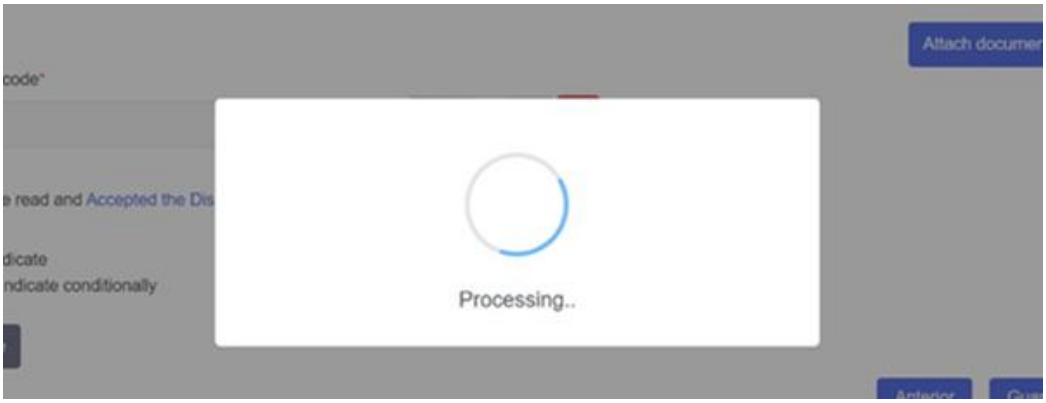
i) The notifier must enter the random key shown as an image in the field called "**Security Code",** as shown in the figure:

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

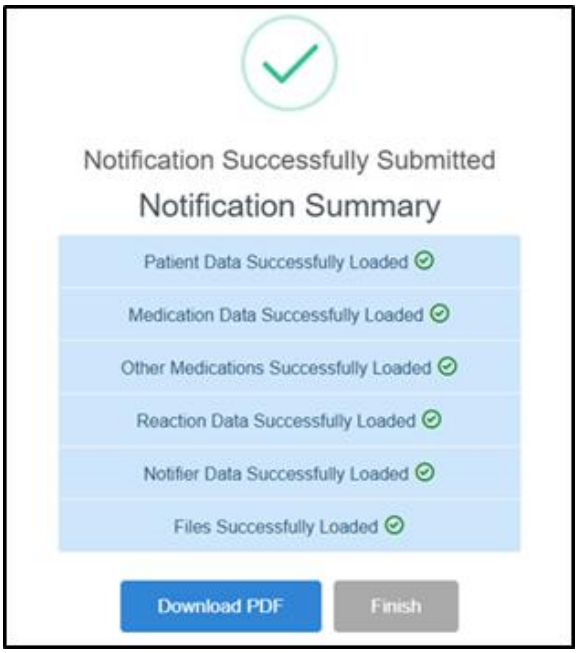


j) For information security purposes, it is necessary for the notifier to select the option "**I have read and accepted the legal Disclaimer**", which will display a window showing the text of the legal notice.

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



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



m) 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.

n) 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

SECRETARÍA EJECUTIVA COMISCA SICA NOTI-FACEDRA

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.

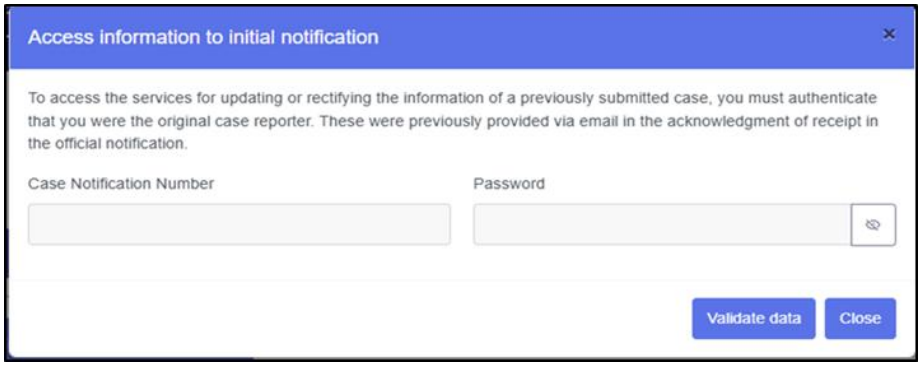
Contacto: Centro Nacional de Farmacovigilancia Guatemala, E-mail: farmacovigilanciadrcpfa@mspas.gob.gt

Follow-up of cases or provision of additional information on 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 2.1** should look for the following information in their email:
   I. Number of the reported case
   II. Individual password of the reported case.

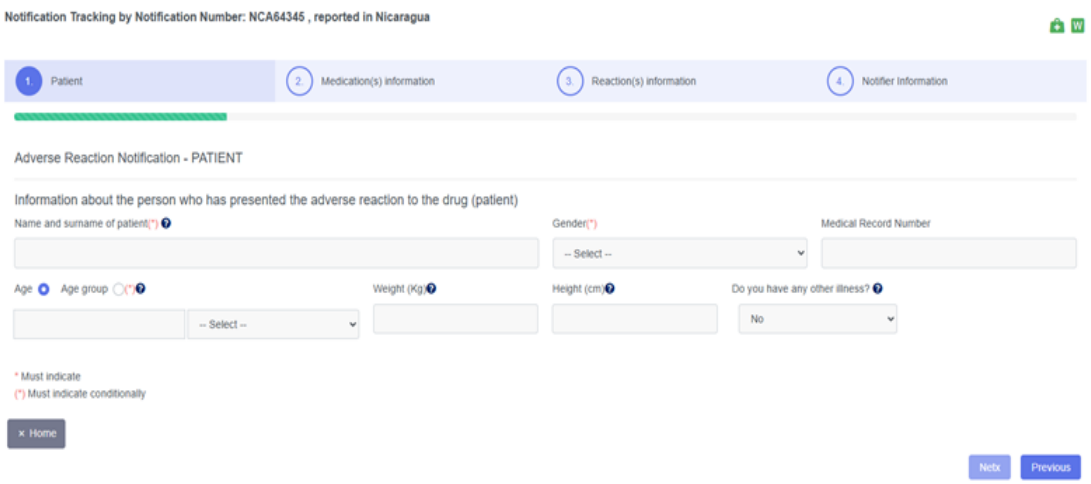
b) Once the information from step a) is available, the notifier must access **Noti-FACEDRA 2.1** through the link www.notificacentroamerica.net and click on "Additional information on a case already notified" where the following screen will be displayed:



In this space you must enter the "**Case Notification Number"** and "**Password"** that was 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:



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.

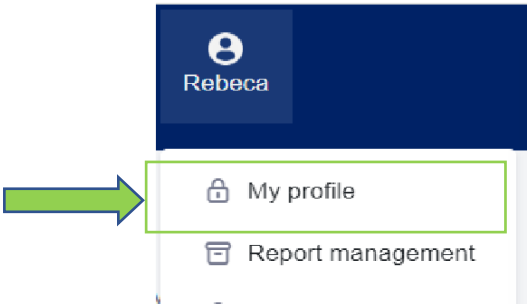
e) To save any corrections or additional information you provide, click the **"Accept"** button**.** If the tracking was successful, a confirmation message will appear, giving you the option to download the PDF again. You will also receive another email with your notification number and password.

Edit my industry profile

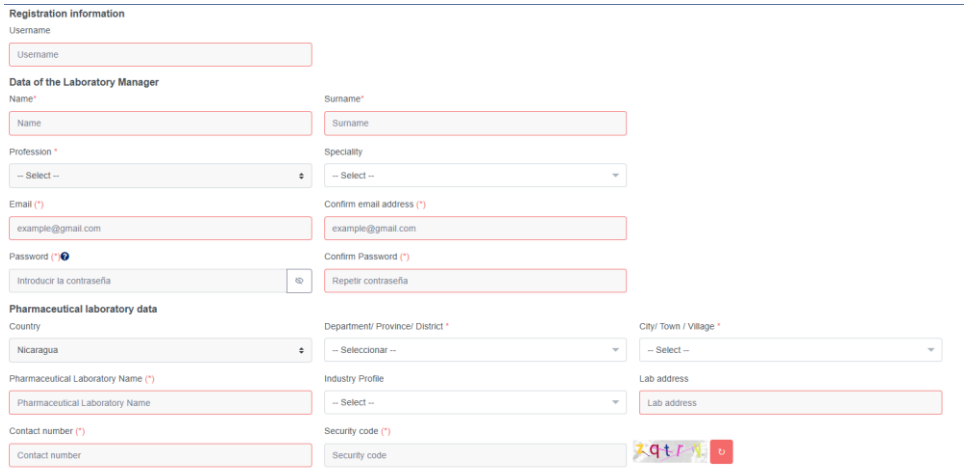
In this section you can edit your user information, and the data with which you registered will be displayed.

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

a) The healthcare professional responsible for the pharmacovigilance department or section of the pharmaceutical industry that manages the logged-in profile must click on my profile.



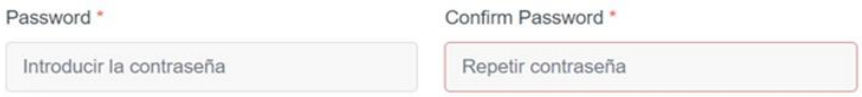
b) Select the **"My Profile"** option to edit your profile information. The following image will be displayed with your data pre-filled:



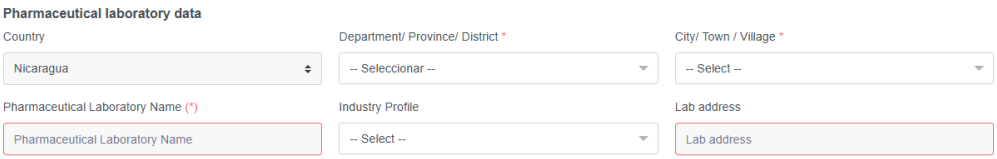
d) You must have the information requested in the fields corresponding to **"Registration Information"** as follows:

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

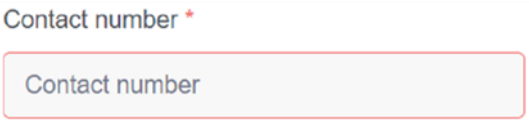
- Next, update the “**Password”** that will give you access to Noti-FACEDRA as a Registered Notifier. The password must be confirmed for it to be accepted, as shown below:



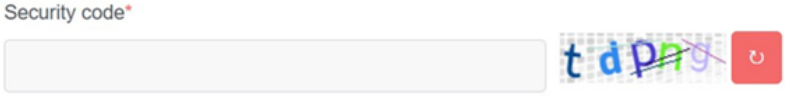
e) To edit your **Pharmaceutical Laboratory Data,** please note that you can only edit information related to the laboratory address, i.e., the department/province, municipality, and the laboratory address. If you wish to change any other information, please contact the platform administrator.



- Edit the **“Contact Number”,** the Notifier must establish the contact phone number at the Service 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:



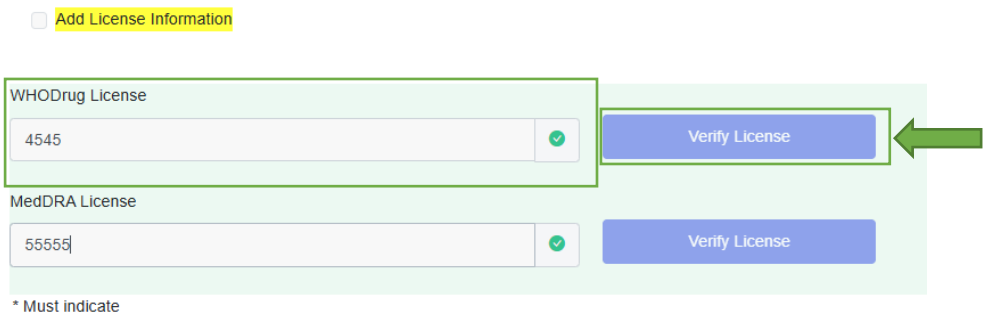
- Once you have edited all the fields to be updated, you must click **“Accept”** to complete the update process.

- You will receive a message confirming the successful modification.

Registration Process for the Drug Dictionary (WHODrug) License

License registration is only available for pharmaceutical industry users who are registered on the **Noti-FACEDRA 2.1 platform** .

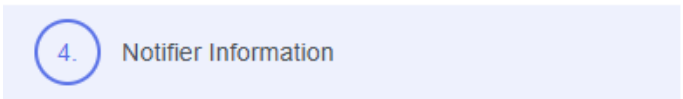
a) Enter **“My Profile”**
b) Click on the “**Add License Information”** box to display the fields where you can enter the license number.
c) Enter your license number in the **“WHODrug License”** field and then click **“Verify License”**

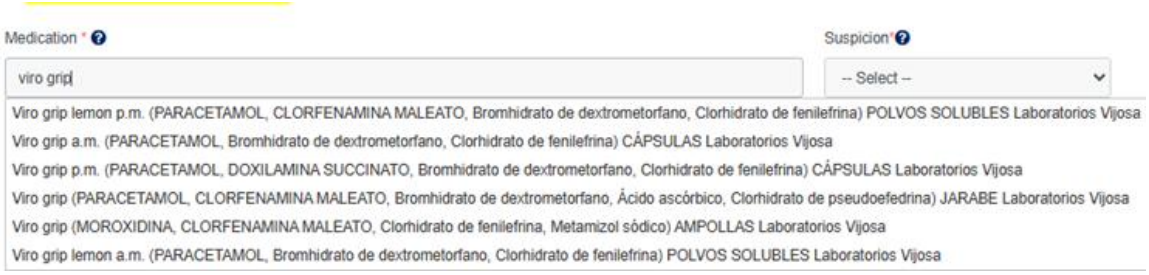


- If the license number entered is not valid or invalid, the platform will indicate this and you must go to: https://who-umc.org/contact-information/help-and-support/ to obtain a valid license.
- If the license number is valid, the following message will appear:

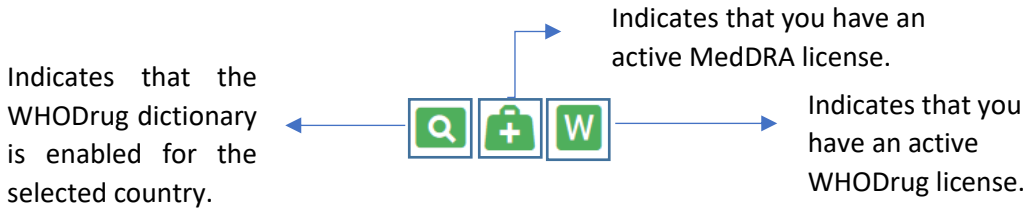
The validity of your license will be automatically verified each month. If your license is no longer valid, the verification button will be re-enabled so you can re-register it once you renew it on the WHODrug website.

Once your license is verified as active, auto-complete will be enabled on medication and vaccination forms, and a green “W” symbol will appear on the notification form, indicating that you have an active dictionary license.





Note: If you have an active WHODrug license, but the dictionary options do not yet appear on the form, please verify that the dictionary icon (green search icon) is enabled next to the WHODrug icon, as this option may not yet be enabled in your country.



If you have any additional questions about the validity of your WHODrug license or are interested in learning more about obtaining a license, you can contact technical support at ***support@who-umc.org*** .

Register a Medical Terminology Dictionary (MedDRA) license

License registration is only available for pharmaceutical industry users who are registered on the **Noti-FACEDRA 2.1 platform** .

a) Enter **"My Profile**"
b) Click the **"Add License Information"** box to display the fields where you can enter the license number.
c) Enter your license number in the **"MedDRA License"** field and then click **"Verify License".**

- If the license number entered is not valid or invalid, the platform will indicate this and you must go to: https://ssa.meddra.org/contact1 to obtain a valid license.
- If the license number is valid, the following message will appear:

The validity of your license will be automatically verified each month. If your license is no longer valid, the verification button will be re-enabled so you can register it again once you renew it on the MedDRA website.

Once your license is verified to be active, the self-completing fields will be enabled on the forms in which MedDRA terminology must be included for the reporting process through the Noti-FACEDRA 2.1 regional portal.

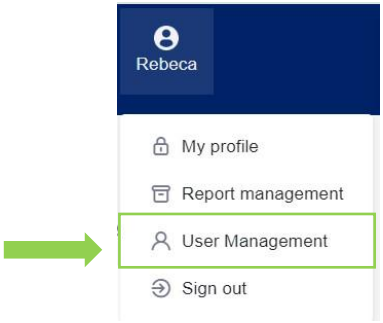
Note: If you have any additional questions about MedDRA licenses or would like more details, please contact technical support at ***mssohelp@meddra.org .***

User management

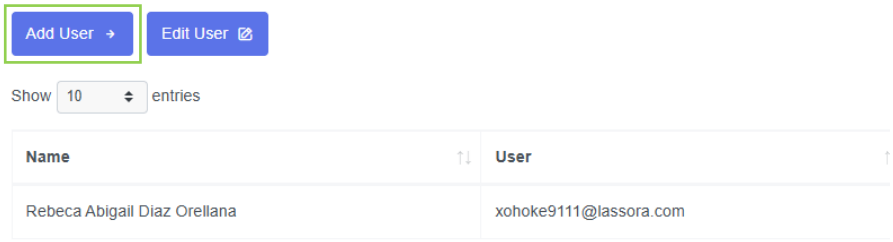
"User Management" module allows for the addition of a ***limited number of users associated*** with the main industry account. If several persons are responsible for creating reports for a specific industry, sharing of profile username and password with all of them is not necessary; each person can have their own username and password.

All notifications made by any of these associated users will be done so with industry data, so the acknowledgment email will be received by the account's primary email. These users will not have access to the "**Report Management**" module; they will only be able to make new notifications and follow up on notifications on behalf of the industry to which they belong.

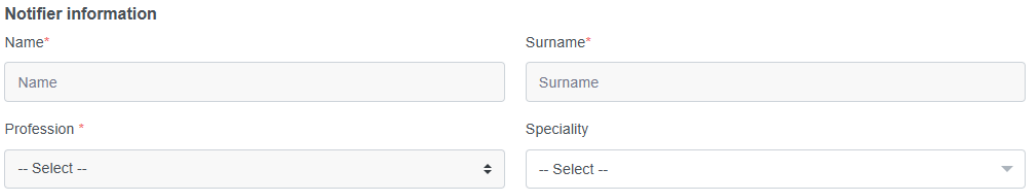
a) To access user management, you must log in, then click on the username that appears in the upper right corner and click on the **"User Management"** option.



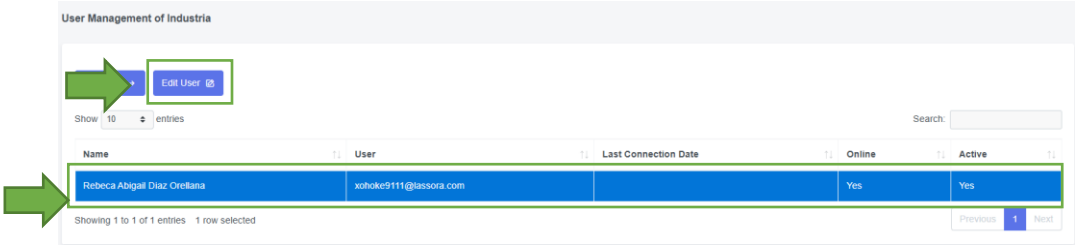
b) A table will appear containing the list of users you've added. To add a new user, click the "**Add User"** button.



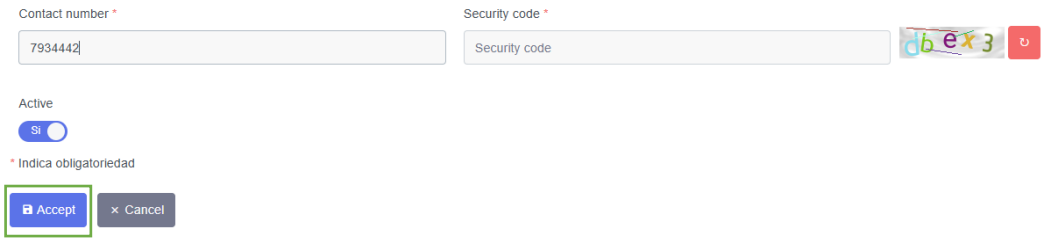
c) A registration form should appear where the information of the user to be associated with industry account will be entered. When these associated users make notifications, the First Name, Last Name, Profession and Specialization information will appear pre-filled in the Notifier Data section, while the other information will be taken from the main data of the industry account.



d) To edit the added users, select the user name in the table and then click on the **"Edit User"** button.
The registration form will appear with pre-filled data for the selected user. Change the required data and then click the **"Accept"** button to save the new data.

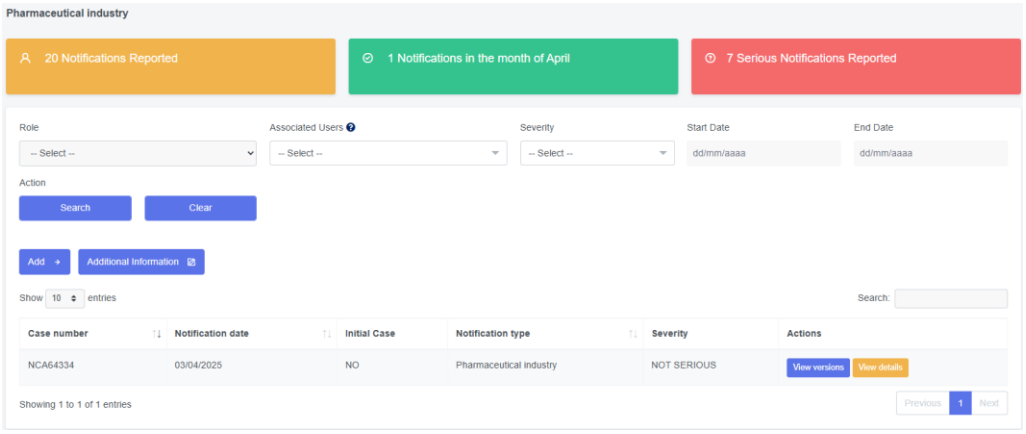


If a user is to no longer send notifications on behalf of a specific industry, this user's account can be deactivated by clicking the Active button. By making this change, users will no longer be able to access the platform, but the record of the notifications that the user sent will be maintained.

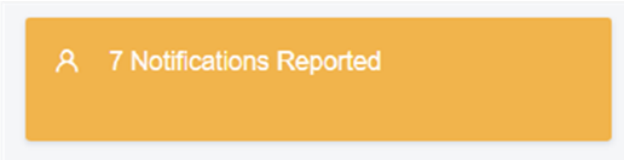


Report management

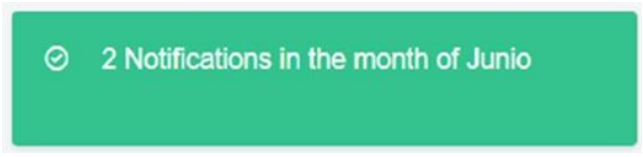
In this section, notifications that have been reported through the **Noti-FACEDRA platform** can be managed. Information on the number of notifications accumulated in the current month, as well as the option to identify serious cases reported, as shown below.



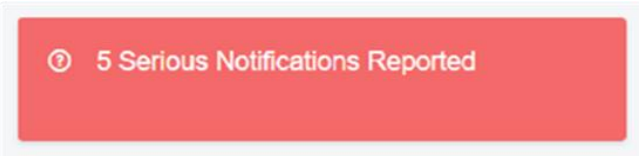
a) Information on the number of notifications made



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



c) Information on the number of Serious notifications

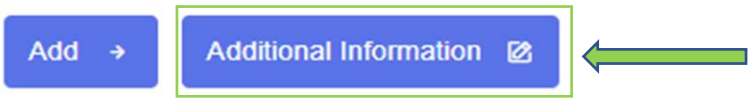


d) To make a new notification you must click on the **"Add"** button.

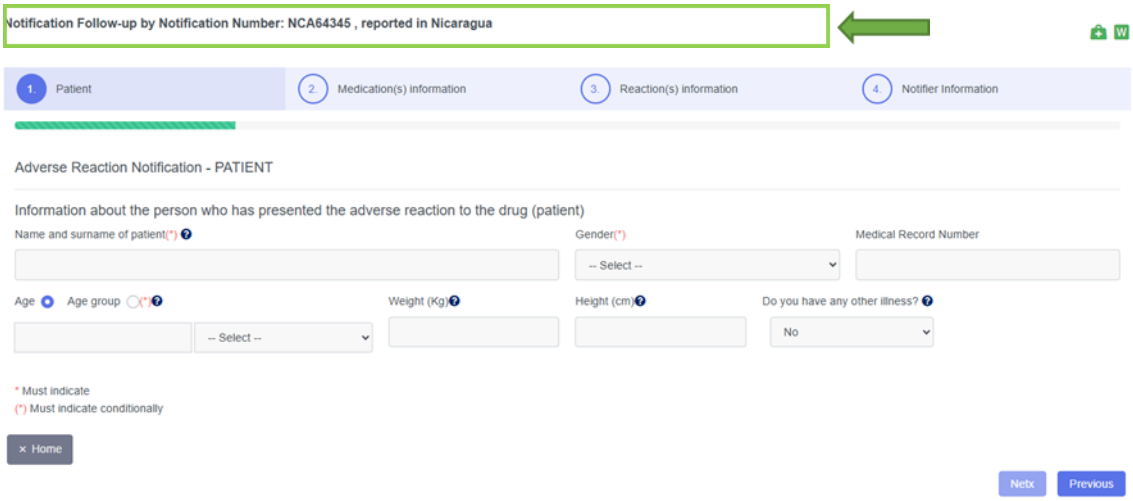
e) To add additional information to a notification, follow these steps:

a. Select a record by clicking on it.

b. Click on the **"Additional Information"** button



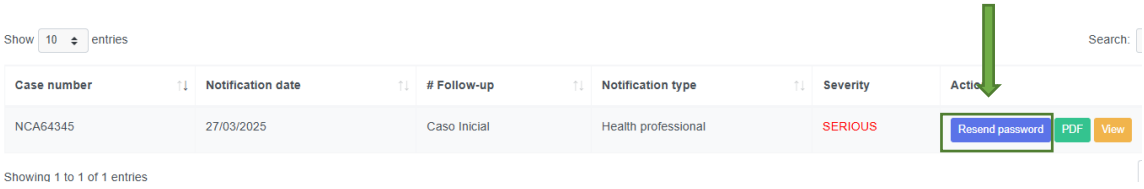
c. This way you can add information to an existing notification.



f) Resend notification password

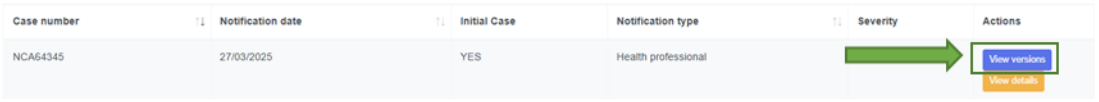
a. Click on the **"View versions"** button for the corresponding case.

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

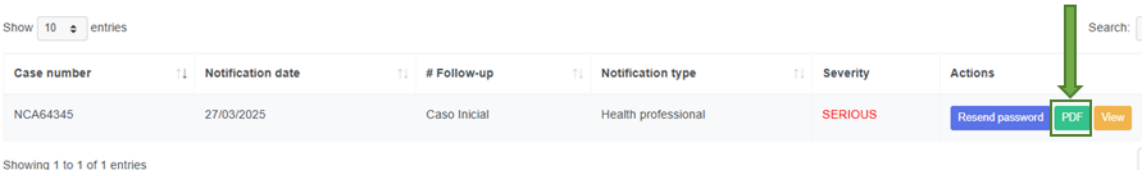


g) To download the PDF of the notification

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

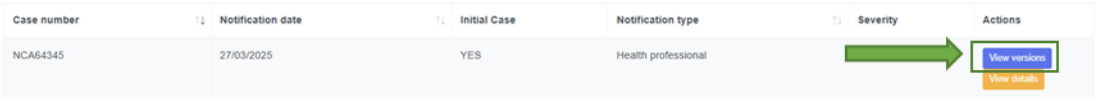


b. Click on the **“PDF”** button.

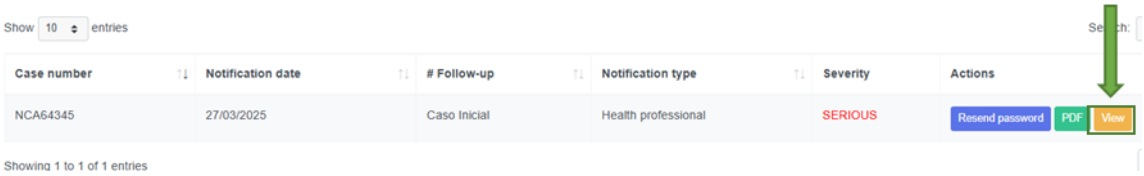


h) View detailed notification information

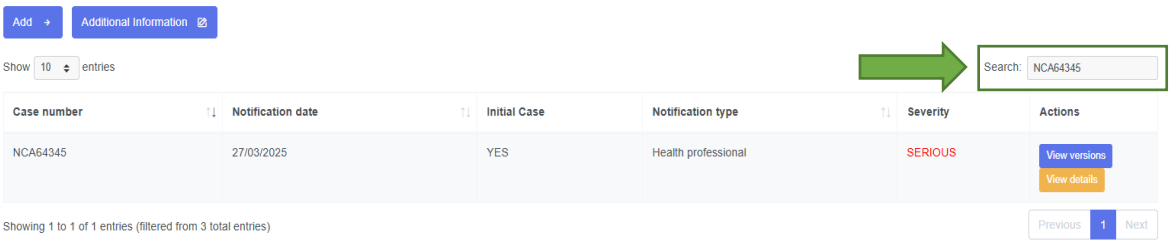
a. Click on the **“View versions”** button for the corresponding case.



b. Click on the **“View”** button.



i) Search or filter notification

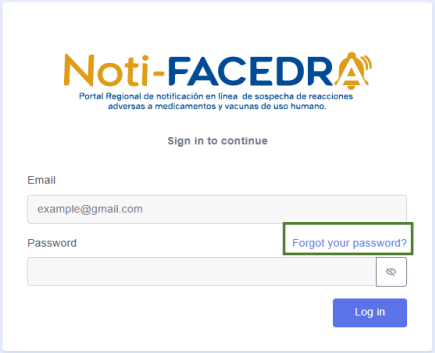


Process to recover password

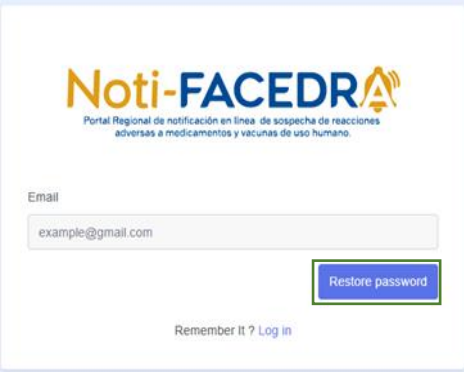
Noti-FACEDRA users also have an option to recover his/her password if it has been forgotten or lost.

On the login screen, a reset your password option is available. Follow these steps:

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



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



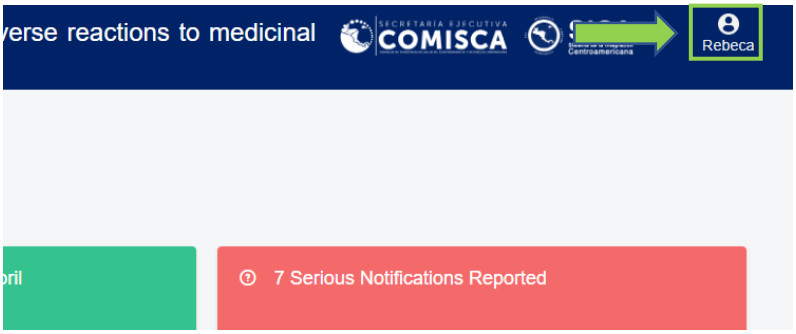
c) Once you have clicked on the "Restore password" button, you will receive the following response, which tells you to check your inbox or spam folder for the email.

d) Check email and log in with the new reset password provided. Update password once logged in.

Log out of the portal

Remember to log out when activities on **Noti-FACEDRA** have been completed**.** To do this, follow these steps:

a) At the top right you will find several options 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 or vaccine is safe?** No medication or vaccine is completely free from producing one or more adverse reactions, but the benefits obtained from using the medication outweigh its potential risks.

   Generally, most people who use a medication or receive a vaccine do not experience any adverse reactions. Even adverse reactions described as common occur in only a small percentage of people who use the medication.

2. **Since I started taking 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 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 manufacturer to report usage problems or monitor patient outcomes. If you think a medication, vaccine, or medicinal plant 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 new medication could have caused the symptoms you are experiencing, several factors must be considered.

If symptoms begin after starting treatment with the new medication, they could be related to that medication, 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 notifications submitted through the Noti-FACEDRA portal?** 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. **What happens to the personal data included in the notification form?** Personal data is managed so that it is not incorporated into the adverse reaction database in an anonymized manner; only the patient's sex and age are processed.

   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 Noto-FACEDRA portal, will any attending physician or other healthcare professional receive a copy?** No, under no circumstances. Once the notification is sent, only the company that notified will receive a copy of the report and the corresponding identification number.

6. **Are you having trouble tracking your case?** If you successfully entered the "Additional information on a reported case" form and, despite completing it correctly, are unable to save the report because the platform displays the following message: " *You must select a country in Central America or the Dominican Republic to submit your report* ," it's likely that you have the "Save and complete addresses" option enabled in your browser. To resolve this issue, you should disable all form autocomplete options in your browser and clear your cache before attempting to save your data again. If, despite following the recommendations, you still cannot save the report, you can report the incident to notifacedra@se.comisca.org .

7. **Are WHODrug and MedDRA licenses paid for and renewed on the Noti-FACEDRA platform?** No. Noti-FACEDRA only verifies whether the

license you are using is valid and current. If you wish to purchase or renew a license, learn about pricing, or find out the validity period of each license purchased, you can contact:

MedDRA: mssohelp@meddra.org

WHODrug: support@who-umc.org

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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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