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

SICA
Sistema de la Integración Centroamericana

USER MANUAL

CITIZEN NOTIFICATION

Noti-FACEDRA

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

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Introduction

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

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

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

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

General considerations

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

If you are concerned about a symptom that you think may be an adverse reaction, please consider the following:

1. Review the medication's package insert. In it you can find a list of known adverse reactions and advises you what to do.

2. Talk to your doctor or pharmacist, and inform him or her of your doubts or fears and of the possible adverse reaction you have experienced. If you believe that you have experienced an adverse reaction to a drug or vaccine, you can also notify it through the electronic form that is available through the link www.notificacentroamerica.net.

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

WHAT TO NOTIFY?

You can notify suspected adverse reactions to any medicines or vaccines for human use, including prescription, non-prescription, or herbal medicines. Do not hesitate to do so if you suspect any problems with the use of these products.

It is especially useful to receive information about suspected adverse reactions that occur in patients in the following cases:

• When it is not mentioned in the insert that accompanies the medicine or vaccine.

• Has caused you problems that in your opinion you consider interfere with your usual activities.

• It is associated with the use of a medication or vaccine recently introduced to the national market.

• It occurs when you are taking more than one medication, and may be caused by an interaction between them, or with some foods.

WHO CAN NOTIFY?

Any person can notify, whether you have an adverse reaction that may be due to the administered medication, or you can notify adverse reactions that your children, an older adult under your care, or a close person may have.

HOW TO COMPLETE THE FORM?

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

1) Details of possible adverse reaction that occurs after the administration of a medication or vaccine
2) Provide the name of the drug you suspect caused the adverse reaction.
3) The information of the person who had the adverse reaction.
4) Information about the person making the notification will also be needed

The electronic form in **Noti-FACEDRA** (available in the following URL www.notificacentroamerica.net) has "help" elements that are presented as a question mark.

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

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

ABOUT THE PROTECTION OF DATA INCLUDED IN Noti-FACEDRA

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

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

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

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

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

How to access the platform?

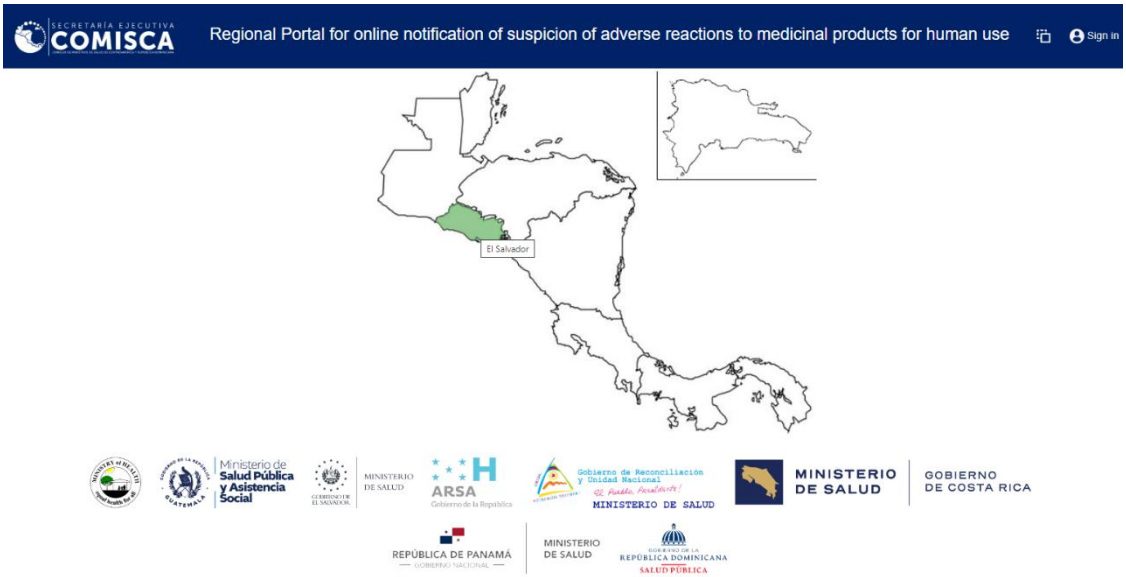
Regional Portal for Online Notification of Suspected Adverse Reactions to Drugs and Vaccines for Human Use, called **Noti-FACEDRA**, is available through an internet address www.Notificacentroamerica.net.

The online notification portal aims to facilitate the online notification of suspected adverse reactions to drugs or vaccines that are detected by health professionals, citizens themselves and the pharmaceutical industry, so that they are reported in an agile and timely manner to the National Pharmacovigilance Centers of the country where they reside.

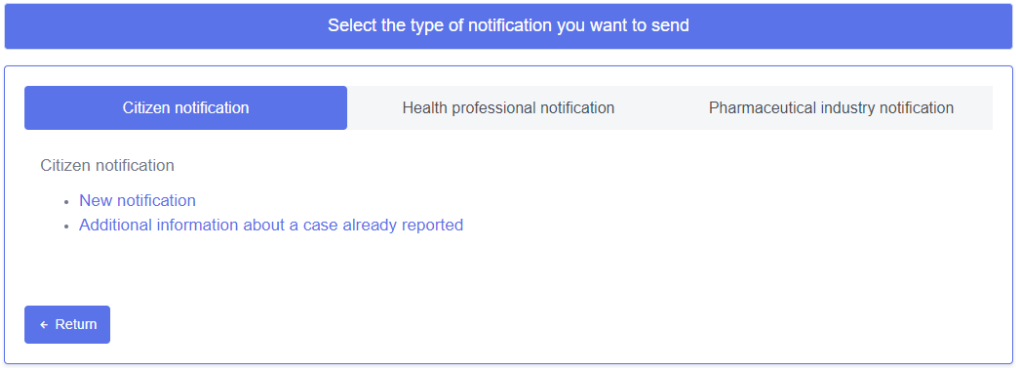
To access the platform, you must follow these steps:

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

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

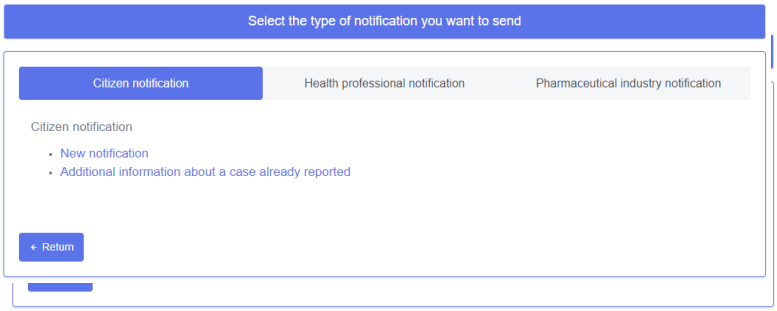


3 Then the **Main Menu** will be displayed, which consists of three options for the type of notification to be sent, you must select the **Citizen Notification** form to initiate the online report of suspected adverse reactions to medications or vaccines through **Noti-FACEDRA**,

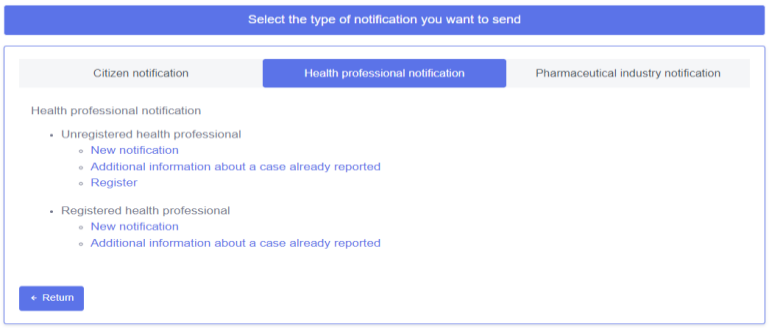


Main menu

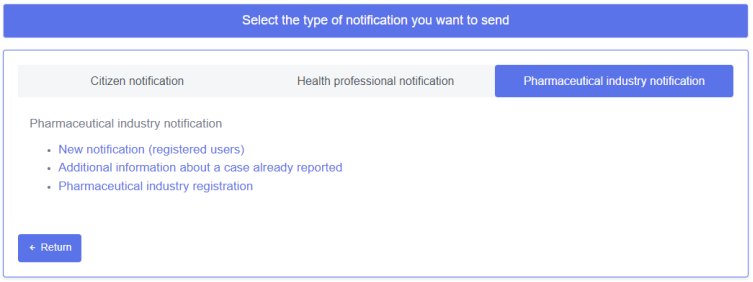
1. The first corresponds to access to the form called **Citizen Notification**, in which access is given to Citizens to directly notify suspected adverse reactions that are detected by them, this includes patients or their caregivers, in case of that the patient cannot do it directly.



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



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



Citizens notification process

In order for Citizens to be able to notify through the **Noti-FACEDRA** electronic form, they must have the necessary information for the notification process of suspected adverse reactions to a medication, including prescription, non-prescription, or herbal medications. Do not hesitate to do so if you suspect any problem with the use of these products.

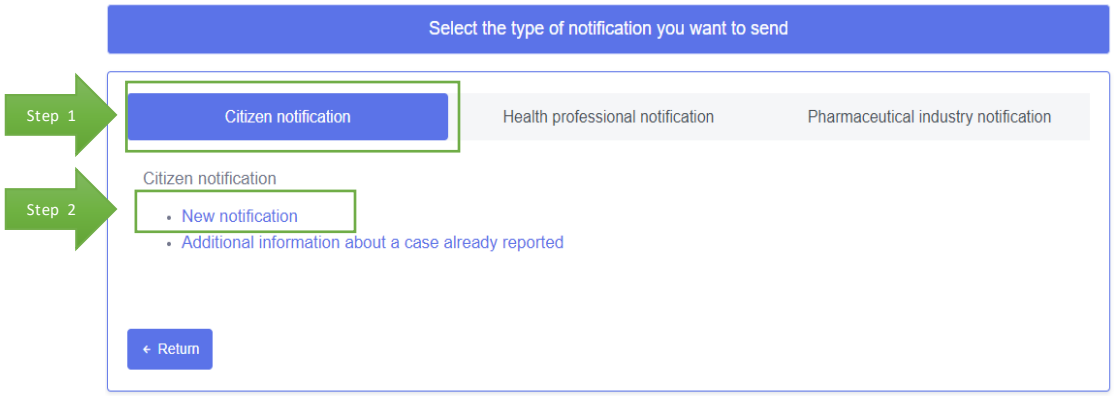
To fill out the form you need to provide information on four important aspects:

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

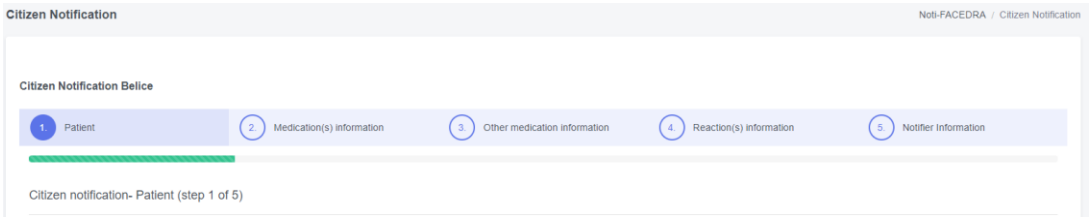
With this information available, Citizens have everything necessary to carry out the process of filling out the electronic form through **Noti-FACEDRA**.

The ***New Notification*** process by Citizens begins by following the following steps:

1. Select the **Citizen Notification** option from the main menu.
2. Then select the **New Notification** option to access the electronic case report form.

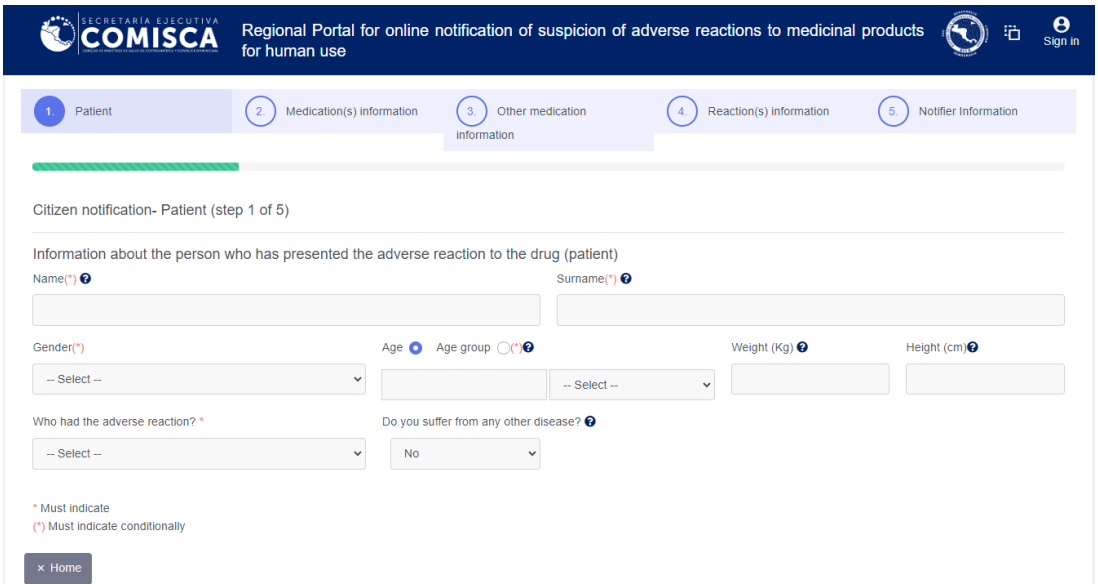


3. The fields of the notification form are presented, they must complement the information of the five sections shown in the following figure:



Patient Data

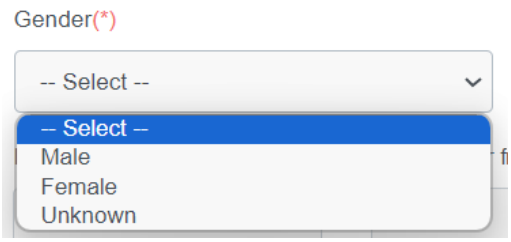
Step 1 of 5: You must place in this section the information related to the person (patient) who has had the adverse reaction to the medication or vaccine:



The following information must be completed:

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

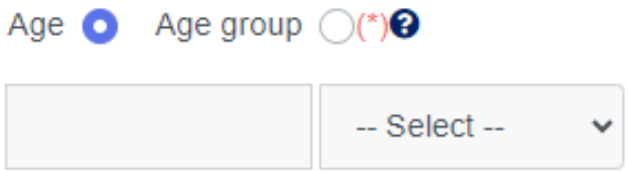
b. **Gender,** you must select one of the options shown in the list to establish sex of the patient, Male or Female, as the following figure shown:



The information marked (*) corresponds to mandatory information.

c. To report the **Age of the patient**, there are two possibilities. The first is by selecting the **Age** option, which allows you to enter a numerical value, accompanied by the

time unit in decades, years, days, hours, months or weeks, as shown in the following figure:



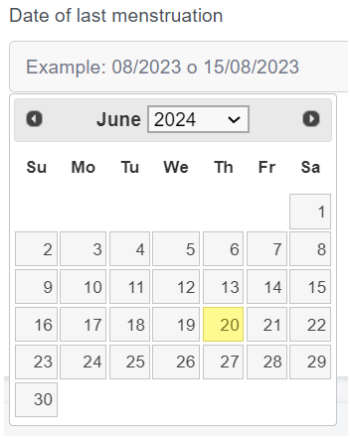
The second possibility is to select the **Age group** option, in which the patient's age is expressed by age groups, selecting one of the options Fetus, Newborn, Infant, Child, Adolescent, Adult or Elderly, as shown in the figure below:

The information marked (*) corresponds to mandatory information.

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

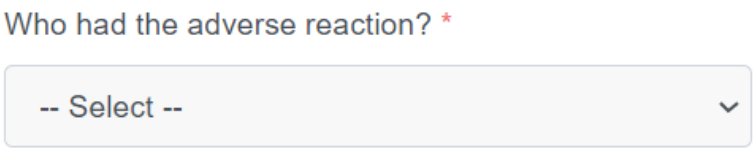
e. **For the Patient's Height,** its value must be indicated in centimeters, entering only the numerical value of the height.

f. **Date of last menstruation,** this field will be displayed only if the patient is female, the patient must indicate the date in month/year or day/month/year format. Example: 08/2023 or 01/08/2023. This information is not mandatory, so if you do not know or remember it, you can leave the field blank.



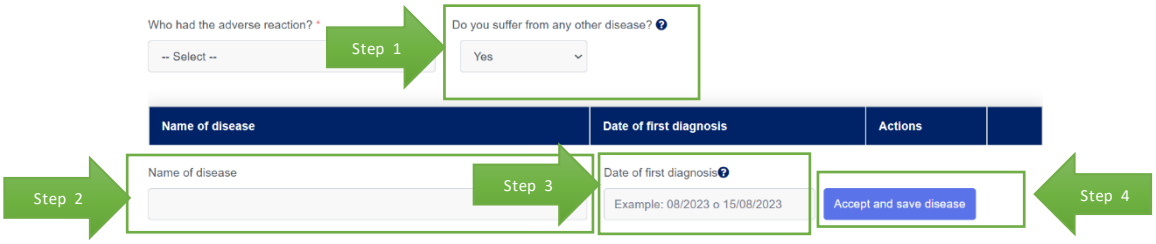
g. For the question of **Who has suffered the adverse reaction?** in this field it is necessary to select one of the three options shown in the figure.

This field is marked (*) which corresponds to mandatory information.



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

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



In the **Name of disease** field, you must enter the name of the disease you suffer from, a menu of medical terminology will assist you, you can select one of these terms to report the disease. In the second field, you must enter the **date of first diagnosis** in month/year or day/month/year format, if you do not know this information, you can leave the field blank.

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

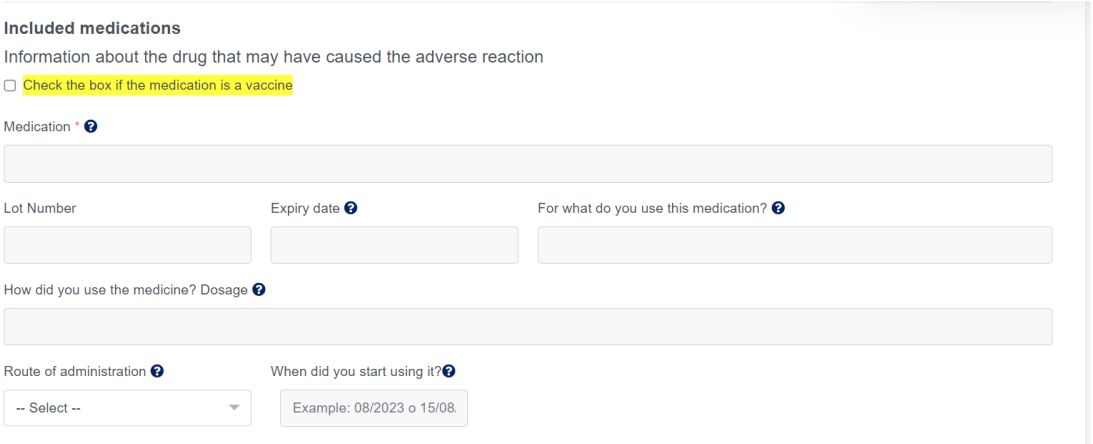
Step 1 ends when you complete the information and click the "Next" button.

Medication(s) information

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

Add a medication

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

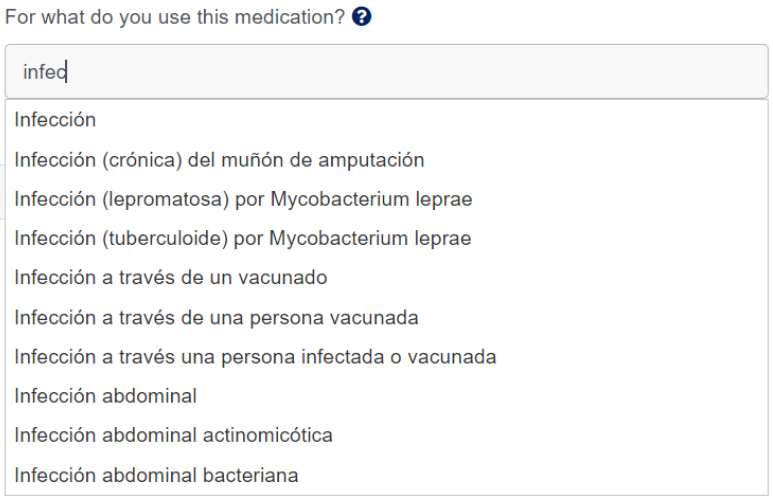


If you do not know or do not have available the name of the active ingredient of the medication, you can enter the commercial name of the suspected medication.

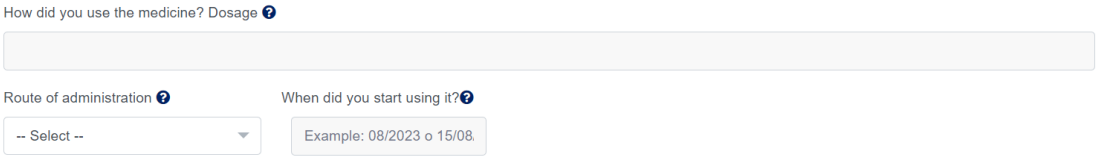
Please note that this is a field marked (*) that corresponds to mandatory information.

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

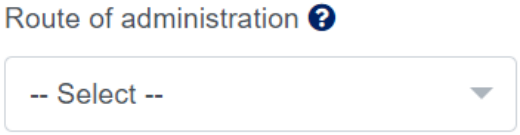
c) To answer the question: **What do you use the medication for?** the patient must enter the use for which the medication was indicated. As you type in this space, you can select one of the options from the drop-down list as shown in the figure below:



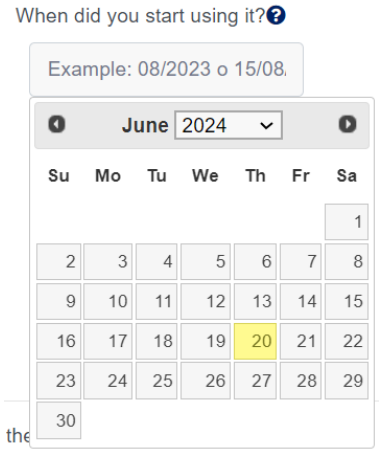
d) To answer the question: **How did you use the medication? (posology),** the patient must indicate in this space the way in which the medication was being taken, for example: one tablet every day or 500 mg twice a day.



e) 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:



f) To answer the question: **When did you start using it?** the patient must establish in as much detail as possible the date on which the use of the medication began. For this, the calendar modality shown below must be used:



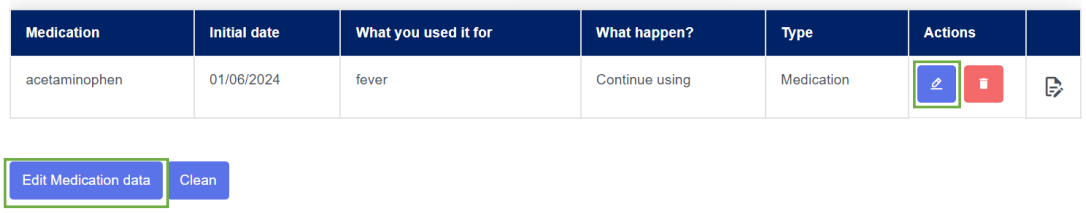
g) To answer the question: **What happened to the medication?** it is necessary for the patient to define what has happened with the use of the medication or the vaccine administered after the appearance of the suspected adverse reaction. To do so, they must select a of the four options shown below:

- If the option ***"It has stopped being used"*** is selected, the patient must establish the most exact date possible on which they stopped taking the medication. For this, the calendar mode must be used.
- If the option ***"It was stopped being used and was used again"*** is selected for this situation, the patient must answer the question if they have had a similar reaction again, selecting the option ***"Yes" or "No"***.
- If you use the ***"Continue using"*** option, it establishes that the patient used the medication until completing the entire indicated treatment period.
- If the option ***"Dose has been reduced"*** is selected, the patient must indicate the suggested modification, completing this information in the field called "Indicate amount/frequency", to do so, indicate the way in which the medication was taken, for example: a tablet every day or 500mg twice a day.

h) To finish recording the data of the medication suspected to be responsible for the adverse reaction, the patient must select the ***"Accept and save medication"*** button. With this action, the record of the suspected medication will be stored, presenting it in the format as follows:

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

i) If it is necessary to make any **correction to the information provided**, the patient can use the modify option to make the necessary changes. When the modifications are completed, they must select the **"Edit medication data"** button."



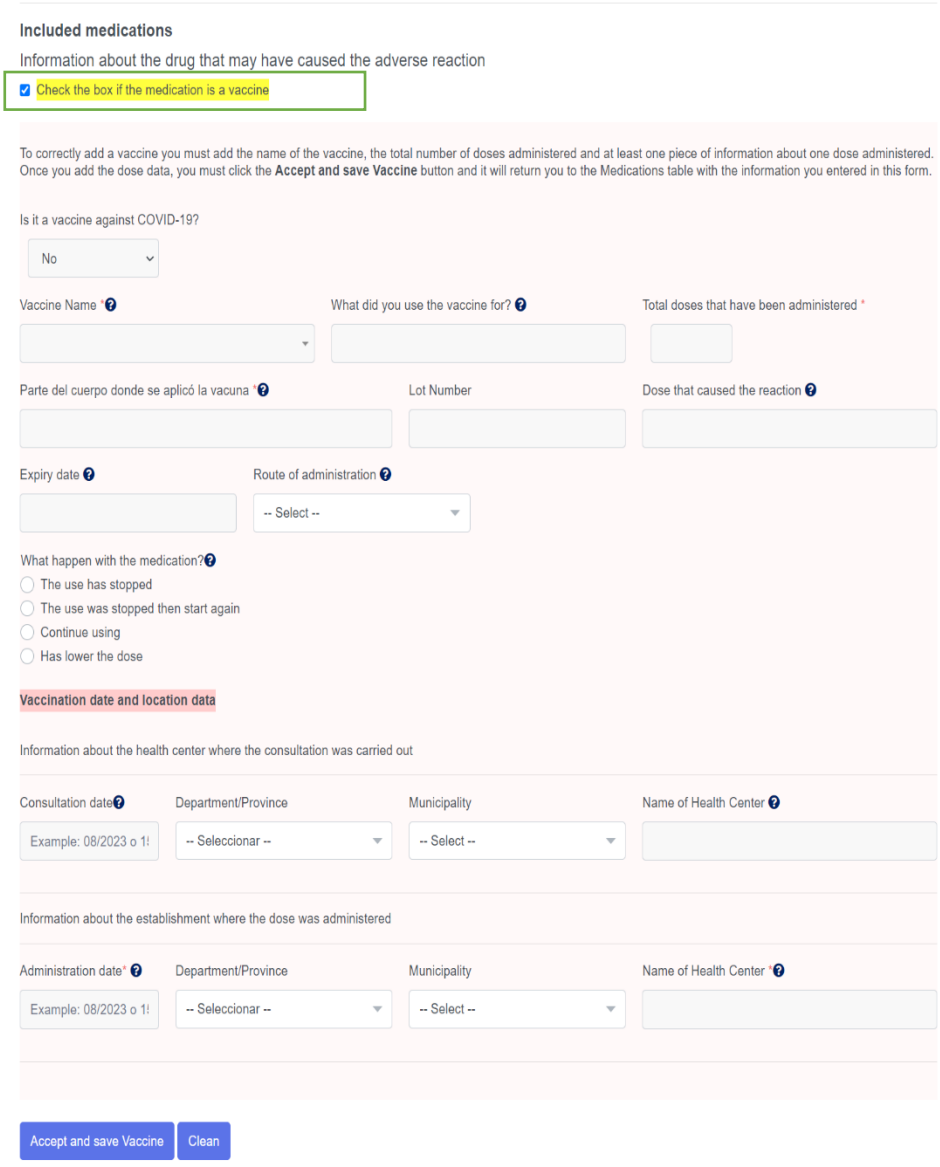
j) **Information about the health center where the consultation was carried out:** If the patient had a consultation at a health center, please provide the following information:

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

Report of suspected ADR from vaccines

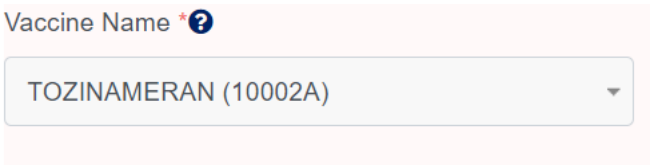
If you wish to report an adverse reaction to a vaccine, you must follow the steps detailed below:

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



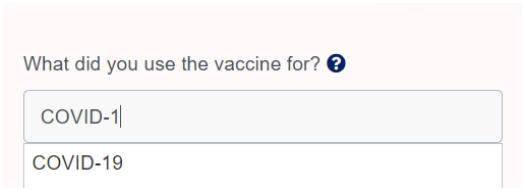
a) To answer the question: **Is it a vaccine against COVID-19?,** the patient must answer **Yes** or **No**.

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



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

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



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

e) **Total doses that have been administered,** you must indicate how many doses have been administered to the patient of the vaccine you report. For example, 1, 2, 3, etc.

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

g) **Dose that caused the reaction,** refers to the specific amount and frequency with which the doses were administered. Example: 0.3 ml, 0.5 mL, etc.

k) To answer the question: **What happened to the medication?** it is necessary for the patient to define what has happened with the use of the medication or the vaccine administered after the appearance of the suspected adverse reaction. To do so, they must select a of the four options shown below:

- ***"It has stopped being used"***
- ***"It was stopped being used and was used again"***
- If you use the ***"Continue using"*** option, it establishes that the patient used the medication until completing the entire indicated treatment period.
- ***"Dose has been reduced"***

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

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

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

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

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

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

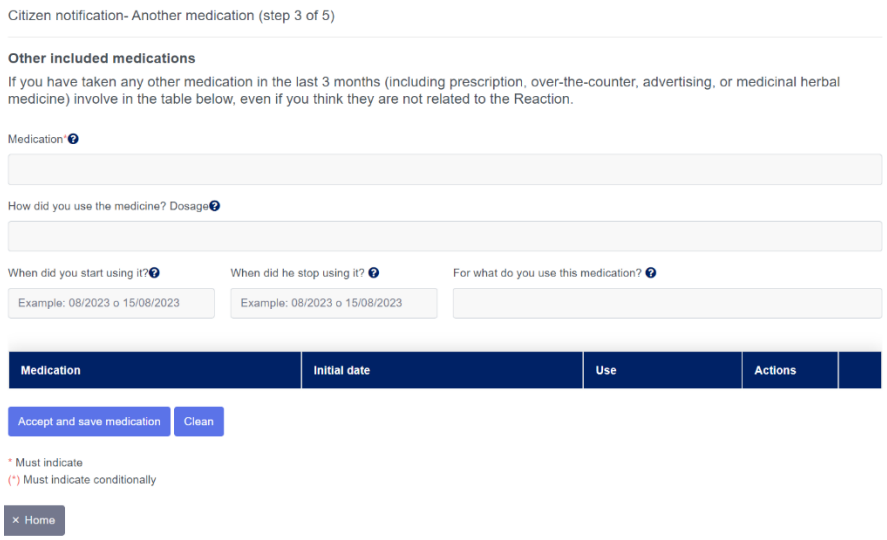
You can repeat the process to add the number of doses needed.

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

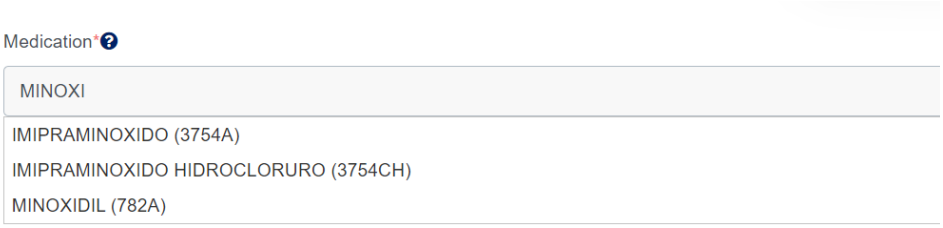
To finish the process, you must select the **“Accept and save vaccine”** button and then click the **“Next”** button.

Information of other medications

For step 3 of 5, called **"Other included medication"**, if the patient has taken any other medication in the last 3 months (including prescription, non-prescription, advertising or herbal medicines), even if they think they are not related to the reaction, they must include them in the following form:



a) **Medication,** to facilitate information about the medication, as you type in this space, you can select from the drop-down list the name of the active ingredient of the medication, as shown in the following figure:



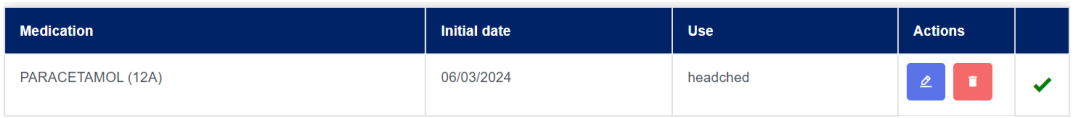
b) To answer the question: **How did you use the medication? (posology),** the patient must indicate the way in which the medication was being taken, for example: one tablet every day or 500 mg twice a day.

c) To answer the question: **When did you start using it?** the patient must establish in as much detail as possible the date on which the use of the medication began. To do so, they can use the month/year format of the start of use of the medication.

d) To answer the question: **When did you stop using it?** the patient must establish the most exact date possible on which they stopped taking the medication. To do this, you can use the month/year format for ending use of the medication.

e) To answer the question: **What do you use the medication for?** the patient must enter the use for which the medication was indicated. As you type in this space, you can select one of the options from the drop-down list as shown. in the figure below:

Once you fill out the information on the form, you must click on the **"Accept and save medication"** button. This will cause the medication information to be saved in the table as follows:

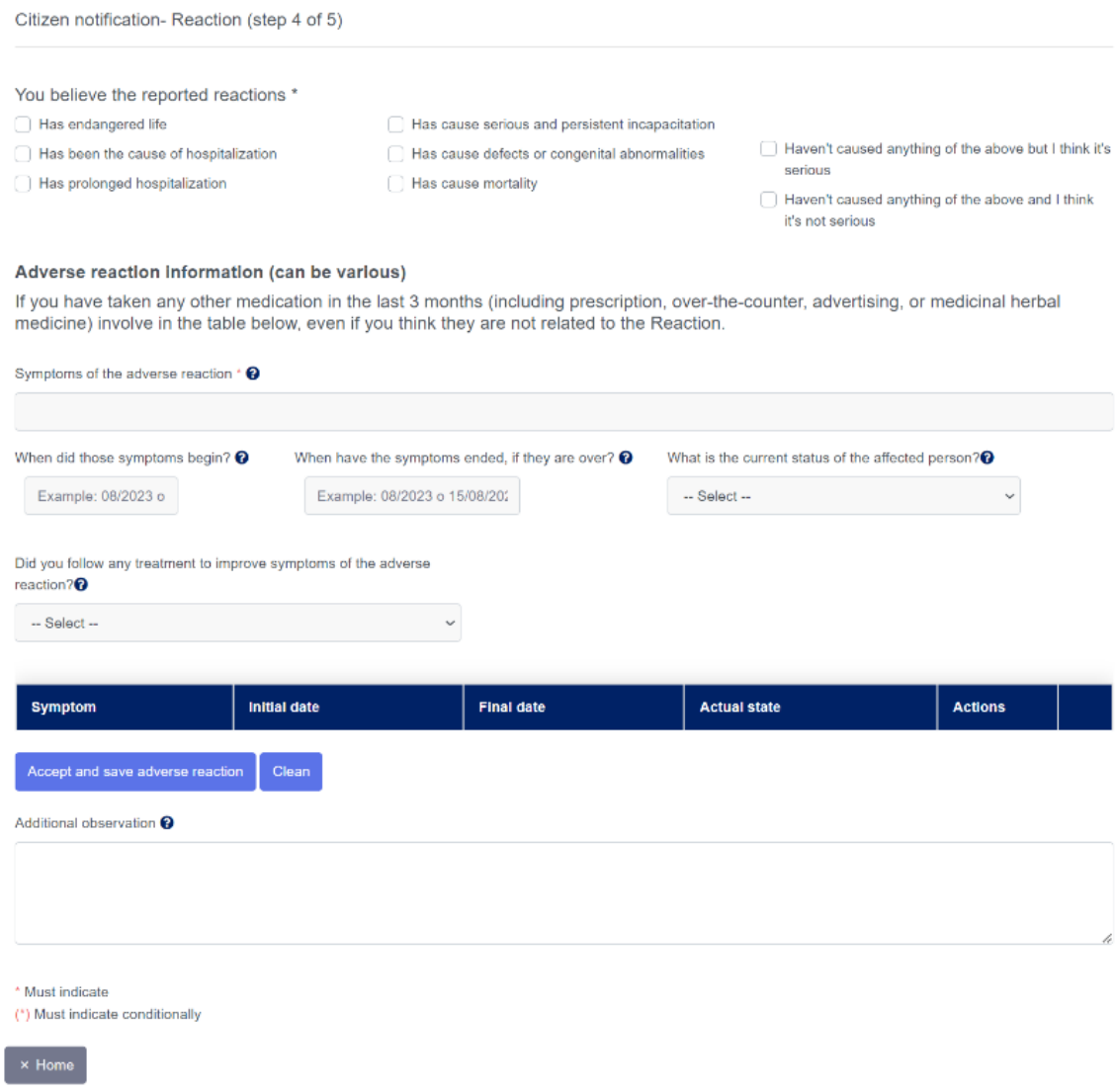


If it is necessary to make any correction, the patient can use the edit option, to make the necessary modifications, when finishing they must select the **"Edit Medication data"** button.

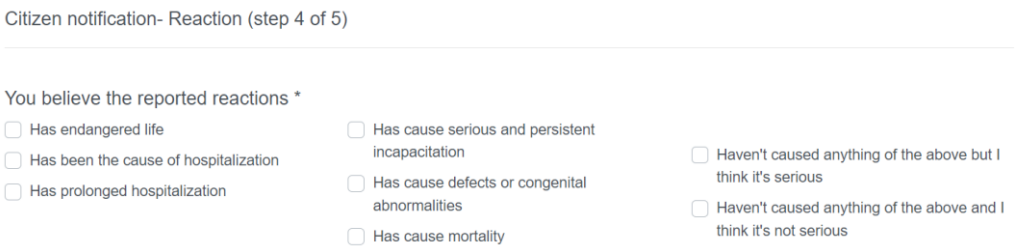
Once all the medications have been added to this section, you must click **"Next".**

Information of adverse reactions

For step 4 of 5, called **"Reaction(s) information"**, related to the necessary information on the possible adverse reactions that have been identified by the patient and that are presumably linked to the medications that the patient is using. For this the following information must be completed:

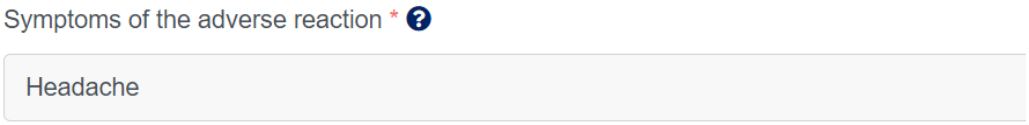


a) The Patient, according to the status of the adverse reaction that has occurred, must select one or more of the criteria shown in the following figure:



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

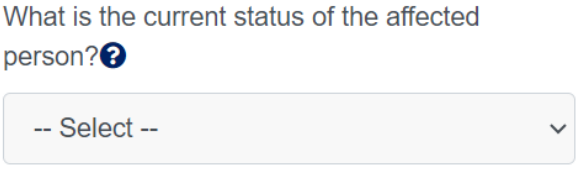
In the field called **"Adverse Reaction"** you must enter the adverse reaction that has occurred with the use of or medications used by the patient. As you type in this space, you can select from the drop-down list with the medical terminology that closer, as shown in the following figure:



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

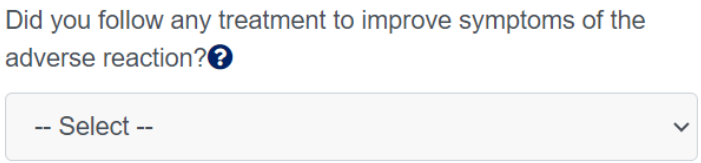
c) Next, you must provide the information on the **"Final Date"** of the adverse reaction, considering that for this information the patient must establish the most exact date possible on which the symptoms have disappeared, if it has happened. To do this you must use the calendar mode and you must enter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

d) To answer the question: **What is the current status of the affected person? at the time of the report**, you must select one of the options shown in the drop-down menu, as shown below:

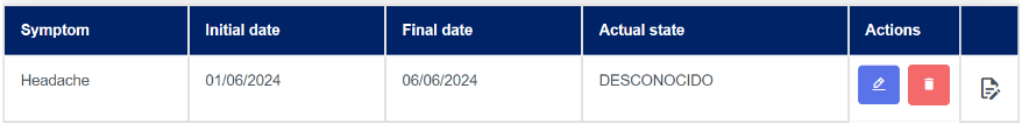


Please note that this is a field marked (*) that corresponds to mandatory information.

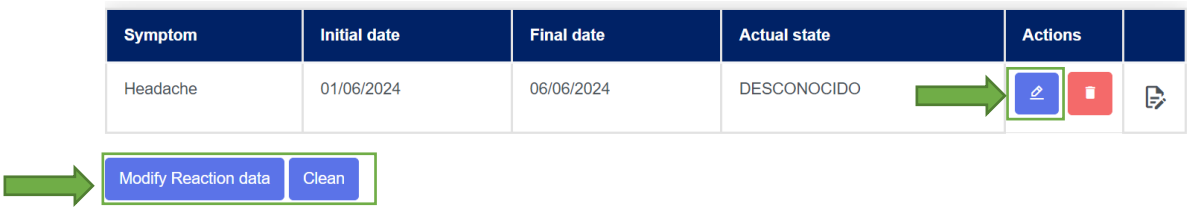
e) To answer the question: **Have you followed any treatment to improve the symptoms of the adverse reaction?** you must select one of the options shown below. If you have not received any treatment you must select the "No treatment" option.



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



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

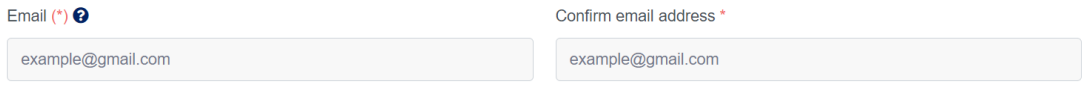


Notifier information

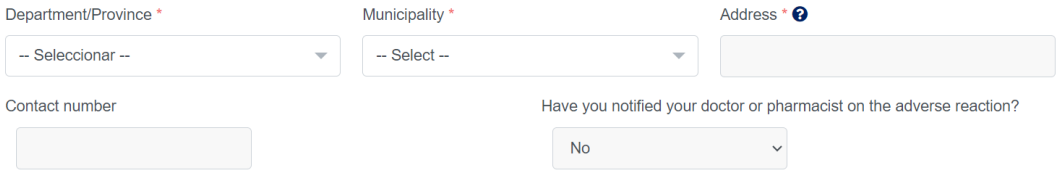
For step 5 of 5, This corresponds to the so-called "Notifier Information", this section details the general information of the person who makes the notification, and you must follow the following steps:

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

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



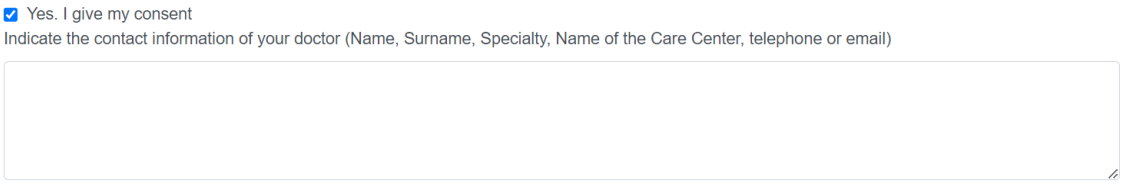
c) The notifier must provide a residence address to be able to contact you if more information is required about the reported case, including the details of the department/province, municipality of the country of notification, and must select one of the options shown in the drop-down menu, as well as also a telephone number, as shown in the following figure:



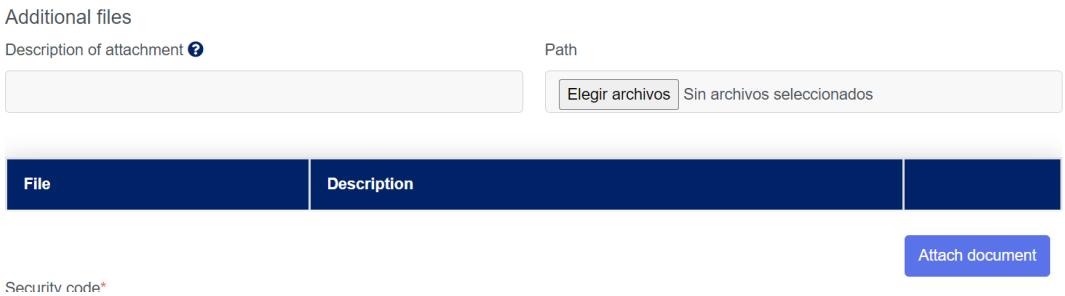
d) To answer the question: **Have you notified your Doctor or Pharmacist of the adverse reaction?** To do this, you must select **"Yes"** if you have already done so or otherwise select the option **"No"** or if you do not have information, select the **"Don't Know"** option.

e) If you have notified your doctor and are willing to give your approval (consent) to contact your treating doctor, you must click to activate the box that you must fill out

with the necessary information to contact you if necessary. necessary, as shown in the following figure:



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



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

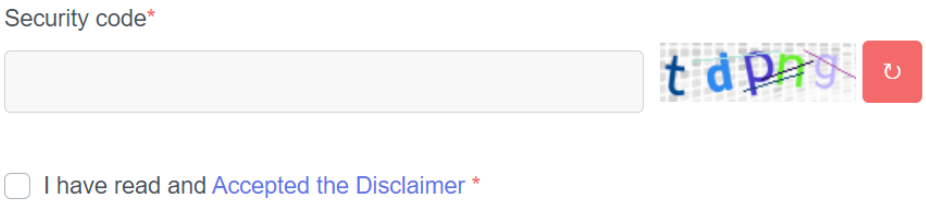
For the field called **"Path"**, you must indicate in which folder on your computer or device the file you want to attach is located.

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

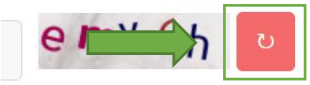
- For text files type: .DOC,
- For image files type: .JPG .GIF and .PDF type

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

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

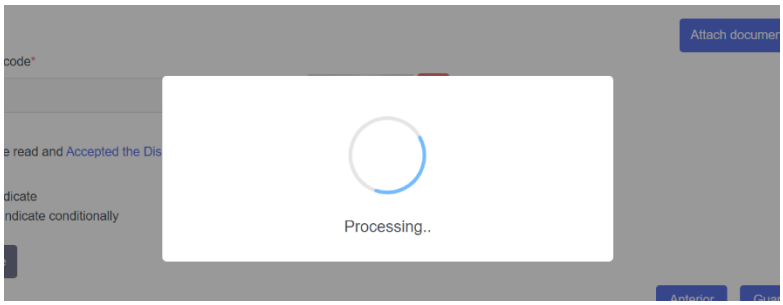


If it is not legible, you can update the image by clicking on the button



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

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



k) You will receive confirmation of sending the form.

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

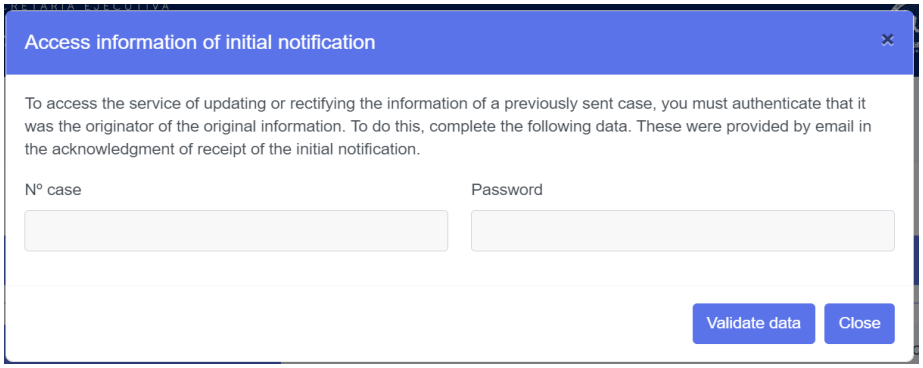
m) After downloading, the notifier will receive an acknowledgment of receipt to the email that was included in literal b), with a summary of the case, the case report code and a unique key for possible follow-up or contribution of more related information.

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

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

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

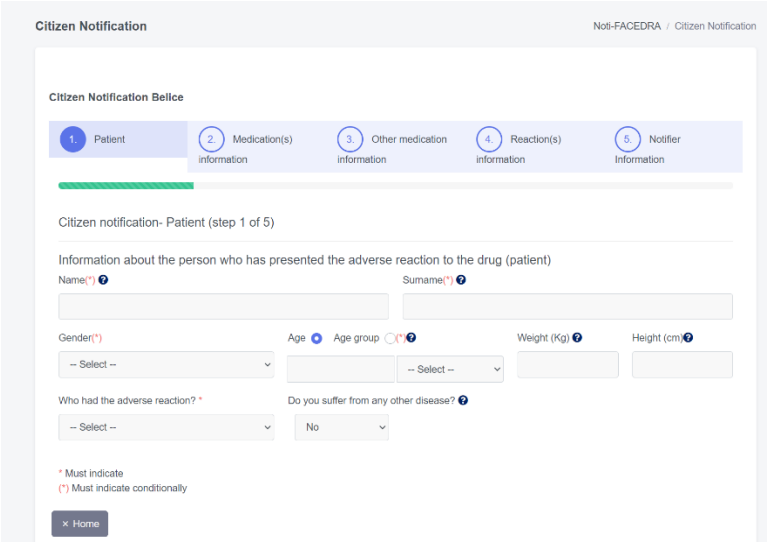
b) Upon having the information from step a), the notifier must access **Noti-FACEDRA** through the link www.notificacentroamerica.net, and click on **"Additional information about a case already reported"** in which the following screen will be displayed:



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

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

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



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

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

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

Frequent Questions

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

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

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

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

   If you are concerned about a suspected adverse reaction, you should discuss it with your doctor or pharmacist.

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

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

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

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

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

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

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

3. **What will happen to the notification I just send?** Notifications are collected and uploaded to a specialized

database that allows them to be quickly analyzed and evaluated.

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

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

4. **My notification is really important?** Yes, it is important. This helps to better understand the actual use of the medication or a vaccine, which will help ensure that medications are used safely.

We need this data in order to identify new adverse reactions or conditions in which they appear; this will reduce the risk of medication and thus optimize treatments.

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

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

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