



# **USER MANUAL**

# PHARMACEUTICAL INDUSTRY NOTIFICATION

# Noti-FACEDR

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, nonprescription, 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.
- Provide the name of the medication that you suspect caused the adverse reaction.
- 3) The data of the person who had the adverse reaction.
- 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 <u>www.notificacentroamerica.net</u>. 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:



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

FACEDR	Regional Portal for online notification of suspicion of adverse reactions to medicinal products for human use COMISCA SICA 9 sprin
Welcome to the Or	nline Notification System Noti-FACEDRA
Welcome to the electron	ic form of the Regional Online Reporting System of Suspected Adverse Reactions to medicines and vaccines for human use.
On this Website, you wi adverse reactions that o	III be able to report possible suspected adverse effects to medicines and vaccines for human use to the National Pharmacovigilance Centers in Central America and the Dominican Republic. This contributes to knowing the cour during the use of medicines that are authorized in the SICA Member States, in an agile and timely manner.
An adverse reaction can adverse reactions may r adverse reactions they o	occur after the administration of a medicine or a vaccine. These may not be expected or desired and can appear even after a person has stopped using the medication, or even after the administration of a vaccine while some not be discovered until many people have used the medication for a king period of time. For this reason, the contribution/support of citizens or patients, health professionals and the pharmaceutical industry to report suspected detect is needed, thereby contributing to the surveillance of the safe use of medicines in the Member States of SICA.
For more information ab Citizen Notification Man Health Professional Noti Pharmaceutical Industry	out the notification process we leave you at your disposat: uat (Click here) fication Manual (Click here) Voltatation Manual (Click here)
If you require support in	the notification process, contact notificedra@comisca net
	State State



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





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

Select the type of notification you want to send					
Citizen notification	Health professional notification	Pharmaceutical industry notification			
Health professional notification					
Unregistered health professional     New notification     Additional information about a case already reported     Register					
Registered health professional     New notification     Additional information about a case already reported					
* Return					

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## 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.

Citizen notification	Health professional notification	Pharmacoutical industry notification
ealth professional notification		
Unregistered health professional		
<ul> <li>New notification</li> </ul>		
<ul> <li>Additional information about</li> <li>Register</li> </ul>	t a case already reported	
· Registered health professional		
<ul> <li>New notification</li> </ul>		
<ul> <li>Additional information about</li> </ul>	t a case already reported	

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: <u>www.notificacentroamerica.net</u>. 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:

Registration information		
Username		
Username		
Data of the Laboratory Manager		
Name'	Sumame*	
Name	Sumame	
Profession *	Speciality	
- Select +	Select v	
Email (*)	Confirm email address (*)	
example@gmail.com	example@gmail.com	
Password (*)	Confirm Password (*)	
Introducir la contraseña	Repetir contraseña	
Pharmaceutical laboratory data		
Country	Department/ Province/ District *	City/ Town / Village *
Nicaragua 🗢	Seleccionar v	- Select - v
Name of pharmaceutical laboratory (*)	Industry Profile	Lab address
Name of pharmaceutical laboratory	Select *	Lab address
Contact number (*)	Security code (*)	
Contact number	Security code	b pp3 v

- 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:

Email (*) 🕑	Confirm email address *
example@gmail.com	example@gmail.com

• 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:

Password *	Confirm Password *	
Introducir la contraseña	Repetir contraseña	

- **c) Pharmaceutical Laboratory Data"** information, the laboratory must follow the following steps:
  - **Department/District/ Province:** You must select an option from the dropdown 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.

Pharmaceutical laboratory data					
Country		Department/ Province/ District *		City/ Town / Village *	
Guatemala 🗘		Seleccionar	-	Select	-
Name of pharmaceutical laboratory (*)		Industry Profile		Lab address	
Name of pharmaceutical laboratory		Select	-	Lab address	

- **"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:

Security code*	
	t d PAS 0

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

Must indicate	
Accept	× Home

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.

Log in		×
User Data		
Email	Password	8
	Log in I forgot my password	Close

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

Health professional notification	n Belice		
1. Patient	2. Medication(s) information	3. Reaction(s) information	4. Notifier Information

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 🖨 W
1. Patient	2. Medica	ation(s) information	3 Reaction(s)	information	(4) N	otifier Information
dverse Reaction Notification -	PATIENT					
nformation about the person what ame and sumame of patient(*)	no has prese	ented the adverse	e reaction to the dru Gender(*)	g (patient)	Medical Re	ecord Number
			Select	~		
ge 🗿 Age group 🔿 (*) 🚱	W	eight (Kg)	Height (cm)	Do you hav	e any other i	Ilness? 🔞
Select	~			No	~	

- 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:

ender(*)	
Select	~
- Select -	
Male	
Female	
Unknown	

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:

Age Age group O(*)	
Select	~

- 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.

Exa	mple:	08/2	023 o	15/08	/202	3
0	J	une	2024	~		0
Su	Мо	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
		11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

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.

#	Name of illness		Date o diagno	f Isis	Actions	
Name	of illness	Date of first diagnosis?				
fieb				Accept and	save illness	

\* Must indicate

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

#	Name of illness	Date of diagnosis	Actions	
1	Headache	01/04/2025	2	~
Name of	Date of first diagn	Sis P Accept and save	illness	
* Must ind (*) Must in × Home	skate ndicate conditionally			
	•		Previous	Net

## **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:

otification country: EI Sa	lvador				<b>Q</b> 🛱 W
1 Patient	2 Medication(s) in	formation	3 Reaction(s) inform	ation (4) No	otifier Information
Adverse Reaction Notif	ication - MEDICATION				
Included medications Health center information wh	ere the consultation was made on is a vaccine				
Medication * 😨				Suspicion*	
				- Select -	*
Lot Number	Expiry date 😧		Reason for prescription 🕑		
Posology 🕑				Route of administration 📀	
				- Select -	С.
Date of Onset 📀	Final date 📀		Action taken 'O		
Example: 08/2023 o 15/0	8/20 Example: 08/2023 o	15/08/20	- Select -	~	
Health center information wh	ere the consultation was made				
Query date 🕑	Department/ Province/ District	City/ Town	/ Village	Name Health Center 🕑	

#### 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:

Medication * 😧	
PARACE	
PARACETAMOL (12A)	

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:

Medication * 😧
Viro grip lemd
Viro grip lemon p.m. (PARACETAMOL, CLORFENAMINA MALEATO, Bromhidrato de dextrometorfano, Clorhidrato de fenilefrina) POLVOS SOLUBLES Laboratorios Vijosa
Viro grip lemon a.m. (PARACETAMOL, Bromhidrato de dextrometorfano, Clorhidrato de fenilefrina) POLVOS SOLUBLES Laboratorios Vijosa

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

dication * 🕐	
alsa	
alsartan (VALSARTAN) 160 mg TABLETAS RECUBIERTAS CON PELÍCULA (COMPRIMIDOS RECUBIERTOS CON PELÍCULA) Argus salu	1
alsartan (VALSARTAN) 320 mg TABLETAS RECUBIERTAS CON PELÍCULA (COMPRIMIDOS RECUBIERTOS CON PELÍCULA) Hetero labs	;

- 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:

Suspected*?		
Select	~	

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:

Reason	for	prescription	0
--------	-----	--------------	---

- 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:

Route of administration 😮	
Select	•

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:

Da	ate of	Onse	t 😮						
	Example: 08/2023 o 15/08/2023								
	0	A	pril	2025	~		0		
н	Su	Мо	Tu	We	Th	Fr	Sa	sultatic	
-			1	2	3	4	5		
Q	6	7	8	9	10	11	12	Depart	
	13	14	15	16	17	18	19	- Se	
Ч	20	21	22	23	24	25	26		
_	27	28	29	30					

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?	Туре	Actions	
acetaminophen	01/06/2024	fever	Continue using	Medication	2	₽

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 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.

Medication	Initial date	What you used it for	What happen?	Туре	Actions	
acetaminophen	01/06/2024	fever	Continue using	Medication	2	Ð
Modify Medication Informati	ion Clear					

- I) 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.

Check the box if medication	is a vaccine					
fo correctly add a vaccine, type /accine" and a table of medica	e the name of the va- tions with the informa	ccine, the total numbe ation provided will be	r of doses administered and at least one date displayed.	of one dose administered	d. Once entered, click on the bo	atton "Accept & Save
s it a vaccine against COVID-1	19?			Suspicion	0	
No 👻				- Selec	d	Ŷ
/accine Name * 😧			What did you use the vaccine for?	0	Number of doses admin	istered *
Inatomical site where the vaco	ine was applied 'O		Lot Number	Reason fo	or prescription 😧	
Expiry date 😧	F	Route of administration	0			
		- Select -	×.			
What happened with the medic	ation? "					
Select	~					
laccination data and location	data					
vaccination date and location	n uata					
nformation about the health ce	inter where the const	ultation was carried or	t.			
Consultation date	Department/ Prov	ince/ District	City/ Town / Village	Name He	aith Center 😧	
Example: 08/2023 o 15/08	- Select -		- Select	-		
nformation about the establish	ment where the dose	e was administered				
				Nome Line	allh Contact	
Idministration date *	Department/ Prov	ince/ District	City/ Iown / Village	Name He	aun Center V	

- 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.

Vaccine Name *?	
TOZINAMERAN (10002A)	•

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:

What did you use the vaccine for? 3
COVID-1
COVID-19

- 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 dropdown list.

Action taken*	
Select	~

 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:

rou believe that the reaction/s re	ported*				
Has endangered life	Has caused set	erious and persistent incapac	itation		
Has been the cause of hospitalization	Has caused d	efects or congenital abnorma	lities Has not cau	ias not caused any of previously provided optic at 1 think it is serious	
Has prolonged hospitalization			Has not cat options me	used any of of previously provided ntioned and I think it is not serious	
ymptoms of adverse reaction *					
Vhen did those symptoms begin? * 😧	When have the symptoms ended	t, if they are over? 😧 W	hat is the current status of th	e affected person? '	
Vhen did those symptoms begin? * @ Example: 08/2023 o 15/08/2023	When have the symptoms ended Example: 08/2023 o 15/08/20	I, if they are over? • W	hat is the current status of th	e affected person? "	
When did those symptoms begin? * Example: 08/2023 o 15/08/2023 bid you follow any treatment to improve seaction?	When have the symptoms ended Example: 08/2023 o 15/08/20 symptoms of the adverse	d, if they are over? • W	hat is the current status of th	e affected person? "	
Vhen did those symptoms begin? * Example: 08/2023 o 15/08/2023 Vid you follow any treatment to improve s eaction? Select	When have the symptoms ended Example: 08/2023 o 15/08/20 symptoms of the adverse	8, If they are over? • W	hat is the current status of th	e affected person? "	

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:

ONS	
Has caused serious and persistent incapacitation	
Has caused defects or congenital abnormalities	Has not caused any of previously provided options
Has caused mortality	but I think it is serious
	<ul> <li>Has not caused any of of previously provided</li> </ul>
	ONS  Has caused serious and persistent incapacitation Has caused defects or congenital abnormalities Has caused mortality

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:

Symptoms of the adverse reaction * 😯
Headache

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:

Outcome *?		
Select	~	

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.

Treatment 🕜	
Select	~

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:

Symptom	Initial date	Final date	Actual state	Actions	
Headache	01/06/2024	06/06/2024	DESCONOCIDO	2	ß

 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.

Symptom	Initial date	Final date	Actual state	Actions	
Headache	01/06/2024	06/06/2024	DESCONOCIDO		B
Modify Reaction d	ata Clean				

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:

Type of notification*	
Espontánea	~

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:

otification country: El Salvador	r			Q 🔒 V
1. Patient	2. Medication(s) information	3. Reaction(s) in	formation	4. Notifier Information
Adverse Reaction Notificatior	1 - REPORTER			
Information about the notifier Name*		Surname*		
Name		Surname		
Profession*		Speciality		
Select	~	Select		~
Email (*) 🕜		Confirm email address	*	
example@gmail.com		example@gmail.com	1	
Industry Profile	Type of center		Workplace*	
Select	- Desconocido	~		
Department/ Province/ District*	City/ Town / Village *		Address * 🕜	
Ahuachapán	·	-		
Contact number				

- a) For the information of the person who fills out the electronic form of Noti-FACEDRA2.1, 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:

Profession*	
Select	~

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:

Email (*) 🚱	Confirm email address *
example@gmail.com	example@gmail.com

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:

Speciality	
Select	-

- 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:

Industry Profile	Center Type	Workplace"
Fabricante	- Select 🗸	Laboratorio Farmacéutico
Department/ Province/ District*	City/ Town / Village *	Address * 😧
Carazo	r	cantón el papalón

g) If necessary, to provide more information related to the reported case, the patient may attach files to the report, as shown below:

escription of attachment		Path
		Elegir archivos Sin archivos seleccionados
File	Description	

Security code\*

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,

I have read and Accepted the Disclaimer\*

- 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:

t d Pars o

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:



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

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Notification Successfully Submitted Notification Summary Patient Data Successfully Loaded Medication Data Successfully Loaded Other Medications Successfully Loaded Reaction Data Successfully Loaded Notifier Data Successfully Loaded	$\checkmark$	
Patient Data Successfully Loaded ⊘ Medication Data Successfully Loaded ⊘ Other Medications Successfully Loaded ⊘ Reaction Data Successfully Loaded ⊘ Notifier Data Successfully Loaded ⊘	Notification Successfully Submitted Notification Summary	
Medication Data Successfully Loaded Other Medications Successfully Loaded Reaction Data Successfully Loaded Notifier Data Successfully Loaded	Patient Data Successfully Loaded ⊘	
Other Medications Successfully Loaded O Reaction Data Successfully Loaded O Notifier Data Successfully Loaded O	Medication Data Successfully Loaded 🥝	
Reaction Data Successfully Loaded O	Other Medications Successfully Loaded ⊘	
Notifier Data Successfully Loaded O	Reaction Data Successfully Loaded 🥝	
	Notifier Data Successfully Loaded 🥝	
Files Successfully Loaded 🥝	Files Successfully Loaded 🥝	

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.

ACEDRA	FACEDRA
ONLINE NOTIFICATION EVITER NOTIFICATION EVITER NOTIFICEDAA ONLINE NOTIFICATION EVITER NOTIFICEDAA Constry Coda Rus Tabiloson Lancer ICAROB Isabiloson Dak 1994005	Annual Annu
Following: No	How was the medication use/2 (Douge and passing): 1 at the Nat John 02/002. End John
New experimental the advance reaction? Un tendar See Fernances New Ferna	REALTON) Republic Accilian. Here are used and distances instantic actions and from the order
Other spycels litens         Object           I         Bitess litens         Object           disferes         020002	Information down the advance reaction (there may be multiple) Include the symptomic that made you support as advance reaction; Uncorrelated/MA) Base date: 30010205 E-04 date: 00102028 What is the convert condition of the advance yourset. DirectConfUSAC/CON(IN EDEXCOOD)
Information about the realization has high box scaled file adverse resultion hypothet: Topophysics toticulation Asseptions: @IREEAATA40 SB ing LFABLETA4.COMPRISCOD; Lakensteine Steller Minist all the resultation and the Topophysical/Add/Add/Add/Add/Add/Add/Add/Add/Add/Ad	Treatment Fernanslepice Additional observations: une de fraincurritionna trapica une est pi dia
Rule of administration, ORAL	NOTIFIES
Mar Nagwar with the reductors' Tiggue additionals for later manufactor (5 table embarazate en of moments de la medicación? Teo. Jamp Sen: 305/3025 March Center where consultation was melar clinica comund	Mehanakan akain Pa panasa nakamiting Ma kelifasakan Fud tama Robasa Alayat DAZ COTCULANA Emark tamang/MBBBBAK con County Cottos Roa ProvinceColganitamic Calagia Caf Tamur Vitaga La Unios Wangkaa anitamis Farina a In Permijan Naunta Tantan Berlan din Pitar
(1961) NEXOCATION If you have taken any other medication in the last 3 membe (including prescription drugs,	Contact planer. 271450000 Heav you reported the adverse reaction to plan dactor or planmacist? No Contact consent No
Protect day 7	

 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:



# 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 <u>www.notificacentroamerica.net</u> and click on "Additional information on a case already notified" where the following screen will be displayed:

		×
o access the services for updating or rectifying the nat you were the original case reporter. These we he official notification.	ne information of a previously submitted case, you must authenticate are previously provided via email in the acknowledgment of receipt in	e n
ase Notification Number	Password	
	8	2

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:

Notification Tracking by Notification Number: NCA64345 , reported in Nicaragua

1. Patient	2	Medication	n(s) information	3. Reaction(s) information		4. Notifier Information	
Adverse Reaction Notification .	PATIENT						
Information about the person w	ho has presented the a	dverse re	eaction to the drug (patient)				
Name and surname of patient(*) 🖗				Gender(*) Select	~	Medical Record Number	
Age 🗿 Age group 🔿 🕐 🛛			Weight (Kg)	Height (cm)	Do you have any	other illness? 🕖	
	Select	۷			No	*	
* Must indicate (*) Must indicate conditionally							

- 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.

Gracias por utilizar el servicio de actualización o rectificación en línea de Sospechas de Reacciones Adversas a Medic ha facilitado ha sido guardada en nuestros sistemas asociad NCA64333	On-Line de Sistema Regional de Notificación amentos:Noti-FACEDRA. La información que nos os a la notificación inicial con el siguiente código:
Podrá volver a enviar más actualizaciones o rectificaciones o referenciando la misma notificación inicial, cuya contraseña	oor el mismo medio. Recuerde que lo deberá hacer es la siguiente:iEs6CGTjkafq
También puede acceder directamente al servicio utilizando e	l siguiente link:
Para cualquier consulta o duda, así como para ejercer sus d facilitado, puede ponerse en contacto con nosotros en el sig	erechos sobre los datos personales que haya uiente correo electrónico:
Contacto: Centro Nacional de Farmacovigilancia República I ministeriodesalud.gob.do	Dominicana, E-mail: <u>farmacovigilancia@</u>

ê 🛛

## 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:

Registration information				
Username				
Username				
Data of the Laboratory Manager				
Name*		Surname*		
Name		Surname		
Profession *		Speciality		
Select	٥	- Select v		
Email (*)		Confirm email address (*)		
example@gmail.com		example@gmail.com		
Password (*)		Confirm Password (*)		
Introducir la contraseña	8	Repetir contraseña		
Pharmaceutical laboratory data				
Country		Department/ Province/ District *		City/ Town / Village *
Nicaragua	¢	- Seleccionar v		- Select - v
Pharmaceutical Laboratory Name (*)		Industry Profile		Lab address
Pharmaceutical Laboratory Name		- Select *		Lab address
Contact number (*)		Security code (*)		
Contact number		Security code	12	XQt/N 0

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:

Email (*) 😧		Confirm email address *
example@gmail.com		example@gmail.com

 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:

Password *	Confirm Password *	
Introducir la contraseña	Repetir contraseña	

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.

Pharmaceutical laboratory data Country	Department/ Province/ District * City/ Town / Village *			
Nicaragua 🗘	Seleccionar	•	Select	-
Pharmaceutical Laboratory Name (*)	e (*) Industry Profile Lab address			
Pharmaceutical Laboratory Name	Select	•	Lab address	

• 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.

Contact number *		
Contact number		

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

Security code*	
	t d Pars o

• 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"

WHODrug License	
4545 Verify License	
MedDRA License	
55555 Verify License	

\* Must indicate

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

	WHODrug license successfully registered			
wн	DDrug License			
		0	Verificar Licencia	

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.





Medication * 📀	Suspicion ??	
viro grip	- Select -	~
Viro grip lemon p.m. (PARACETAMOL, CLORFENAMINA MALEATO, Bromhidrato de dextromet	orfano, Clorhidrato de fenilefrina) POLVOS SOLUBLE	S Laboratorios Vijo
Viro grip a.m. (PARACETAMOL, Bromhidrato de dextrometorfano, Clorhidrato de fenilefrina) CÁ	PSULAS Laboratorios Vijosa	
Viro grip p.m. (PARACETAMOL, DOXILAMINA SUCCINATO, Bromhidrato de dextrometorfano, d	Clorhidrato de fenilefrina) CÁPSULAS Laboratorios Vij	osa
Viro grip (PARACETAMOL, CLORFENAMINA MALEATO, Bromhidrato de dextrometorfano, Ácid	lo ascórbico, Clorhidrato de pseudoefedrina) JARABE	Laboratorios Vijosa
Viro grip (MOROXIDINA, CLORFENAMINA MALEATO, Clorhidrato de fenilefrina, Metamizol sóc	tico) AMPOLLAS Laboratorios Vijosa	
Viro grip lemon a.m. (PARACETAMOL, Bromhidrato de dextrometorfano, Clorhidrato de fenilefrir	na) POLVOS SOLUBLES Laboratorios Vijosa	

**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".

Add License Information			
WHODrug License			
4545	0	Verify License	
MedDRA License			
55555	0	Verify License	

\* Must indicate

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

MedDRA license successfully registered

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.

Add User → Edit User Ø		
Show 10 ¢ entries		
Name	↑↓	User
Rebeca Abigail Diaz Orellana		xohoke9111@lassora.com

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.

Notifier information	
Name*	Surname*
Name	Surname
Profession *	Speciality
Select \$	Select 💌

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.

Contact number *	Security code *	
7934442	Security code	db ex 3 v
Active		
Si		
* Indica obligatoriedad		
Accept × Cancel		

## **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.

Pharmaceutical industry								
久 20 Notifications Reported		⊘ 1 Notificati	ons in the mo	nth of April		⑦ 7 Serious	Notifications	Reported
Role	Associated Use	ers 🕑		Severity		Start Date		End Date
Select	- Select		-	Select		dd/mm/aaaa		dd/mm/aaaa
Action Search Clear Add + Additional Information (8)								
Show 10 ¢ entries								search:
Case number 11 Notification	date ↑↓	Initial Case	Notification t	/pe	†. Se	everity	Actions	
NCA64334 03/04/2025		NO	Pharmaceutica	al industry	N	DT SERIOUS	View versions	View details
Showing 1 to 1 of 1 entries								Previous 1 Next

a) Information on the number of notifications made



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.

Add					
Show 10 🗢 entries				Search:	
Case number 1	Notification date	Initial Case	Notification type	Severity	Actions
NCA64345	27/03/2025	YES	Health professional	SERIOUS	View versions View details
NCA64342	25/03/2025	YES	Health professional	SERIOUS	View versions View details

b. Click on the "Additional Information" button



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

Patient	2. Medication(s)	nformation 3.	Reaction(s) information	4. Notifier Information	
se Reaction Notificati	on - PATIENT				
nation about the perso	on who has presented the adverse re	eaction to the drug (patient)			
and surname of patient(*)	>	Gender	")	Medical Record Number	
		Sel	ect	¥	
Age group (*)	Weig	Iht (Kg) Height (	cm) 🖗 Do you ha	e any other illness? 🚱	
	Select 🗸		No	*	
f) Resenc a.	d notification pass Click on the <b>"Vie</b>	word <b>w versions"</b> but	ton for the corr	esponding case	Netx Previous
f) Resenc a.	d notification pass Click on the <b>"Vie</b>	word <b>w versions"</b> but	ton for the corr	esponding case	Netx Previous
f) Resence a.	d notification pass Click on the <b>"Vie</b>	sword w versions" but	ton for the corr	esponding case	Neb: Previous C. Actions
f) Resence a. Case number NCA64345	d notification pass Click on the <b>"Vie</b> Notification date 27/03/2025	word w versions" but	ton for the corr	esponding case	Neb: Previous C. Actions Were versions Were versions Were details
f) Resence a. Case number NCA64345	d notification pass Click on the <b>"Vie</b>	word w versions" but	ton for the corr	esponding case	Neb: Previous C. Actions Vew veniors Vew details
f) Resence a. Case number NCA64345	d notification pass Click on the <b>"Vie</b> 11 Notification date 27705/2025	sword w versions" but ii Initial Case YES	Notification type Health professional	esponding case	Neb: Previous
f) Resence a. Case number NCA64345 b.	d notification pass Click on the <b>"Vie</b> 11 Notification date 27703/2025 Click on the <b>"Res</b>	sword w versions" but i Initial Case YES wend Password"	ton for the corr	esponding case	Neb: Previous e. Actions / Vew versions / Vew deals
f) Resence a. a. case number NCA64345 b.	d notification pass Click on the <b>"Vie</b> Notification date 27703/2025 Click on the <b>"Res</b>	sword w versions" but	ton for the corr	esponding case	Net: Previous e. Actions (Vew versions (Vew versions) (Vew version
f) Resence a. a. case number NCA64345 b. 0 • entries	d notification pass Click on the <b>"Vie</b> 1 Notification date 27/03/2025 Click on the <b>"Res</b>	sword w versions" but i Initial Case YES send Password" # Follow-up 11 No	tton for the corr	esponding case	Netz Previous e. Actions (Vew versions) Vew-details DW-upps. Search:

Showing 1 to 1 of 1 entries

#### g) To download the PDF of the notification

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

<complex-block>And the set of the se</complex-block>	Case number	1 Notification date	Initial Case	Notification type	Severity	Actions
<complex-block></complex-block>	NCA64345	27/03/2025	YES	Health professional		View versions
<complex-block></complex-block>						View details
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## **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.

verse reactions to	medicinal		Centreamericans	<b>e</b> Rebeca
bril	⑦ 7 Seri	ous Notifications Rep	orted	

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

FACEDRA	Regional Portal for online products for human use	notification of suspicion of adverse reactions to	o medicinal COMISCA SICA	8 Rebeca
Pharmaceutical industry				습 My profile 급 Report management 수 User Management ④ Sign out
久 20 Notifications Rep	orted	1 Notifications in the month of April	7 Serious Notifications Reported	

## **Frequently Asked Questions**

 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 report to 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.  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: <a href="mailto:mssohelp@meddra.org">mssohelp@meddra.org</a>

WHODrug: support@who-umc.org



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

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