Instructions for the use of e-Reporting for health professionals and patients/consumers
Reporting of adverse drug reactions

e-Reporting is a standardized electronic format for reporting adverse drug reactions (diseases caused by drugs) developed to facilitate reporting by healthcare professionals and patients/consumers. Notifications entered in this electronic format are transmitted directly and immediately to the database of the National Pharmacovigilance Center. The updated interface of e-Reporting allows its use on mobile devices and tablets.

1. Objective

Guide health professionals and patients/consumers about the correct filling of the fields corresponding to the e-Reporting format.

2. Entry to e-Reporting

You can enter e-Reporting through two ways:

1) Through the following link:
https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=MX

2) Through the Cofepris website a. **https://www.gob.mx/cofepris** b. On the main screen, in the "LINKS OF INTEREST" section, click on **"Did a medicine hurt you?"** c. On the page How to report a suspected adverse reaction? Click on the e-Reporting link.

The initial screen that will be displayed will be the following *(verify the national logos):*

Note: Before starting to enter the information, make sure that the logos in the header of the page correspond to those of Cofepris and the Ministry of Health.

Next, click on the box that says “I accept the terms and conditions”. You can review these by clicking on the green text and a window with the information will be displayed. Subsequently, the two boxes will be activated that indicate the type of notifier that corresponds, that is, who fills out the electronic form (patient/consumer or a health professional).

Click on the box corresponding to your profile.
Next, the format will be broken down according to the one chosen.

Note: Mandatory fields are indicated with a red asterisk (*). If this information is not available, perform a search in order to send the report to the National Pharmacovigilance Center as complete as possible.

If you choose the "Healthcare professional notification" profile, go to point 4 of this instruction.
If you choose the "Medication user/patient notification" profile, continue with point 3 of this instruction.

3. Notification of patient or consumer (user of the medication/patient).

First page

3.1 Describe what happened*, detail in chronological order in your own words what ailments occurred after consuming the medication(s); include relevant details, dates, medications used, signs, symptoms, illnesses, reactions, laboratory results, or any other relevant situation that provides useful information to analyze the case.

After filling in the field, you will find the section **"Reaction(s)/Symptom(s)",** where you must provide the following information: • **Reaction/Symptom*:**

Describe each adverse reaction or discomfort caused by the medication. Examples: Throbbing headache, dizziness, rash, myalgia, itching, etc.

- **Reaction onset date*:** Enter the date on which the adverse reaction or discomfort began in the format *dd/mm/yyyy* (IF YOU DO NOT KNOW THE DATE COMPLETE, YOU CAN ENTER AT LEAST THE YEAR)
- **End Date:** Enter the date the adverse reaction or discomfort disappeared in the format *dd/mm/yyyy* (IF YOU DO NOT KNOW THE COMPLETE DATE, YOU MAY ENTER AT LEAST THE YEAR). If the reported reaction/discomfort continues, leave this field blank.

- **Duration of the reaction or discomfort:** In the free field, enter the amount of time and from the catalog select the corresponding unit of time. If the reported reaction/discomfort continues, leave this field blank.
- **Current state of the reaction/symptom:** Choose from among the options, the state in which the patient/medication user is currently in regards to the reaction or discomfort reported:

  o Recovered/Resolved: Choose in the case where the reaction no longer occurs and was resolved without generating consequences for the patient/consumer. o In Recovery/In resolution: Choose when the patient/consumer shows improvement in their health status, but still has symptoms related to the event.

  o Not recovered/Not resolved: Select if the event or symptom still manifests itself in the patient/consumer.
  o Recovered with sequelae: Choose in the case where the reaction no longer occurs or has been resolved, but it generated a consequence for the patient/consumer. o Mortal: Choose if the patient died after the event. or Unknown; the current status of the patient is unknown.

- **Did the reaction produce any of the following consequences?:** If the reaction or discomfort was severe, select one or more of the following options:

o Caused death o
Threatened life o
Caused disability o
Caused/prolonged hospitalization o
Caused congenital malformation o
Caused another major medical condition

If the reaction or discomfort was not serious, leave the previous field blank.

In the event that your report includes more than one reaction or discomfort, click on ***"Add another reaction/ symptom"*** and record the information of the other reaction(s)/discomfort as previously explained. If you wish to remove all information for an adverse reaction/discomfort, click on the icon at the top right of the **reaction/symptom section.**

Once the reaction/discomfort information is complete, click on “Next section”.

3.2 Medicines

second page

In this section, detail the medication(s) you were taking before the reaction occurred and that you consider to be (are) suspected of causing the reaction/discomfort. Press the button **"Add another medication"** for each new medication that requires reporting, it is important that you include any herbal medication preparation, drug use or other alternative medication that you have been consuming, also check the medication (s) that you consider to be the one you caused the reaction.

Include the following information for each field: •
Medication Name*: Enter the trademark or generic name as indicated on the medication package. If it contains more than one component (active ingredients), place them in the same order that they appear on the
packing.
Below this field you will find the box **"This medicine is probably the cause of the reaction",** enable it if you consider that the medicine caused the reaction or discomfort, if not, leave the box blank, but consider that it is necessary to have at least one suspected drug for the report to be valid and can be sent

• **Manufacturing pharmaceutical company:** Enter the name of the manufacturing/distributing pharmaceutical company as it appears on the medication packaging.

• **Lot number:** Enter the lot number of the medication as it appears on the the medication packaging.
• **Concentration:** Place the concentration of the medication indicated on the package. If the reported medication has more than 1 active ingredient, place the concentration of all the active ingredients separated by a slash (/).

Example: 100mg/250mg.
It is important to place the concentrations in the same order as the active ingredients appear on the medication packaging.

- **Dose:** Indicate the dose that the patient/consumer took of that medication (in pediatrics, indicate the dose per kg of weight).
  Example: 2 tablets twice a day for 3 days.
- **Route of administration:** Select from the catalog the option that corresponds to the route by which the medication was administered, for example: oral, cutaneous, ophthalmic. • **Medication Start Date:** Refers to the date you started using the medication. Use the format dd/mm/yyyy (IF YOU DO NOT KNOW THE COMPLETE DATE, ENTER AT LEAST THE MONTH AND YEAR).

- **End date of drug administration:** Refers to the date when the drug was stopped. Use the format dd/mm/yyyy (IF YOU DO NOT KNOW THE COMPLETE DATE, ENTER AT LEAST THE MONTH AND YEAR). If you continue to take the medication, please leave this field blank.

- **Duration of medication administration:** In the free field, enter the quantity and select the unit of time from the catalog. If you continue to take the medication, please leave this field blank.

- **Indication of medication administration:** In this free text field, indicate the reason why the medication was prescribed to the patient/consumer. (For example: hypertension, nausea, pain)

- **Action taken with the medication:** Choose the appropriate option from the catalog to the action taken regarding the medication. The options are:
  - o Drug withdrawn o Reduced dose
  - o Increased dose o Unchanged dose o Unknown
  - o Not applicable

Do not forget to add each of the medications that you have been taking and that may be related to your reactions or discomfort. To add another medication, click on the "Add another medication" option.

If you want to delete all the information about a medication, click on the icon located at the top right of the medication section .

Once the information is completed, click on "Next section".

3.3 Additional information

Third page

In this section, add relevant information from the patient's medical history that helps to evaluate the case, since some reactions may occur due to

or in combination with previous illnesses, food, drug use, other medications, smoking habits, alcohol intake or allergies.

- **Previous or current illnesses:** Describe the important data of the medical history such as diagnoses, allergies, pregnancy, previous surgery, concomitant pathologies, laboratory test results, include dates of onset of illnesses.

- **Additional comments:** Include any other aspects that are considered relevant for the understanding of the case.

Once the information is completed, click on “Next section”.

3.4 User of the medication

Fourth page

In this section, record the following patient/medication user information: • **Initials*:** Capitalize the first letter of the paternal surname, followed by the first letter of the maternal surname and the first letter of the name(s).

Example: Jose Juan Gonzales Allende

Please initial as follows:

• First letter of father's surname = G • First letter of mother's surname = A • First letter(s) of name(s) = JJ

Remaining as follows:

GAJJ

Since it is a mandatory field to be able to send the report, if you do not have this information, put "UNKNOWN".

- **Sex*:** Choose the option as appropriate o Male
  o Female o
  Unknown

In case of selecting the female gender, two boxes will be displayed that can be checked in the case of a pregnant and/or lactating user. • **Weight:** Enter the information in kilograms and if necessary, use a point as a decimal separator.

- **Date of Birth*:** Enter the patient's date of birth, beginning with the day, month, and year in the format *dd/mm/yyyy.* It is necessary to enter the full date.

  Example: If the patient was born on July 27, 1981, you should enter the date like this: 07/21/1981 If you do not have the date of birth, provide the **Age at the beginning of the reaction.** In the free field, place the amount of time and from the catalog select the unit of time. *Example:* If the adverse reaction occurred in a 12-year-old patient, place the quantity in the free field, that is, 12, and select the unit of time from the catalog, in this case “years”.

  When birth malformations are reported, report the age and sex of the baby at the time of detection and add the mother's identification data in the section corresponding to “Describe what happened”.

- **Country where the reactions began:** Mexico will appear by default. **No Modify.**

Once the information is completed, click on “Next section”.

3.5 Contact information

Fifth page

Provide the following information in the corresponding fields.

- **Email*:** Enter a valid email, since the notifier would be contacted through it if additional information is needed. • **Telephone:** Enter a valid telephone number (cellular or landline) to have another means of contact, if necessary.

Once the information is completed, click on “Next section”.

3.6 Summary of the report

Sixth page

This section will show you all the information you entered in the report. If you identify information that is not correct, press the ***Edit report*** button to return to the corresponding section and modify it. If the information is correct, submit the report by clicking the ***Submit Report button.***

Once the report has been sent, the screen will appear indicating that **"The report has been sent correctly".** In this window you will be provided with the generated report identifier.

You can download the report in PDF format to use as an acknowledgment of receipt.

4. Notification of healthcare professional (health professional)

The healthcare professional interface is similar to the patient/consumer interface but the order in which the sections are presented is different.

4.1 User of the drug

To fill out the fields in this section, review section **3.1 Medication user** of this document, provide the same information.

4.2 Describe what happened

To fill in the fields in this section, review section **3.1 Describe what happened** in the same document, provide the same information.

4.3 Medicines

To fill out the fields in this section, review section **3.1 Medications** of this document, provide the same information.

4.4 Additional information

To fill out the fields in this section, review section **3.3 Additional information** in this document, provide the same information.

4.5 Contact information

Provide the following information in the appropriate fields corresponding to the health professional making the report.

- **Profession:** Three options will be displayed, select the one that corresponds to your profile, Doctor, pharmacist and Other health professional (eg nurse)
- **Name(s):** Enter your first name or names, not including last names. • **Last Name(s):** Enter your last name(s). • **Health establishment:** Enter the name of the health institution or establishment of which it is a part, adding the federal entity where the establishment is located. For example, Hospital Médica Sur, Mexico City • **Email*:** Enter a valid email, since, through this, if necessary, the notifier would be contacted for more information. • **Telephone:** Enter a valid telephone number (cellular or landline) to have another means of communication, if necessary.

4.6 Summary of the report

Review section 3.6 Summary of the report of this document, as it applies in the same way.

IMPORTANT: The sending of any notification does not necessarily constitute a causal relationship between the medication and the adverse reactions or discomforts.