ADVERSE EVENTS REPORTING GUIDELINES FOR PATIENTS, CARETAKERS AND CONSUMERS.

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

1 HISTORY

This is the first edition of this document.

2 APPLICATION – (Guidance for Patients / Consumers)

This document is for the guidance and support of the patients, consumers of therapeutic goods and relatives of a patient for reporting of adverse events and adverse events following immunization (AEFI) to National Pharmacovigilance Center, DRAP.

3 PURPOSE

Patients are the consumers of the therapeutic goods they might experience any abnormal effects with drugs and therapeutic goods. Therefore, they are also considered the primary reporter of adverse events or adverse events following immunization. The purpose of this document is to. -

3.1. Guide patients, consumers, and relatives of a patient for reporting of adverse events or adverse events following immunization with therapeutic goods to NPC, DRAP;

3.2. To enhance the participation of patients in the adverse events reporting system of the country; and

3.3. To develop a spontaneous reporting culture in the country.

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4 INTRODUCTION

Although therapeutic goods such as drugs, vaccines and biological are extensively tested in humans during clinical trials, everything related to their safety i.e. ADRs can not be determined in this short period. Therefore, after registration when these new therapeutic goods are released into the market and a large population is exposed, some new and unexpected serious ADRs can occur. Therefore, there is a dire need to have a vibrant National pharmacovigilance centre to monitor the safety of therapeutic goods after these are registered and released into the market. In line with international practices, the DRAP has established the National Pharmacovigilance Centre (NPC), under the Division of Pharmacy Services, DRAP, Islamabad, to monitor therapeutic goods' safety across the country. NPC has developed different reporting forms that are available through the official website and a mobile application for patients, consumers and relatives of a patient for reporting of any AE or AEFI and accordingly play their part in ensuring the safety of therapeutic good for all.

5 DEFINITION AND ACRONYMS

ADR: **"**Adverse Drug Reaction" means response to drug or therapeutic goods which is noxious and unintended that occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. A response in this context means that a causal relationship between a therapeutic good and an adverse event is at least a reasonable possibility. An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a therapeutic good and an occurrence is suspected.

AE: "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product (therapeutic good) and which does not necessarily have a causal relationship with this treatment;

AEFI: "Adverse Event Following Immunization" means any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine"

DRAP: the Drug Regulatory Authority of Pakistan.

ME Medication Errors (ME) means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient

	or consumer
NPC:	National Pharmacovigilance Centre
Serious Event:	"serious adverse reaction" or "serious adverse event" means an untoward medical occurrence that at any dose results in patient death, is life-threatening, requires inpatient hospitalization or results in prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is judged to be a medically important event or reaction;
Therapeutic Goods:	(Drugs, vaccines, biological, alternative medicines and/ or medical devices), It includes drugs or alternative medicine or medical devices or biologicals or other related product as may be notified by DRAP.

6 WHY TO REPORT

Even though therapeutic goods such as drugs, vaccines and biological are extensively tested in humans during the clinical trials (initial testing in humans), not everything about their safety in the form of ADRs can be determined during these trials. Many drugs and therapeutic goods display unexpected ADRs that can vary from individual to individual. Many of these effects are identified during the drug development, but, since clinical trials are conducted in selected subjects with disease conditions, the occurrence of rare ADRs may be unlikely during this phase. Therefore, new information about the safety of therapeutic goods that was not previously determined during the clinical trials may be identified when these are registered and used by a wider population. By reporting AEs the consumer can help to provide more information about drugs and therapeutic goods, which will ultimately help to make them safer and in this way, the public may contribute in ensuring the safety of therapeutic goods. Reporting AEs offers an opportunity to us to identify and further investigate previously unknown or poorly described ADRs and helps in continuous monitoring of the safety of the therapeutic good throughout its life.

7 WHAT TO REPORT

An ADR is an unwanted symptom or effect caused by therapeutic goods, which can be mild or serious. Experts say that ADR varies for each patient and depends largely on their general health, the state of disease, age, weight, gender and genetic makeup.

Patients/consumers cannot always be certain that what they are experiencing is caused by the therapeutic good; but by reporting AE they can help the DRAP in their investigations, which will lead to safer therapeutic goods. Therefore, patients/consumers should report all those unusual symptoms or effects (AE) suspected to be caused by the therapeutic goods to NPC, DRAP.

7.1 Necessary Information in a Report

The patient and consumers of therapeutic goods should provide the maximum information in the AE reporting form about the following:

7.1.1. Information about the person/patient who has experienced an AE or AEFI (age, gender, weight and name etc);

7.1.2. The description of an AE or AEFI including how it happens, what the patient experience, and the onset date of the event;

7.1.3. Information about the therapeutic goods (brand name, generic name, batch number, dose, strength, indication, route of administration, start and stop date etc.);

7.1.4. Information about any other drug or therapeutic good that the patient was taking at the same time;

7.1.5. Information about any other illness or medical condition; and

7.1.6. Information about past allergies if any.

8 WHERE AND HOW TO REPORT

8.1 Ask Your Healthcare Professional to Report the Adverse Event.

The patient or consumer of therapeutic goods should at first, report the AE or AEFI to his/her healthcare professional (physician, pharmacist, nurse or any other healthcare professional) as suspected ADR or AEFI reporting is their ethical responsibility. Therefore, the patient or consumer or relative of a patient should get in touch and talk to the healthcare professional by providing complete information about the event. The patient should pay attention to the suspected ADRs when they are using therapeutic goods, if the patient experiences any AE, it should be noted and on the very next visit, healthcare professionals should be informed. The patient should always consult his/her healthcare professional in case of an untoward event and ask the healthcare professional to report the AE or suspected ADR to the concerned quarters. However, the patient should not stop the therapeutic good without consulting their physician as in some cases not treating the disease may be more harmful than experiencing a mild AE or suspected ADR.

8.2 Report Your Adverse Event by Yourself to NPC, DRAP.

If the patient/consumer of therapeutic goods or relative of a patient doesn't have access to the healthcare professionals or healthcare professional is not willing to report the AE, then he/she can directly report to NPC, DRAP. The patient should request their healthcare professionals to help them in filling the AE reporting form that can be reported through any of the following means:

8.2.1 Online Reporting through Med Vigilance E Reporting System.

An AE or AEFI can be reported to NPC through Med Vigilance E Reporting System, available on the official website (**Annexure B**). A telephone number in the relevant field of the E-reporting system should be provided in case staff from NPC, DRAP intends to get further information in the form of follow-up.

Here is a brief introduction of "Med Vigilance E-Reporting System" (**Annexure B**):

- This online reporting form can be accessed through the DRAP website. The online reporting form is divided into different sections/tabs such as patient, drugs, reactions, additional information and reporter. In order to move to the next section, you have to fill in/answer the previous section.
- The fields in sections/tabs are structured into drop-down lists, calendar selection, ticks or open fields, where data can be typed. There are some mandatory fields in each section, if these are not filled the report does not proceed forward unless you fill it.
- Overall the fields are the same as of yellow reporting form but these are customized into electronic format for easy reporting by patients and their relatives. There are also options to "add another medicine" and "add another reaction" where you can add more than one drug or reaction.

HOW TO REPORT THROUGH MED VIGILANCE E REPORTING SYSTEM?

1. On the very **First Page,** you will be asked to report either as a patient/relative of the patient or as a healthcare professional. You have to select as *"I am reporting for myself or a relative*" and accept the terms and conditions.

2. In the section **"Describe what happened",** you have to provide details of the reaction/symptom such as its start and end date, seriousness, duration and outcome. There is also a field of description where you can narrate how, when and where the event occurs along with chronology. Also tick one of the seriousness categories provided, if the reaction is serious. If

you intend to add more than one reaction select add another reaction at the bottom.

3. In the section **"Medicine(s)**, you have to provide details of medicine such as its name, producer/manufacturer, strength, dosage, batch number, route of administration, start and stop date, duration of treatment, reason of use and action taken after the reaction had developed. If you intend to add more than one medicine click add another medicine at the bottom.

4. In the section **"Additional Information"**, details of your/ patient current and past medical illness and medications and any additional comments can be provided.

5. In the section "**User of Medicine"** you have to provide the initial or name, sex, age or date of birth and weight of the patient.

6. In the section of "**Contact Detail"** provide your email address and contact number for follow-up from our side.

7. **Upon completion** of the online reporting form, a summary report would be generated for your review and you would be asked to send the report to NPC. A confirmation email will be sent to you once the report is received at NPC, DRAP.

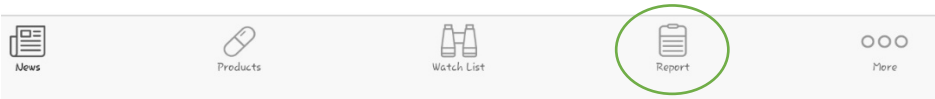
8.2.2 Reporting through Med Safety Mobile Application.

Similarly, there is a Med Safety Mobile Application developed by WEB-RADR in collaboration with the Medicines and Health Products Regulatory Agency (MHRA), United Kingdom and Uppsala Monitoring Centre (UMC) Sweden for AE or AEFI reporting. Patient/ consumer of therapeutic goods or relative of a patient can directly report an AE or AEFI to NPC, DRAP through this mobile application.

This app is user friendly and reporting form can be filled both in online and offline mode. For using the Med Safety application you would need to create an account or continue as a guest user. The Med Safety Mobile app is available for download from the App Store (for iOS devices) and Google Play (for Android devices). Necessary guidelines on downloading the mobile application are available in **Annexure A**. The video on how to use Med Safety Mobile Application to understand how to fill and report the AE can be accessed on the WEB-RADR website.

I- HOW TO REPORT AE THROUGH THE MED SAFETY APP?

1. Create an account by entering your details or continue as a guest user.
2. From the icons given at the bottom choose report



3. Select the "**new report**" tab and choose the relevant reporting form in this case "**adverse event to any medicine".**
    a. Adverse event with vaccine "Adverse Event Following Immunisation" (AEFI).
    b. An adverse event in COVID-19 patient
    c. Adverse event to any medicine
    d. If you are a healthcare professional then "Report a suspected side effect to a medicine (Healthcare Professional)"
4. **Personal details** are required if you are a guest user.
5. Add the **patient details** i.e (gender, age, name initials) and click next.
6. Add **suspect medicine** and related details which you think has caused the adverse event and any **other medicines** being used.
7. Select next and add "**Reaction Details**".
8. Add all the reactions/symptoms due to the medicine, separately.
9. Select if any serious outcome from the relevant options had occurred.
10. Describe in your own words the adverse events if desired, at the bottom-most section in the "Reaction Details".
11. Add as much information in the report regarding the medicine and reaction as you know.
12. Click next and add the "**Medical History**" of the patient if any.
13. Select submit at the bottom right or save in case the internet is not available, and add the report in your pending reports section for transferring it later.
14. After submitting the report, you will also receive a confirmation email once the report is received in NPC, DRAP.

2. HOW TO REPORT AEFI THROUGH MED SAFETY APP?

1. Follow steps 1 to 3 and select reporting of AEFI.
2. Add your details as the reporter
3. Add details of the patient
4. Add details of the health facility/vaccination centre
5. Add vaccine details (name, date and dose) and other medicines if any.
6. Select from the serious adverse event if any and/or from any other reactions and its outcome.
7. You can also describe the adverse event in your own words.

8. Add the patient's medical history if any and submit or save the report for transferring later.
9. You will receive an email acknowledgement once the report is submitted to NPC, DRAP.

8.2.3 Provide Information on Landline Number.

Necessary information related to the AE or AEFI could also be provided through telephone through the following two landline numbers from 09:00 AM to 05:00 PM during working days:

1- +92 (051)-9107413

2- +92 (051)-9107299

8.3 Avoid Reporting Through Multichannel to Avoid Duplication.

Considering the multiple tools/channels of reporting AE and AEFI for the patient, help or assistance from any healthcare professional can be requested to fill out the AE reporting form, which can be reported through any of the following channels:

8.3.1 Through the HCP's yellow reporting form

8.3.2 Med Vigilance E reporting system

8.3.3 Med Safety Mobile App

8.3.4 Landline Numbers

8.3.5 Through the pharmaceutical company

The patient and consumer should keep one thing in mind which is to "report an adverse event through the one channel only", to avoid duplication of reports. If a healthcare professional has already reported the AE or suspected ADR or AEFI to NPC, DRAP, the patient should avoid reporting the same.

9 WHEN TO REPORT

The patient should report a serious AEs or AEFI as soon as possible to healthcare professionals, the National Pharmacovigilance Centre or the pharmaceutical company or importer of therapeutic goods. Sometimes, the AE might be unexpected and might be posing harm to other patients. Therefore, earlier reporting by the patient will be helpful to minimize harm to other patients. Further, the non-serious/mild AEs should also be reported at the earliest through the above channels.

10 WHAT HAPPENS TO REPORT

NPC collects reports of AEs, suspected ADRs and AEFI from Healthcare Professionals, Patients, Provincial Pharmacovigilance centres, Public health Programmes, and Pharmaceutical companies having registration of therapeutic goods. Staff at NPC, at first check the report for mandatory and essentially required information. If there is any missing mandatory information, the reporter is contacted. The staff also contacts the reporter for more information about serious adverse events.

NPC compiles the reports received against a therapeutic good via different channels and performs a complete assessment where possible. The reports are checked for new signals by safety experts to determine if there is any new information about the safety of the therapeutic good. After evaluation of the safety signals, NPC, DRAP may issue:

10.1 New warning/ contraindication,

10.2 Remove indication of therapeutic goods for specific diseases or age groups,

10.3 Advice on how the therapeutic good should be used, or

10.4 In some cases even stop the use of therapeutic goods.

Overall, the processing at NPC, DRAP is to monitor the safety of therapeutic goods in order to optimize the use of therapeutic goods with minimum harm to the patient.

11 REFERENCES

1. Pakistan National Pharmacovigilance Guidelines.
2. Take & Tell Brochure of the Uppsala Monitoring Centre, Sweden.
3. European Medicine Agency adverse reaction reporting guidelines for patients.

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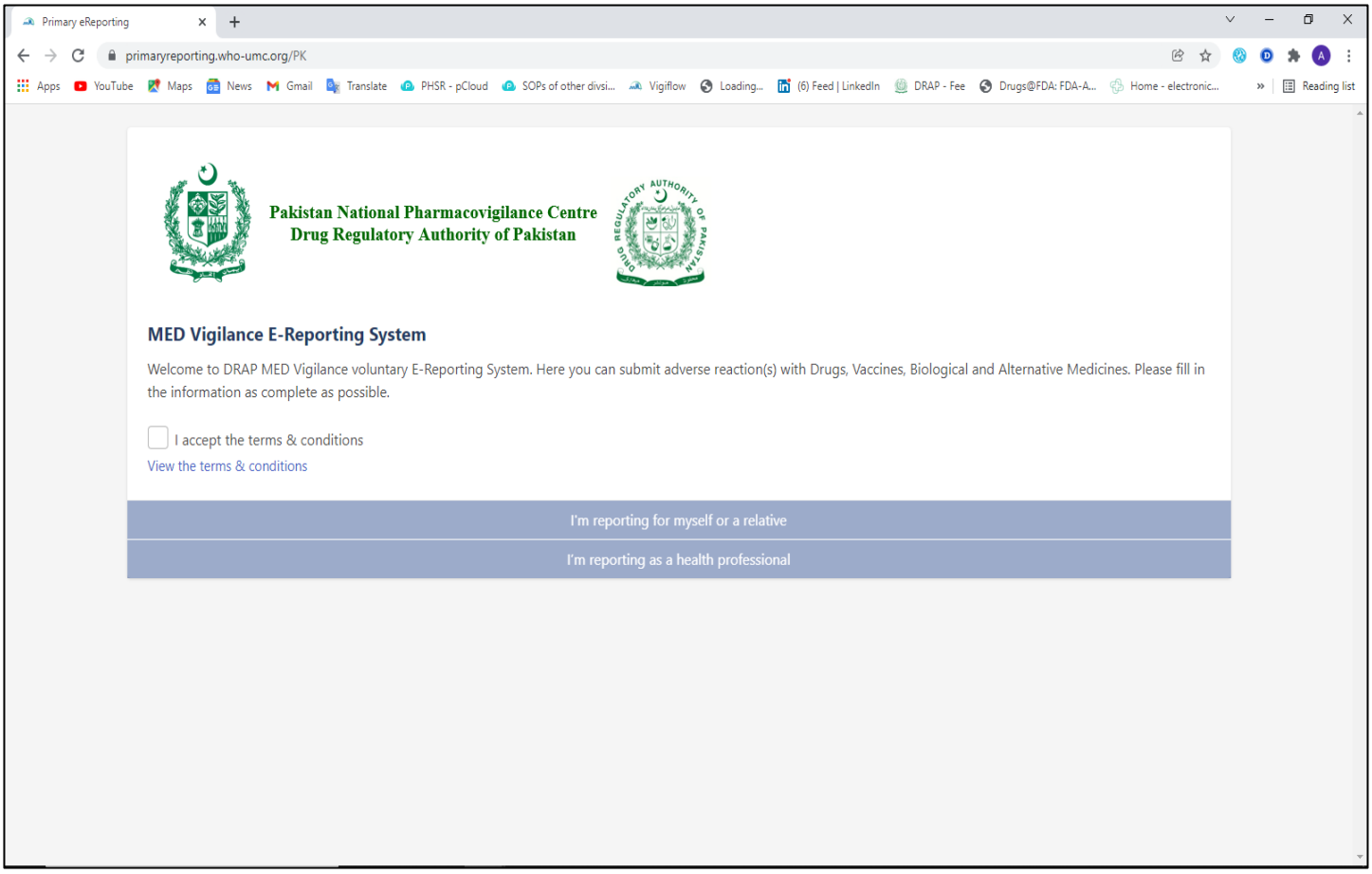
ANNEXURE A

Med Safety Mobile App Pakistan

ANNEXURE B


Primary eReporting
primaryreporting.who-umc.org/PK
Pakistan National Pharmacovigilance Centre
Drug Regulatory Authority of Pakistan
MED Vigilance E-Reporting System
Welcome to DRAP MED Vigilance voluntary E-Reporting System. Here you can submit adverse reaction(s) with Drugs, Vaccines, Biological and Alternative Medicines. Please fill in the information as complete as possible.
I accept the terms & conditions
View the terms & conditions
I'm reporting for myself or a relative
I'm reporting as a health professional

Describe what happened

Describe what happened in your own words, any symptoms or side effects you suspect were caused by your medicine, and what happened since then.

Other specific details about each medicine and relevant dates can be entered below, but please include enough information here to connect to the Reactions/Symptoms section below

Description

Reactions/Symptoms

Describe the reactions in your own words. Click the 'Add another reaction/symptom' button for each reaction you will describe.

Reaction/Symptom

Start date

dd mm yyyy

Fill in as complete as possible

End date

dd mm yyyy

Fill in as complete as possible

Duration

Outcome of reaction

Did the reaction lead to any of the following?

Select those that apply or leave blank

- [ ] Death
- [ ] Life threatening
- [ ] Disabling/incapacitating
- [ ] Caused/prolonged hospitalisation
- [ ] Congenital anomaly/birth defect
- [ ] Other medically important condition

Add another reaction/symptom

Next

Medicines

Enter the name and details for each medicine you were taking before the reaction occurred. Click on "Add another medicine" for each new medicine you need to describe. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.

Medicine name

Full name of medicine (as on the package)

☑ Probably causing the reaction

Uncheck if you do not believe this medicine caused the reaction

Medicine producer

Company name on package

Batch number

Strength

As on package. For example: '50 mg', '10 mg/ml'

Dosage

How much did you take? For example: '2 tablets 3 times a day'

How was the medicine administered

Start date

dd mm yyyy

Fill in as complete as possible

End date

dd mm yyyy

Please leave blank if the medicine is still being taken

Duration

Reason for taking the medicine

Why did you take the medicine? (For example: Diabetes, headache)

Action taken with medicine

Add information on all medicines, one by one. Please do not forget about "over the counter" medicines, herbal preparations, recreational drugs or other alternative medicines.

Add another medicine

Previous Next

Additional information

Please give a short description of your medical history. This is important since some reactions only appear with a combination of previous or ongoing disease, special diets, recreational drugs, smoking habits, alcohol intake or allergies. You can also enter other comments you feel are important.

Current and previous illnesses

Additional comments

Previous Next

User of the medicine

Initials

Sex

Male Female Unknown

Weight

kg

Date of birth

dd mm yyyy

Complete Date of birth or Age must be entered

Age at time of reaction

Complete Date of birth or Age must be entered

Country where the reaction started

Pakistan

This is important if the environment has been a trigger for the reaction/symptom

Previous Next


Contact details
Email
Telephone
Previous
Next

Review

This is the summary of your report. Please verify that the information is correct. If it's not, use the Edit button to change the information. To send the report, click the Send button.

Send report

Reactions/Symptoms

Description

test

Reactions/Symptoms

Reaction/Symptom

test

Start date

1 January 1900

Medicines

Medicine name

test

☑ Probably causing the reaction

Additional information

User of the medicine

Initials

test

Sex

Female

Date of birth

1 January 1900

Country where the reaction started

Pakistan

Contact details

Email

abcd@mail.com

Edit report

Send report