# USER GUIDE FOR ONLINE REPORTING

**IMPORTANT NOTES:**

- *Please use 'Google Chrome' as your web browser.*
- ***Mandatory fields (marked with *):** Please fill in all mandatory fields in order to successfully submit the form.*
- ***Non-mandatory fields**: Please give as much information as you can. If the relevant information is not known, kindly leave the field(s) blank.*

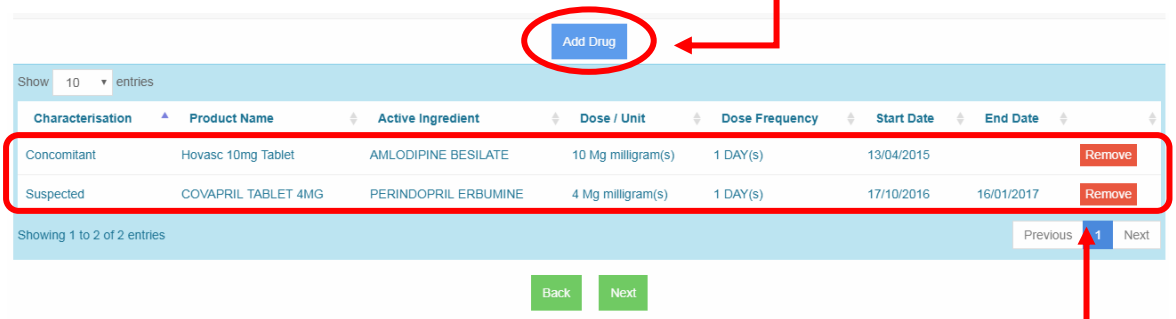
| Section 1: Report Form | |
|---|---|
| **FIELD(s)** | **NOTES** |
| **Report Type** | **Initial report:** First submission of report to NPRA of a particular patient involving a particular ADR. |
| | **Follow-up report:** Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report.<br><br>*Please insert the **Initial Report Number** or mention **the date of initial report** at "Report Comment" column (under Section 7 : Reporter Information) for reference.* |
| **Case Type** | **Normal case**<br><br>**Parent Child Case:** used primarily when a foetus/child has suffered the reaction after the parent has taken the drug, e.g.: exposure during pregnancy or through breastfeeding. |

| Section 2: Patient Demographic | |
|---|---|
| **FIELD(s)** | **NOTES** |
| **Patient Initials** | **Preferably full NRIC (without "-").** |
| **Patient Age** | **IMPORTANT NOTE:**<br>[Numeric fields] Whole numbers only; **NO DECIMAL NUMBERS** |
| **Weight (kg)** | |
| **Height (cm)** | |

# Section 6: Drug Details

**IMPORTANT NOTE**

1. **Remember! Please click the Add Drug button each time after you have completed all the columns for each suspected/interaction/concomitant drug.**




2. **Please check if the drug details have been added to the table as shown above.**

| FIELD(s) | NOTES |
|---|---|
| **Dose** | **IMPORTANT NOTE:**<br>[Numeric fields] Whole numbers only; **NO DECIMAL NUMBERS/ SPECIAL CHARACTERS.**<br><br>**Dose / Dose Unit** \| **Dose / Dose Unit**<br>**500 MG milligrams** \| ~~0.5 G grams~~<br>**500 µG micrograms** \| ~~0.5 MG miligrams~~<br>*For fixed-dose-combination drugs (e.g. 10 MG/0.5 MG)*<br>**1 DF** \| ~~*10 MG/0.5 MG @10/0.5 MG*~~<br>**2 DF** \| ~~*20 MG/1 MG @20/1 MG*~~ |
| **Dose Interval / Frequency; Dose Interval / Frequency Unit** | OD: **1 DAY(s)** EOD: **2 DAY(s)**<br>BD: **12 HOUR(s)** TDS: **8 HOUR(s)**<br>QID: **6 HOUR(s)**<br><br>STAT: *Please state "**STAT**" at the "Reporter Comment" Column*<br>PRN: *Please state "**PRN**" at the "Reporter Comment" Column* |
| **Cumulative Dose / Day** | **Total dose administered** to the patient between **therapy start date** until **first sign of the suspected ADR**. |

| Field | Example 1: 0.5 mg 3 times a day for 5 days | Example43: 0.5 mg 3 times a day for 2 doses | Example 3: 10 mg/0.5 mg (in one dose) every other day for 30 days | Example 4: 20 mg STAT |
|---|---|---|---|---|
| **Dose** | 500 | 500 | 1 | 20 |
| **Dose Unit** | MG milligrams | MG milligrams | DF | MG milligrams |
| **Dose Interval / Frequency** | 8 | 8 | 2 | 1 |
| **Dose Interval / Frequency Unit** | HOUR(s) | HOUR(s) | DAY(s) | DAY(s) |
| **Cumulative Dose / Day** | 7500 | 1000 | 15 | 20 |
| **Cumulative Dose / Day Unit** | MG milligrams | MG milligrams | DF | MG milligrams |
| **Reporter Comment** | | | | STAT |

| | |
|---|---|
| **Indication** | **Please state the specific indication of the suspected drug e.g.:**<br>• **'pneumonia due to *S. Pneumoniae*'- NOT 'infection' or 'antibiotic';**<br>• **'lower back pain'- NOT 'painkiller' or 'NSAID'.** |
| **Reaction reappeared after reintroducing suspected drug** | If Yes (i.e. the ADR reappeared after reintroducing drug), please **describe the rechallenge fully** (**dose given, timing, brand used**, etc.) under Section 5 : Adverse Drug Reactions.<br><br>**Rechallenge:** at least **ONE (1) dose interval** has been **skipped** with the patient **recovering fully from the reaction(s) in that period.** |
| **Concomitant** | If the patient **was NOT** taking any concomitant drugs, please state "**No concomitant drugs**" at the "*Reporter Comment*" Column. |

## How to keep a copy of your ADR web form:

(1) **Go to 'Summary' Tab** BEFORE proceeding to click 'Submit' at 'Reporter Information' Tab
(2) **Go to chrome menu ⋮ > 'Settings' > 'Print', OR, use a keyboard shortcut: Ctrl + P**
(3) **Select a destination:**
- Choose your printer for a hardcopy, OR
- Choose 'Save as PDF' for a softcopy

Any further queries, please contact 03-7801 8466/ 7883 5464,
or email to fv@npra.gov.my with the subject line: [ADR Online Reporting].