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.*

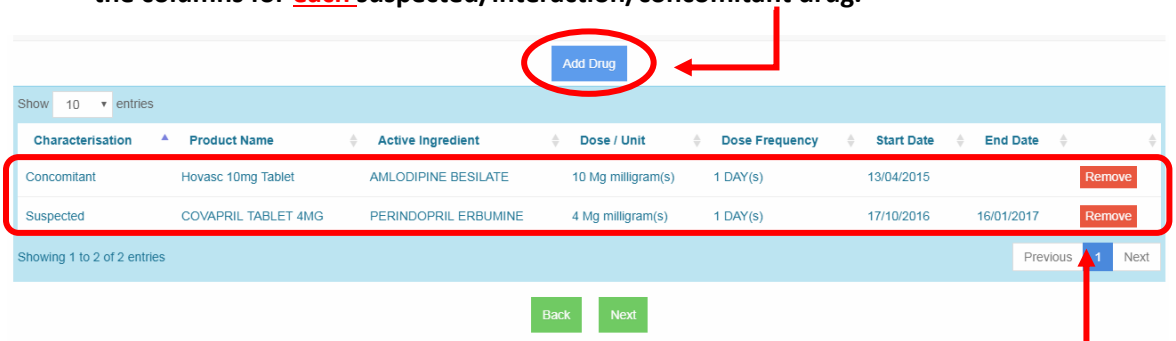
Section 1: Report Form	
FIELD(s)	**NOTES**
Report Type	**Initial report:** First submission of report to NPRA of a particular patient involving a particular ADR.
	Follow-up report: Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report. *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** **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:** [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
Input Method **Active Ingredient** **Product Name** **MAL Number** **Reporter comment**	For **traditional medicine** products with a long list of active ingredients, Input Method: Select "**Unknown brand / Unregistered**" Active Ingredient: Enter "**TRADITIONAL MEDICINE**" Product Name: Enter "<**Product Name**>" MAL Number: *<Not available if 'Unknown brand / Unregistered" is selected>* Reporter comment: Enter "**MAL Number**" *Rationale: "Registered" products have to be directly selected from the Quest3plus database and editing is not allowed. If the long list of active ingredient exceeds the text number limit (250AN characters), the reporter will NOT be able to **add drug** and further **proceed** with report submission.*
Dose	**IMPORTANT NOTE:** [Numeric fields] Whole numbers only; **NO DECIMAL NUMBERS/ SPECIAL CHARACTERS.** **500 MG milligrams** ~~0.5 G grams~~ **500 µG micrograms** ~~0.5 MG milligrams~~ *For fixed-dose-combination drugs (e.g. 10 MG/0.5 MG)* **1 DF** ~~*10 MG/0.5 MG @10/0.5 MG*~~ **2 DF** ~~*20 MG/1 MG @20/1 MG*~~

Dose Interval / Frequency; Dose Interval / Frequency Unit	**OD:** **1 DAY(s)** **EOD:** **2 DAY(s)** **BD:** **12 HOUR(s)** **TDS:** **8 HOUR(s)** **QID:** **6 HOUR(s)** **STAT:** ***Please state "STAT" at the "Reporter Comment" Column*** **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 g 3 times a day for 5 days	Example 2: 0.5 g 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.: • 'pneumonia due to *S. Pneumoniae'*- NOT 'infection' or 'antibiotic'; • '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. **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.

To keep a copy of your ADR web form:

(1) Go to **'Summary'** Tab
(2) Click '**Print'** button BEFORE proceeding to click **'Submit'** button
(3) **Select a destination:**
- Choose your printer for a hardcopy, OR
- Choose 'Save as PDF' for a softcopy

Any further queries, please contact 03-7883 5498/5505
or email to fv@npra.gov.my with the subject line: [ADR Online Reporting].