

USER GUIDE FOR ONLINE REPORTING

IMPORTANT NOTE:

Please fill every section of the ADR web form. Kindly state '**none/nil/not applicable**' if necessary.

Section 1: Report Form	
FIELD(s)	NOTES
Report Type	<p>Initial report: First submission of report to NPRA of a particular patient involving a particular ADR.</p> <p>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.</p> <p>Please insert the Initial Report Number or mention the date of initial report at "Report Comment" column (under Section 7: Reporter Information) for reference.</p>
Case Type	<p>Normal case</p> <p>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.</p>

Section 2: Patient Demographic	
FIELD(s)	NOTES
Patient Initials	Preferably full NRIC (without "-").
Patient Age	<p>IMPORTANT NOTE: Whole numbers only; no decimal points.</p>
Weight (kg)	
Height (cm)	

Section 6: Drug Details

IMPORTANT NOTE

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

The screenshot shows a table with the following columns: Characterisation, Product Name, Active Ingredient, Dose / Unit, Dose Frequency, Start Date, and End Date. There are two rows: one for a 'Concomitant' drug (Hovasc 10mg Tablet) and one for a 'Suspected' drug (COVAPRIL TABLET 4MG). A red circle highlights the 'Add Drug' button above the table. A red box highlights the two rows in the table. A red arrow points from the 'Add Drug' button to the table. Another red arrow points from the 'Next' button below the table to the table.

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

FIELD(s)	NOTES				
Dose; Dose Unit:	<p>IMPORTANT NOTE: <i>Whole numbers only; no decimal points.</i></p> <table border="1" style="width: 100%;"> <tr> <td style="background-color: #4F81BD; color: white;">500 MG milligrams</td> <td style="background-color: #4F81BD; color: white;">0.5 G grams</td> </tr> <tr> <td style="background-color: #4F81BD; color: white;">500 µg micrograms</td> <td style="background-color: #4F81BD; color: white;">0.5 MG milligrams</td> </tr> </table>	500 MG milligrams	0.5 G grams	500 µg micrograms	0.5 MG milligrams
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500 µg micrograms	0.5 MG milligrams				
Dose Interval / Frequency; Dose Interval / Frequency Unit	<p>OD: 1 DAY(s) BD: 12 HOUR(s) TDS: 8 HOUR(s) QID: 6 HOUR(s) STAT: Please state "STAT" at the <i>"Reporter Comment"</i> Column PRN: Please state "PRN" at the <i>"Reporter Comment"</i> Column</p>				
Cumulative Dose/day	Total dose administered to the patient between therapy start date until first sign of the ADR .				
Indication	<p>Please state the specific indication of the suspected drug e.g.:</p> <ul style="list-style-type: none"> • 'pneumonia due to S. Pneumoniae'- <u>NOT</u> 'infection' or 'antibiotic'; • 'lower back pain'- <u>NOT</u> 'painkiller' or 'NSAID'. 				
Reaction reappeared after reintroducing suspected drug	<p>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.</p> <table border="1" style="width: 100%;"> <tr> <td>Rechallenge: at least ONE (1) dose interval has been skipped with the patient recovering fully from the reaction(s) in that period.</td> </tr> </table>	Rechallenge: at least ONE (1) dose interval has been skipped with the patient recovering fully from the reaction(s) in that period.			
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Concomitant	If the patient was NOT taking any concomitant drugs, please state "No concomitant drugs" at the <i>"Reporter Comment"</i> Column.				

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