Turks and Caicos Islands
Pharmacovigilance Programme (TPP)

Suspected Adverse Drug Reaction (ADR) Reporting Form - Confidential

Report type:

☐ Adverse Drug Reaction - Complete all sections

☐ Substandard/Falsified (SF) Product - Complete sections B, C & D

FOR OFFICIAL USE ONLY

Case #:

Date received: dd/mm/yyyy

A. PATIENT INFORMATION

1. Patient's Initials:

2. Date of Birth: dd/mm/yyyy

3. Sex: Male ☐ Female ☐

4. Height:_____cm **or** _____ft and ____inches

5. Weight:____kg **or**_____lbs

B. SUSPECTED ADVERSE DRUG REACTION DETAILS

6. Date reaction started: dd/mm/yyyy

7. Date reaction ended: dd/mm/yyyy

8. Describe reaction or problem:

9. Seriousness: Death ☐ Life-Threatening ☐ Disability ☐ Congenital Anomaly ☐ Other ☐

(*Tick all that apply)* Prolonged Hospitalisation ☐ Intervention required to prevent permanent damage ☐

10. Outcomes: Recovered ☐ Recovering ☐ Not Recovered ☐ Fatal ☐ Unknown ☐

Recovered with an after-effect ☐

11. Treatment given: No ☐ Yes ☐ If yes, please specify:_____

C. SUSPECTED MEDICATION (S)

12. Date started: dd/mm/yyyy

13. Date stopped: dd/mm/yyyy

14. Drug name	**Manufacturer** (if known)	**Dose taken**	**Route**	**Frequency**	**Expiry date**	**Batch number**
					dd/mm/yyyy	
					dd/mm/yyyy	
					dd/mm/yyyy	

15. Action Taken: Drug withdrawn ☐ Dosage changed ☐ Dose unchanged ☐ Unknown ☐

16. ADR subsided after stopping drug/reducing dosage? No ☐ Yes ☐ Unknown ☐ Drug continued ☐

17. ADR reappeared after reintroducing drug/dosage? No ☐ Yes ☐ Unknown ☐ Drug restarted ☐

18. Other relevant information (e.g. allergies, lab results, medical history, pregnancy):

D. REPORTER DETAILS

19. Reporter's Initials:

20. Institution:

21. Email:

22. Telephone:

23. Role/Profession: Focal point ☐ **Pharmacist** ☐ **Physician** ☐ **Nurse** ☐ **Patient/Giver** ☐

Other Health Professional ☐ **Other** ☐

24. Date of Report: dd/mm/yyyy

CONFIDENTIALITY: The patient's identity is held in strict confidence and protected to the fullest extent. Report and contact information will not be shared with unauthorised persons or organisations.

INSTRUCTIONS

Use this form to report the following:

i. Suspected adverse drug reactions (ADR) to pharmaceuticals, biologics and natural health products,

ii. Quality issues arising from suspected substandard or falsified medicinal products to the Ministry of Health, Agriculture, Sports and Human Services (MoHASHS)

NOTE: Submission of a report **does not** constitute an admission that medical personnel or manufacturer of the product caused or contributed to the reaction.

To all Focal Points, Health Professionals, Patient and Patient Representatives:

1. Ensure that the form is completed in full. You may follow-up with the reporter if needed.
2. **DO NOT** include the patient's or the reporter's name.
3. This information will be stored for follow-up or archived by the National Pharmacist as a part of the Turks and Caicos Pharmacovigilance Programme (TPP).

Definitions:

Adverse Drug Reaction (ADR): a response to a medicine used in humans or animals, which is noxious (harmful, poisonous, or very unpleasant) and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine.

Falsified: medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Substandard also called "out of specification", these are authorised medical products that fail to meet either their quality standards or specifications, or both.

How to Submit this Form:

Email to:

Dr. Nadia Astwood - Director of Health Services/Chief Medical Officer (ncastwood@gov.tc)
Andre Morgan - National Pharmacist (amorgan@gov.tc)

Deliver to:

Ministry of Health, Agriculture, Sports and Human Services

2nd Floor Naynelly's Plaza
Lighthouse Road
Grand Turk
Turks and Caicos Islands

2nd Floor Town Centre Mall, Parade Ave
Downtown
Providenciales
Turks and Caicos Islands

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS FORM