**Alert for serious adverse events to the TB programme**

**CONFIDENTIAL – To be sent even upon suspicion of a serious adverse event**



|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IS THIS REPORT A NEW EVENT?** | YES |  | NO | GIVE DATE WHEN PREVIOUS SAE FORM SENT: (\_\_\_/\_\_\_/\_\_\_\_) |

|  |  |  |  |
| --- | --- | --- | --- |
| **1. PATIENT DETAILS** |  |  |  |
| SURNAME: |  |  | FIRST NAME: |
| SEX | Male | Female |  |
|  |  |  |  |
|  |  |  | DATE OF BIRTH: |
| PREGNANCY | NO | YES |  |
| ID NUMBER |  |  | PHONE NO: |
| ADDRESS |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Day | MMM | YYYY |  |  |

*age in years if DOB unknown*

**SUSPECTED DR**

**2. SUSPECTED and CONCOMITANT MEDICINE(S)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NAME (Brand name or Generic)** | **Total daily dose** | **Date started** | **Date stopped** | **Continues** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**3. DETAILS OF SERIOUS ADVERSE EVENT**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **DATE EVENT STARTED** |  |  | **DATE EVENT STOPPED** |  |  |
|  |  |  |  |  |  |
| **DESCRIPTION OF EVENT** |  |  |  |  |  |
|  |  |  | | |  |
|  |  |  | | |  |
|  |  |  | | |  |
|  |  |  | | |  |
| **WHY IS THE EVENT**  **CONSIDERED SERIOUS?** |  | Death | | |  |
|  | Life-threatening event (specify………………………………………………………….) | | |  |
|  |  | Hospitalization or prolongation of hospitalization | | |  |
|  |  |  |
|  |  | Persistent or significant disability (specify…………………………………………………) | | |  |
|  |  |  |
|  |  | Congenital anomaly | | |  |
|  |  |  |
|  |  | Other (specify…………………………………………………) | | |  |
|  |  |  |

**4. ACTION TAKEN**

* + Medication withdrawn
  + Dose increased
  + Dose reduced
  + Dose not changed
  + Unknown

1. **REPORTER**

NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FACILITY/CLINIC:

ADDRESS:

**5. OUTCOME OF SERIOUS ADVERSE EVENT**

* Recovered / resolved
* Recovering / resolving
* Recovered with sequelae
* Not recovered / not resolved
* Died
* Unknown

POSITION:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| E-MAIL: | |  | PHONE NO. |  |  |  |  |
| SIGNATURE |  | | DATE SENT | DD | MMM | YYYY |  |
|  |  |
|  |  |  |  |  |

**Explanatory Note**

**TO BE ADAPTED ACCORDING TO THE LOCAL SITUATION**

* This form is intended for the Core Package of active tuberculosis drug-safety monitoring and management (aDSM)[[1]](#footnote-1). For more details please refer to other documents on aDSM. The spontaneous reporting form in use by the national pharmacovigilance authorities may be adapted to provide for the purposes of alerting the TB programme of SAEs and avoiding parallel reporting structures.
* The completed form can be sent electronically, via email or fax to <address> and the responsible authority alerted by phone.
* The report should be sent within <number> hours after it is detected, even upon suspicion of seriousness.
* The report should be sent even if not all details are available and regardless of certainty of association with any particular medicine. The essential details are the identifiers of the patient and the reporter; the name of the suspected medicine(s); and basic details on the serious adverse event.
* If the report relates to a previously notified event indicate this under section 3; if more than one serious adverse event occur in the same individual, send separate forms for each event.
* All health care professionals are encouraged to report. Patients and relatives may also report.
* Upon receipt of the information the responsible authority will review the information and contact the reporter and/or facility for more details. All information, including identity of the patient and reporter, will be handled in strict confidence. Apart from action to protect public health, anonymised statistics from these reports will be used to improve drug-safety.
* When reporting please use DD MMM YYYY format to report dates. Under DESCRIPTION OF EVENT in section 3, provide a single diagnosis and include anatomical location if applicable. If diagnosis is unknown, describe clinical picture.

1. Active tuberculosis drug-safety monitoring and management (aDSM). Framework for implementation. Geneva: World Health Organization; 2015 (WHO/HTM/TB/2015.28; http://apps.who.int/iris/ bitstream/10665/204465/1/WHO\_HTM\_TB\_2015.28\_eng.pdf, accessed 15 February 2019) [↑](#footnote-ref-1)