**ADVERSE EVENT (AE) REPORT FORM**

***(FOR USE AT DRUG ADMINISTRATION SITE IN PREVENTIVE CHEMOTHERAPY PROGRAMMES)***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Country:*** | | ***Date Of Report:*** | | | | ***ID No. (if available):*** | | |
| ***Patient Name & contact details:*** | | | | | | | | |
|  | | | | | | | Age: | Sex (M/F): |
| Treatment site (Village/District): | | | | | | | | |
| Which drugs were administered? | | Dose administered | | Brand and Manufacturer Name | | Batch Number | | | *Time and Date of treatment:* (hour, day/month/year) |
| albendazole | |  | |  | |  | | |  |
| azithromycin | |  | |  | |  | | |  |
| diethylcarbamazine (DEC) | |  | |  | |  | | |  |
| ivermectin | |  | |  | |  | | |  |
| mebendazole | |  | |  | |  | | |  |
| praziquantel | |  | |  | |  | | |  |
| other (specify) | |  | |  | |  | | |  |
| Explain the circumstances of past and concomitant treatment(s) with same or other medicines and when they were given (if applicable): | | | | | | | | | |
| ***Time and date of onset of the adverse event:*** | | | | | | | | | |
| ***Description of adverse event: Please describe clinical signs and symptoms and diagnosis if known.***  *Please tick boxes as appropriate****:***  *death*  *life-threatening*  *in-patient hospitalization or prolongation of an existing hospitalization*  *persistent or significant disability/incapacity*  *birth defect*  *none of the above* | | | | | | | | | |
| **Past medical history and other relevant information** (e.g. other diseases, suspected parasitic infections such as malaria or loiasis, laboratory results, dates of hospitalisation or death, alcohol intake within 24hrs of treatment, pregnancy): | | | | | | | | | |
| **Any treatments administered to manage adverse event:** | | | | | | | | | |
| Patient currently recovered  **Yes/No/Unknown** | | | | | Do you think that the treatment was a possible cause of the adverse event?  Yes/No  If Yes, which drug do you think was responsible: | | | | |
| ***Reporter’s name & contact details:*** | | | | | ***Signature and date:*** | | | | |

**Notes**

1. Send copies of this form to your District Medical Officer or Ministry of Health, the National Drug Regulatory Authority, the National Pharmacovigilance Centre and local WHO office.
2. Conceal the patient's name and forward scanned copies within one working day via email to [pctdata@who.int](mailto:pctdata@who.int) and concerned relevant manufacturers as shown below:

Mectizan® Donation Program Fax number: +1-**404-393-9042**

325 Swanton Way, Decatur, GA30030 Email: [mectizan@taskforce.org](mailto:mectizan@taskforce.org)

Merck Global Safety Fax number: +1-**215-661-6229**

Email:

GlaxoSmithKline UK Case Management Group Fax number: +44 208 754 7821

Email: [UKCMG@gsk.com](mailto:UKCMG@gsk.com)

Johnson&Johnson Fax number:

Email:

Pfizer Fax number:

Email:

Eisai Co., Ltd, Global Pharmacovigilance Fax number: +81-3-3811-2710

Email: Eisai-asia\_safety@hhc.eisai.co.jp

Merck KGaA, Global Drug Safety Fax number: +49 6151 726914

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