WHO IMPLEMENTATION TOOL FOR MONITORING THE TOXICITY OF NEW ANTIRETROVIRAL AND ANTIVIRAL MEDICINES IN HIV AND VIRAL HEPATITIS PROGRAMMES

JULY 2018

World Health Organization

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CONTENTS

ABBREVIATIONS AND ACRONYMS

ART	antiretroviral therapy
ARV	antiretroviral
aDSM	active tuberculosis drug safety monitoring and management
DAA	direct-acting antivirals
DRV/r	darunavir/ritonavir
DTG	dolutegravir
EDS	Enhanced Data System
EFV	efavirenz
NASCOP	national AIDS and STI control programme
NVP	nevirapine
RAL	raltegravir
TLD	fixed-dose combination of tenofovir disproxil fumarate, lamivudine and dolutegravir
TB	tuberculosis

DEFINITIONS

Active toxicity monitoring. A system in which active measures are taken to detect the presence or absence of adverse drug reactions occurring during or after exposure to a pharmaceutical product. The adverse drug reactions may be detected by interviewing patients, performing specific investigation or by screening patient records.

Active TB drug safety monitoring and management (aDSM). Active and systematic clinical and laboratory assessment of people being treated for drug-resistant tuberculosis (TB) or with new TB medicines or novel multidrug-resistant TB regimens to detect, manage and report suspected or confirmed drug toxicities.

Adverse event. Any untoward medical occurrence that may present during treatment with a pharmaceutical product but that does not necessarily have a causal relationship with this treatment.

Adverse drug reaction. A response that is harmful and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or for modifying physiological function. An adverse drug reaction, in contrast to an adverse event, is characterized by the suspicion of a causal relationship between the drug and the occurrence: that is, assessed as being at least possibly related to treatment by the reporting or a reviewing health professional.

Pharmacovigilance. The science and activities relating to detecting, assessing, understanding and preventing adverse effects or any other drug-related problem.

Routine toxicity monitoring. Monitoring of treatment-limiting ARV drug toxicity (see below for definition) integrated into the monitoring and evaluation of national HIV treatment programmes using patient monitoring tools and reporting systems.

Signal. Information reported on a possible causal relationship between an adverse event and a medicine, the relationship being unknown or previously incompletely documented. Usually more than a single report is required to generate a signal, depending on the seriousness of the event and the quality of the information.

Treatment-limiting toxicity. A serious adverse drug reaction that results in drug discontinuation or substitution. This includes serious adverse drug reactions: any adverse reaction that can cause one of the following: death; threatening life; requiring or prolonging hospitalization; disability or permanent damage; or congenital anomaly or birth defect. In addition, any reaction that leads to treatment interruption or requires changing the drug or regimen because of an adverse drug reaction is also considered a serious adverse drug reaction.

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Please send any comments on this tool or suggestions to hiv-aids@who.int