ASSURING SAFETY OF PREVENTIVE CHEMOTHERAPY INTERVENTIONS FOR THE CONTROL OF NEGLECTED TROPICAL DISEASES

PRACTICAL ADVICE FOR NATIONAL PROGRAMME MANAGERS ON THE PREVENTION, DETECTION AND MANAGEMENT OF SERIOUS ADVERSE EVENTS.

World Health Organization

WHO Library Cataloguing-in-Publication Data

Assuring safety of preventive chemotherapy interventions for the control of neglected tropical diseases: practical advice for national programme managers on the prevention, detection and management of serious adverse events.

1.Neglected diseases - prevention and control. 2.Endemic diseases - drug therapy. 3.Parasitic diseases - drug therapy. 4.Anti-infective agents - therapeutic use. I.World Health Organization.

ISBN 978 92 4 150219 1 (NLM classification: WC 680)

ACKNOWLEDGEMENTS

This document is based on and should be read in conjunction with *Preventive chemotherapy in human helminthiasis : coordinated use of anthelminthic drugs in control interventions : a manual for health professionals and programme managers, WHO 2006.*

This document has largely relied on existing WHO publications from which much inspiration and materials have been derived: *Surveillance of adverse events following immunization - Field guide for managers of immunization programmes WHO/EPI/TRAM/93.02 REV.1, Immunization safety surveillance: Guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization WPRO/EPI/99.01, The safety of medicines in public health programmes: pharmacovigilance an essential tool, WHO 2006; The importance of pharmacovigilance,* WHO 2002; *Safety monitoring of medicinal products,* WHO/UMC 2000; *Expecting the Worst - Anticipating, preventing and managing medicinal product crises,* WHO-UMC 2003.

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TABLE OF CONTENTS

GLOSSARY 1

ABBREVIATIONS 3

1. PURPOSE 4

2. Adverse events following large-scale preventive chemotherapy interventions (AE) 5

2.1 Reactions to the medicines 7

Use in pregnancy 7

Use in Young Children 8

Interactions 8

2.2 Operational errors 8

2.3 Coincidental events 9

3. Approach to management of SAEs 11

3.1 Communicating information on known AEs and SAEs 11

3.2 Preparing preventive chemotherapy interventions to properly and timely manage SAEs 11

3.3 Treating affected patients 11

4. Responding to SAEs 12

4.1 Providing care 12

4.2 Establishing the facts 12

4.3 Communicating with the communities 12

4.4 Communicating with the media 13

4.4.1 Understanding the media perspective 14

4.4.2 Holding a media conference 14

4.4.3 Preparing a press release 15

4.5 Fixing the underlying problem (in the case of an operation error) 15

5. Reporting serious AEs 16

5.1 What events should be reported? 16

5.2 Who should report? 16

5.3 When to report? 17

5.4 How to report? 17

5.5 How to overcome under-reporting? 18

6. Investigating reported SAEs 19
6.1 Which reports should be investigated? 19
6.2 Who should investigate? 19
6.3 When to investigate? 19
6.4 How to investigate? 19
6.4.1 Investigating AE clusters 20
6.5 Outline of an investigation 20
6.6 Causality assessment 22

7. Establishing preventive chemotherapy safety surveillance 24
7.1 Objectives 24
7.2 Differences between preventive chemotherapy safety surveillance and pharmacovigilance in general 24
7.3 Roles and responsibilities for safety surveillance: involving all concerned parties 25
7.4 Learning and training 26
7.5 Steps for establishing a system 27

8. Evaluation of the safety surveillance system 28
ANNEX A - SIMPLE AE REPORT FORM 29
ANNEX B - COMPREHENSIVE AE REPORT FORM 30
ANNEX C - AE INVESTIGATION FORM 33
ANNEX D - COMMUNICATING WITH THE MEDIA 34
ANNEX E - CHECKLIST FOR A SAFETY SURVEILLANCE SYSTEM 36
ANNEX F - MANAGING PATIENTS EXPERIENCING ADVERSE EVENTS AT THE DRUG DISTRIBUTION LEVEL 37
ANNEX G - MODEL SAFETY INFORMATION SHEETS 38

GLOSSARY

a) Definitions adopted by the WHO Programme on International Drug Monitoring[1]

side effect: 'any unintended effect of a pharmaceutical product occurring at doses normally used in man, which is related to the pharmacological proprieties of the drug'. Essential elements in this definition are the pharmacological nature of the effect, that the phenomenon is unintended, and that there is no overt overdose.

adverse reaction: 'a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man'. In this description it is of importance that it concerns the response of a patient, in which individual factors may play an important role, and that the phenomenon is noxious (an unexpected therapeutic response, for example, may be a side effect but not an adverse reaction).

adverse event or ***experience:*** 'any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment'. The basic point here is the coincidence in time without any suspicion of a causal relationship.

Serious adverse events can be defined as those that:

a. are life-threatening or fatal
b. cause or prolong hospital admission
c. cause persistent incapacity or disability; or
d. concern misuse or dependence.

b) Definitions adopted for and applicable to this document

Adverse event following preventive chemotherapy (AE)	A medical incident that takes place after a preventive chemotherapy intervention and is suspected to be but is not necessarily caused by the medicines used in the intervention. Some AE, after investigation, may be found to have been caused by the medicine. Such AE will also be referred to as adverse drug reactions or side effects.
Adverse experience	Synonym of adverse event
Adverse drug reaction	'a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man'. In addition to that, an adverse reaction can also be the consequence of a medicine's efficacy in killing parasites. See also Adverse event following preventive chemotherapy (AE)
Cluster	Two or more cases of the same or similar event related in time, geography, and/or medicine administered. National programme managers should decide upon a more precise and locally meaningful definition.
Preventive chemotherapy	Regular, systematic, large-scale interventions involving the administration of one or more medicines to selected population groups with the aim of controlling NTDs such as lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, and soil-transmitted helminthiasis. Its aim, and greatest challenge, is to extend regular drug coverage as a public health intervention to reach all individuals at risk of the morbidity caused by selected NTDs.

[1] The Importance of Pharmacovigilance - WHO, 2002 - http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

Management of adverse events following preventive chemotherapy	A set of policies and measures aimed at ensuring preventive chemotherapy safety based on detecting, reporting, investigating, and responding to serious adverse events and clusters of adverse events, and to the concerns they generate in the affected communities.
Preventive chemotherapy safety	The public health practices and policies dealing with the various aspects of the correct administration of medicines in large-scale preventive chemotherapy. The term encompasses the spectrum of events from proper manufacture to correct administration. *The term includes both the safety of the operational aspects of interventions as well the safety of the medicinal product itself.*
Preventive chemotherapy safety surveillance	A system for ensuring preventive chemotherapy safety through the proper management of adverse events. Preventive chemotherapy surveillance requires *ad hoc* reporting pathways and response mechanisms which are not usually present in a typical pharmacovigilance system.
Safe intervention management practice	Those public health and operational practices and policies which ensure that the process of administering medicines for the control of NTDs carries the minimum of risk, regardless of the specific purpose of the intervention or the medicinal product(s) used.
Serious adverse event following preventive chemotherapy (SAE)	Any untoward medical occurrence that at any dose results in death, requires hospital admission or prolongation of existing hospital stay, results in persistent or significant disability/ incapacity, or is life threatening; Cancers and congenital anomalies or birth defects should be regarded as serious; Medical events that would be regarded as serious if they had not responded to acute treatment should also be considered serious. The term **"severe"** is often used to describe the intensity (severity) of a medical event, as in the grading "mild", "moderate", and "severe". A severe AE is not necessarily serious. from: *Adverse drug reactions: definitions, diagnosis, and management* *I Ralph Edwards, Jeffrey K Aronson - Lancet 2000; 356: 1255–59*
Severe adverse event	see Serious adverse event. The term **"severe"** is often used to describe the intensity (severity) of a medical event, as in the grading "mild", "moderate", and "severe".
Surveillance	The systematic collection of information on disease and use of medicines in preventive chemotherapy interventions that is analysed and disseminated to enable public health decision-making, action to protect the health of populations, and to ensure the safety of preventive chemotherapy interventions.