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## African Traditional Medicine – Technical Guidelines for Safety of Finished Medicinal Products

Draft African Standard for comments only — Not to be cited as African Standard

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**Table of contents**



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This African Standard was prepared by ARSO *Technical Committee on African Traditional Medicine* (ARSO/TC 82)

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## Introduction

Herbal medicines have become a popular form of therapy. Medicinal plants constitute source of raw material for both traditional systems of medicine (e.g Ayurvedic, Chinese, USANI, Hometherapy) and modern medicine. As such, they represent a substantial proportion of the global drug market. According to WHO estimates, 80% of the world's population depends on traditional medicines for their primary health care needs and major part of traditional therapy involves the use of plant extracts or their ingredients.

Recent advancement in research on herbal medicine has shown the need for its standardization to ensure quality and consumer safety. In almost all the traditional medicine systems from where herbal drugs have come into therapeutics, safety and quality are utmost essential which requires changes in their approaches based on modern concepts.

Major differences in the assessment of quality, safety and efficacy would hinder free circulation of herbal products and may represent a risk for consumers. The complexity of herbal drug and the inter operation of biographic data on safety and efficacy reflecting the experience gathered during long term use are best addressed by involving expertise. Safety of herbal products is directly linked to pharmaceutical details such as the way of production and the specification of the extract.

Safety of herbal products is essential. Drug safety refers to the frequency of adverse drug effects (i.e., physical or laboratory toxicity that could possibly be related to the drug) that are treatment emergent – that is, they emerge during treatment and were not present before treatment, or they become worse during treatment compared with the pretreatment.

This standard seeks to develop guidelines for ensuring safety of finished herbal products to meet international standard.

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# African Traditional Medicine – Technical guidelines for safety of finished medicinal products

## 1 Scope

This Standard specifies requirements and related procedures for ensuring the safety of Finished Medicinal Products.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AOAC Official Method 2008.02, Aflatoxins B1, B2, G1, and G2 and Ochratoxin A in ginseng and ginger by multi-toxin immunoaffinity column clean up and Liquid Chromatographic Quantitation

## 3 Terms and definitions

For the purpose of this standard the following definitions apply.

**3.1 Abbreviations**

3.1.1 SAE: Serious Adverse Event

3.1.2 SAR: Serious Adverse Reactions

3.1.3 SUSAR: Suspected Unexpected Serious Adverse Events Reporting

ATM: African Traditional Medicine

**3.2**

**Herbal Drug**

Herbal drug has been defined by WHO as, labelled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty acids, essential oils, or any other substances of this nature. Herbal medicines may contain excipients in addition to active ingredients

**Safety**

A systematic examination of the extent to which an entity (part or product) is capable of meeting specified requirements. The result of safety evaluation may be used for qualification, approval and registration or accreditation purposes.' Safety evaluation may be used to determine manufacturing safety capability.

**3.3**

**Toxicity**

It is defined as the extent to which a product is poisonous or harmful.

**3.4**

**Pharmacovigilance**

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It Is the monitoring of the effects of medical drugs after they have been licensed for use, especially in order to identify unreported adverse reactions

**4.0 Safety studies**

**4.1 Requirements for assessment of safety**

The minimum requirements for the assessment of safety are

a. Botanical identification/authentication Latin name (genus and species) of the plant species, local names and family.
b. Information (via Literature published research papers search/database)
c. Information regarding the safety and efficacy of the product.
d. In the absence of published results of toxicological studies, documented experience of long-term use should form the basis of the risk assessment

If the product has a long history of use without demonstrated harm, specific restrictive regulatory action is not necessary, unless new evidence indicates a need for a revised risk–benefit assessment. If there is a known toxicological risk, standard toxicological studies are mandatory. The absence of any reported or documented side-effects is not an absolute assurance of safety for traditional medicines; some toxicological tests may therefore be necessary

**4.2 Toxicity studies involves the following:**

a) *in vitro* and in mice to assess genotoxicity
b) *in vitro* to assess cytotoxicity
c) in one rodent model and one non-rodent model to investigate repeat dose (1, 3, 6, 9 months) toxicological effects
d) in a rodent model and in the rabbit to assess reproductive toxicity
e) in the rat to assess carcinogenicity

**4.2.1 Single dose toxicity:** in rodents to assess single-dose acute toxicity and maximum tolerated dose

**4.2.2 Acute toxicity**. Suggested tests should include those for immunotoxicity (e.g. tests for allergic reactions), genotoxicity, carcinogenicity and reproductive toxicity through long-term use.

## 5.0 Requirements for Residuals of biological and non-biological contaminants

Plants used as drugs, growth, collection, storage, and transportation are exposed to multitude of environmental influence which is responsible for contamination. The important contaminants considered for quality control purposes are either Non Biological Contaminants viz. heavy metal e.g. lead from exhaust etc and plant protection substances (pesticides and fumigation residues) or Biological Contaminants viz. microorganisms (bacterial moulds) and poisonous substances such as Aflatoxin produced by *Aspergillus flavus* which grows on herbs.

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**5.1 Determination of Heavy metal**

Significance: - to prevent health hazards.

To prevent the contamination & toxicity of material (extracts & finished products) the total amount of heavy metals shall be calculated by adding up the values obtained for Lead (Annex D), Arsenic (Annex E) and Mercury (Annex F). The report shall be given in ppm using Atomic Absorption Spectrophotometer (AAS) of (AAS

**5.2 Determination of Cadmium**

This test applies to crude herbal extracts & finished products.

Evaluation: - Atomic Absorption.

**5.3 Determination Mercury**

Significance: - to prevent the contamination & toxicity of material. Extracts & Finished products

Evaluation: - suitable methods e.g atomic absorption spec can be used in detection of mecury of other heavy metals

**5.4: Residual Pesticides**

Significance: - to prevent the contamination & toxicity of material.

Evaluation: - Chemical Analysis.

Application: - Extracts & Finished products.

Table 1 — Chemical, physical and mycotoxin requirements (WHO, 2007)

For use of pesticides, reference shall be made to the CODEX list of approved pesticides for spices and their maximum residue limits (MRLs) (WHO, 2007).

**5.5 Radioactive residues**

The WHO guidelines emphasize that the health risk, in general, due to radioactive contamination from naturally occurring radio nuclides is not a real concern, but those arising from major nuclear accidents may be serious and depend on the specific radionuclide, the level of contamination, and the quantity of the contaminant consumed. Taking into account the quantity of herbal medicine normally consumed by an individual, they are unlikely to be a health risk. Therefore, at present, no limits are proposed for radioactive contamination

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**Table 1 — Chemical, physical and mycotoxin requirements**

| *S/N* | *Characteristics* | *Limits(seeds)* | *Ref. Test methods* |
|---|---|---|---|
| 1 | Lead (pb), max. mg/kg | 20µg per gm | USP 30, NF 25 Pg. 231 |
| 2 | Cadmium (Cd), max. mg/kg | " | USP 30, NF 25 Pg. 231 |
| 3 | Arsenic (As), max. mg/kg | " | USP 30, NF 25 Pg. 231 |
| 4 | Chromium (Cr), max. mg/kg | " | USP 30, NF 25 Pg. 231 |
| 5 | Mercury (Hg), max. mg/kg | " | USP 30, NF 25 Pg. 231 |
| 6 | Copper (Cu), max. mg/kg | 20µg per g | USP 30, NF 25 Pg. 231 |
| 7 | Total ash (aerial parts), max. % | 4 – 8% | USP 30, NF 25 |
| 8 | Total ash (roots), max. % | " | USP 30, NF 25 |
| 9 | Acid – insoluble ash (leaves), max. % | 2% | USP 30, NF 25 |
| 10 | Acid – insoluble ash (roots), max. % | 4 – 8% | USP 30, NF 25 |
| 11 | Foreign matter, max. % | 2 – 3 % | USP 30, NF 25 |
| 12 | Total Aflatoxin ($AFB_1$ + $AFB_2$ +$AFG_1$ +$AFG_2$), ppb | 2ppb | AOAC 2008.2 |
| 13 | Aflatoxin B1 only, ppb | 4ppb | AOAC 2008.2 |

The inputs and Methods are based on USP 30, NF 25 of May 1, 2007.
Aflatoxin Test Method is from AOAC 2008.2

## 6.0 Microbiological Requirements:

Normally, a large number of bacteria and moulds are present in medicinal plants materials because of the contamination from the environment. Amongst those, the aerobic soil forming bacteria play a major role. The practices of harvesting, handling and production may cause further contamination. The main organism contaminants are *E.coli*, and other moulds. Herbal drugs contain organic constituents that are liable to microbiological contamination during harvesting, transportation, and storage if suitable environmental conditions such as proper drying, packaging storage are not maintained. Microbial load testing is carried out to ensure the absence of pathogenic bacteria and other fungi.

### 6.1 Total viable aerobic count

The total viable aerobic count **(TVC)** of the herbal material being examined is determined, as specified in the test procedure below, using one of the following methods: membrane-filtration, plate count or serial dilution. Aerobic bacteria and fungi (moulds and yeasts) are determined by the **TVC**.

Usually a maximum permitted level is set for most products, but when the TVC exceeds this level then it is unnecessary to proceed with determination of specific organisms; the material should be rejected without being subjected to further testing.

### 6.2
### Tests for Aerobic Bacteria:

**Significance: -** to prevent microbial contamination.

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**Evaluation: -** Microbiologically

**Application:** Pre-treated plant material

**The microbial and heavy metal contaminants should not exceed the limits stated below in table 2.**

**Table 2 — Microbiological limits (Purity tests for herbal medicines)**

| No | Parameter | Limits | Test method |
|---|---|---|---|
| **A** | ***Raw medicinal plant and herbal materials intended for further processing*** (*including additional decontamination by a physical or chemical process*) | | |
| (1) | Yeasts and moulds, max. per g | $10^5$ CFU/g | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (2) | *E. coli*, max. per g | $10^4$ CFU/g | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (3) | Shigella, per g or ml | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| **B** | ***Herbal materials that have been pretreated (***For *herbal materials that have been pretreated* (*e.g. with boiling water as used for herbal teas and infusions*) *or that are used as topical dosage forms)* | | |
| (4) | Aerobic bacteria/g | $10^7$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (5) | Yeasts and moulds, max. per g | $10^4$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (6) | *E. coli*, max. per g | $10^2$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |

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| No | Parameter | Limits | Test method |
|---|---|---|---|
| (7) | Enterobacteria and certain Gram-negative bacteria / g | $10^4$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (8) | *Salmonella,* per g | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (9) | Shigella, per g or ml | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (10) | Clostridia, per gram | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| **C** | ***Other herbal materials for internal use*** | | |
| (11) | Aerobic bacteria/g | $10^5$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (12) | Yeasts and moulds, max. per g | $10^4$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (13) | *Escherichia coli*, max. per g | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (14) | *Salmonella,* per g | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (15) | Enterobacteria and certain Gram-negative bacteria / g | $10^3$ | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |

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| No | Parameter | Limits | Test method |
|---|---|---|---|
| (16) | Clostridia, per gram | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |
| (17) | Shigella, per g or ml | Absent | WHO (1998) Quality control methods for medicinal plants materials. Geneva, World Health Organization. |

**7.0. Packaging and Labeling:**

Refer to standard on quality of finished herbal product

**7.1 Requirement of Packaging**

The following guidelines are to be used to regulate the packing, storage and transport of medicinal plants in adequate manner in order to get good quality plant material which can be granted to enable the testing efficiency of the procedures used.

a) After the repeated control and eventual elimination of low quality material and foreign bodies, the product should be packaged on a clean and dry preferably new sacks, bags or cases. The label must be clear, permanently fixed and made from non toxic material.
b) Packing materials should be stored in a clean and dry place that has to be free from pest and inaccessible for livestock and domestic animals it must be granted that no contamination of the product take place by the use of packing material, particularly in the case of fiber bags.
c) Reusable packaging material should be cleaned and perfectly dried before their usage.it must be granted no contamination takes place by reusing bags.

**7.2 Labelling**

In addition to the provisions of ARS 56, Pre-packaged foods - Labelling and Codex Alimentarius Commission (CODEX STAN 1-1985; Rev-8-2010) on General Standard for the labelling of Pre-Packaged food, the following shall be inscribed on the package:

a) Name of the product (type of raw material).
b) The Plant name and species (Qualitative and quantitative composition of product by unit dose or percentage)

c) The date and method of collection (i.e. wild or cultivated) (Can be applied in the compilation of file for registration of product or marketing authorization, this is may be heavy for the primary or secondary label)

d) The geographical origin of the species (Can be applied in the compilation of file for registration of product or marketing authorization, this is may be heavy for the primary or secondary label)
e) Method of administration and posology
f) Warning, precaution and storage if any.
g) Name and address of the manufacturer, packer, co-packer, distributor, importer, exporter or vendor.
h) Code or batch number
i) Net weight of product in grams (quantitative composition)
j) Manufacturing date and expiry date
k) Producing country or country of origin
l) Name of Non active ingredients, if present shall be declared.

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m) The disclaimer of the product will be added if there is no evidence of clinical trials. Marketing authorization number or country standard registration number if any.

**8.0 Pharmacovigilance**

**8.1 Requirement**

8.1.1 Well-articulated pharmacovigilance centres should be designated and made known to the public. The centre should have well defined and publicized lines of collecting reports on suspected adverse effects from consumers or health care professionals. Where there is no pharmacovigilance centre, consideration should be given to designating other relevant organizations, such as the national regulatory authority, poisons centres, drug information centres and consumer complaints authorities as the focal point.

8.1.2 Designated relevant staff members with relevant technical training (e.g. pharmacognosy, phytochemistry, ethnobotany, ethnopharmacology) and in the use and provision of herbal medicines8.1.3 Access to suitable analytical testing facilities for analysis of potentially causative products about which there is often insufficient information for ATM

8.1.4 Relevant report forms for reporting / data collection

8.1.5 Access to reliable information support on herbal medicines

**8.2 roles and responsibility**

Roles and responsibilities of each staff in pharmacovigilance centre should be well define and designated.

**8.3 Procedure for reporting suspected adverse reactions**

All suspected adverse reaction following the use of ATM should be reported such that each case contains adequate information for identification and assessment. Information can be gathered with the help of reporting form (Annex F.9) developed to request for all relevant information expected in a case report, as follows:

a) identification of the patient/consumer in order to avoid duplications and facilitate follow-up
b) age, sex and a brief medical history of the consumer/patient (when relevant); in some countries, ethnicity may need to be specified
c) name and common vernacular name of medicinal plant) and/or brand or ingredient name(s), including the part of medicinal plant used, preparation methods; manufacturer, country of origin, batch number, expiry date and provider
d) dose and quantity supplied, dosage form, route, start/stop dates
e) indication or reason for use
f) date of first administration to onset of event, description of reaction(s)with symptoms and signs, severity and seriousness, results of clinical investigations and tests, course and outcome, and challenge/rechallenge with the same product, where appropriate
g) all other medicines used (including self-medication), with administration details
h) risk factors, e.g. age, impaired renal function, previous exposure to the herbal medicine(s) concerned, previous allergies, drug misuse or abuse, the social use of drugs
i) name and address of reporter (to be considered confidential and to be used only for data verification, completion and case follow-up).

**8.4 Reporting Process**

**Use of report forms**

A single reporting form designed for ATMS should be used (example of report for is shown in Annex F.9. A standard printed or electronic reporting form can be used. These reporting forms should be widely available and easily accessible. Reports can also be sent by telephone, letter or e-mail. If possible, a sample of the herbal product and its packaging should be submitted with the report. Educational materials, including a list of simple terminology that can be easily understood, should be developed to inform and assist all parties providing information.

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**8.5 Confidentiality and accuracy in reporting**

Unless by written permission, the identity of both patient and the reporter of suspected adverse reactions should remain confidential. Under no circumstances should information obtained during pharmacovigilance activities be divulged for commercial purposes.

Reporting on herbal medicines should be as accurate and complete as possible however, the fact that information is less than optimal should not in any case prevent reporting.

**8.6 Procedure for Assessing case report**
**Approach to Assessing Report Data**

Standard approach should be adopted in assessing each data element captured in a report. It is most important to determine whether a reaction is caused by the way a herbal medicine has been used, prepared or sourced. Each assessment should be based on the following:

a) the association in time between administration of the herbal product and the event
b) the outcome of de-challenge and re-challenge
c) known pharmacology (including current knowledge of the nature and frequency of adverse reactions)
d) medical or pharmacological plausibility (the sequence of symptoms, signs and laboratory tests and also pathological findings and knowledge of mechanisms)
e) likelihood of other causes or their exclusion
f) testing for adulterants or contaminants that could be the source of adverse events.
g) In appropriate use.

Note: all consumer/patient and reporter information will remain confidential.

**8.7 Investigation and analysis of the cause of suspected adverse event** Serious Adverse Reaction, Suspected Unexpected Serious Adverse Reaction in particularly should be further investigated scientifically. The investigations may include the following:

i. medical investigation of the adverse reactions: pathology, clinical pharmacology, clinical toxicology, pharmacogenetic studies
ii. pharmaceutical investigation of the adverse reactions: pharmacokinetics, pharmaco-dynamics and pharmaceutical, pharmacological and toxicological analysis
iii. pharmacognostical/phytochemical investigation (including authentication) of the herbal medicines
iv. physicochemical analysis to identify the constituents of the herbal medicines
v. pharmacoepidemiology.

**8.8 Procedure for Data Management**

**8.8.1 Data quality**

Strenuous efforts should be made to ensure that there are quality controls on data processing and that the data elements of reports are as complete and accurate as possible. Mechanisms to check for duplications should be instituted.

**8.8.2 Data storage.**

Computer databases should be managed at very high standard to facilitate access to and use of the data. Software should be selected with expert advice so that analytical needs can be met.

**8.8.3 Data analysis**

Programmes should be developed to provide for regular analyses and data output appropriate for local needs.

**8.9. Procedure for communicating results of assessment of SAE, SAR or SUSAR**

The successful safety monitoring of herbal medicines depends on good communication. Transparent communication is essential to ensure that all players collaborate to meet the goal of the safe and effective use of ATM.

Effective and timely communication of results of monitoring is essential so that pharmacovigilance activities can have positive impact on the health of the people and so that manufacturers can take

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appropriate action regarding their products. Communication between the following levels is suggested:

i. the national pharmacovigilance centre and health professionals
ii. the national pharmacovigilance centre and providers of herbal medicines
iii. health professionals and providers of herbal medicines, and consumers and patients
iv. providers of herbal medicines and those for other medicines
v. the national pharmacovigilance centre and consumers
vi. the national pharmacovigilance centre and the regulatory authority
vii. the national pharmacovigilance centre and such centres in other countries, within the region or in other regions
viii. the national pharmacovigilance centre and UMC
ix. the national pharmacovigilance centre and the mass media.

The development of effective communication needs to be adequately resourced.

**8.10 Procedure for risk communicating**

**8.10.1 Risk communication**

Communication strategies should be established to effectively reach all relevant target audiences, such as providers of ATMs, other health professionals, manufacturers and patients/consumers. Communication of safety information is a shared responsibility between national pharmacovigilance centres, national regulatory agencies, manufacturers, health professionals and patients/consumers. Different risk communication vehicles can be considered, including:

i. adverse reaction bulletins or articles distributed in reputable journals
ii. public advisories or warnings
iii. “Dear Health Professional” letters.

Various methods of information dissemination can be considered, such as:

a) Internet posting
b) direct mass mailing to providers of ATM and health professionals
c) briefings to the mass media
d) briefings to patient/consumer associations
e) education sessions at health professional society meetings.

In order to reach consumers and the wide range of providers of ATM successfully, messages should be tailored to suit the recipients, including translation into local languages where appropriate.

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ANNEX

## Annex F
(informative)

## Pharmacological properties and applications of *Plant material*

### F.1 Pharmacological properties

#### F.1.1 Pharmacodynamic properties

The following is a summary of pharmacological activities of *Plant material*

#### F.1.2 Anti-inflammatory action

#### F.1.3 Hypoglycaemic and Anti-diabetic activities

#### F.1.4 Antioxidant and hepatoprotective activity

#### F.1.5 Hypolipidemia activity

#### F.1.6 Anti-microbial properties

#### F.1.7 Antimalarial

#### F.1.8 Anti-hypertensive Activity

#### F.1.9 Anthelmintic activity

#### F.1.10 Molluscicide and anti-schistosomiasis activity

#### F.1.11 Antifertility activity

#### F.1.12 Phytoestrogen effect

#### F.1.13 Anti-cancer Activity

#### F.1.14 Oxytocic property

#### F.1.15 Anticoagulant and antithrombic activities

and 200 mg/kg induced 40 and 50% inhibition against thrombosis in mice. (Awe *et al.*, 1998)

#### F.1.16 Analgesic and Antipyretic activities

### F.2 Safety data

### F.3 Key (proposed) usage

#### F.3.1 Therapeutic indications

#### F.3.2 Dosage/posology

#### F.3.3 Contraindications

#### F.3.4 Special warnings and precautions for use

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**F.3.5 Interactions**

**F.3.6 Pregnancy and lactation**

**F.3.7 Adverse effects**

**F.3.8 Overdose**

**F.3.9 Evaluation of efficacy**

Traditional and pharmacological evidence in many respects.

**F.4 Safety and interaction classification:**

**F.5 Clinical Studies**

**F.6 Trade information**

**F.7 Regulatory information**

British Pharmacopoeia 2012

WHO Monograph on Selected Medicinal Plants 1999

European Pharmacopoeia 7.0 (2008)

**F.8 Possible developments**

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## F.9 Example of Reporting form for suspected adverse reaction to medicines, including herbal medicines and vaccines (WHO, 2004)

Patient/consumer identification (please complete or tick boxes below as appropriate)

| | | |
|---|---|---|
| Last name | First name(s) | Patient/record number |
| Ethnicity | | |
| Address (place and region, or health facility may be used) | | Date of birth |
| | | Sex ☐M ☐F |

List of all medicines/vaccines/herbal medicines used by the patient. Please indicate suspected medicines with an asterisk (*) (please complete boxes below)

| Medicine(s)Vaccine(s) + batch no. | Daily dose | Route of administration | Date started | Date stopped | Reason for use |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

For herbal medicines please give detailed information on the product
Product name:

How was the product obtained?

List of product ingredients; attach product label if available:

Name and address of the manufacturer;

Name and address of the distributor:

Other relevant information:

Description of the suspected adverse reaction (please complete boxes below)

| |
|---|
| Date of onset of reaction (dd/mm/yy): |
| Description of reaction (please include results of laboratory tests if available): |

Outcome of the suspected adverse reaction (please tick boxes as appropriate)

| | | | | |
|---|---|---|---|---|
| Recovered ☐ | Not yet recovered ☐ | Unknown ☐ | Fatal ☐ | Date of death |
| Severe? Yes ☐ No ☐ | | Rechallenge? Result: | Yes ☐ | No ☐ |
| Was the patient admitted to hospital? If yes, give name and address of hospital: | | | Yes ☐ | No ☐ |

Other factors (please tick box or describe as appropriate)

| | | | |
|---|---|---|---|
| Kidney disease ☐ | Liver disease ☐ | Allergy (please describe) ..... ..... | |
| Other illnesses (please describe): | | | Malnutrition ☐ |

Reporter identification

| |
|---|
| Type (please circle): nurse/doctor/pharmacist/other health worker /manufacturer/ distributor/supplier |
| Name: |
| Address:<br>Telephone: |
| E-mail address: |

Signature of reporter: ..... Date: .....

Please send completed form to: .....

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## Bibliography

Absorption Spectrophotometer (AAS) of (AAS) KS 1764: 2018

ARS 53, General principles of food hygiene — Code of practice

ARS 56, Pre-packaged foods — Labelling

ARS 950-2016, ATM - Terms and terminology

ARS 952:2016: Guidelines on Good Agricultural and Collection Practice (GACP) for Medicinal Plants

ARS 955-2016, African Traditional Medicine — Technical guidelines for safety, efficacy and quality of raw materials and herbal medicines

British Pharmacopoeia 2012

Chemical, physical and mycotoxin requirements (WHO, 2007); (Upton & AHP, 2012)

CODEX STAN 150, Standard for food grade salt

CODEX STAN 192, General standard for food additives

CODEX STAN 193, Codex general standard for contaminants and toxins in food and feed

CODEX STAN 1:1985; Rev. 8:2010, General Standard for the labelling of Pre-Packaged food

European Pharmacopoeia 7.0 (2008)

Microbiological limits WHO (1998). Quality control methods for medicinal plants materials. Geneva, World Health Organization. WHO Monograph on Selected Medicinal Plants 199

*The International Pharmacopoeia* - Ninth Edition, 2019

USP 30, NP 25, (2007), United States Pharmacopeia 30, National Formulary 25, 2: 1-1256

WHO (2003). Regulation and Prequalification. www.who.int/teams/regulation-prequalification/pharmacovigilance February 2021.

WHO (2004). Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.

WHO 2007 guidelines for assessing herbal medicines

WHO (2012). SAFETY MONITORING of MEDICINAL PRODUCTS, Reporting system for the general public

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