DRUG

NATIONAL

AUTHORITY

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GUIDELINES for REGULATION of PUBLIC HEALTH PRODUCTS in UGANDA

March 2007

LIST OF ACRONYMS

FAO	Food and Agriculture Organization
INN	International Non-proprietary Name. (Internationally recognised non-proprietary name of such a product or Name of the active substance or such other name as the NDA may determine).
NDA	National Drug Authority
PHP	Refer to public health product or substance
WHO	World Health Organization

TABLE OF CONTENTS

1.0 INTRODUCTION

These guidelines apply to the regulation of public health products. No Public Health Product shall be manufactured or imported into Uganda and marketed unless it has been notified with the National Drug Authority.

Definitions

Public Health Product: *Is a product or item or device used for public health programs for vector control or for other recognized health protection uses, including mitigation of viruses, bacteria, or other micro-organisms (other than viruses, bacteria or micro-organisms on or in living man or other living animal) that pose a threat to public health.* (EPA, 2002 [1]; WHO, 2003 [9]).

(For the purposes of this guideline, Public Health Products and Public Health Substances will be used interchangeably)

Vector
Any insect, rodent, nematode, fungus, weed, or any form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organisms (except viruses, bacteria or other micro-organisms on or in living man or other living animals) that pose a threat to public health. It is capable of transmitting the causative agent of human disease or of producing human discomfort or injury. Examples; include, acarines, rodents, mosquitoes, flies, fleas, cockroaches, or other insects. (EPA, 2002 [1]; WHO, 2003 [9]).

Organism:
A biological entity unicellular or multi-cellular.

Residues:
Remains of a public health chemical after it has been sprayed or applied onto a targeted point of application. Includes substances resulting from degradation or metabolism of the control agent.

Public Health
The science and the art of preventing disease, prolonging life, and promoting physical health and mental health and efficiency through organized community efforts toward a sanitary environment; the control of community infections; the education of the individual in principles of personal hygiene; the organization of medical and nursing service for the early diagnosis and treatment of disease; and the development of the social machinery to ensure to every individual in the community has a standard of living adequate for the maintenance of health (Winslow C.E.A, 1920) [12].

1.1 All documents are to be submitted typewritten or computer printed in ENGLISH. Where originals are in another language, copies shall be presented together with certified English translations.

1.2 Each complete application must contain a complete index to the various appendices and each page of the application dossier must be numbered.

1.3 A prescribed application fee shall accompany each complete application form. Subsequent applications to amend any part of the application shall be accompanied by a prescribed fee per change and guidelines on submission of amendment applications shall be followed.

A fee shall be charged annually to retain PHP on the notification list.

1.4 Notification procedures shall commence only if application form with its appendices has been properly completed. Only the information required in the appendices should be furnished.

1.5 All documents shall be addressed to:

The Executive Secretary / Registrar,
National Drug Authority, Plot 46–48 Lumumba Avenue
PO Box 23096, Kampala, UGANDA

Phone: (+256) 41-255665 / 347391/ 347392
Fax: (+256) 41-255758
E-mail: ndaug@nda.or.ug

1.6 Payment of fees can be made by Bank Transfer to:

National Drug Authority Account no: 0240060034201
Stanbic Bank Uganda Limited, Kampala

or by bank draft in favour of National Drug Authority

2.0 APPLICANT

2.1 Application for the notification of a Public Health Chemical/Product shall be made only by:

- the patent holder
- the manufacturer
- a distributor authorised by the manufacturer or patent holder
- an authorised Local Technical Representative (LTR) of the manufacturer or patent holder (see section 5 below)

The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.

3.0 PARTICULARS OF THE PUBLIC HEALTH PRODUCT

3.1 ***Proprietary name*** means the (trade or brand) name which is **unique** to a particular PHP and by which it is generally identified (and by which it is registered in the country of origin/manufacture). All PHP shall be notified as per their proprietary Name.

3.1.1 The Proprietary Name should not be derived from INN name and should not have an INN stem.

3.1.2 If derived from Generic Name should not be similar to the Generic Name.

3.1.3 Each dosage form and strength will require a unique Proprietary Name.

3.1.4 Each Name used should be distinctive in sound and in writing not to be confused with Names of other Products.

3.1.5 The Name should not be misleading or likely to lead to improper use of PHP.

3.1.6 The use of “Umbrella/Brand Naming” is not acceptable, each product type should have its own unique Name.

3.1.7 Any Phrase that implies superiority, speed or better performance over other products shall not be allowed.

3.1.8 Meaning of abbreviations, symbols, alpha-numerals must be explained in a covering letter.

3.1.9 A proprietary name should not carry a connotation that is interpreted to refer to the benefit or the use of the product unless the implied meaning of the name is backed with a strong scientifically proven report that support the connotation.

3.1.10 When the Name being applied for is identical or very close to already registered Name, applicant shall be advised to change to another Name.

3.2 ***Strength*** shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/mL, mg per 5mL spoonful, mg per G, etc.

3.3 ***Dosage form*** shall mean the form in which the public health product is presented, e.g. solution, suspension, Tablet, emulsion, Capsules, Sachet, etc.

3.4 ***Description of the Product*** shall mean a full visual description of the PHP including colour, size, shape and other relevant features, e.g. white coloured vaporized, odourless powder in a pressurized spray can or pink coloured liquid etc.

3.5 ***Labelling & packaging:*** The applicant shall ensure that the primary (immediate) packaging of the product is labelled according to the law applicable in Uganda. The following minimum information shall be required in English on the label of the immediate packaging:

(i) Brand name where appropriate
(ii) International non-proprietary name/generic name where it is applicable
(iii) Quantity of active ingredients per dosage.
(iv) Total packed quantity in a unit pack.
(v) Date of manufacture
(vi) Date of expiry
(vii) Batch number
(viii) Storage conditions
(ix) Instructions for use of PHP
(x) Warning and handling precautions (for transportation, storage & use of PHP)
(xi) Symbol of PHP hazardous classification (e.g. Symbols for Poisonous, Corrosive, Flammable or Explosive agents)
(xii) Measures for treating toxicity & adverse effects (in case of accidental ingestion or physical contact with the PHP).
(xiii) Name and address of manufacturer
(xiv) User information leaflet in case sufficient information (ix) to (xii) above is not availed directly on packaging container).

- Where a secondary packaging is provided with labelling details, the name of the manufacturer on the primary pack may be substituted with a trade-mark or other symbol. However these details shall appear in full on the secondary packaging.

- All PHPs should have the following precautionary symbols indicated on their labels depending on the nature of hazard they present.

  - Danger
  - Warning
  - Caution
  - Poison
  - Corrosive
  - Flammable
  - Explosive

Packaging:

(i) The packaging for every PHP shall be sufficiently durable, designed and constructed so that it will contain the PHP safely under practical conditions of storage, display and distribution.

(ii) Packaging must allow easy withdraw or application of contents in a manner safe to the user.

(iii) Closures on packaging containers should ensure contents are protected from leakage or spillage.

(iv) Containers should ensure contents are protected against degradation or loss of potency resulting from interaction with contact surfaces or from effects of radiation, moistures, air or any other means.

3.6 ***Information leaflet:*** Applicants should be encouraged to include Scientific Package Inserts in PHP Packs. Package Inserts will ensure that PHPs are safely and effectively used under normal conditions of use.

Package inserts should not carry promotional statements and make comparison of its product to other products.

In case of changes in the scientific package information leaflet after product has been notified, NDA should be notified.

The leaflet shall include the following minimum information:

i) Proprietary Name
ii) Approved INN/Generic Name if it's applicable
iii) Identification: Brief description of the physical appearance of the product.
iv) Presentation: Dosage form and total quantity presented per unit pack e.g. ml, gm, Number of Tablets e.t.c.
v) Composition of product's active ingredients, stating name of each active ingredient and content in a unit dose.
vi) Name of the preservative and unit quantity per dose added into the product.
vii) Name of Anti-oxidants and unit quantity per dose added into the product.
viii) Warning and handling precautions.
ix) Treatment of poisoning due to PHP or accidental surface contact with the PHP.
x) Approved Name of any other inactive ingredients contained in the formulation.
xi) Targeted benefit for use of PHP. Brief description of vulnerable organisms targeted by the PHP.
xii) Dosage and directions for use, application for use of PHP.
xiii) Storage instructions and Shelf-life.
xiv) Name and address of the manufacturer.

3.7 ***Trade Marks and logos:*** Applicant should be aware that; Infringements on Trade marks or logos are the concern of the applicant and not NDA.

4.0 PARTICULARS OF THE MANUFACTURER(S) AND ACTIVITY

The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided.

Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated as in the examples below.

	Name	Address	Activity
1.	UgaPest Chem	Plot 4, City Rd, Kampala PO Box 5445, Kampala, Uganda Tel: 222207	Mixing & compounding
2.	T.M. Holdings	Plot 73, Gayaza Town, Wakiso District PO Box 3459, Kampala Tel: 222218	Filling
3.	Chem-Plus	Plot 5, 6th Street, Industrial Area Kampala PO Box 3459, Kampala Tel: 222218	Packaging

A copy of a valid manufacturing licence shall be provided for each site.

Each manufacturing facility for the PHP must comply to applicable regulatory requirements e.g. standards for Quality assurance, ISO, GMP and Hazardous Chemical regulation requirements. Proof of compliance must be provided.

5.0 AUTHORISED REPRESENTATIVE IN UGANDA

A body corporate (company) authorised to handle Public Health Chemicals/Products, shall be the applicant's local representative in Uganda with legal authorisation to take full responsibility for the product on behalf of the applicant, and will be answerable to NDA.

This body corporate shall be called the **Local Technical Representative (LTR)**. A copy of the legal authority given to the representative or agent shall be enclosed. Such a body may be:

A business entity dealing in PHPs, supervised by a Scientist with an appropriate qualification in Chemistry, Public Health, Biochemistry, Pharmacy or Microbiology or as defined by the Authority.

6.0 SIGNATORY

The signatory shall be a qualified personnel working for and/or authorised by the manufacturer / applicant. The designation and qualification of the qualified personnel shall be stated.

7.0 APPENDIX 1 (Specifications of Packaging Materials & Product Composition)

7.1 SPECIFICATIONS OF THE PACKAGING MATERIAL

The following information shall be provided:

a) A general description of the container and closure system including primary (inner) and secondary (outer) packaging materials used.
b) Specifications for primary (immediate) packaging components such as: glass containers, plastic containers, rubber closures.
c) Evidence of suitability of the container and closure system for the finished product and proof of compatibility of primary packaging components with finished product.

7.2 COMPOSITION OF THE PRODUCT

a. State the approved / INN /generic name(s) of the active and inactive ingredients in the PHP. Trade names shall not be used.

b. State quantities of each ingredient per unit dose e.g. mg/tablet, mg/mL, etc.

c. Where applicable state the Reference text or Reference to official specifications for each ingredient e.g. BP 2004 page 111.

d. State reason for inclusion of each inactive ingredient in the PHP.

e. Each PHP shall have necessary chemical, physical composition and uniformity of mix necessary for it to be effective for the purposes for which it is intended.

8.0 APPENDIX 2 (Chemistry & Manufacturing aspects)

8.1 Raw material specifications

Raw material specifications and certificates of analysis shall be given.

Copies of the supplier's or manufacturer's Certificates of Analysis shall be supplied for each raw material as proof of conformance to all declared specifications.

8.2 **Details of the procedures involved in the various stages of manufacture**, including packaging shall be given. This may be in the form of a detailed flow diagram.

8.3 **Summarised specifications of the final product** shall be given, ie. the acceptable limits of all the physical, chemical, biological and (where applicable) microbiological parameters. A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above shall be given.

The Finished product specification should include the following tests;

a) Description
b) Identity - test method should be specific for active ingredient(s)
c) Assay - test method should be specific and stability indicating for active ingredient(s)
d) Impurity limits - to determine the level of degradation products of active ingredients, and active ingredient-excipient interaction impurities.
e) Water content
f) Microbial limits whenever applicable

g) pH
h) Specific gravity
i) Any other relevant test.

All tests should be performed unless development studies or process validation prove that they are unnecessary. Such proof should be provided in the application dossier.

9.0 APPENDIX 3 (Data relating to Efficacy and Safety of PHP)

Applicant should provide the following;

9.1 Documented evidence of the effectiveness of the PHP with respect to its intended purpose of use and efficacy studies done in areas of similar transmission.
9.2 Data relating to safety of the product to persons occupationally exposed to it when it is manufactured, stored, displayed, distributed or used.
9.3 Data relating to safety of product to host plant, animal or article in relation to which it is to be used.
9.4 Data relating to effects of the PHP on representative species of non-target organisms relative to the intended use of the PHP.
9.5 Degree of persistence, retention and movement of the PHP and its residue.
9.6 Suitable methods for detoxification or neutralization of the PHP in soil, water, air or on articles.
9.7 Suitable methods for disposal of PHP and its empty packages.
9.8 Stability of the product under practical conditions of storage and display
9.9 Compatibility of the PHP with other control agents and chemicals with which it is recommended or likely to be mixed with.
9.10 Data relating to effects of the PHP or its residue when administered to test animals for the assessing of any risk to humans or animals.

10.0 APPENDIX 4 (Registration Status in other countries)

10.1 Applicant should provide a registration certificate or authorization to market the product in the country of manufacture. (If product is not registered in country of manufacture, a valid explanation must be given)

10.2 A copy of the manufacturing licence shall be provided.

11.0 APPENDIX 5 (References to literature & Samples)

11.1 References to literature shall be precise, quoting the year of publication and the relevant page(s). Photocopies of relevant literature may be attached.

11.2 A minimum of two samples of the final product for each package size being applied for must be provided in the form in which it shall appear on the market.

12.0 MONITORING AND CONTROL OF PHPs

12.1 Each consignment of PHPs that is imported into Uganda shall be inspected at the port of entry and sampled for testing at National Drug Quality Control Laboratory whenever it is deemed necessary by the authority, the cost of analysis shall be covered by the importer.

12.2 PHPs batches that fail tests of analysis shall be rejected. The destruction shall be supervised by NDA at the expense of the importer.

12.3 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis that states;

i) Name of the PHP
ii) Batch Number
iii) Manufacturing date
iv) Packaging Date if different from Manufacturing date
v) Expiry date
vi) Identification for active agent
vii) Assay for each active agent in the product
viii) Impurity tests
ix) Specific tests for applicable dosage form e.g. pH, viscosity, wt/ml for oral liquid dosage forms.
x) Tests for microbial limits where necessary.

12.4 **Usage and handling of PHP**:

i) Must be handled and stored in licensed and suitable premises.
ii) Personnel in these premises should wear protective clothes.
iii) Premises should have hand washing and bathing facilities for hand washing or bathing following handling or exposure to PHP.
iv) PHP should not be kept together with foodstuffs or drugs.

12.5 **Locally manufactured PHPs**.
Must be manufactured from inspected and licensed facilities.

13.0 RETURNS

Importers and local manufacturers of PHP are required to submit returns of PHP being handled by them to NDA.

14.0 EXEMPTIONS:

i. Substances administered directly on or in humans and domestic animals to treat, mitigate, diagnose or prevent a disease (These are regulated as drugs).

ii. Substances used for preservation of food for human consumption during cooking or processing (These should meet requirement for dietary ingredients)

iii. Substances used for preservation of wood or other materials.

REFERENCES AND RESOURCE LIST:

1. EPA (2002). Pesticide Registration (PR Notice) Notice 2002-1 (http://www.epa.gov/opppmsd1/PR_Notices/pr2002-1.pdf); Accessed on March 10th 2007.

2. FAO (1995) Guidelines on Good Labelling Practice for Pesticides (http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/label.doc); Accessed on March 10th 2007.

3. FAO (1995). Pesticide storage and stock control manual (http://www.fao.org/ag/AGP/AGPP/Pesticid/Disposal/common/ecg/103809_en_No_3___Storage.pdf); Accessed on March 10th 2007.

4. FAO (1999) Guidelines for the management of small quantities of unwanted and obsolete pesticides (http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103825_en_No_7___Small_quantities_stocks.pdf); Accessed on March 10th 2007.

5. FAO (2002) International Code of Conduct on the Distribution and Use of Pesticides (http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/default.htm); Accessed on March 10th 2007.

6. FAO (2006) Manual on development and use of FAO and WHO specifications for pesticides (http://www.fao.org/ag/agp/agpp/pesticid/); Accessed on March 10th 2007.

7. FAO, Prevention of accumulation of obsolete pesticide stocks, (http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Disposal/common/ecg/103807_en_v7460e.pdf); Accessed on March 10th 2007.

8. FAO, Specifications for Agricultural Pesticides (http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Specs/pes_alp1.htm); Accessed on March 10th 2007.

9. WHO (2003). Draft guidelines on the management of public health pesticides (http://whqlibdoc.who.int/hq/2003/WHO_CDS_WHOPES_2003.7.pdf); Accessed on March 10th 2007.

10. WHO (2005). Pesticides and their application. (http://whqlibdoc.who.int/hq/2005/WHO_CDS_WHOPES_GCDPP_2005.12.pdf); Accessed on March 10th 2007.

11. WHO (2007) WHO analytical methods (http://www.who.int/whopes/quality/analytical_methods/en/); Accessed on March 10th 2007.

12. Winslow C.E.A. (1920) "The untilled field of public health." *Modern Medicine*, **2**:183-191.