GOVERNMENT NOTICE NO……..published on……

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT,
(CAP. 219)

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REGULATIONS

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(Made under Section 122 (1) (y))and 77(2)

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THE TANZANIA FOOD, DRUGS AND COSMETICS (SCHEDULING OF MEDICINES)(AMENDMENT)REGULATIONS, 2018

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Citation
G.N No 63
of 2015

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Scheduling of Medicines) (Amendments) Regulations, 2018 and shall be read as one with the Tanzania Food, Drugs and Cosmetics (Scheduling of Medicines) Regulations,2015 hereinafter referred to as the "principal Regulations"

Addition new of Part II

2. The principal Regulations are amended by adding immediately after Part I a new Part II as follows:

"PART II
ADMINISTRATIVE PROVISIONS

Establishment of Scheduling of Medicines Advisory Committee

3A.-(1) Subject to section 13 of the Act, there shall be established a technical committee to be known as the Scheduling of Medicines Advisory Committee.

(2) The Scheduling of Medicines Advisory Committee shall-

(a) when handling scheduling of human medicines, reconstitute itself and operate as such under the auspice of the Human Medicines Registration Technical Committee established as such under Section 13 of the Act;

(b) when handling scheduling of veterinary medicines, reconstitute itself and operate as such under the auspice of the Veterinary Medicines Technical Committee established as such under Section 13 of the Act;

Functions of Scheduling of Medicines

3B. The functions of Scheduling of Medicines Advisory Committee shall be to:

Advisory Committee

(a) provide technical advice and recommendations scheduling of human or veterinary medicines to the Director General;
(b) provide technical advice on the restrictions (accessibility and availability) on particular medicine or any other matter referred to it by the Director General; and
(c) undertake any other related function prescribed as such under these regulations or as may be directed by the Director General.

Conduct of meetings

3C.-(1) The Scheduling of Medicines Advisory Committee shall ordinarily meet at such times and places as it deems necessary for transaction of its business, but shall meet at least four times a year.

(2) Notwithstanding subsection (1), the conduct of meetings of the Human Medicines Registration Technical Committee and the Veterinary Medicines Technical Committee shall respectively apply *mutatis mutandis* to the conduct of meetings of the Scheduling of Medicines Advisory Committee."

Amendment of Part II

3. The principal Regulations are amended by designating the contents of Part II as contents of Part III.

Addition of regulations 5A, 5B and 5C

4. The principal Regulations are amended by deleting Regulation 5 and replacing the new Regulations as follows:

Criteria for Scheduling of medicines

5. The criteria for scheduling of categories medicines referred to in regulation 5 shall generally take recourse to-

(a) risk and benefit profile of a medicine;
(b) purpose for which the medicine is intend to be used;
(c) toxicity profile;
(d) dosage, formulation, labeling, package and presentation;
(e) potential for abuse; and
(f) any matter considers necessary for the interest of the public.

Criteria for scheduling of human medicines

5A. Without prejudice to the generality of regulation 5, the criteria for scheduling controlled human medicines shall be as follows:

(a) narcotics and psychotropic substances:

(i) these medicines are under the International Drug Control Treaties which the United Republic of Tanzania has signed; the Treaties (i.e. Convention on Narcotic Drugs of 1961 and Convention on Psychotropic Substances

of 1971) recognizes that the medical use of such medicines continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes, but in view of their addiction potential, places these medicines under very strict control;

(ii) the control is exercised over more than 116 narcotic drugs under the 1961 Convention; they include mainly natural products such as opium and its derivatives, morphine, codeine and heroin, but also synthetic narcotics such as Methadone and Pethidine as well as Cannabis and Cocaine;

(iii) about 111 psychotropic substances are controlled by the 1971 Convention, and most of them are contained in pharmaceutical products acting on the central nervous system; these include hallucinogens, stimulants and depressants and some analgesics, and specific criteria include:

(aa) addictive properties of a medicine;
(bb) risk of abuse;
(cc) threat to public health; and
(dd) therapeutic value.

(b) For Prescription Only Human Medicines:

(i) medicines for symptoms or ailment which require medical or dental intervention;

(ii) medicines which requires adjunctive therapy or evaluation or specialized handling administration during use;

(iii) medicines that may produce dependency when used at established dosage but has moderate propensity for misuse, abuse or illicit use;

(iv) medicines which the margin of safety between therapeutic index and toxic dosage requires prescriber intervention to minimize the risk of using the medicines;

(v) medicines which requires monitoring or intervention of a prescriber due to seriousness or severity and frequency of the interactions with other medicines, food or disease;

(vi) medicines which its use will contribute

or likely to contribute to communal harm; and

(vii) medicines which experience on use under normal clinical conditions is limited.

(c) Pharmacy Only Medicine (PO)- Behind the Counter (BTC):

(i) medicines which is substantially safe with Pharmacist intervention to ensure safe use of the medicine; There may be potential for harm if used inappropriately;

(ii) medicines which use is not expected to produce dependency at either established therapeutic dose or at sub therapeutic doses;

(iii) medicines with well-defined risk profile and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist;

(iv) medicine intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicines;

(v) medicines which it is used use at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition;

(vi) medicines prepared at a pharmacy after a prescription from the medical practitioner, dentist, or any other authorized prescriber; and

(vii) medicines announced for use in special programme but require special storage conditions or unusual requirements for safe disposal by the person administering.

(d) For Pharmacy Only Medicine – Over The Counter (OTC):

(i) medicines which use is substantially safe for short term treatment and potential for harm from inappropriate use is low;

(ii) medicines which use is very unlikely to produce dependency and the medicine is very unlikely to be misused or abused or illicitly used;

(iii) medicines which risk profile is well defined and the risk can be identified

and managed by a consumer through appropriate packaging and labeling, including consultation with a health professional if directed by labeling;

(iv) medicines which need special precaution on handling to the person administering the product;

(v) medicine which is not suitable for sale under General Sales but which do not meet the criteria for classification as prescription drugs or controlled drugs;

(vi) medicines which proper use can be achieved by labeling and packaging;

(vii) medicines which requires advice on the probability of undesirable effects and interaction with other widely used Medicines.

(e) ADDO Human Prescription Medicines:

(i) medicines based upon the contents of dispensary drug kit and in some instances lifesaving potential in rural areas where pharmacies or emergency health providers are distant from a community;

(ii) medicines announced for use in special programme but require prescription or unusual requirements during dispensation to the person administering.

(f) For General Sales Human Medicines:

(i) medicines which safety profile has long been established and considered to be stable;

(ii) medicines that is evaluated to be safe at recommended dosage and are commonly used for treatment of minor ailments or symptoms; and

(iii) medicines which poses no significant risk during administration or risk during disposal to the environment.

Criteria for scheduling of veterinary medicines

5B. Without prejudice to the generality of regulation 5A, the criteria for scheduling controlled veterinary medicines shall be as follows:

(a) Controlled medicines include narcotics and psychotropic substances.

(i) These medicines are also under the International Drug Control Treaties which the United Republic of Tanzania has signed. The Treaties (i.e. Convention on Narcotic Drugs of 1961 and Convention on Psychotropic

Substances of 1971) recognizes that the medical use of such medicines continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes, but in view of their addiction potential, places the medicines under very strict control.

(ii) The control is exercised over more than 116 narcotic drugs under the 1961 Convention. They include mainly natural products such as opium and its derivatives, morphine, codeine and heroin, but also synthetic narcotics such as methadone and pethidine, as well as cannabis and cocaine

(iii) About 111 psychotropic substances are controlled by the 1971 Convention. Most of them are contained in pharmaceutical products acting on the central nervous system. Broadly speaking, these include hallucinogens, stimulants and depressants and some analgesics.

(aa) Addictive properties of a medicine
(bb) Risk of abuse
(cc) Threat to public health
(dd) Therapeutic value

(b) Prescription Only Veterinary Medicines:

(i) Where diagnosis of the condition for which the drug is intended would be beyond the competence of the livestock owner and therefore requires the service of a registered professional or enrolled/enlisted paraprofessionals;
(ii) Where administration of the drug must be done by a professional or paraprofessional, that that is , when the route of administration is parenteral and the animal needs to be monitored by the professional or paraprofessional in person.
(iii) Where the drug is classified as potential for misuse by farmers (e.g. indiscriminate use of oxytetracycline);
(iv) Where the drug administered changes/alters significantly the animal physiology, causes severe adverse reactions and requires monitoring of the patient by veterinarian or (e.g. the use of anticoagulants);
(v) The drugs is highly toxic (narrow therapeutic index) and the dose/toxicity level is finely balanced;
(vi) All biological (e.g. vaccine in order to balance treatment regimens)

(c) Pharmacy Only Medicine (P)

(i) These are substances that can with reasonable safety be sold or supplied under the supervision of pharmacist. All aspects of the safety of the drug and drug products are relevant factors to be considered;
(ii) These drugs or drug products which are not suitable for sale under general sales list for animals but which do not meet the criteria for classification as prescription drugs;
(iii) These substances are for food producing animals but need not special precaution against the potential risk

to the person administering the product;

(iv) These are drugs that require advice on the probability of undesirable effects and interaction with widely veterinary drugs;

(v) These drugs or compounds prepared at a pharmacy after prescription from veterinarian;

(d) General Sales Medicines (GSL)

(i) Drugs, which require no any specific technical advice concerning its method of use;

(ii) Drug that poses no significant risk to the animal being treated, the person administering the substance, the consumer or the environment;

(iii) In considering (i) and (ii) above, account should be taken of the nature of the active ingredient, its concentration in the product, the recipient used, the target specific and the method of administration;

(iv) Drug will be sold to person who the registered veterinarian/pharmacist knows or has reasonable cause to believe that the person has an animal in his or her charge and will use that product for the treatment of his or her animal concerned;

(g) criteria prescribed in regulation 5B (c) shall apply for Pharmacy Only Veterinary Medicines;

criteria prescribed in regulation 5B (d) shall apply for General Sale (GS);

Amendment of regulations 19

5. The principal Regulations are amended in regulation 19 by-

(a) designating the contents of regulation 19 as contents of regulation 19(1);

(b) adding immediately after subsection (1) as designated the following-

(2) Subject to sub regulation (1), the schedule of prescription only human medicine shall include human biological products which may require special storage conditions.

Amendment of regulations 25

6. The principal Regulations is amended in regulation 25 by adding immediately after sub regulation (1) the following:

(1A) Subject to sub regulation (1), the schedule of prescription only veterinary medicine shall include veterinary biological products which may require special storage conditions.

Amendment of Second Schedule

7. The principal Regulations are amended in the Second Schedule by-

(a) inserting between the medicines titled "Aurothioglucose" and "Chlorprothixene and its salts" the following medicines-

"Azacyclonol and its salts
Azaribine
Azatadine and its salts
Azathioprine and its salts
Azithromycin and its salts and derivatives
Azlocillin and its salts and derivatives
Aztreonam and its salts
Bacitracin and its salts and derivatives (for parenteral use)

Baclofen and its salts
Bambuterol and its salts
Basiliximab
Becaplermin
Bemegride
Benactyzine and its salts
Benazepril and its salts and derivatives
Bendazac and its salts
Benoxaprofen and its salts
Benserazide and its salts
Benzathine penicillin and its salts and derivatives
Benzoyl peroxide (in concentrations greater than 5% or when sold in combination with another medicinal ingredient)
Benztropine and its salts
Benzydamine and its salts
Beractant
Betahistine and its salts
Betaine and its salts (when sold or recommended for the treatment of homocystinuria)
Betaxolol and its salts
Bethanechol chloride
Bethanidine and its salts
Bexarotene
Bezafibrate and its salts and derivatives
Bicalutamide
Biperiden and its salts
Bishydroxycoumarin and its salts and derivatives
Bisoprolol and its salts
Bitolterol and its salts
Bleomycin
Boldenone
Bosentan and its salts and derivatives
Botulinum Toxin Type A
Bretylium tosylate
Bromal hydrate
Brometone
Bromisoval
Bromocriptine and its salts
Bromoform
Budosenide
Bumetanide and its salts and derivatives
Bupivacaine and its salts
Bupropion (see amfebutamone and its salts)
Buserelin and its salts
Buspirone and its salts
Busulfan
Butalbital
Butaperazine and its salts
Butoconazole and its salts
Butorphanol
Butyl chloral hydrate
Cabergoline and its salts
Calcipotriol
Calcitonin
Calcitriol
Calcium bromide

Calcium bromolactobionate
Calcium carbimide
Calcium chloride in injectable form for parenteral use
Calcium gluconate in injectable form for parenteral nutrition
Candesartan and its salts and derivatives
Candicidin and its salts and derivatives
Capecitabine and its salts and derivatives
Captodiamine and its salts
Captopril and its salts
Carbachol
Carbamazepine
Carbenicillin and its salts and derivatives
Carbenoxolone and its salts
Carbetocin and its salts
Carbidopa and its salts
Carbimazole
Carbocisteine
Carbromal
Carisoprodol
Carmustine
Carphenazine and its salts
Carvedilol and its salts
Caspofungin and its salts and derivatives
Cefdinir and its salts and derivatives
Cefepine and its salts and derivatives
Cefonicide and its salts
Cefoperazone and its salts and derivatives
Cefprozil and its salts and derivatives
Ceftibuten and its salts and derivatives
Celecoxib and its salts (NSAIDs)
Centella asiatica extract and active principles
Cephalosporin C and its salts and derivatives
Cetirizine and its salts (in concentrations greater than 8.5 mg cetirizine base per dosage unit)
Chickenpox
Chloral
Chloral hydrate (oral)
Chloralformamide
Chloralimide
Chlorambucil and its salts and derivatives
Chloramphenicol and its salts and derivatives
Chlorcyclizine and its salts (except in preparations for external use only)
Chlorhexidine and its salts (when used as a topical oral preparation)
Chlorisondamine and its salts
Chlormezanone
Chlorodehydromethyltestosteron
Chloroquine and its salts
Chlorotestosterone
Chlorothiazide and its salts and derivatives

(b) adding in the appropriate alphabetical order the following medicines-

Misoprostol
Triprolidine
Abelacimab
Abivertinib
Adriforant
Alteminostat

Amelparib
Amlivirsen
Ampreloxetine
Asalhydromorphone
Aticaprant
Avasopasem Manganese
Avoplacel
Azelaprag
Bamadutide
Bempegaldesleukin
Bevifimod
Bintrafusp Alfa
Birtamimab
Brilaroxazine
Budigalimab
Camsirubicin
Cemiplimab
Cenupatide
Ceralasertib
Cimlanod
Cintirorgon
Coblopasvir
Cotadutide
Crovalimab
Danicopan
Dersimelagon
Dilanubicel
Dilpacimab
Dostarlimab
Durlobactam
Eftozanermin Alfa
Elopultide
Eluforsen
Encequidar
Ensifentrine
Exicorilant
Osgemcitabine Palabenamide
Osifloxuridine Nafalbenamide
Foslinanib
Fosmanogepix
Rovocimab
Futibatinib
Galicaftor
Gancotamab
Golexanolone
Gosuranemab
Hydromethylthionine
Iadademstat
Idecabtagene Vicleucel
Ilginatinib
Lenzumestrocel
Leriglitazone
Linrodostat
Lisocabtagene Maraleucel
Marstacimab
Masupirdine

Miricorilant
Mivavotinib
Murlentamab
Neluxicapone
Nerinetide
Nevanimibe
Nirsevimab
Nomacopan
Obexelimab
Odevixibat
Olacaftor
Olenasufligene Relduparvovec
Olinvacimab
Olorinab
Omburtamab
Ontamalimab
Orilanolimab
Osocimab
Otilimab
Prademagene Zamikeracel
Relatlimab
Reldesemtiv
Reproxalap
Resmetirom
Ripretinib
Rocacetrapib
Rodatristat
Rolinsatamab
Rolinsatamab Talirine
Roluperidone
Rovafovir Etalafenamide
Ruxotemitide
Selatogrel
Sintilimab
Siremadlin
Soticlestat
Spesolimab
Tabituximab
Tabituximab Barzuxetan
Tafasitamab
Talditercept Alfa
Taniborbactam
Tavapadon
Telaglenastat
Temelimab
Teserpaturev
Tildacerfont
Tirbanibulin
Tirzepatide
Tofersen
Toripalimab
Umibecestat
Vafidemstat
Valecobulin
Zampilimab

(c) adding in the appropriate alphabetical order the following medicine-

Codeine and its salts (in preparations exempted from the Regulations to the Controlled Drugs and Substances Act), which is deleted from the Second Schedule

Amendment of Fifth Schedule

8. The principal Regulations are amended in the Fifth Schedule by adding in the appropriate alphabetical order the following medicines:

"Amoxycillin Dispersible Tablets 125 mg and 250 mg"

Amendment of Seventh Schedule

9. The principal Regulations are amended in the Seventh Schedule by adding in the appropriate alphabetical order the following medicines:

"Buparvaquone
Infectious Bursal Disease Vaccine
Iron dextran
Multivitamins injectable solutions
New Castle vaccine
Sulphadimidine Sodium
Toltrazurile"

Amendment of Ninth Schedule

10. The principal Regulations are amended in the Ninth Schedule by adding in the appropriate alphabetical order the following medicine:

"Multivitamin + Minerals powders"

Deletion of Tenth Schedule

11. The principal Regulations are amended by deleting the whole of Tenth Schedule.

Dodoma,

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UMMY A. MWALIMU

Minister for Health, community Development, Gender, Elderly and Children