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GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965(ACT NO. 101 OF 1965), AS AMENDED

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MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965), AS AMENDED.

GENERAL REGULATIONS

The Minister of Health has, in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), in consultation with the Medicines Control Council, made the regulations in the Schedule.

SCHEDULE

DEFINITIONS

1. In these Regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates-

"the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended;

"adverse drug reaction" means a response in human or animal to a medicine which is harmful and unintended and which occurs at any dosage and can also result from lack of efficacy of a medicine, off-label use of a medicine, overdose, misuse or abuse of a medicine;

"applicant" means a person who submits an application for the registration of a medicine, an update or amendment to an existing registration;

"as determined by council" means as determined by Council in the guidelines as published in the *Gazette* from time to time;

"authorised prescriber" means any person authorised by the Act to prescribe any medicines;

"batch" or "lot" in relation to a medicine means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

"batch number" or "lot number" means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer;

"bioequivalence" means the absence of a significant difference in the bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study;

"bonded warehouse" means a customs and excise warehouse licenced in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);

"clinical trial" means an investigation in respect of a medicine for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy;

"counterfeit medicine" means a medicine in respect of which a false representation has been made with regard to its contents, identity or source by any means including its labelling and packaging;

"compound" means to prepare, mix, combine, package and label a medicine for dispensing as a result of a prescription for an individual patient by a pharmacist or a person authorised in terms of the Act;

"dispense"-

(a) in the case of a pharmacist, means dispense as defined in the Regulations Relating to the Practice of Pharmacy made in terms of the Pharmacy Act, 1974; and

(b) in the case of a medical practitioner, dentist, practitioner, nurse or any authorised prescriber to dispense medicines, means-

(i) the interpretation and evaluation of a prescription;
(ii) the selection, reconstitution, dilution, labelling, recording and supply of the medicine in an appropriate container; or
(iii) the provision of information and instructions to ensure safe and effective use of a medicine by a patient;

"expiry date" means the date up to which a medicine will retain the strength and other properties which are mentioned on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used;

"holder of a certificate of registration" means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration;

"manufacture" means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls;

"manufacturer" means a person manufacturing a medicine and includes a manufacturing pharmacy;

"minimum legibility" means a printing in 6-point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof;

"parallel importation" means the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder;

"parallel importer" means a person who parallel imports a medicine into the Republic on the authority of a permit issued in terms of regulation 7(3);

"person" means both a natural and a juristic person;

"proprietary name", "brand name" or "trade name" means the name which is unigue to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(5) of the Act;

"responsible pharmacist" means a responsible pharmacist as defined in the Pharmacy Act, 1974, (Act No. 53 of 1974);

"Site Master File" means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production and/or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings; and

"trademark" means a trademark as defined under section 2 of the Trade Marks Act, 1993 (Act No. 194 of 1993).

"wholesaler" means a dealer who purchases medicines from a manufacturer and sells them to a retailer and includes a wholesale pharmacy;

REQUIREMENTS FOR THERAPEUTIC EQUIVALENCE

2. (1) A medicine is considered therapeutically equivalent to another medicine if both medicines-

(a) are pharmaceutically equivalent, i.e., contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; and

(b) after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.