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GOVERNMENT NOTICE

NATIONAL TREASURY

No. R. 344

23 April 2015

INCOME TAX ACT, 1962**REGULATIONS IN TERMS OF PARAGRAPH (e) OF DEFINITION OF
"RESEARCH AND DEVELOPMENT" IN SECTION 11D(1) OF THE INCOME TAX
ACT, 1962, ON CRITERIA FOR CLINICAL TRIALS IN RESPECT OF DEDUCTION
FOR RESEARCH AND DEVELOPMENT**

I, Nhlanhla Musa Nene, Minister of Finance, in terms of paragraph (e) of the definition of "research and development" in section 11D(1) of the Income Tax Act, 1962 (Act No. 58 of 1962), in consultation with the Minister of Science and Technology, hereby make the regulations as set out in the Schedule hereto.

**NHLANHLA MUSA NENE, MP****MINISTER OF FINANCE****Date:**

SCHEDULE

Definitions

1. In these Regulations, unless the context indicates otherwise, any word or expression to which a meaning has been assigned in the Act bears the meaning so assigned, and—

“**clinical trial**” means a clinical trial as defined in Appendix F to the Guidelines;

“**Guidelines**” means the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa issued by the Department of Health (2006);

“**the Act**” means the Income Tax Act, 1962 (Act No 58 of 1962);

Criteria for deduction for research and development in respect of a clinical trial

2. Any research and development being carried on in respect of a clinical trial must, for the purposes of approval under section 11D(9) of the Act, be carried on in accordance with the Guidelines.

Exclusions in respect of deduction for research and development in respect of a clinical trial

3. Despite regulation 2, the following activities do not qualify as research and development in respect of clinical trials being carried on for the purposes of section 11D of the Act:

- (a) a phase IV clinical trial, as defined in Appendix F to the Guidelines other than a clinical trial conducted for the purpose of developing new indications, developing new methods of administration or developing new combinations of pharmaceutical products;
- (b) post-marketing research;
- (c) cost-effectiveness research;
- (d) an activity undertaken solely for the purpose of compliance with regulatory requirements;
- (e) a product familiarisation program;

- (f) research carried on for statistical purposes (meta-analysis);
- (g) epidemiological research; or
- (h) research activities undertaken in preparation for the registration of a clinical trial.

Short title and commencement

4. These regulations are called the Regulations on the additional criteria for clinical trials for the purposes of the deduction for research and development in terms of section 11D of the Income Tax Act, 1962, and are deemed to have come into operation on 1 October 2012.

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