



**national treasury**

Department:  
National Treasury  
REPUBLIC OF SOUTH AFRICA

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**DRAFT REGULATIONS FOR PUBLIC COMMENT**

**17 JULY 2014**

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

Proposed regulations in terms of section 11D(1)(e) of the Income Tax Act, 1962, on the criteria for clinical trials in respect of the deduction for research and development are hereby published for public comment.

Please forward comments on the proposed regulations in writing by the close of business on **17 August 2014** to:

Nombasa Nkumanda at [Nombasa.nkumanda@treasury.gov.za](mailto:Nombasa.nkumanda@treasury.gov.za) and  
Adele Collins at [acollins@sars.gov.za](mailto:acollins@sars.gov.za).

## 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) research in respect of the clinical interaction between a pharmaceutical product and other medicine;
- (h) epidemiological research; or
- (i) research activities undertaken in preparation for the registration of a clinical trial.

#### **Short title and commencement**

4. These regulations are called the Regulations in terms of section 11D(1)(e) of the Income Tax Act, 1962, on the additional criteria for clinical trials in respect of the deduction for research and development and is deemed to have come into operation on 1 January 2014.