national treasury
Department:
National Treasury
REPUBLIC OF SOUTH AFRICA

DRAFT REGULATIONS FOR PUBLIC COMMENT

17 JULY 2014

INCOME TAX ACT, 1962: REGULATIONS IN TERMS OF SECTION 11D(1)*(d)* OF THE INCOME TAX ACT, 1962, ON THE ADDITIONAL CRITERIA FOR MULTISOURCE PHARMACEUTICAL PRODUCTS IN RESPECT OF THE DEDUCTION FOR RESEARCH AND DEVELOPMENT

Proposed regulations in terms of section 11D(1)*(d)* of the Income Tax Act, 1962, on the additional criteria for multisource pharmaceutical products 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 and
Adele Collins at 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 Act bears the meaning so assigned, and—

"the Act" means the Income Tax Act, 1962 (Act No 58 of 1962);

"multisource pharmaceutical products" means multisource pharmaceutical products as defined in the WHO Technical Report Series;

"WHO Technical Report Series" means the WHO Technical Report Series, No. 937, 2006 Annex 7 Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability issued by the World Health Organisation.

Criteria for deduction for research and development in respect of multisource pharmaceutical products

2. (1) Any research and development being carried on in respect of multisource pharmaceutical products must, for the purposes of approval under section 11D(9), constitute–

(a) (i) *(aa)* any activity in respect of the analysis or characterisation of the properties of a pharmaceutical product with the purpose of determining the excipients to be utilised in the formulation of the multisource pharmaceutical product;

(bb) compatibility tests between active pharmaceutical ingredient excipients and other ingredients; and

(cc) dosage form design;

(ii) *(aa)* laboratory scale reformulation through experimentation on active pharmaceutical ingredient excipients and other ingredients; and

(bb) pilot plant scale reformulation; or

(iii) the activities, tests, design and reformulation referred to in sub-subregulations (i) and (ii);

(b) Determination of analytical and stability testing methods if those methods are determined in conjunction with—

(i) the activities, tests and design referred to in subregulation *(a)*(i);

(ii) the reformulation referred to in subregulation *(a)*(ii); or

(iii) the activities tests and design referred to in subregulation *(a)*(i) and the reformulation referred to in subregulation *(a)*(ii).

(2) For the purposes of this regulation **"active pharmaceutical ingredient excipient"** carries the meaning ascribed thereto in Annex 4, WHO Technical Report Series, No 970, 2012.

Short title and commencement

4. These regulations—

(a) are called the Regulations in terms of section 11D(9)*(d)* of the Income Tax Act, 1962, on the other criteria for multisource pharmaceutical products for the purpose of the deduction for research and development; and

(b) are deemed to have come into operation on 1 January 2014.