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NATIONAL TREASURY

No. R. 346 **23 April 2015**

INCOME TAX ACT, 1962

REGULATIONS IN TERMS OF PARAGRAPH *(d)* OF DEFINITION OF "RESEARCH AND DEVELOPMENT" IN SECTION 11D(1) OF INCOME TAX ACT, 1962, ON ADDITIONAL CRITERIA FOR MULTISOURCE PHARMACEUTICAL PRODUCTS

I, Nhlanhla Musa Nene, Minister of Finance, in terms of paragraph *(d)* 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

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, 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 and other ingredients to be utilised in the formulation of the multisource pharmaceutical product;

(bb) compatibility tests between the 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"** carries the meaning ascribed thereto in Annex 4 of the WHO Technical Report Series, No 970, 2012 (WHO Expert Committee on Specifications for Pharmaceutical Preparations).

Short title and commencement

3. These regulations—

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

(b) are deemed to have come into operation on 1 October 2012.

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