
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:

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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;

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.