Industry Research and Development (clinical trials, phase 0, I, II, III, pre-market pilot stage, pre-market pivotal stage, for an unapproved therapeutic good) Amendment (Minor Corrections) Determination 2022

I, Kelley Wiggins, acting General Manager, Research and Development Tax Incentive, delegate of Industry Innovation and Science Australia, make the following determination.

Dated 29 June 2022

Kelley Wiggins
Acting General Manager, Research and Development Tax Incentive, delegate of Industry Innovation and Science Australia

Authorised Version F2022N00150 registered 29/06/2022

Contents

1 Name

This instrument is the *Industry Research and Development (clinical trials, phase 0, I, II, III, pre-market pilot stage, pre-market pivotal stage, for an unapproved therapeutic good) Amendment (Minor Corrections) Determination 2022*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 31D(1) of the *Industry Research and Development Act 1986*.

Note: See also subsection 33(3) of the *Acts Interpretation Act 1901*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Industry Research and Development (clinical trials, phase 0, I, II, III, pre-market pilot stage, pre-market pivotal stage, for an unapproved therapeutic good) Determination 2022

1 Section 1

Omit "*clinical trials, phase 0, I, II, III, pre-market pilot stage, pre-market pivotal stage, for an unapproved therapeutic good*", substitute "*Clinical Trials*".

2 Section 4 (note)

Repeal the note, substitute:

Note: A number of expressions used in this instrument are defined in the *Industry Research and Development Act 1986* by reference to definitions in Division 355 of the *Income Tax Assessment Act 1997*, including the following:

(a) core R&D activities;

(b) R&D entity.

3 Section 4

Insert:

biological has the same meaning as in section 32A of the *Therapeutic Goods Act 1989*.

4 Section 4 (definition of *biosimilar medicine*)

Omit "***biosimilar*** *medicine*", substitute "***biosimilar medicine***".

5 Section 4 (definition of *generic product*)

Omit "a registered medicine (the comparison medicine)", substitute "a registered medicine (the ***comparison medicine***)".

6 Section 4 (paragraph (b) of the definition of *phase 0 clinical trial*)

Omit "preclinical studies", substitute "preclinical".

7 Section 4 (definition of *phase I clinical trial*)

Omit "In includes", substitute "Such trials typically include".

8 Section 4 (definition of *phase I clinical trial*)

After "routes of administration.", insert "Trials may be phase Ia or phase Ib as follows:".

9 Section 4 (paragraphs (a) and (b) of the definition of *phase I clinical trial*)

Repeal the paragraphs, substitute:

(a) ***phase Ia***: a clinical trial that involves a single ascending dose;

(b) ***phase Ib***: a clinical trial that involves multiple ascending doses.

10 Section 4 (definition of *phase II clinical trial*)

After "biological.", insert "Trials may be phase IIa or phase IIb as follows:".

11 Section 4 (paragraphs (c) and (d) of the definition of *phase II clinical trial*)

Repeal the paragraphs, substitute:

(a) ***phase IIa***: a clinical trial to demonstrate clinical efficacy or biological activity through pilot studies and to explore therapeutic dose range;

(b) ***phase IIb***: a clinical trial to determine optimum therapeutic dose and regimen (with efficacy as the primary endpoint); and to resolve uncertainties regarding the design and conduct of subsequent trials.

12 Section 4 (definition of *phase III clinical trial*)

After "biological.", insert "Trials may be phase IIIa or phase IIIb as follows:".

13 Section 4 (paragraph (a) of the definition of *phase III clinical trial*)

Omit "Phase IIIa.", substitute "***phase IIIa***".

14 Section 4 (paragraph (a) of the definition of *phase III clinical trial*)

Omit ").", substitute ");".

15 Section 4 (paragraph (b) of the definition of *phase III clinical trial*)

Omit "Phase IIIb.", substitute "***phase IIIb***".

16 Section 4 (definition of *phase IV clinical trial*)

Repeal the definition, substitute:

phase IV clinical trial *(therapeutic use)* means a clinical trial of a medicine or biological that includes the following:

(a) post-marketing surveillance or resolution of treatment uncertainties;

(b) monitoring safety in real-world populations;

(c) refining knowledge of the risk-benefit balance, detecting rare or long-term adverse effects, and drug interactions;

(d) pharmacoeconomics to gather data in support of the use;

(e) comparative effectiveness and community-based research (sometimes described as ***phase V trials***);

(f) trial combinations with existing products.

17 Section 4 (definition of *pre-market pilot stage clinical trial*)

Omit "a medical", substitute "a medical".

18 Section 6 (heading)

Omit "6 **Exclusions**", substitute "**6 Exclusions**".

19 Paragraph 6a)

Omit "a)", substitute "(a)".

20 Paragraph 6b)

Omit “b)”, substitute “(b)”.

21 Paragraph 6c)

Omit “c)”, substitute “(c)”.

22 Paragraph 6d)

Omit “d)”, substitute “(d)”.

23 Paragraph 6e)

Omit “e)”, substitute “(e)”.

24 Paragraph 6f)

Repeal the paragraph, substitute:

(f) activities that are within the scope of subsection 355-25(2) of the *Income Tax Assessment Act 1997*;

25 Paragraph 6g)

Omit “g)”, substitute “(g)”.

26 Note to section 6

Omit “subsubsections”, substitute “paragraphs”.