Submission no. 18

Section 1: Legislation

1 Are the additional guidance documents listed in this section appropriate?

Yes

2 Are there other guidance documents relevant to the conduct of clinical trials of medicines in New Zealand that should be considered for inclusion?

No

3 Comments or suggestions

Comments or suggestions for section 1:
Medicines New Zealand appreciates the updating of the title of our Guidelines on Clinical Trials Compensation listed in section 1.2 'Additional guidance material relating to clinical trials', to reflect our previous name change.

Section 2: Overview of regulation of clinical trials in New Zealand

1 Does this section adequately describe the situations when approval is required for clinical trials, and the types of approvals that are required?

Yes

2 Was the information appropriately presented?

Yes

3 Are there any changes you would like to suggest?

No

4 Comments or suggestions

Comments or suggestions on section 2:
The proposed revisions make it clear when a clinical trial requires approval under section 30 of the Medicines Act 1981.

Section 3: Application for approval of a clinical trial

1 Are the roles and responsibilities of the various parties involved clearly explained?

Yes

2 Is the application process adequately described?

Yes

3 Is the sole circumstance for an abbreviated process for clinical trial approval clearly explained?

Yes

4 Comments or suggestions

Comments or suggestions on section 3:
Section 3.3 'Submitting an application for approval of a clinical trial' makes reference to section 4.3 for further information on the responsibilities of the applicant. We suggest that for clarity, reference should also be made to section 5, specifically 5.2.1 and section 6 which outline in detail the requirements, roles and responsibilities of the clinical trial applicant/sponsor.

Section 4: Notification of clinical trial sites

1 A revised (simplified) process has been proposed for notifying clinical trial sites where subjects stay overnight as part of the investigation. Is the explanation of the requirements clear?

Yes

2 Is the revised process adequate to ensure that only trial sites with adequate access to emergency medicine facilities are used in clinical trials?

Yes

3 Are the instructions on the accompanying Clinical Trial Site Notification Form clear and easy to understand?

Yes

4 Is it clear that clinical trial applicants no longer have to notify trial sites where subjects stay overnight, and that this is the responsibility of the site manager?

Yes

5 Do you have changes to suggest that could be considered?

No

6 Comments or suggestions

Comments or suggestions on section 4:

Section 5: Good clinical practice requirements

1 Does the text in this section adequately explain what is required?

No

2 Are there other good clinical practice-related safety issues or safety concerns that you consider should be included in this section?

Yes

3 Comments or suggestions

Comments or suggestions on section 5:
We do not believe section 5.3 ‘Investigational products’ adequately explains the requirements. The two new paragraphs in this section outline that ‘the principal investigator’ must maintain the product specification file and must verify that the investigative product meets specification and is suitable for release. We do not believe this is appropriate because these are responsibilities of the medicine’s manufacturer and the clinical trial sponsor and these new paragraphs should appropriately reflect this. We believe that ‘the principal investigator’ should be replaced with ‘the sponsor’ in these two paragraphs.

Section 6: Records and reporting

1 Are the responsibilities of the sponsor regarding record keeping and reporting clear?

No

2 Do you agree that submitting a synopsis of the final report of the clinical trial is sufficient, and that a full report does not need to be submitted unless this is asked for by Medsafe?

Yes

3 Do you have suggestions or recommendations to make that could be included in this section?

Yes

4 Comments or suggestions

Comments or suggestions on section 6:
Section 6.6.1 ‘Amendments to the trial’ states that “changes to essential trial documents such as investigator brochures (see the CHMP GCP guideline for other examples) should be notified together with the submission of the changed documents.” However, the CHMP GCP guideline lists document types that are not required to be submitted with the initial clinical trial application. We suggest specifying the document types that Medsafe require to be submitted and the timeframes for notification.

In section 6.7 ‘How to submit changes to clinical trials, adverse reaction reports and study reports to Medsafe’, it is advised that all reports and applications related to clinical trials should be submitted using the online clinical trial application system, or by email to info@medsafe.govt.nz . However, there is also reference made in section 6.3 ‘Reporting other adverse events’ that sponsors should follow the process in the Part 8 Pharmacovigilance Guideline for reporting adverse reactions. Therefore we believe some clarity is needed on the process to follow for reporting. As an example, should a Significant Safety Issue or DLT SUSAR report submitted by email be submitted to info@medsafe.govt.nz as outlined in section 6.7 of the proposed Part 11 Clinical Trial Guideline, or to medsafeadrquery@moh.govt.nz which is provided in the Part 8 Pharmacovigilance Guideline, or to both? We suggest some further clarity may be achieved by a reordering of information to bring all of the information on clinical trial adverse reaction reporting together in the proposed guideline.

General: Layout and format of the guideline

1 Do you agree with the proposed structure of the guideline?

Yes

2 Do you have suggestions, recommendations or other information that could be included in this guideline?

No

3 Comments or suggestions

Comments or suggestions on layout and format:
Overall, we consider the proposed revised guideline to be of good quality, aside from the specific points of concern we have raised about specific sections.

Clinical Trial Site Notification Form

1 Does this form capture the appropriate essential information?

Yes

2 Is it obvious who should make the notification?

Yes

3 What information do you think would be useful to be published on Medsafe's list of clinical trial sites?

Comments or suggestions on what would be useful:

Re-notification of clinical trial site

1 Since the self-certification process is changing to a notification procedure, would you be amenable to re-notifying your clinical trial site (if applicable) when this revised and updated guideline takes effect, so that the list of clinical trial sites is up-to-date?

Not Answered

2 Comments or suggestions

Comments or suggestions on re-notification:

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
Medicines New Zealand

Address:
XXXXXXXXXXXXXX
XXXXXXXXXX
XXXXXXXXXXXX
XXXXXXXXXXXXXXX

Phone number:
XXXXXXXXXXXXXXXXXXX

Email address:
XXXXXXXXXXXXXXXXXX

2 This submission is:

made on behalf of a group or organisation(s)

3 I am, or I represent an organisation, based in:

New Zealand

If you selected other, please specify:

4 I am, or I represent, a:

Industry organisation

If you selected health professional, please indicate your type of practice:

If you selected other, please specify:

Publishing submissions and privacy

1 Publishing submissions

You may publish this submission

2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

3 Commercially sensitive information

This submission does not contain commercially sensitive information

If your submission contains commercially sensitive information, please let us know where.:

Help us improve our consultations

1 How easy did you find using this website to make a submission?

Adequate

2 If you have made submissions to Medsafe or the Ministry of Health before, was making today's submission:

Harder

3 If there was one change you could make to the submission process, what would it be?

Top suggested change:
We would suggest addition of a free text box or the choice to upload a cover letter, which submitters could use to provide background on their organisation, reasoning for their interest in the consultation and/or general comment on the proposed changes being consulted on.

4 Any other comments or suggestions?

Other comments:
Medicines New Zealand and its member companies were disappointed by the lack of communication given to them about this consultation. Medicines New Zealand and its member companies were not alerted by Medsafe through its standard communication channels for consultations (i.e email and or the 'Additions to the Medsafe Website' email subscription). Our members reported finding out about the consultation only by visiting Medsafe's website or by a notification from us or another third party.

Medicines New Zealand aims to remind our member companies of consultations that may affect them as soon as possible. However, we recommend that all medicine sponsors are notified of consultations with an email from Medsafe and/or the 'Additions to the Medsafe Website' email subscription in the first instance.

We also suggest that a printable version of all the consultation questions is made available to aid submitters with preparing consultation responses.