Submission no. 17

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:
No additional comments.

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?

Yes

4 Comments or suggestions

Comments or suggestions on section 2:
2.4 Determining whether a clinical trial requires approval under the Medicines Act

XXXXXXXXX appreciates the clarity in the proposed guideline with respect to Medsafe's definition of an "unapproved medicine".

"'Unapproved medicines' include new chemical or biological entities and new
dosage forms and new strengths of approved medicines."

The guideline goes on to state:

"Approval under section 30 is not required for a clinical trial that uses only medicines for which Ministerial consent for distribution in New Zealand has been granted (ie, approved medicines). This applies even if the trial is investigating a new indication. However, the medicine used in the trial must be the actual medicine formulation for which consent for distribution in New Zealand has been granted"

"Approval is required for a clinical trial of an unapproved (ie, different) formulation of an approved medicine. This includes the situation of an unapproved dose form of an approved medicine. It also includes the situation where the clinical trial may involve different strengths of the same medicine but the formulations are not directly proportionate."

However XXXXXXX suggests consistency with the prior definition of an unapproved medicine (new dosage form or strength) in the section above rather than the use of "formulation" which has a broader meaning.

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:
No additional comments.

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:
No additional comments.

Section 5: Good clinical practice requirements

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

Yes

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:
With respect to the two paragraphs under section 5.3 on the proposed role of the principal investigator, XXXXXXXXX do not believe it is appropriate for the principal investigator to be responsible for maintaining the product specification file and ensuring the product meets its specifications and is suitable for release. This responsibility is appropriate for the sponsor of the study.

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:
6.5 Notifying overseas actions relating to an investigational product

XXXXXXXX requests that the guideline is clarified to state “Medsafe must be informed within 7 calendar days of the local Sponsor becoming aware of any of the following…” This will clarify the “day 0” for the local reporting requirements.

6.6 Study reporting requirements

It is clear in the proposed guideline that protocol amendments are required to be submitted and approved prior to implementation. However, XXXXXXXX requests greater clarity for which other changed documents are required to be submitted to Medsafe and acceptable timeframes for the proposed notification of changed documents.

The proposed guideline references the GCP guideline’s “essential documents” but a number of these documents are not required to be submitted with the initial clinical trial application (for example Informed Consent Forms.)

XXXXXXXX request clarity on the document types Medsafe requests for submitted and whether the 6 monthly report can be used as a timepoint for notification of documents which have changed in the prior 6 month period.

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:

XXXXXXXX appreciates the overall improvements in clarity and structure of the proposed guideline.

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:
No additional comments.

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?

No

2 Comments or suggestions

Comments or suggestions on re-notification:

This section is not applicable to XXXXXXXX as a clinical trial sponsor.

Your details

1 Your details

Name and designation:
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Company/organisation name (if applicable):
Roche Products (New Zealand) Limited

Address:
XXXXXXXXXXXXXXX
XXXXXXXXXXXXXXX
XX XXXXXXXXXXX

Phone number:
XXXXXXXXXXXX

Email address:

XXXXXXXXXXXXXXXX

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:

Sponsor

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?

Easy to use

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

I haven't made a submission before

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

Top suggested change:
No additional comments.

4 Any other comments or suggestions?

Other comments:
No additional comments.