24 August 2015

Amendments to the Medicines New Zealand Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial

Dear Clinical Trial Service Partner and/or Clinical Research Organisation

Medicines New Zealand is writing to advise of amendments to the Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial. A copy of the updated Guidelines are attached and can also be found at the following location on our website:

http://www.medicinesnz.co.nz/clinical-trials/

The two updates to what was previously referred to as the Researched Medicines Industry Association (RMI) Guidelines On Clinical Trials Compensation For Injury Resulting From Participation In An Industry Sponsored Clinical Trial have been undertaken for the sole purposes of providing factual accuracy rather than material change to the intent and content of the Guidelines.

1. References to relevant Act of Government

The RMI Guidelines made reference to The New Zealand Rehabilitation and Compensation Insurance Act Section 1.1, this reference has been corrected to the New Zealand Accident Compensation Act 2001 Section 1.1. in the Medicines New Zealand Guidelines.

2. Industry Association Nomenclature

The Researched Medicines Industry Association ceased to be the name of the industry association in 2010 and was replaced by the name Medicines New Zealand Incorporated. The Guidelines have therefore been corrected to accurately reflect this change; i.e. the name Researched Medicines Industry Association of New Zealand Inc. or derivatives thereof have been replaced with the name Medicines New Zealand Incorporated in the Medicines New Zealand Guidelines.

During the development of these amendments, Medicines New Zealand has worked in in consultation with the secretariat for the Health and Disability Ethics Committees (HDECs) within the Ministry of Health. The secretariat will be assisting with notification to all relevant clinical trial service partners over the August - September 2015 period.
The HDECs wish to convey that Medicines New Zealand advises that there is no change to the content of the guidelines, and the reason for the change is to reflect the change in the name of the society. HDEC approvals which refer to the previous name of the guidelines are not affected by this change and will continue to apply in the same way as before the change. HDECs are working to ensure that any future references to the guidelines in applications seeking HDEC approval use the new name.

The Medicines New Zealand Guidelines have taken effect from 7 August 2015 and replace all previous versions of our Guidelines.

All clinical research organisations and/or clinical trial service partners to the pharmaceutical industrial are therefore asked to utilise and make reference to the 7 August 2015 version of the Medicines New Zealand Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry Sponsored Clinical Trial, and cease use of older versions of the Guidelines.

Yours sincerely,

Graeme Jarvis, PhD, MBA

General Manager
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