### 駐紐西蘭台北經濟文化辦事處與紐西蘭商工辦事處 依據OECD針對優良實驗室操作(GLP)監控機構之指引 承認符合OECD GLP規範協議

駐紐西蘭台北經濟文化辦事處與紐西蘭商工辦事處(以下簡稱參與雙方)於2014年12月5日在臺灣臺北完成簽署一份關於認證合作之協議(以下稱為「2014年協議」)。本協議之執行機構係財團法人全國認證基金會(TAF)與紐西蘭國際認證(IANZ)。

2014年協議第六條第四項規定如下:

相互承認優良實驗室操作 (GLP)符合性監控計畫 依據經濟合作暨發展組織 (OECD)規範對彼此 GLP符合性監控系 統進行評估,據以簽署相互承認協議,以促成對方經濟體之權責 機關接受符合 OECD 之 GLP 要求所出具之數據。

根據對上述 GLP 符合性監控系統令人滿意的評估,參與雙方決定如下:

依據 OECD GLP 規範執行化學品非臨床安全性試驗、且經 TAF 查核並視為符合 OECD GLP 規範之位於臺灣的試驗單位,將獲 紐西蘭 IANZ 承認視為一 GLP 符合性試驗單位,並將向紐西蘭權 責單位建議接受此等試驗之 GLP 符合性地位,以及

依據 OECD GLP 規範執行化學品非臨床安全性試驗、且經 IANZ 查核並視為符合 OECD GLP原則之位於紐西蘭之試驗單位,將獲臺灣 TAF承認視為一 GLP符合性試驗單位,並將向臺灣權責單位建議接受此等試驗之 GLP符合性地位。

本協議自最後簽署日生效。本協議有關效期與終止適用 2014 年協議第9條規定。

本協議以中文及英文各繕一式兩份,2種文字約本同一作準。

 駐紐西蘭台北經濟文化辦事處
 紐西蘭商工辦事處

 介文汲代表
 涂慕怡代表

 2017年\_\_\_\_月\_\_\_日於威靈頓
 2017年\_\_\_\_月\_\_\_日於臺北

簽署

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### Arrangement

# to Recognise Compliance with the OECD Principles of Good Laboratory Practice (GLP) under the OECD Guidance for GLP Monitoring Authorities between

## The Taipei Economic and Cultural Office in New Zealand and

### The New Zealand Commerce and Industry Office

On 5 December 2014 in Taipei, Taiwan, the Taipei Economic and Cultural Office in New Zealand and the New Zealand Commerce and Industry Office (the Participants) signed an Arrangement Regarding Accreditation Cooperation (the 2014 Arrangement). The Implementing Bodies to this Arrangement are the Taiwan Accreditation Foundation (TAF) and International Accreditation New Zealand (IANZ).

Paragraph 6, Section 4 of the 2014 Arrangement provides for the following:

Mutual Recognition of Good Laboratory Practice (GLP) Compliance Monitoring Undertake evaluations, against Organisation for Economic Cooperation and Development (OECD) criteria, of each body's GLP Compliance Monitoring programmes, in order to sign a Mutual Recognition Arrangement to enable regulators in each other's economies to accept data that meet OECD GLP requirements.

Following satisfactory evaluations of such GLP Compliance Monitoring programmes, the Participants mutually decide the following:

Test facilities conducting non-clinical safety studies of chemicals in Taiwan in accordance with the OECD Principles of Good Laboratory, and having been inspected and found to be in compliance with the OECD Principles of Good Laboratory Practice by TAF, will be recognised by IANZ in New Zealand as a GLP Compliant test facility and will recommend to New Zealand regulatory authorities the acceptance of the GLP compliance status of such studies, and;

Test facilities conducting non-clinical safety studies of chemicals in New Zealand in accordance with the OECD Principles of Good Laboratory, and having been inspected and found to be in compliance with the OECD Principles of Good Laboratory Practice by IANZ, will be recognised by TAF in Taiwan as a GLP Compliant test facility and will recommend to Taiwan regulatory authorities the acceptance of the GLP compliance status of such studies.

This Arrangement will come into effect on the date of the last signature. Paragraph 9 of the 2014 Arrangement regarding the terms of the duration and termination shall apply to this Arrangement.

Signed in duplicate in the Chinese and English languages, both texts having equal validity.

For the Taipei Economic and Cultural Office in New Zealand	For the New Zealand Commerce and Industry Office
Wen-Chieh Jieh Representative	Moira Turley Director
Signed at Wellington this day of 2017	Signed at Taipei this day of 2017