SECTORAL ANNEX I

MEDICINAL PRODUCTS

This Sectoral Annex specifies the implementation arrangements in respect of medicinal products.

Section 1: Scope

1.1 This Sectoral Annex applies to the Good Manufacturing Practice (GMP) inspection of manufacturers of medicinal products carried out in the territories of the Parties.

1.2 The Mandatory Requirements covered by this Sectoral Annex are the mandatory GMP requirements of the Parties.

1.3 Part III of this Agreement shall apply to this Sectoral Annex.

1.4 For the purpose of this Sectoral Annex:

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation granted by the importing Party;

Inspection Service means a Regulatory Authority responsible for the inspection of manufacturers of medicinal products and the granting of manufacturing licences or certificates for medicinal products; and

medicinal products means all products regulated by the pharmaceutical legislation in each Party. For the purposes of this Annex, the definition of medicinal products excludes veterinary products.

Section 2: Obligations

2.1 New Zealand shall accept the conclusions of GMP inspections of manufacturers carried out by Singapore's Inspection Service and manufacturing certificates issued by Singapore's Inspection Service in accordance with Section 4.

2.2 Singapore shall accept the conclusions of GMP inspections of manufacturers carried out by New Zealand's Inspection Service and manufacturing certificates issued by New Zealand's Inspection Service in accordance with Section 4.

2.3 With respect to medicinal products covered by the mandatory GMP requirements of one Party but not the other, manufacturing companies can request that, for the purpose of this Sectoral Annex, an inspection be made by the other Party's Inspection Service.

2.4 In addition, the manufacturer's certification of the conformity of each batch to its specifications will be recognised by the other Party without re-testing and certification at import.

Section 3: Inspection Services

3.1 For the purpose of this Sectoral Annex, New Zealand's Inspection Service shall be:

Medsafe, The New Zealand Medicines and Medical Devices Safety Authority
Ministry of Health

3.2 For the purpose of this Sectoral Annex, Singapore's Inspection Service shall be:

Audit and Licensing Division
Health Products Regulation Group
Health Sciences Authority

Section 4: Certification of Manufacturers

4.1 At the request of an exporter, importer or the regulatory authority of the other Party, the Inspection Service shall assess and, where appropriate, certify that the manufacturer:

(a) is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;

(b) is regularly inspected by the authorities; and

(c) complies with the national GMP requirements recognised as equivalent by the two Parties in accordance with Article 2.3. In cases where different GMP requirements are used as a reference, this is to be mentioned in the certificate.

4.2 Certificates shall also identify the site(s) of manufacture and contract testing laboratories (if any). The format of the certificate is attached as Appendix 1 and may be modified through agreement by the Parties.

4.3 Certificates shall be issued expeditiously and the time taken shall not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 calendar days.

Section 5: Operational Provisions

5.1 Transmission of Inspection Reports

5.1.1 Upon reasoned request, the relevant Inspection Service shall forward a copy of the last inspection report of the manufacturing site or contract testing laboratory in the case where analytical operations are contracted out. The request may concern a "full inspection report" or a "detailed report" (see Section 5.2). The requesting Party shall deal with these inspection reports with the degree of confidentiality requested by the other Party.

5.1.2 If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than three years or a particular need to inspect has been identified by either Party, a specific and detailed inspection may be requested by either Party. Where the last inspection dates back to three years or less, the Party shall ensure that inspection reports are forwarded to the other Party in no more than 30 calendar days. Where the last inspection dates back to more than three years, this period to forward the inspection reports to the other Party may be extended to 60 calendar days.

5.2 Inspection Reports

5.2.1 A "full inspection report" comprises a Site Master File (compiled by the manufacturer and verified by the Inspection Service) and a narrative report by the Inspection Service. A "detailed report" responds to specific queries about a manufacturer by the other Party.

5.3 Reference GMP

5.3.1 For the avoidance of doubt, with respect to medicinal products covered by the mandatory GMP requirements of the importing Party but not the exporting one, GMP inspections by the Inspection Service of the exporting Party shall be in relation to the mandatory GMP requirements of the importing Party. This shall also be the case when the mandatory GMP requirements of both Parties are not regarded as equivalent in accordance with Article 2.3.

5.3.2 Equivalence of GMP requirements for specific products or classes of products shall be determined according to a procedure established by the Parties.

5.4 Nature of Inspections

5.4.1 Inspection Services shall routinely assess the compliance of the manufacturer with mandatory GMP requirements.

5.4.2 Inspection Services shall, on the request of the other Party, undertake product specific assessments of a manufacturer's compliance with mandatory GMP requirements.

5.5 Safeguard Clause for Inspections

5.5.1 Each Regulatory Authority may, subject to the laws and regulations of the other Party, conduct its own inspection of manufacturers in the other Party for reasons identified to the other Party. Such inspections shall be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause shall only be exercised in exceptional circumstances for the purpose of health and safety and shall only occur with the consent of the manufacturer.

5.6 Exchange of Information between Regulatory Authorities and Harmonisation of Requirements

5.6.1 In accordance with this Agreement, the Parties shall exchange any information necessary for the mutual recognition of inspections.

5.6.2 In addition, the relevant Regulatory Authorities in New Zealand and in Singapore shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult with the other Party before their adoption and shall endeavour to work towards their harmonisation or equivalence.

5.7 Inspectors Training

5.7.1 In accordance with this Agreement, training sessions for inspectors on GMP, organised by the Regulatory Authorities, shall be accessible to inspectors of the other Party. The Parties shall keep each other informed of these sessions.

5.8 Joint Inspections

5.8.1 In accordance with this Agreement, and by mutual agreement between the Parties, joint inspections may be conducted. These inspections are intended to develop common understanding and interpretation of practice and requirements.

5.8.2 The fee for a joint inspection will be charged only by the Regulatory Authority of the Party in whose territory the inspection is carried out if the Inspection Service of the other Party participates in the joint inspection for the purposes of training.

5.9 Alert System

5.9.1 Contact points shall be agreed between the Parties to permit Regulatory Authorities and manufacturers of one Party to inform the Regulatory Authorities of the other Party with appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

5.9.2 The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with mandatory GMP requirements

and which could affect the protection of public health, is communicated to each other with the appropriate degree of urgency.

5.10 Contact Points

5.10.1 For the purpose of this Sectoral Annex, the contact points for any technical question, such as exchange of inspection reports, inspectors' training sessions and technical requirements, will be:

5.10.2 For New Zealand:

For GMP:
Manager, Compliance Management Branch
Medsafe
The New Zealand Medicines and Medical Devices Safety Authority
Ministry of Health
PO Box 5013
Wellington
New Zealand

Tel.: +64-4-819 6800
Email: gmp@moh.govt.nz

For the Alert System:
Manager, Compliance Management Branch
Medsafe
The New Zealand Medicines and Medical Devices Safety Authority
Ministry of Health
PO Box 5013
Wellington
New Zealand

Tel: +64 4 819 6800
Email: recalls@moh.govt.nz

5.10.3 For Singapore:

For GMP:
Division Director, Audit and Licensing Division
Health Products Regulation Group
Health Sciences Authority

Tel: +65 6866 3509
Fax: +65 6478 9068

For the Alert System:
Director, Vigilance and Compliance Branch
Health Products Regulation Group
Health Sciences Authority

Tel: +65 6866 3415

5.11 Divergence of Views

5.11.1 The Regulatory Authorities shall use their best endeavours to resolve any divergence of views concerning any aspect governed by this Sectoral Annex on Medicinal Products *inter alia* compliance of manufacturers and conclusions of inspection reports.

Section 6: Entry into Force

6.1 For the avoidance of doubt, this Sectoral Annex shall enter into force on the day that this Agreement enters into force.

APPENDIX 1

(Letterhead of Competent Authority)

Certificate No: _ _ _/_ _ _/_ _

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
ISSUED UNDER THE PROVISIONS OF THE MUTUAL RECOGNITION AGREEMENT
BETWEEN SINGAPORE AND NEW ZEALAND

As requested by ……..……..…… on …/…/… (*date*), the competent authority of …….....…… (C*ountry*) confirms the following:

The company ……., whose legally registered address is:

…….
…….

has been authorised, in accordance with ……., transposed in the following national legislation …….

under the authorisation reference number ……..…….., covering the following site(s) of manufacture:

1. …….
2. …….

to carry out the following manufacturing operations:

+ complete manufacture, or
+ partial manufacture*

in the following dosage forms/product types (see attached list of categories):

……

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on …/…/… (*date*), it is considered that the company complies with the mandatory Good Manufacturing Practice requirements referred to in the Sectoral Annex (Medicinal Products) of the Mutual Recognition Agreement on Conformity Assessment between New Zealand and Singapore.

This certificate remains valid for three years from the date of last inspection.

…/…/… (*date*)

Name and signature of a responsible officer of the Competent Authority of (*country*)

…….
(name)
(title)

(national authority)
(phone and fax numbers)

_____

(* delete that which does not apply)