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# MUTUAL RECOGNITION AGREEMENTS
## Sectoral Annex on Good Manufacturing Practices

Issues related to
Investigational Medicinal Products
Coverage from 1 May 2004

### Introduction

The scope and coverage sections in the MRAs between EC and Third Countries, Sectoral Annexes on GMP, include Investigational Medicinal Products (IMPs). Nevertheless in the past IMPs could not be covered by the operational MRAs because they were not covered by the EC GMP legislation.

As of 1 May 2004 the Clinical Trial Directive 2001/20/EC has come into force and hence investigational medicinal products are now covered by EC GMP legislation. Annex 13 of the EC Guide to Good Manufacturing Practice (GMP) provides supplementary guidance on the application of the principles and guidelines of GMP to investigational medicinal products. The updated Annex 13 refers to Directive 2001/20/EC regarding quality and release of investigational medicinal products. It applies to human medicinal products.

In the EU importers of IMPs may make use of the batch certificate and GMP certificate facilities outlined in the current MRAs to comply with Article 13.3(b) of 2001/20/EC. There is no requirement for re-control of IMPs in the EU at point of importation. The international harmonised batch certificate has been updated to include IMPs.

### Information on Investigational Medicinal Products in MRA partner countries:

| | **IMPs covered by the MRA** | **limitations** |
|---|---|---|
| **Australia** | **yes** | **Clinical trial products in phase I trials are excluded as they are not GMP regulated in Australia** |
| **Canada** | **yes** | **currently limited to sites in Canada already holding an establishment licence** |
| **Japan** | **no** | **may be in the future** |
| **New Zealand** | **yes** | **same as Australia** |
| **Switzerland** | **yes** | |
| **United States** | **no** | **MRA not operational** |

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mail@emea.eu.int http://www.emea.eu.int