Mutual Recognition Agreements (MRAs) and Key Elements — Status: 18.10.2004

Country/ Element	Japan	Switzerland	USA	Canada	Australia	New Zealand
Status	On 28 April 2004 the European Communities and Japan have exchanged diplomatic notes confirming the completion of the preparatory work under the Mutual Recognition Agreement's Sectoral Annex on GMP for Medicinal Products. Following this exchange of diplomatic notes, the Sectoral Annex on GMP **became operational on 29 May 2004**. Under the Sectoral Annex on GMP for Medicinal Products, certificates issued for confirmed manufacturing facilities in compliance with the GMP requirements of one of the Parties and in accordance with the provisions of the MRA will be accepted in the EC and Japan without additional testing. Therefore, both parties expect that the MRA will facilitate trade between the Parties by reducing costs for companies. For the moment the Sectoral Annex will cover a limited number of human medicinal products. The Parties will review the scope for its possible expansion in the future.	The Agreement on mutual recognition in relation to conformity assessment **came into operation on 1 June 2002**. Chapter 15 details the medicinal and veterinary medicinal products GMP inspection and batch certification. It also covers the Official Control Authority Batch Release. Necessary modifications of Annex 1 of the Agreement due to changes in the legal framework of both parties have been agreed by Decision No 2/2002 of January 2003. The revised explanatory note to Chapter 15 has been published on F2 website. The certificate of GMP compliance for manufacturers and batch certificate have been agreed and posted on the EMEA website. A Two-way alert system based on the European system is in operation.	There has been little activity on this MRA since the transitional period officially ended on 30 November 2001. No decision on a formal extension of the transitional period has been taken. The FDA has been asked several times and last during the 9th meeting of the Joint Committee on 6 March 2003 to provide an evaluation programme for Member States. This seems still to be under consideration at the FDA. A Two-way alert system is in operation.	The Sectoral Annex on Good Manufacturing Practice **started its operational phase on 1 February 2003**. The Joint Sectoral Group met on 17 January 2003 and agreed that the transitional activities should end. The Joint Committee was informed and recorded at its 6th meeting on 13 March 2003 that this sector is operational now. The list of products covered under the Annex includes human and veterinary medicinal products. Veterinary immunological products are not included. At present the Annex is not in operation for pre-approval inspections and stable medicinal products derived from human blood or human plasma. The agreement is based on exchange of certificates of GMP compliance for manufacturers and batch certificates. The contents of these certificates are agreed and available on the EMEA website. The two-way alert system is in operation.	The Sectoral Annexes on Medicinal products GMP Inspection and Batch Certification to the MRA in relation to conformity assessment, certificates and markings between the European Community and Australia have been **in operation since 1 January 1999 for human and 1 July 2001 for veterinary medicinal products**. The agreement is based on exchange of certificates of GMP compliance for manufacturers and batch certificates. The contents of these certificates have been agreed with Australia. A Two Way Alert System based on the European system is in operation.	The Sectoral Annexes on Medicinal products GMP Inspection and Batch Certification to the MRA in relation to conformity assessment, certificates and markings between the European Community and New Zealand have been **in operation since 1 January 1999 for human medicinal products and since 1 June 2002 for veterinary medicinal products**. The agreement is based on exchange of certificates for manufacturers and batches. The contents of these certificates have been agreed with New Zealand. A Two Way Alert System based on the European system is in operation.

Country/ Element	Japan	Switzerland	USA	Canada	Australia	New Zealand
Initialled	16 December 2000	26 February 1999	20 June 1997	30 May 1997	19 July 1996	19 July 1996
Signed	04 April 2001	21 June 1999	15 May 1998	14 May 1998	24 June 1998	26 June 1998
Entry into force	01 January 2002	01 June 2002	01 December 1998	01 November 1998	01 January 1999	01 January 1999
Legal reference	Council Decision 2001/747/EC of 27 September 2001 concerning the conclusion of the agreement on mutual recognition between the European Community and Japan	Council and Commission Decision 2002/309/EC, Euratom of 4 April 2002 as regards the Agreement on scientific and technological cooperation on the conclusion of seven Agreements with the Swiss Confederation	Council Decision 99/78/EC of 20 June 1998 on the conclusion of an MRA between the European Community and the united States of America	Council Decision 98/566/EC of 20 July 1998 on the conclusion of an MRA between the European Community and Canada	98/508/EC: Council Decision of 18 June 1998 on the conclusion of an Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia	98/509/EC: Council Decision of 18 June 1998 on the conclusion of an Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand
Published in	OJ L 284 of 29.10.01	OJ L 114 of 30.04.2002	OJ L 31 of 04.02.1999	OJ L 280 of 16.10.1998	OJ L 229 of 17.08.1998	OJ L 229 of 17.08.1998
Amendments	OJ L 278 of 16.10.2002	OJ L 56 of 01.03.2003 OJ L 66 of 11.03.2003 OJ L 68 of 12.03.2003	OJ L 278 of 16.10.2002	OJ L 278 of 16.10.2002	OJ L 278 of 16.10.2002	OJ L 278 of 16.10.2002
Framework text	Yes	Yes	Yes	Yes	Yes	Yes
Joint Committee	Yes	Yes	Yes	Yes	Yes	Yes
Joint Sectoral Committee	Sub-Committee	No	Joint Sectoral Committee	Joint Sectoral Group	No*	No*
Requirements to inspect against	GMP of exporting party and specific requirements of marketing authorisation	GMP of exporting party and specific requirements of marketing authorisation	GMP of exporting party and specific requirements of marketing authorisation	GMP of exporting party and specific requirements of marketing authorisation	GMP of exporting party and specific requirements of marketing authorisation	GMP of exporting party and specific requirements of marketing authorisation
Transitional / confidence building period	18 months until 30 June 2003; preparatory work has been extended; MRA is operational as of 29 May 2004	No	3 years; transitional period ended 30 November 2001	Has been expected to be 18 months; extended until 31.01.2003	2 years for veterinary medicinal products; has been extended until 30 June 2001	3 years for veterinary medicinal products; has been extended until 31 May 2002
Exchange of Inspection reports	Upon reasoned request full or detailed inspection report [1]	Upon reasoned request full or detailed inspection report [1]	Yes (normally endorsed)	Upon reasoned request full or detailed inspection report [1]	Upon reasoned request full or detailed inspection report [1]	Upon reasoned request full or detailed inspection report [1]

[1] "Full inspection report" = Site master file and narrative report by the inspectorates, "detailed report" = report on a specific query

* until now no official Joint Sectoral Group has been established but a sectoral working group has met several times

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Exchange of inspection certificates	Details have still to be developed	• 30 days • 60 days, if new inspection	No	• 30 days • 60 days, if new inspection	• 30 days • 60 days, if new inspection	• 30 days • 60 days, if new inspection
Batch certificate	Batch certificate of manufacturer according to Internationally Harmonised Requirements for Batch Certification signed by "qualified person"	Batch certificate of manufacturer according to Internationally Harmonised Requirements for Batch Certification signed by "qualified person". QP relieved from batch re-control	Batch certificate of manufacturer; EU "qualified person will be relieved of batch re-control	Batch certificate of manufacturer according to Internationally Harmonised Requirements for Batch Certification signed by "qualified person"	Batch certificate of manufacturer according to Internationally Harmonised Requirements for Batch Certification signed by "qualified person"	Batch certificate of manufacturer according to Internationally Harmonised Requirements for Batch Certification signed by "qualified person"
Joint inspections during transitional period	Yes	No	Yes	Yes	Yes, for veterinary medicinal products	Yes, for veterinary medicinal products
Pre-approval inspection	Yes*	Covered	Covered	Covered since 1 October 2004	Yes	Yes
Right for own inspection in safeguard clause	Yes (in framework agreement)	Yes	Yes	Yes	Yes	Yes
Automatic access to training sessions	Yes	Yes	No reference	No reference	Yes	Yes
"Surrogate inspections" [2]	Not mentioned	No	Yes (but other party may participate)	Yes	No	No
Official Authority Batch Release Control required	At request issued by the authorities of exporting party*	Mutual recognition of official batch control is part of the Agreement	Not covered	Not covered	At request issued by the authorities of exporting party*	At request issued by the authorities of exporting party*
Alert system	Yes	Yes	Yes	Yes	Yes	Yes

[2] Inspection of other EU inspection service than that of the Member State hosting the manufacturer

* The importing party may ask the manufacturing authorisation holder to provide the certificate issued by the authority of the exporting party

Mutual Recognition Agreements and Product Coverage

Country/ Element	Japan	Switzerland	USA	Canada	Australia	New Zealand
Human pharmaceuticals Prescription and Non-prescription	Yes***	Yes	Yes	Yes	Yes	Yes
Human biologicals: vaccines/immunologicals	No	Yes	Yes	Yes	Yes	Yes
Human biologicals: stable medicinal products derived from human blood or blood plasma	No	Yes	No	No	Yes	Yes
Human biologicals: biotherapeutics	No	Yes	No[3]	Yes	Yes	Yes
Human radiopharmaceuticals	Yes	Yes	No	Yes	Yes	Yes
Medicinal gases	No	Yes	No	Yes	Yes	Yes
Veterinary pharmaceuticals Prescription and Non-prescription	No	Yes	Yes	Yes	Yes	Yes
Veterinary premixes and preparations for medicated feed (US: preparation Type A)	No	Yes	Yes	Yes	Yes	Yes
Veterinary vaccines/immunologicals	No	Yes	No	No	Yes	Yes
Homoepathic medicinal products	Yes	Yes*	No	Yes*	Yes	Yes
Vitamins, minerals, herbal remedies	Yes	Yes*	No	Yes*	Yes*	Yes*
Products intended to be used in clinical trials/ investigational medicinal products	Currently not included	Yes*	No	Yes	Yes*	Yes*
Starting materials, intermediate products, active pharmaceutical ingredients / bulk pharmaceuticals	****	Yes*	Yes	Yes	Yes	Yes

[3] Different category in each Party's legislation

* Where appropriate, limitations or related to unilateral legislation
** Only intermediate products and active pharmaceutical ingredients (APIs)
*** sterile medicinal products are currently not covered by the Annex
**** active pharmaceutical ingredients at present not included; further confirmation from Japan concerning starting materials and intermediate products awaited