Implementation of the EU-Israel Agreement on Conformity Assessment and Acceptance of industrial products (ACAA)

1. Lists of products and activities covered by the ACAA and to be made publicly available (Annex, Section II, 3, clause 1)

The products covered by the ACAA include medicinal products, active pharmaceutical ingredients, pharmaceutical excipients or mixtures thereof, for human or veterinary use. This also includes chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, and herbal medicinal products.

The products excluded from the coverage of the ACAA for the time being are medicinal products derived from human blood or human plasma, advanced therapy medicinal products, investigational medicinal products, homoeopathic medicinal products, medicinal gases and veterinary immunologicals.

The activities covered by the ACAA are the once referred to in the Annex of the Agreement.

2. Contact points (Annex Section IV, clause 11)

European Commission, Directorate General for Health and Consumers,
Mr Stefano Soro, Head of Unit, Medicinal products - Quality, Safety and Efficacy,
DM 24 02/050
1049 Brussels
Telephone: +32 2 296 75 43
SANCO-PHARMACEUTICALS-D6@ec.europa.eu

3. Lists of legislation applicable in the European Union on manufacture and good manufacturing practices of medicinal products (Annex Section I)

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. (Articles 40, 41, 42, 46 (a) – (g), (i), 46a, 48, 49, 50, 52, 111 (1) - (3), (5) – (7)).

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. (Articles 44, 45, 46, 50 (a)-(g), 50a, 52, 53, 54, 56, 57, 80 (1) – (3), (5) – (7)).

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (with the exception of all rules related to investigational medicinal products).

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Current version of the Guide to good manufacturing practices volume IV of Rules governing medicinal products in the European Union.

4. Lists of equivalent agreements to be made publicly available (Annex, Section II, clause 3)

MRA EC-Switzerland	Commission Decision 2/2002, Agreement of Annex 1, Chapter 15, Section II	OJ L 14/369 of 30.04.2002; OJ L 68/1 of 12.03.2003
MRA EC-Canada	Council Decision 98/566/EC Agreement, Sectoral Annex on GMP, Appendix 2	OJ L280/3 of 16.10.1998
MRA ECAustralia	Council Decision 98/508/EC Agreement, Sectoral Annex on medicinal products/GMP, Section II	OJ L 229/1 of 17.08.1998
MRA EC-New Zealand	Council Decision 98/509/EC Agreement, Sectoral Annex on medicinal products/GMP, Section II	OJ L 229/61 of 17.08.1998
MRA EC-Japan	Council Decision 2001/747/EC Agreement, Sectoral Annex on GMP, Part B	OJ L 284/3 of 29.10.2001