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)).


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

| MRA ECAustralia    | Council Decision 98/508/EC Agreement, Sectoral Annex on medicinal products/GMP, Section II | OJ L 229/1 of 17.08.1998 |