AGREEMENT BETWEEN ISRAEL AND THE EU ON CONFORMITY ASSESSMENT AND ACCEPTANCE OF INDUSTRIAL PRODUCTS

QUESTIONS AND ANSWERS

1. IS ACAA SIMILAR TO A MUTUAL RECOGNITION AGREEMENT THAT THE EU HAS CONCLUDED WITH OTHER COUNTRIES

Answer: Yes. An Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) is a type of a Mutual Recognition Agreement (MRAs) based on the alignment of the legislative system and infrastructure of the country concerned with those of the European Union. An ACAA has the objective of promoting trade in goods between the European Union and third countries by facilitating market access. It is a bilateral agreement, and aims to benefit industry by providing easier access to conformity assessment.

2. QUESTION: WHEN DID ACAA ENTER INTO FORCE?

Answer: The ACAA entered into force on the 19 January 2013. Article 16 of the Protocol states that: *"The Protocol shall enter into force 30 days after the date of the later written communication, through diplomatic channels, by which the parties have notified each other that their respective internal legal requirements for the entry into force of this Protocol have been fulfilled"*. This has been done from the side of the EU on the 21/11//2012 and from the side of Israel on 20/12/2012. Counting 30 days from the later written communication (being that of Israel on the 20/12/2012), takes us to the 19 of January 2013.

http://www.consilium.europa.eu/policies/agreements/search-the-agreements-database?command=details&lang=en&aid=2010015&doclang=EN

3. QUESTION: WHAT ARE THE PRODUCTS COVERED BY THE AGREEMENT?

Answer: The products covered by the ACAA include medicinal products, active pharmaceutical ingredients, pharmaceutical excipients or mixtures thereof, for human or veterinary use. http://ec.europa.eu/health/files/international/2013_acaa_implementation.pdf

4. QUESTION: WHAT ARE THE PRODUCTS EXCLUDED FROM THE COVERAGE OF ACAA?

Answer: 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, homeopathic medicinal products, medical gases and veterinary immunologicals. http://ec.europa.eu/health/files/international/2013_acaa_implementation.pdf

5. QUESTION: WHAT ARE THE OBLIGATIONS OF EACH PARTY TO THE AGREEMENT?

Answer: The parties to the Agreement have the following obligations:

- Recognition of the conclusion of inspections. Each party to the Agreement shall recognise the conclusions of inspections of compliance of manufacturers and importers with the principles and guidelines of EU GMP and equivalent Israeli GMP. GMP Certificates issued by either party are mutually recognised. This applies also to inspections conducted outside the territories of the parties.

- Each Party shall recognise the relevant manufacturing and import authorisations confirming compliance with legislation on manufacture and importation and the principles and guidelines on EU GMP and equivalent Israeli GMP.

- Certification of the conformity of each batch to its specifications by either the manufacturer established in one of the parties, or the importer, shall be recognised by the other party without re-control at import from one party to the other. The batch certificate should follow the internationally harmonised template published in Eudralex Volume 4 Part III ("MRA Batch Certificate").

The provisions mentioned above do not apply to products imported from a third country that have been exclusively tested in and inspected by a competent authority of that or another third country.

6. IN ORDER TO RELEASE THE BATCH UPON IMPORTATION INTO THE EU DOES THE QUALIFIED PERSON (QP) NEED TO CARRY OUT RETESTING?

Answer: No. However, the QP still has to certify the batch.

7. ARE GMP CERTIFICATES ISSUED BY IL AND THE EU MEMBER STATES BEFORE THE ENTRY INTO FORCE OF THE ACAA COVERED BY THE AGREEMENT?

Answer: Yes. Certificates issued by IL and the EU member states before the entry into force of the Agreement are covered.