EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
**Medicines: policy, authorisation and monitoring**

PHARM 713

**PHARMACEUTICAL COMMITTEE**
**28 April 2016**

**Subject**: **Agreements on Conformity Assessment and Acceptance of industrial products (ACAA) / Mutual Recognition Agreements: recent developments with Swiss, Japan, Australia and Israel**

**Agenda item 5b ii**

We would like to inform the Pharmaceutical Committee on the following developments with regard to the Agreement on Mutual Recognition with Switzerland and Japan, as well as on the recent exchanges in the context of the ACAA with Israel and MRA with Australia.

Switzerland

At the Joint Committee meeting in November 2014, Switzerland mentioned their intention to propose amendments to Chapter 15 of the MRA which would allow the mutual recognition of GMP inspections in third countries. Switzerland suggested as well alignment of the material scope of the Chapter 15 with the scope of the MRA Agreement to cover also products manufactured outside Switzerland.

The question was indeed raised by inspectors on one of the EMA GMDP IWP meetings whether it would be possible to give legal basis for the recognition of the conclusions of the Swiss inspections in a third country. The inspectors referred to the inspections of Swissmedic in the context of EDQM.

In June 2015 Switzerland issued their proposal which was discussed with the Commission services (SANTE, TRADE) on several occasions.

As the result of these discussions, the DG SANTE advised DG TRADE to accept the Swiss proposal to recognize the outcomes of GMP inspections in third countries as this would allow better allocation of inspection resources. As regards the proposed alignment of the scope of Chapter 15 with the scope of MRA, DG SANTE advised DG TRADE to accept it only on the condition that a medicinal product manufactured outside

Switzerland and imported into the EU from Switzerland can be retested in the EU in case it was not tested on the Swiss territory. Similar guarantee is provided in ACAA with Israel which applies also to products manufactured in third countries.

DG TRADE is currently preparing an EU-Switzerland Joint Committee Decision proposing mentioned amendments to the Chapter 15 of the EU-Switzerland MRA. The decision, before being presented to the Joint Committee, has to be adopted by the Commission.

Japan

The EU has been pursuing the objective of the extension of the EU-Japan MRA from 15 to 28 Member States for several years. Discussions towards achieving this objective received a new momentum thanks to the launch of the Free Trade Agreement negotiations with Japan and the accession of MHLW/PMDA to PIC/S on 1 July 2014. After intensive exchange of information, we have been informed that Japan had completed its internal process. The formal extension of the MRA from 15 to 28 Member States is expected take place on 22 April 2016 through exchange of diplomatic letters.

Exchanges between the EU and Japan and technical work will continue for the inclusion, subject to a positive outcome, of new types of products (i.e. APIs, sterile products and some biological products) in the scope of the MRA.

Australia

The Australian Veterinary Agency (APVMA) contacted EMA and DG SANTE in December 2015 in order to receive the information on the requirements for the recognition, under the terms of MRA agreement, of APVMA inspections. Currently only human medicines agency (TGA) is consider as equivalent in the context of MRA and as a results only GMP certificates of that agency are recognized by the EU. On a basis of Memorandum of Understanding between two agencies, the TGA is performing GMP inspections on the sites manufacturing veterinary products and issues the GMP certificates in case these are interested in exporting to EU.

The Australian partners were informed on the requirements and the procedure for recognition of new agency. APVMA is still contemplating whether to apply formally.

ACAA with Israel

Israel contacted the European Commission in November 2015 asking to initiate the discussion on the extension of ACAA to the medicinal products derived from human blood and plasma. DG SANTE replied that a preliminary condition to start such a discussing is a notification of adoption of Israeli law aligning to the relevant EU legislation. Israel law aligning with the EU law on blood and plasma is still under preparation.

**Action to be taken:**
For information