The 4th EU-Japan Business Dialogue Round Table: MRA Working Party

Framework

1. Confirmation of last year's joint statement

(1) Agreement on EU-Japan MRA in four sectors

On April 4, 2001, the EU and Japan signed an MRA in four sectors: electronics, telecommunications, chemicals (GLP) and pharmaceuticals (GMP). We requested the MRA become effective as early as possible.

(2) Negotiation on the MRA on medical devices

a) A pilot study focusing on diagnostic imaging equipment

We proposed starting a pilot study in diagnostic imaging equipment in order to clarify regulatory problems, initiated by the medical industry associations on both sides.

b) Maximum use of the GHTF progress

The MRA on medical devices should be proposed in line with GHTF(Global Harmonization Task Force) activities, and make as much use of GHTF output as possible.

2. The progress of the MRA in four sectors

(1) The MRA officially started on January 1st, 2002

We welcome the result, and appreciate the efforts done by the officials of the EU and Japan.

(2) The actual implementation is not started yet.

- Electronics and telecommunications:
  There is no CAB (Conformity Assessment Body) registered yet on both sides, therefore, the actual implementation seems as early as this fall.
- Chemical (GLP):
  EU and Japan have exchanged the list of approved laboratories, and the MRA has been in the implementation stage.
- Pharmaceuticals (GMP)
  It is during the preparation period of 18 months.

(3) Industries to take initiative to utilize the MRA

- Because of the first MRA between the EU and Japan, it has been taking time.
- Governments' efforts: PR activities (MRA seminars)
- The base of the MRA has built, therefore, industries are to utilize and promote the MRA by themselves.

3. The MRA on medical devices

(1) Activities since the last EJBDRT Meeting

COCIR and JIRA have had two meetings on the proposed MRA Pilot Study for Medical Devices on March 3, 2002 in Vienna and April 19, 2002 in Brussels. During these meetings, the approach for the inclusion of medical devices into the EU-Japan MRA has been confirmed referring to the situation of the MRA between EU and USA. A task force team has been formed to implement the pilot study including the comparison of regulatory schemes.

(2) Agreement between COCIR and JIRA

a) Principle of this pilot study

- Target diagnostic imaging equipment
  Easy to implement, Good way to build trust, Cooperation between involved industry associations for this product area COCIR and JIRA
- Make maximum use of the GHTF progress and ISO standards for the pilot study.
- Based on the provisions of the revised Pharmaceutical Affairs Law (PAL) in Japan.

b) Recommendations

- Requirements on quality management systems should be the same for Japan as for the EU, based on the international standard ISO 13485.
- Both Japan and the EU should adopt the GHTF documents, such as the Summary Technical Documentation (STED).
- An eventual MRA should include pre-market review and quality system, but exclude post-market surveillance.

(3) Future Activities

COCIR and JIRA will continue to evaluate the regulatory requirements for medical device focusing on diagnostic imaging equipment in Europe and Japan. Based on this pilot study, COCIR and JIRA will develop a proposal for the inclusion of medical devices into the EU-Japan MRA.

4. Common understanding

(1) The MRA in the four sectors will be implemented in short since most of the procedural difficulties have been settled. We understand that it has come the time for the industry to take the initiative to utilize and promote this MRA. There is an estimate that the effect of the MRA will be a few billion Euro per year.

(2) Regarding the inclusion of the medical devices to this MRA, the European Commission and the Japanese government had agreed to start negotiation in 2004, after the two years from the effective date of the current MRA. It is written in the progress report prepared by the EU and Japan. The industries of medical devices from both sides have been working for the preparation to support the negotiation. We support the industries' initiative on this move.

(3) We understand the first objective of this MRA working group has been achieved since the agreement in the four sectors has become officially effective and also the both sides agreed to look at the possibility for the medical devices. The arrangement of the MRA has become much more technically specialized in each sector, therefore, we think each industry association on both sides should take the initiative to implement the MRA. We will take the MRA at the next EJBDRT meeting only if some significant issues were newly raised.

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