6 July 2001

# The 3rd EU-Japan Business Dialogue Round Table
# MRA Working Party

## Joint Statement (draft)

## 1. Ongoing EU-Japan MRA in four sectors

On April 4, 2001, the EU and Japan signed an MRA in four sectors: electronics, telecommunications, pharmaceuticals (GMP) and chemicals (GLP). The request we made at the 2nd EJBDRT has been filled—we appreciate their effort—and we expect the MRA to become effective this fall at the latest.

Each industry, together with related governmental bodies and conformity assessment bodies, should monitor the implementation and work to solve any problems if necessary.

## 2. EU-Japan MRA on medical devices

At the 2nd EJBDRT, we asked the EU and Japanese governments to include medical devices in the MRA. Industrial associations on both sides sent request letters to officials of their respective governments based on our proposal last year, and the governments agreed to start talks two years after the current MRA becomes effective.

(1) A pilot study focusing on diagnostic imaging equipment

We should utilize the experiences from the present MRA between the EU and the US in medical devices in order to proceed effectively with the MRA between the EU and Japan. We propose starting a pilot study in diagnostic imaging equipment in order to clarify regulatory problems. This study will be initiated by the medical industry associations on both sides, COCIR and JIRA, and we believe this pilot study will be the base for governmental talks and negotiations on the MRA and help facilitate it.

(2) Maximum use of the GHTF progress

The GHTF (Global Harmonization Task Force) is a multinational activity among regulatory authorities and industry in the medical device field working to harmonize different national conformity assessment procedures using next to its own documents, ISO and other international standards. We believe the MRA on medical devices should be proposed in line with GHTF activities, and make as much use of GHTF output as possible. It is also important to harmonize GHTF documents and regulatory systems in the EU and Japan.

## 3. Common understanding

This MRA working party made significant progress and achieved one of our proposals from last year. We hope each industry on both sides take the initiative and promote the MRA in each sector. Regarding the MRA on medical devices, we agreed to complete the proposed pilot study on diagnostic imaging equipment within two years from the date on which the current MRA enters into force.

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