EU-Japan Business Round Table

RECOMMENDATIONS

"EU-Japan Cooperation - New Opportunities for Global Growth"

8 and 9 April 2014

(Tokyo, Japan)

1. Introduction

The EU-Japan Business Round Table (BRT) held its Annual Meeting in Tokyo on 8 and 9 April 2014 with the theme of "EU-Japan Cooperation - New Opportunities for Global Growth." The meeting was chaired by Mr. Hiromasa Yonekura, Chairman and CEO of Sumitomo Chemical Co., Ltd., and Mr. Fabrice Brégier, President and CEO of Airbus SAS.

The BRT had the pleasure and honour of welcoming high-level representatives of the Japanese and EU Authorities: Mr. Toshimitsu Motegi, Minister of Economy, Trade and Industry of Japan, Mr. Yoshihiko Isozaki, Parliamentary Vice Minister of Economy, Trade and Industry of Japan, Mr. Norio Mitsuya, Parliamentary Senior Vice-Minister for Foreign Affairs of Japan, Mr. Takao Makino, Parliamentary Vice-Minister for Foreign Affairs of Japan, Mr. Yasumasa Nagamine, Deputy Minister for Foreign Affairs of Japan, Mr. Masahiro Yoshizaki, Vice-Minister for Policy Coordination (International Affairs), Ministry of Internal Affairs and Communications of Japan, Mr. Daniel Calleja Crespo, Director-General for Enterprise and Industry of the European Commission, and Mr. Antonio Parenti, Deputy Chief Negotiator for the EU-Japan FTA, European Commission.

The meeting consisted of the following:

- 1. Discussion on, and adoption of, general and sectoral recommendations;
- 2. Discussions on (i) the negotiations on an EU-Japan Free Trade Agreement (FTA) /Economic Partnership Agreement (EPA), (ii) the New Industrial Revolution in relations to sustainability, and (iii) important business themes for the EU and Japan in the post FTA/EPA era;
- 3. Discussions with the Japanese and EU Authorities.

The BRT Members agreed to submit their joint recommendations to European Council President Herman Van Rompuy, European Commission President José Manuel Barroso, and Prime Minister Shinzo Abe of Japan.

2. Background

The BRT recognises that the Japanese and European economies are now growing, albeit modestly, and is optimistic that that growth will continue given the right policy framework and continued growth in the emerging economies.

The BRT broadly supports the Japanese Government's strategy of 'Abenomics' and specifically the policy measures aimed at spurring private sector-led growth,

including significant regulatory and institutional reform. The Japanese business community anticipates that 2014 will see the Japanese economy steering out of the prolonged deflation and into complete revitalisation. The BRT broadly welcomes the rebalancing of the European economy and the improvement in its external competitiveness, and notes that the growth rates of the EU economy and of the euro area are predicted to increase, and agrees with the European Commission's view that it is important not to be complacent.

As the BRT has stated in the past, it agrees with the view of the EU and Japanese Authorities that concluding FTAs/EPAs with key strategic economic partners will help revitalise their respective economies, strengthen the still vulnerable global economy, as well as transforming the EU-Japan economic relationship.

Since the last BRT meeting in Paris, the BRT issued a Joint Statement¹ welcoming the launch of the EU-Japan FTA/EPA negotiations and urged that the negotiations should be completed as early as possible and their outcome be compatible with the high level of their ambition. Apart from the statement from the BRT, the EU and Japanese business communities have voiced their support on several occasions to promote the earliest possible conclusion of the negotiation, including the sectoral dialogue held in Brussels this March. The BRT appreciates the recognition that the Summit leaders gave the BRT and its recommendations, and the reaffirmation of the Summit leaders' "determination to continue cooperation with the business communities on both sides, notably through the BRT".

3. Calls and Recommendations

The BRT appreciates and welcomes the efforts that the EU and Japanese Authorities have made in the FTA/EPA negotiations. With a strong conviction that an EU-Japan FTA/EPA could boost trade and investment, promote job creation, and spur growth in both economies and that it will also help create new opportunities for global economic growth, the BRT reiterates its call that the EU and Japanese Authorities should step up their efforts to tackle and resolve the substance of the outstanding issues and that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA should be concluded as soon as possible. The BRT reaffirms its commitment to make every effort to support the early realisation of an EU-Japan FTA/EPA. BRT Members are ready to make available industry expertise to achieve this objective.

As two of the world's largest and most advanced economies, the EU and Japan should work together and play a leadership role to promote global regulatory cooperation and standards harmonisation, which other so-called 'mega' agreements, such as TPP and TTIP, also try to achieve, with the aim of developing an open, seamless global business environment that will help create new growth opportunities not just for the EU and Japanese economies but also for the rest of the world.

At the same time, the BRT urges that the EU and Japan should extend and deepen their cooperation beyond the framework of an FTA/EPA to address a wide variety of

_

¹ "Strengthening the EU-Japan Economic Partnership – Unleashing the potential of economic relations through the swift conclusion of a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA". It was submitted to the EU and Japanese Authorities on 15/11/2013.

global challenges and should particularly explore opportunities to cooperate in businesses in or with third countries as well as in areas relating to innovation, energy, natural resources, environment and climate change, demographic changes, global financial markets, small and medium enterprises and human resources development.

The BRT also calls on the EU and Japanese Authorities to address the following issues:

(A) Trade, Investment, and Regulatory Cooperation

The BRT calls on the EU and Japan to:

- Step up their efforts to tackle and resolve the substance of the outstanding issues so that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA can be concluded as soon as possible. The BRT reaffirms its commitment to make every effort to support the early realisation of an EU-Japan FTA/EPA.
- Further make efforts to contribute to WTO's DDA negotiations, so as to vitalise and create momentum to move the negotiations forward.
- Strive to mutually recognise products certified under similar and equivalent product standards and to cooperate on harmonising regulations and systems where possible. They should also aim for enhanced cooperation in promoting new global standards.
- Support the timely development of business. Specifically, the BRT calls for expansion of the number of bilateral social security agreements that have been concluded and for liberalisation of the movement of intra-corporate transferees within the framework of an FTA/EPA.
- Develop measures that will promote and assist each other's SMEs within their own jurisdictions. The BRT also calls for cross-support, such as logistic support, various tax incentives, and other measures, to be included in the EU-Japan FTA/EPA negotiations.

Moreover, the BRT calls for the EU Authorities to speedily resolve the EU-specific issues identified in the Working Party A document by the Japanese Members of the BRT, and for the Japanese Government to resolve the Japan-specific issues identified in the Working Party A document by the EU Members of the BRT.

(B) Life Sciences and Biotechnologies, Healthcare and Well-Being General Introduction

 The EU and Japan should formulate concrete strategies and action plans in Life Sciences & Biotechnology, thereby focus on measures to support the improvement of efficient healthcare practices, food security / supply and innovations in Biotechnology.

HealthCare (Pharmaceuticals, Medical Devices, Medicinal Gases, etc.)

 The EU government should reinforce its innovation policy to member states and clarify its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals and medical devices. In addition, MHLW should consult all key stakeholders with respect to any new HTA (Health Technology Assessment) issues.

- Japan should further support the implementation of new innovation-rewarding pricing systems for pharmaceutical products, including the abolishment of the rule of re-pricing by market expansion, thereby enhance a competitive pricing system in order to promote innovative products.
- Japan should also promote an innovation-rewarding pricing system for medical devices in order to move towards a product-based, market-oriented reimbursement pricing system.
- The EU and Japan should improve the pharmaceutical and medical device business environments by proceeding with regulatory harmonization and further extension of "Mutual Recognition Agreements" in order to avoid redundant inspections of manufacturing facilities (e.g. injectable pharmaceuticals and APIs) and ensure recognition of quality management audit results for lower risk medical devices.
- Japan should support the reinforcement of strict regulations for GMP on medicinal gases.

Animal Health

- Europe should introduce a 1-1-1 concept (one dossier one assessment one decision on marketing authorization) for all animal health products, thereby further harmonize the regulatory requirements for product registrations, shorten review times and recognize the GMP certification for veterinary products.
- Europe and Japan should promote the responsible use of antibiotics in Animal Health
- Japan should clarify registration requirements and shorten the review process of introducing recombinant vaccines from Europe.
- Japan should promote animal welfare in animal drug administration by accepting more overseas data and alternative approach.

Plant Protection & Biotechnology

- The EU and Japan with the support of companies should speed up research in Plant Protection & Biotechnology and inform the public regularly and accurately about the state of GMOs, based on sound scientific knowledge, thereby closely working with private sectors.
- The EU should shorten the review times for new applications / product registrations in both plant protection and biotechnology.

(C) Innovation, Information & Communication Technologies

ICT

- Internet drives growth. Both sides' Authorities should continue maintaining an open and transparent online environment under a balanced multi-stakeholder approach.
- The BRT requests both sides' Authorities to cooperate for ITA expansion and liberalisation of services over the internet.

- The BRT calls on both sides' Authorities to increase cybersecurity cooperation to build a safe and robust online environment.
- Balancing privacy protection and innovation is important when reviewing personal data protections regimes. This includes unhindered cross-border business and data flows.

Innovation in General

- Both sides' Authorities should favour joint R&D programmes geared towards international standardisation.
- The procedure to prepare and launch coordinated calls should be well discussed by both parties and better standardised.
- The BRT recommends further enhancement of tax credits for R&D, in particular for SMEs.

Aeronautics

- The BRT requests that the Authorities deepen their dialogue and significantly upgrade the scale of EU-Japan industrial cooperation in aeronautics.
- The BRT recommends a better bilateral cooperation at an increased level on navigation regulations for helicopters.

Space

- The Authorities should significantly upgrade bilateral industrial cooperation.
- The Authorities should bring about a mutual backup cooperation scheme of all government launches using their respective satellite launcher fleets.

Defence

• Japan's three principles on transfer of defense equipment should be complemented by clear and transparent procedures.

Railways

• The Authorities should continue and deepen their bilateral dialogue focusing, among others, on safety and innovation.

(D) Financial Services, Accounting and Tax Issues

- The BRT requests that regulating bodies fully address the impact of reforms and new regulations on the real economy notably in the implementation phase and take a co-ordinated approach to avoid negative effects on global business activities and efficient allocation of resources.
- The BRT recommends that, as to the BEPS (base erosion and profit shifting) Action Plan, the authorities should carefully consider the risks of excessive disclosure requirements and anti-tax avoidance measures so as not to hamper multinational enterprises' business activities.
- The BRT maintains its serious concern over the EC's proposed financial transaction tax (FTT), particularly with respect to its wider application and extraterritorial impact.

• The BRT requests that Japanese Government shall devise a detailed roadmap towards its goal of primary-balance surplus by fiscal 2020.

(E) Energy, Environment, and Sustainable Development Basic energy policy

• Energy is the basis of all economic activity. Securing a stable energy supply at a reasonable price, developing the necessary infrastructure as well as reducing energy needs are not only crucial for sustainable business activities but also for the creation of new business opportunities. At the same time, it is important to consider the environmental impact of energy use.

Nuclear Energy

- Safe nuclear power generation can play an important role in the energy mix of the EU and Japan. It could be a valuable asset supporting EU and Japanese competitiveness, supplying base load electricity at low cost and contributing to grid stability, economic growth and jobs creation.
- The EU and Japan should establish energy policies which preserve a role for nuclear power, one of the effective means of reducing greenhouse gas emissions, while paying utmost attention to safety.

Safety measures

• The EU and Japan should cooperate bilaterally and in the relevant multilateral fora on all aspects of nuclear energy, in particular the development and effective implementation of harmonized international nuclear power safety standards.

Renewable energy

Uncertainties remain about the cost and security of supply of renewable energy. However, it has the potential to complement conventional energy with emitting no greenhouse gas and reducing import dependency. Renewable energy sources are available in many forms, including wind, solar, hydro, geothermal, tidal, biomass, etc. Storage batteries can also contribute to ironing out fluctuations in the supply and demand for energy.

It is necessary to study carefully how the adoption of renewable energy sources will be specifically carried out.

Energy conservation and energy efficiency

 The EU and Japan should consider taking further measures to promote energy conservation, by financing research projects to develop technologies and methodologies for improving energy efficiency and by sharing their best practices.

Importance of measures against global warming

 Mitigating global warming is a global challenge. Emerging countries are already overtaking developed countries as the world's major greenhouse gas emitters. It is consequently imperative that emission reductions are also undertaken by



emerging countries. The EU and Japan should work together to create a comprehensive and effective mechanism for reducing global greenhouse emissions.

(A) - (E) summarise the BRT's detailed regulatory and sectoral Recommendations.